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

ANNUAL REPORT PURSUANT TO SECTION 13
1934

FORM 10-K ☑

For the fiscal year ended January 2, 2022

Transition Report Pursuant to Section 13 or 15(d) of t
for the transition period from

or ☐

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

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

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

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

Title of each class
Common Stock, Par Value $1.00
0.650% Notes Due May 2024
5.50% Notes Due November 202
1.150% Notes Due November 202
1.650% Notes Due May 2035

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $445 billion.

On February 10, 2022, there were 2,629,268,158 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement f close of the registrant's fiscal year (the "P (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

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

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

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

Risks Related to the Company's Strategic Initiatives, Healthcare Market Trends and the Planned Separation of the Company's Consumer Health Business

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

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics, including the novel coronavirus (COVID-19) pandemic;

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

Risks Related to Supply Chain and Operations

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

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

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 141,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer Health, Pharmaceutical and 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® products, inspired by nature, and the PEPCID® line of acid reflux products. Baby Care includes the JOHNSON'S® and AVEENO Baby® line of products. Oral Care includes the LISTERINE® product line. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a new, publicly traded company. The Company is targeting completion of the planned separation in 18 to 24 months after initial announcement.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS and COVID-19), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer), Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; the Janssen COVID-19 vaccine, authorized for use under Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory

syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older; EDURANT® (rilpivirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment

for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for patients with prostate cancer; ERLEADA® (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX® (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD), for the treatment and secondary prevention of thromboembolism in pediatric patients, and for thromboprophylaxis in pediatric patients following the Fontan procedure; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral and intravenous, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

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 include advanced and general surgery offerings (Ethicon), 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. Beginning in the fiscal first quarter of 2022, the Medical Devices segment will be referred to as the MedTech segment.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 141,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer Health," "– Pharmaceutical" and "– 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 9.7% of the Company's total revenues for fiscal 2021. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA®. The latest expiring United States composition of matter patent expires in 2023. The latest expiring European composition of matter patent expires in 2024.

Sales of the Company’s second largest product, collectively DARZALEX® (daratumumab) and DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj), accounted for approximately 6.4% of the Company's total revenues for fiscal 2021. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX®, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029. The latest expiring licensed European patent expires in 2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO®.

Trademarks

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

Seasonality

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

Competition

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

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company’s compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company’s businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the 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 U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and congress on 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 healthcare providers. Various transparency laws and regulations require disclosures of payments and other transfers of value made to physicians and teaching hospitals and, beginning with disclosures in 2022, to certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payers 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 healthcare generally.

U.S. government actors 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 healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

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 2, 2022 and January 3, 2021, the number of employees were approximately:

	2021	2020
Employees[1]	144,300	136,400
Full-time equivalent (FTE) positions[2]	141,700	134,500

[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.

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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 2021, 91% of global employees across 77 countries participated in Our Voice Survey which was offered in 36 languages.

Growth and Development

To continue to lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources

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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 2021, 45.8% 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 8%.

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 health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—help ensure employee health protection from emerging health risks.

Safety and COVID-19 Pandemic Response

Protecting and supporting our employees during the COVID-19 pandemic continues to be a top priority and our approach includes: keeping employees informed of local COVID-19 transmission rates and corresponding risk levels; promoting the health and safety of our employees in the workplace through robust layers of protection; enhanced cleaning and access to cleaning supplies and personal protective equipment; supporting employees with pay continuity, benefits and well-being tools; and recognizing extraordinary employee contributions at work and in our communities. In 2021, in recognition of the new way of working, we initiated J&J Flex, a hybrid model that empowers our office-based employees to find the right productivity and balance of in-person and remote work. This model allows for work to happen seamlessly across a variety of workplaces and is enabled by an array of enhanced collaboration tools and technology to optimize productivity and connection. J&J Flex rolled out in fourth quarter 2021 globally, and will continue deployment through 2022 as protocol and requirements related to the COVID-19 pandemic allow. The Company is evaluating flexible work strategies for its on-site workforce, such as virtual on-boarding and training, to help our employees balance their personal and professional lives. Also, we continued to enhance our benefits offerings with access to wellness tools, on-site vaccine clinics, mental health support resources and delivery of at-home testing kits. In addition, as COVID-19 vaccines were broadly distributed and administered in 2021, including the one developed by Johnson & Johnson, we adopted policies in the U.S., Puerto Rico, and certain other countries to require proof of vaccination from Johnson & Johnson employees and contingent workers, in order

to return to our sites, where permitted by local law and regulation. In the U.S. and Puerto Rico, this requirement took effect on October 4, 2021, with processes established for granting accommodations to those with medical or religious needs. Select manufacturing and distribution employees and contractors in the U.S. and Puerto Rico, as well as certain additional countries, are adopting similar policies through early 2022.

Available Information

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

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

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

Item 1A. RISK FACTORS

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

Risks Related to Our Business, Industry and Operations

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

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's Pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's Medical Devices 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 85 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

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

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

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

Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

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

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

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, epidemics and pandemics, including the global outbreak of coronavirus and its variants (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 and impact of variants. Any resurgence in COVID-19 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 COVID-19 vaccine, including uncertainties related to the risk that our continued development programs may not be successful, commercially viable or receive approval from regulatory authorities; risks associated with clinical trial and real-world data, including further analyses of its efficacy, safety and durability; the risk that data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by national immunization technical advisory groups (NITAGs) and regulatory authorities; disruptions in the relationships between us, our third-party suppliers 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 continue to experience manufacturing delays once a manufacturing site is activated, or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine or product candidate, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods indicated, and other challenges and risks associated with the pace of our vaccine development program; and pricing and access challenges for such products, including in the U.S.

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.

Risks Related to 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 Devices products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among healthcare providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU, United Kingdom, Japan and China, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

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

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

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

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

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

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action by national, state and local government agencies in the U.S. and other countries in which it operates. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of healthcare industry business practices by government agencies and state attorneys general in the U.S., and any

resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 19, "Legal Proceedings—Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

Risks Related to Product Development, Regulatory Approval and Commercialization

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

The Company’s continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving healthcare needs of patients, providers and consumers. Development of successful

products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2021 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

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

Risks Related to Financial and Economic Market Conditions

The Company faces a variety of financial, economic, legal, social and political risks associated with conducting business internationally.
The Company's extensive operations and business activity throughout the world are accompanied by certain financial, economic, legal, social and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2021, approximately 50% of the Company's sales occurred outside of the U.S., with approximately 25% in Europe, 6% in the Western Hemisphere, excluding the U.S., and 19% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

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 and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

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

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is

heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the healthcare providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities;

therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K. Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from healthcare programs.

Other Financial, Economic, Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

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

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

Risks Related to the Planned Separation of our Consumer Health Business

The planned separation of the Company's Consumer Health business may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.
In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a new, publicly traded company. The planned separation is intended to qualify as a tax-free transaction for U.S. federal income tax purposes. The Company is targeting completion of the planned separation in 18 to 24 months after initial announcement. Completion of the planned separation will be subject to the satisfaction of certain conditions, including, among others, consultations with works councils and other employee representative bodies, as required, final approval of the Company's Board of Directors, receipt of a favorable opinion and Internal Revenue Service ("IRS") ruling with respect to the tax-free nature of the transaction, and the receipt of other regulatory approvals. There can be no assurance regarding the ultimate timing of the planned separation or that such separation will be completed. Unanticipated developments could delay, prevent or otherwise adversely affect the planned separation, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances.

The costs to complete the planned separation will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the planned separation of the Company's Consumer Health business.
The Company will incur significant expenses in connection with the planned separation. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the planned separation. The anticipated benefits of the planned separation are based on a number of assumptions, some of which may prove incorrect.

Following the planned separation, the price of shares of the Company's common stock may fluctuate significantly.
The Company cannot predict the effect of the planned separation on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the planned separation. In addition, the price of the Company's common stock may be more volatile around the time of the planned separation.

The planned separation could result in substantial tax liability.
The Company intends to obtain an opinion from its U.S. tax advisors and a ruling from the IRS as to the tax-free nature of the planned separation under the U.S. Internal Revenue Code of 1986, as amended. The opinion and ruling will be based on, among other things, various factual assumptions and representations that the Company and the New Consumer Health Company will make regarding the past and future conduct of the companies' respective businesses and other matters. If any of these assumptions or representations are, or become, inaccurate or incomplete, reliance on the opinion and ruling may be jeopardized. If subsequent to the planned separation it is determined that the transaction does not qualify for tax-free treatment for U.S. federal income tax purposes, the resulting tax liability to the Company and its shareholders could be substantial. The planned separation may also not qualify for tax-free treatment in other countries around the world, and as a result may trigger substantial tax liability to the Company.

Other Risks

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

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

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

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation.
To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses

these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely

impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 85 manufacturing facilities occupying approximately 15.0 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer Health	4,562
Pharmaceutical	5,517
Medical Devices	4,908
Worldwide Total	14,987

Within the U.S., four facilities are used by the Consumer Health segment, five by the Pharmaceutical segment and 17 by the Medical Devices segment. Outside of the U.S., 23 facilities are used by the Consumer Health segment, 13 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	26	4,233
Europe	25	5,991
Western Hemisphere, excluding U.S.	9	1,733
Africa, Asia and Pacific	25	3,030
Worldwide Total	85	14,987

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

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

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

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) operated under a consent decree, signed in 2011 with the U.S. FDA, which governed certain McNeil Consumer Healthcare manufacturing operations, and required McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following U.S. FDA inspections McNEIL-PPC received notifications from the U.S FDA that all three manufacturing facilities were in conformity with applicable laws and regulations, and commercial production restarted in 2015.
Under the Consent Decree, after receiving notice from the U.S. FDA of being in compliance with applicable laws and regulations, each of the three facilities was 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. U.S. FDA inspections of the facilities which have been delayed due to COVID-19 were completed and the Consent Decree was vacated in July of 2021.

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

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Information with regard to the directors of the Company is incorporated herein by reference to the material captioned “Item 1. Election of Directors” in the Proxy Statement.

Name	Age	Position
Vanessa Broadhurst	53	Member, Executive Committee; Executive Vice President, Global Corporate Affairs[a]
Joaquin Duato	59	Chief Executive Officer; Chairman, Executive Committee[b]
Peter M. Fasolo, Ph.D.	59	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[c]
William N. Hait, M.D., Ph. D.	72	Member, Executive Committee; Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer[d]
Mathai Mammen, Ph. D.	54	Member, Executive Committee; Executive Vice President, Pharmaceuticals, R&D[e]
Ashley McEvoy	51	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[f]
Thibaut Mongon	52	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer Health[g]
James Swanson	56	Member, Executive Committee; Executive Vice President, Chief Information Officer[h]
Jennifer L. Taubert	58	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[i]
Michael H. Ullmann	63	Member, Executive Committee; Executive Vice President, General Counsel[j]
Kathryn E. Wengel	56	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[k]
Joseph J. Wolk	55	Member, Executive Committee; Executive Vice President, Chief Financial Officer[l]

(a) Ms. V. Broadhurst joined the Company in 2005 as Worldwide Vice President, Anemia & Oncology Supportive Care. She then went on to become Vice President of the Cardiovascular & Institutional Franchise in 2008, and President of Janssen Therapeutics in 2011 before becoming U.S. President, Internal Medicine in 2012. From 2013 to 2017, she held General Manager roles at Amgen in Inflammation & Cardiovascular, and Cardiovascular & Bone. In 2017, Ms. Broadhurst rejoined Johnson & Johnson as U.S. President, Cardiovascular & Metabolism and a member of the Janssen Americas Leadership Team. In this role she also provided operational oversight of the full portfolio of Janssen medicines in Puerto Rico and Canada. In 2018, she was appointed Company Group Chairman, Global Commercial Strategy Organization. In 2022, Ms. Broadhurst was named Executive Vice President, Global Corporate Affairs and a

member of the Executive Committee, leading the Company's global marketing, communication, design and philanthropy functions.

(b) Mr. J. Duato became Chief Executive Officer and Chairman of the Executive Committee and joined the Board of Directors in January 2022. He joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in all business sectors and across multiple geographies and functions. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, where he provided strategic direction for the Pharmaceutical and Consumer Health sectors and oversaw both the Global Supply Chain, Information Technology and Health & Wellness teams. As a dual citizen of Spain and the United States, Mr. Duato's international perspective and global lens gives him a deep appreciation of diverse thoughts and opinions.

(c) Dr. P. M. Fasolo joined the Company in 2004 as Worldwide Vice President, Human Resources in the Medical Devices segment, and subsequently served as the Company's Chief Talent Officer. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation benefits, employee relations and all aspects of the human resources agenda for the Company. He also serves on the Boards of the Human Resources Policy Association, Tufts University and Save the Children and was named a Fellow of the National Academy of Human Resources in 2017.

(d) Dr. W. Hait joined the Company in 2007 as Senior Vice President, Worldwide Head of Oncology Research. He then served as the first Global Therapeutic Area Head for Oncology from 2009 to 2011, and then as Global Head, Janssen Research & Development from 2011 through 2018. From 2018 to 2022, he was Global Head, Johnson & Johnson Global External Innovation. In 2022, he became Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer, and a member of the Executive Committee. He is responsible for leading external sourcing and creation of transformational innovation to help Johnson & Johnson achieve its mission to improve human health utilizing the Company's excellence in pharmaceuticals, medical devices and consumer products. He also has oversight over Global Public Health and the Office of the Chief Medical Officer.

(e) Dr. M. Mammen joined the Company in 2017 as Global Head of R&D at the Janssen Pharmaceutical Companies of Johnson & Johnson. Prior to joining Janssen in June 2017, Dr. Mammen was Senior Vice President at Merck Research Laboratories, responsible for research in the areas of Cardiovascular, Metabolic and Renal Diseases, Oncology/lmmuno-Oncology and Immunology. Prior to Merck, he led R&D at Theravance, a company he co-founded in the San Francisco Bay Area in 1997 based on his work at Harvard University. In 2022, he was named as Executive Vice President, Pharmaceuticals R&D, and a member of the Executive Committee. He is responsible for a team whose mission is to make transformational medicines with unequivocal benefit for patients worldwide, working across a wide range of therapeutic areas and biological pathways in the areas of: Oncology, Cardiovascular and Metabolic Disease, Retinal Disease, Pulmonary Hypertension, Immunology, Neuroscience and Infectious Disease and Vaccines. These Therapeutic Areas are fueled by world-class Global Functions in Discovery Sciences and Manufacturing, Regulatory Affairs, Development Operations and Data Science.

(f) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, 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.

(g) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held positions of increasing responsibility until he transitioned to the Pharmaceutical sector in 2012, as the Global Commercial Strategy Leader for the Neuroscience therapeutic area. In 2014, he joined the Consumer Health sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer Health, and became a member of the

Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

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

responsible for enhancing Johnson & Johnson's business impact and shaping its direction through the strategic use of technology. Mr. Swanson, Executive Vice President, Chief Information Officer, joined the Executive Committee effective January 3, 2022.

(i) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President, and she held several executive positions of increasing responsibility in the Pharmaceutical sector. In 2012, she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert is responsible for the Pharmaceutical sector globally, including shaping the company's strategy of transformational medical innovation and for successfully bringing to market critical new medicines that significantly improve the lives of patients living with cancer, immune-related diseases, cardiovascular disease, infectious diseases, pulmonary hypertension and serious mental illness.

(j) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1998 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, healthcare compliance, global brand protection and privacy.

(k) 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. Ms. Wengel has enterprise-wide responsibilities for Supply Chain, Quality & Compliance, Procurement, Engineering & Property Services, Environmental Health & Safety and Sustainability.

(l) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 10, 2022, there were 127,899 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 2021. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 4, 2021 through October 31, 2021	549,068	$ 163.78	-	-
November 1, 2021 through November 28, 2021	100,000	163.23	-	-
November 29, 2021 through January 2, 2022	5,391,956	165.09	-	-
Total	6,041,024			

(1) During the fiscal fourth quarter of 2021, the Company repurchased an aggregate of 6,041,024 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 141,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health, Pharmaceutical and 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, distributors, hospitals and healthcare 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 Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer Health, Pharmaceutical and 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 2021 sales. In 2021, $14.7 billion was invested in research and development reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the diversity of its 141,700 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.

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Results of Operations
Analysis of Consolidated Sales
For discussion on results of operations and financial condition pertaining to the fiscal years 2020 and 2019 see the Company’s Annual Report on Form 10-K for the fiscal year ended January 3, 2021, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition.

In 2021, worldwide sales increased 13.6% to $93.8 billion as compared to an increase of 0.6% in 2020. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2021	2020
Volume	12.9 %	3.5 %
Price	(0.7)	(2.3)
Currency	1.4	(0.6)
Total	**13.6 %**	**0.6 %**

The net impact of acquisitions and divestitures on the worldwide sales growth was a negative impact of 0.6% in 2021 and a negative impact of 0.3% in 2020.

Sales by U.S. companies were $47.2 billion in 2021 and $43.1 billion in 2020. This represents increases of 9.3% in 2021 and 2.5% in 2020. Sales by international companies were $46.6 billion in 2021 and $39.5 billion in 2020. This represents an increase of 18.2% in 2021 and a decrease of 1.3% in 2020.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 5.5%, 4.5% and 6.5%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.7%, 5.0% and 2.6%, respectively.

In 2021, sales by companies in Europe achieved growth of 24.3% as compared to the prior year, which included operational growth of 20.7% and a positive currency impact of 3.6%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 7.8% as compared to the prior year, which included operational growth of 7.3% and a positive currency impact of 0.5%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 14.1% as compared to the prior year, including operational growth of 11.4% and a positive currency impact of 2.7%.

The Company estimated that the inclusion of a 53rd week in the fiscal year 2020 results negatively impacted the 2021 comparative sales growth by approximately 1.0%. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). 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 2021, the Company utilized three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2020, the Company had three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0% and 12.0% of the total consolidated revenues.

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Note: values may have been rounded

Analysis of Sales by Business Segments

Consumer Health Segment

Consumer Health segment sales in 2021 were $14.6 billion, an increase of 4.1% from 2020, which included 2.8% operational growth and a positive currency impact of 1.3%. U.S. Consumer Health segment sales were $6.5 billion, an increase of 2.4%. International sales were $8.1 billion, an increase of 5.6%, which included 3.1% operational growth and a positive currency impact of 2.5%. In 2021, acquisitions and divestitures had a net negative impact of 1.0% on the operational sales growth of the worldwide Consumer Health segment.

Major Consumer Health Franchise Sales:

(Dollars in Millions)	2021	2020	% Change '21 vs. '20
OTC	$ 5,227	4,824	8.4 %
Skin Health/Beauty	4,541	4,450	2.0
Oral Care	1,645	1,641	0.2
Baby Care	1,566	1,517	3.2
Women's Health	917	901	1.8
Wound Care/Other	739	720	2.6
Total Consumer Health Sales	**$ 14,635**	**14,053**	**4.1 %**

The OTC franchise sales of $5.2 billion increased 8.4% as compared to the prior year. Growth was primarily attributable to Analgesics, TYLENOL® and MOTRIN®, digestive health and the hydration benefit offering (ORSL).

The Skin Health/Beauty franchise sales of $4.5 billion increased 2.0% as compared to the prior year. Growth was primarily due to COVID-19 recovery, strong performance of NEUTROGENA® and AVEENO®, and eCommerce acceleration partially offset by the divestiture of DR. CI:LABO - Sedona business in Asia Pacific and external supply constraints.

The Oral Care franchise sales of $1.6 billion increased 0.2% as compared to the prior year. Market growth in the U.S. along with strong performance in the Asia Pacific region due to successful brand building and promotional campaigns and the positive impact of currency offset the negative impact of the floss divestiture and U.S. external supply constraints.

The Baby Care franchise sales of $1.6 billion increased 3.2% compared to the prior year. Growth was driven by AVEENO® Asia Pacific eCommerce strength, innovation and COVID-19 recovery.

The Women's Health franchise sales of $0.9 billion increased 1.8% as compared to the prior year primarily driven by COVID-19 market recovery, favorable price and strong brand building in Asia Pacific partially offset by disruptions in Europe due to flooding.

The Wound Care/Other franchise sales of $0.7 billion increased 2.6% as compared to the prior year. Growth was due to strong performance of BAND-AID® Brand Adhesive Bandages in the U.S. partially offset by product discontinuations and competitive pressures in Asia Pacific.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a new, publicly traded company. The Company is targeting completion of the planned separation in 18 to 24 months after initial announcement.

Pharmaceutical Segment

Pharmaceutical segment sales in 2021 were $52.1 billion, an increase of 14.3% from 2020, which included operational growth of 13.1% and a positive currency impact of 1.2%. U.S. sales were $28.0 billion, an increase of 8.6%. International sales were $24.1 billion, an increase of 21.6%, which included 18.8% operational growth and a positive currency impact of 2.8%. In 2021, acquisitions and divestitures had a net negative impact of 0.5% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous sales reserve estimates were approximately $0.7 billion and $0.6 billion in fiscal years 2021 and 2020, respectively.

Major Pharmaceutical Therapeutic Area Sales*:

(Dollars in Millions)	2021	2020	% Change '21 vs. '20
Total Immunology	**$ 16,750**	**15,055**	**11.3 %**
REMICADE®	3,190	3,747	(14.9)
SIMPONI®/SIMPONI ARIA®	2,276	2,243	1.4
STELARA®	9,134	7,707	18.5
TREMFYA®	2,127	1,347	57.9
Other Immunology	24	11	**
Total Infectious Diseases	**5,861**	**3,574**	**64.0**
COVID-19 VACCINE	2,385	—	**
EDURANT®/rilpivirine	994	964	3.1
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	2,083	2,184	(4.6)
Other Infectious Diseases	399	427	(6.5)
Total Neuroscience	**7,011**	**6,548**	**7.1**
CONCERTA®/methylphenidate	667	622	7.3
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/ TREVICTA®	4,022	3,653	10.1
RISPERDAL CONSTA®	592	642	(7.7)
Other Neuroscience	1,729	1,632	6.0
Total Oncology	**14,548**	**12,367**	**17.6**
DARZALEX®	6,023	4,190	43.8
ERLEADA®	1,291	760	70.0
IMBRUVICA®	4,369	4,128	5.8
ZYTIGA® /abiraterone acetate	2,297	2,470	(7.0)
Other Oncology[(1)]	568	821	(30.8)
Total Pulmonary Hypertension	**3,450**	**3,148**	**9.6**
OPSUMIT®	1,819	1,639	11.0
UPTRAVI®	1,237	1,093	13.1
Other Pulmonary Hypertension	395	416	(5.0)
Total Cardiovascular / Metabolism / Other	**4,460**	**4,878**	**(8.6)**
XARELTO®	2,438	2,345	4.0
INVOKANA®/ INVOKAMET®	563	795	(29.3)
PROCRIT®/EPREX®	479	552	(13.3)
Other	981	1,186	(17.3)
Total Pharmaceutical Sales	**$ 52,080**	**45,572**	**14.3 %**

*Certain prior year amounts have been reclassified to conform to current year presentation

** Percentage greater than 100% or not meaningful

[(1)] Inclusive of VELCADE® which was previously disclosed separately

Immunology products achieved sales of $16.8 billion in 2021, representing an increase of 11.3% 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 and uptake in Psoriatic Arthritis. This was partially offset by lower sales of REMICADE® (infliximab) due to biosimilar competition.

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

The latest expiring United States patent for STELARA® (ustekinumab) will expire in September 2023. STELARA® (ustekinumab) U.S. sales in fiscal 2021 were approximately $5.9 billion. The expiration of a product patent or loss of market exclusivity is likely to result in a reduction in sales.

Infectious disease products achieved sales of $5.9 billion in 2021, representing an increase of 64.0% as compared to the prior year. Growth was primarily driven by the contribution of the COVID-19 vaccine. This was partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA® in certain countries outside the U.S.

Neuroscience products achieved sales of $7.0 billion, representing an increase of 7.1% as compared to the prior year. Paliperidone long-acting injectables growth was driven by sales of INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA TRINZA®/TREVICTA® from new patient starts and persistence as well as the launch of INVEGA HAFYERA™.

Oncology products achieved sales of $14.5 billion in 2021, representing an increase of 17.6% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) driven by continued strong market growth, share gains in all regions and solid uptake of the subcutaneous formulation launched in 2020; the continued global launch uptake of ERLEADA® (apalutamide) and IMBRUVICA® (ibrutinib) growth primarily driven by market and continued share leadership. The growth of IMBRUVICA® (ibrutinib) was partially offset by competitive pressures from novel oral agents and COVID-19 related market dynamics including delays in new patient starts.

Pulmonary Hypertension products achieved sales of $3.5 billion, representing an increase of 9.6% as compared to the prior year. Sales growth of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to continued share gains and market growth.

Cardiovascular/Metabolism/Other products sales were $4.5 billion, a decline of 8.6% as compared to the prior year. The decline was primarily attributable to lower sales of INVOKANA®/INVOKAMET® (canagliflozin) due to share erosion and PROCRIT®/ EPREX® (epoetin alfa) due to biosimilar competition.

During 2021, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs

Product Name (Chemical Name)	Indication	US Approval	EU Approval
BYANNLI®	Maintenance Treatment of Schizophrenia in Adults		●
CABENUVA (rilpivirine and cabotegravir)	HIV treatment for use every two months		
COVID-19 Vaccine	COVID-19 Emergency Use	●	●
COVID-19 Vaccine Booster Shot	COVID-19 Emergency Use	●	●
DARZALEX® (daratumumab)	Subcutaneous (SC) formulation Treatment for Newly Diagnosed Systemic Light Chain Amyloidosis and Gains an Additional Approval in Pre-Treated Multiple Myeloma		●
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)	Combination with Carfilzomib and Dexamethasone for Patients with Multiple Myeloma After First or Subsequent Relapse	●	
INVEGA HAFYERA (paliperidone palmitate)	First and Only Twice-Yearly Treatment for Adults with Schizophrenia	●	
PONVORY (Ponesimod)	Treatment of Adults with Relapsing Forms of Multiple Sclerosis with Active Disease Defined by Clinical or Imaging Features		●
PONVORY (Ponesimod)	Oral Treatment for Adults with Relapsing Multiple Sclerosis	●	
RYBREVANT (amivantamab-vmjw)	Treatment for Patients with Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations	●	
SPRAVATO® (esketamine)	Rapid reduction of depressive symptoms in a psychiatric emergency for patients with major depressive disorder		●
STELARA®	Treatment of		

Medical Devices Segment

The Medical Devices segment sales in 2021 were $27.1 billion, an increase of 17.9% from 2020, which included operational growth of 16.2% and a positive currency impact of 1.7%. U.S. sales were $12.7 billion, an increase of 14.9% as compared to the prior year. International sales were $14.4 billion, an increase of 20.6% as compared to the prior year, which included operational growth of 17.3% and a positive currency impact of 3.3%. In 2021, the net impact of acquisitions and divestitures on the Medical Devices segment worldwide operational sales growth was a negative 0.6% primarily due to the divestiture of Advanced Sterilization Products (ASP). The Company has seen a market recovery in global procedural volumes in the Medical Devices segment as compared to the prior year which had significant negative impacts from COVID-19. This procedural volume recovery is the primary driver of sales and earnings growth as compared to the prior year.

Major Medical Devices Franchise Sales:

(Dollars in Millions)	2021	2020	% Change '21 vs. '20
Surgery	**$ 9,812**	**8,232**	**19.2 %**
Advanced	4,622	3,839	20.4
General	5,190	4,392	18.1
Orthopaedics	**8,588**	**7,763**	**10.6**
Hips	1,485	1,280	16.0
Knees	1,325	1,170	13.3
Trauma	2,885	2,614	10.4
Spine, Sports & Other	2,893	2,699	7.2
Vision	**4,688**	**3,919**	**19.6**
Contact Lenses/Other	3,440	2,994	14.9
Surgical	1,248	925	34.9
Interventional Solutions	**3,971**	**3,046**	**30.4**
Total Medical Devices Sales	**$ 27,060**	**22,959**	**17.9 %**

The Surgery franchise achieved sales of $9.8 billion in 2021 representing an increase of 19.2% from 2020. The growth in Advanced Surgery was primarily driven by Endocutter, Biosurgery and Energy products attributable to market recovery, market expansion and the success of new products offsetting competitive pressures in the U.S. The growth in General Surgery was primarily driven by market recovery and the continued strength of the suture portfolio partially offset by the impact of the ASP divestiture in the prior year.

The Orthopaedics franchise achieved sales of $8.6 billion in 2021, representing an increase of 10.6% from 2020. The growth in hips reflects the market recovery combined with continued strength of the portfolio including the ACTIS® stem and enabling technologies – KINCISE™ and VELYS™ Hip Navigation. The growth in knees was primarily driven by procedure recovery and new product introductions. The growth in Trauma was driven by global market recovery and uptake of new products. The growth in Spine, Sports & Other was primarily driven by procedure recovery and new product introductions.

The Vision franchise achieved sales of $4.7 billion in 2021, representing an increase of 19.6% from 2020. The Contact Lenses/Other operational growth was due to market recovery and market share gains from new products. Surgical Vision operational growth was primarily due to market recovery and uptake of recently launched products.

The Interventional Solutions franchise achieved sales of $4.0 billion in 2021, an increase of 30.4% from 2020. Growth in the electrophysiology and stroke businesses were driven by market recovery and success of new products and commercial strategies.

Beginning in the fiscal first quarter of 2022, the Medical Devices segment will be referred to as the MedTech segment.

Analysis of Consolidated Earnings Before Provision for Taxes on Income
Consolidated earnings before provision for taxes on income was $22.8 billion and $16.5 billion for the years 2021 and 2020, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 24.3% and 20.0%, in 2021 and 2020, respectively.

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

Cost of Products Sold and Selling, Marketing and Administrative Expenses:

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

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

- Non-recurring prior year COVID-19 production related slow-downs and related inventory impacts
- Fixed cost deleveraging in the Medical Devices business in the fiscal 2020
- Favorable mix within the Pharmaceutical business as well as at the enterprise level with a higher percentage of sales coming from the Pharmaceutical business
- Supply chain efficiencies in the Consumer Health segment

The intangible asset amortization expense included in cost of products sold was $4.7 billion for both fiscal years 2021 and 2020.

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

- Leveraging in the Medical Devices business resulting from the recovery of sales from the prior years impact of COVID-19

  Partially offset by:
- Increased brand marketing expenses in the Consumer Health business

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

	2021		2020	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Consumer Health	$ 455	3.1 %	$ 422	3.0 %
Pharmaceutical	11,882	22.8	9,563	21.0
Medical Devices	2,377	8.8	2,174	9.5
Total research and development expense	$ 14,714	15.7 %	$ 12,159	14.7 %
Percent increase/(decrease) over the prior year	21.0 %		7.1 %	

*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:

- General portfolio progression in the Pharmaceutical business
- COVID-19 vaccine expenses, net of governmental reimbursements

In-Process Research and Development (IPR&D): In fiscal year 2021, the Company recorded a partial IPR&D charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The Company will continue to monitor the remaining $1.5 billion Ottava platform intangible asset as development program activities are ongoing. 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.

On January 28, 2022, subsequent to the fiscal year 2021, additional information regarding efficacy became available which led the Company to the decision to terminate the development of bermekimab for Atopic Dermatitis (AD). The Company recorded an intangible asset impairment charge of approximately $0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of AD and Hidradenitis Suppurativa (HS). The impairment charge is related to the AD indication and is a nonrecognized subsequent event and will be reflected in the first quarter 2022 financial statements. The Company acquired all rights to bermekimab from XBiotech, Inc. in fiscal year 2020.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), unrealized gains and losses on investments, income and losses associated with certain employee benefit programs, 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 2021 was favorable by $2.4 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2021	2020	Change
Litigation expense[1]	$ 2.3	5.1	(2.8)
Acquisition, Integration and Divestiture related[2]	(0.5)	(1.1)	0.6
(Gains)/losses on securities	(0.5)	(0.5)	0.0
Restructuring related	0.1	0.1	0.0
Employee benefit plan related	(0.6)	(0.4)	(0.2)
Other[3]	(0.3)	(0.3)	—
Total Other (Income) Expense, Net	$ 0.5	2.9	(2.4)

[1]2021 is primarily related to talc and Risperdal. 2020 is primarily related to talc and the opioid litigation settlement.
[2]2021 is primarily related to divestiture gains of two pharmaceutical brands outside the U.S.
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]2021 includes Consumer Health separation costs of $0.1 billion. Costs in future years are expected to be significantly higher.

Interest (Income) Expense: The fiscal year 2021 included net interest expense of $130 million as compared to $90 million net interest expense in the fiscal year 2020. This was primarily due to lower rates of interest earned on cash balances and a higher average debt balance, partially offset by the benefit from net investment hedging. Cash, cash equivalents and marketable securities totaled $31.6 billion at the end of 2021, and averaged $28.4 billion as compared to the cash, cash equivalents and marketable securities total of $25.2 billion and $22.2 billion average cash balance in 2020. The total debt balance at the end of 2021 was $33.8 billion with an average debt balance of $34.5 billion as compared to $35.3 billion at the end of 2020 and an average debt balance of $31.5 billion.

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

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**
Consumer Health	$ 1,294	(1,064)	14,635	14,053	8.8 %	(7.6)
Pharmaceutical	18,181	15,462	52,080	45,572	34.9	33.9
Medical Devices	4,373	3,044	27,060	22,959	16.2	13.3
Total [1]	23,848	17,442	93,775	82,584	25.4	21.1
Less: Net expense not allocated to segments [2]	1,072	945				
Earnings before provision for taxes on income	$ 22,776	16,497	93,775	82,584	24.3 %	20.0

[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 2021, the Consumer Health segment income before tax as a percent of sales was 8.8% versus a loss before tax of 7.6% in 2020. The increase in the income before tax as a percent of sales was primarily driven by the following:

- 2021 litigation expense includes $1.6 billion of talc expenses; 2020 includes $3.9 billion of talc expenses
- Supply chain efficiencies

partially offset by:

- Increased brand marketing expenses and commodity inflation

Pharmaceutical Segment:
In 2021, the Pharmaceutical segment income before tax as a percent to sales was 34.9% versus 33.9% in 2020. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Divestiture gains of $0.6 billion related to two pharmaceutical brands outside the U.S. in fiscal 2021
- 2021 litigation expense includes $0.6 billion primarily related to Risperdal; 2020 includes $0.8 billion primarily related to the opioid litigation settlement

partially offset by:

- Research & Development investment in the COVID-19 vaccine net of governmental reimbursements and general portfolio progression

Medical Devices Segment: In 2021, the Medical Devices segment income before tax as a percent to sales was 16.2% versus 13.3% in 2020. The increase in the income before tax as a percent to sales was primarily driven by the following:

- Recovery of prior year COVID-19 production related slow downs and related inventory impacts
- Overall expense leveraging resulting from the Medical Devices sales recovery
- Litigation expense of $0.1 billion in 2021 vs. $0.3 billion in 2020

partially offset by:

- A contingent consideration reversal of approximately $1.1 billion in the fiscal 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition
- A higher IPR&D charge of $0.7 billion ($0.9 billion in 2021 related to the general surgery offering in digital robotics (Ottava) acquired with the Auris Health acquisition 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 the end of 2022. The Company expects to record pre-tax restructuring charges of approximately $2.1 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2021, the Company recorded a pre-tax charge of $0.5 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.8 billion have been recorded since the restructuring was announced. The program is set to be completed at the end of 2022.

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

Provision for Taxes on Income: The worldwide effective income tax rate was 8.3% in 2021 and 10.8% in 2020.

For discussion related to the fiscal 2021 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $14.5 billion at the end of 2021 as compared to $14.0 billion at the end of 2020.

(Dollars In Billions)	
$ 14.0	Q4 2020 Cash and ca
23.4	cash generated from
(8.7)	net cash used by inve
(14.0)	net cash used by fina
(0.2)	effect of exchange ra
$ 14.5	Q4 2021 Cash and ca

The primary sources and uses of cash that contributed to the $0.5 billion increase were:

In addition, the Company had $17.1 billion in marketable securities at the end of fiscal year 2021 and $11.2 billion at the end of fiscal year 2020. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $23.4 billion was the result of:

(Dollars In Billions)	
$ 20.9	Net Earnings
6.8	non-cash expenses and other adjustments primaril stock-based compensation and asset write-downs provision, net gain on sale of assets/businesses an receivable allowances
(1.1)	a decrease in current and non-current liabilities
2.4	an increase in accounts payable and accrued liabil
(5.6)	an increase in accounts receivable, inventories an
$ 23.4	Cash Flow from operations

Investing activities use of $8.7 billion of cash was primarily used for:

(Dollars In Billions)	
$ (3.7)	additions to property, plant and equipmer
(5.4)	net purchases of investments
0.7	proceeds from the disposal of assets/busi
0.2	Credit support agreements activity, net
(0.1)	acquisitions
(0.4)	other (primarily licenses and milestones)
$ (8.7)	Net cash used for investing activities

Financing activities use of $14.0 billion of cash was primarily used for:

(Dollars In Billions)	
$ (11.0)	dividends to shareholders
(3.5)	repurchase of common stock for empl
(1.0)	net repayment from short and long ter
1.0	proceeds from stock options exercised
0.3	Credit support agreements activity, ne
0.2	other and rounding
$ (14.0)	Net cash used for financing activities

As of January 2, 2022, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of January 2, 2022, the net debt position was $2.1 billion as compared to the prior year of $10.1 billion. There was a decrease in the net debt position due to repayment of debt and an increase in cash, cash equivalents, and marketable securities generating from operations. The debt balance at the end of 2021 was $33.8 billion as compared to $35.3 billion in 2020. 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 Company's approximate $1.1 billion in contractual supply commitments associated with its development of the COVID-19 vaccine, the opioid litigation settlement for $5.0 billion and the establishment of the $2.0 billion trust for talc related liabilities (See Note 19 to the Consolidated Financial Statements for additional details). In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. Effective beginning in fiscal 2022, the U.S. Tax Cuts and Job Act of 2017 currently requires the Company to deduct U.S. and international research and development expenditures for tax purposes over 5 to 15 years, instead of in the current fiscal year. As a result, the Company is expecting an increase in annual cash tax payments to the U.S Treasury of an incremental $1.0 to 1.5 billion beginning in fiscal 2022. The Company will concurrently record a deferred tax benefit for the future amortization of the research and development (R&D) for tax purposes and therefore, the Company is not expecting a significant impact to its effective tax rate related to this change. The requirement to expense R&D as incurred is unchanged for U.S. GAAP purposes and the impact to pre-tax R&D expense is not affected by this provision. 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. During the fiscal third quarter of

2021, in accordance with the terms of the agreement associated with the acquisition of Actelion, the Company's undrawn credit facility with Idorsia was terminated.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of January 2, 2022: 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
2022	$ 812	2,131	909	3,852
2023	1,522	1,551	893	3,966
2024	2,029	1,518	843	4,390
2025	2,536	1,732	789	5,057
2026	—	1,995	744	2,739
After 2026	—	23,189	8,786	31,975
Total	**$ 6,899**	**32,116**	**12,964**	**51,979**

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 $1.1 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 2, 2022 market rates would increase the unrealized value of the Company's forward contracts by $0.1 billion. Conversely, a 10% depreciation of the U.S. Dollar from the January 2, 2022 market rates would decrease the unrealized value of the Company's forward contracts by $0.1 billion. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $2.2 billion. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

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

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $0.1 billion.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2021, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 8, 2022. Interest charged on borrowings under the credit line agreement is based on either Secured Overnight Financing Rate (SOFR) Reference Rate or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2021 and 2020 were $33.8 billion and $35.3 billion, respectively. The decrease in borrowings was due to the repayment of debt. In 2021, net debt (cash and current marketable securities, net of debt)

was $2.1 billion compared to net debt of $10.1 billion in 2020. Total debt represented 31.3% of total capital (shareholders' equity and total debt) in 2021 and 35.8% of total capital in 2020. Shareholders' equity per share at the end of 2021 was $28.16 compared to $24.04 at year-end 2020.

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

Dividends
The Company increased its dividend in 2021 for the 59th consecutive year. Cash dividends paid were $4.19 per share in 2021 and $3.98 per share in 2020.

On January 4, 2022, the Board of Directors declared a regular cash dividend of $1.06 per share, payable on March 8, 2022 to shareholders of record as of February 22, 2022.

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 2, 2022 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 2, 2022, 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, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the 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 2021 and 2020.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based

sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in

sales to customers. 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 2, 2022 and January 3, 2021.

Consumer Health Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2021				
Accrued rebates [(1)]	$ 289	893	(895)	287
Accrued returns	76	136	(136)	76
Accrued promotions	428	1,958	(1,999)	387
Subtotal	$ 793	2,987	(3,030)	750
Reserve for doubtful accounts	39	0	(7)	32
Reserve for cash discounts	12	213	(210)	15
Total	$ 844	3,200	(3,247)	797
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

(1) Includes reserve for customer rebates of $80 million at January 2, 2022 and $66 million at January 3, 2021, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2021				
Accrued rebates [1]	$ 9,837	37,922	(37,428)	10,331
Accrued returns	460	345	(285)	520
Accrued promotions	6	13	(16)	3
Subtotal	10,303	38,280	(37,729)	10,854
Reserve for doubtful accounts	52	18	(20)	50
Reserve for cash discounts	70	1,163	(1,139)	94
Total	10,425	39,461	(38,888)	10,998
2020				
Accrued rebates [1]	$ 9,013	32,415	(31,591)	9,837
Accrued returns	500	233	(273)	460
Accrued promotions	5	10	(9)	6
Subtotal	$ 9,518	32,658	(31,873)	10,303
Reserve for doubtful accounts	36	24	(8)	52
Reserve for cash discounts	65	1,034	(1,029)	70
Total	$ 9,619	33,716	(32,910)	10,425

(1) Includes reserve for customer rebates of $218 million at January 2, 2022 and $174 million at January 3, 2021, recorded as a contra asset.

(2) Includes prior period adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2021				
Accrued rebates[1]	$ 1,174	5,942	(5,670)	1,446
Accrued returns	138	559	(563)	134
Accrued promotions	52	140	(138)	54
Subtotal	1,364	6,641	(6,371)	1,634
Reserve for doubtful accounts	202	12	(66)	148
Reserve for cash discounts	9	96	(95)	10
Total	1,575	6,749	(6,532)	1,792
2020				
Accrued rebates[1]	$ 1,013	5,144	(4,983)	1,174
Accrued returns	118	578	(558)	138
Accrued promotions	46	118	(112)	52
Subtotal	$ 1,177	5,840	(5,653)	1,364
Reserve for doubtful accounts	155	95	(48)	202
Reserve for cash discounts	10	88	(89)	9
Total	$ 1,342	6,023	(5,790)	1,575

(1) Includes reserve for customer rebates of $845 million at January 2, 2022 and $707 million at January 3, 2021, recorded as a contra asset.

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

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

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.7 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

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

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

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

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

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. 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 2, 2022.

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 help 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.
- *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 and 2021, 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 for services to be delivered and contractually obligated to be paid to these contract manufacturing organizations of approximately $1.1 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 continues to evaluate and monitor both its internal and external supply arrangements, including its contract with Emergent BioSolutions and related production activities at its Bayview, Maryland facility. The Company has established a global vaccine supply network, where, in addition to its internal manufacturing site in Leiden, the Netherlands, ten other manufacturing sites will be involved in the production of vaccine across different countries and continents. The Company does not believe that a disruption at a vaccine manufacturing site, or the resulting delay would have a material financial impact on the Company’s consolidated financial statements or results.

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of healthcare. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2011 - 2021, in the U.S., the weighted average compound annual growth rate of the Company’s net price increases for healthcare products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. 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.

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 2021 would have increased or decreased the translation of foreign sales by approximately $0.5 billion and net income by approximately $0.2 billion.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to

greater audit scrutiny of profits earned in other countries. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

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

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

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

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 2, 2022, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

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

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 10, 2022, there were 127,899 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 2, 2022 and January 3, 2021
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2021	2020
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	14,487	13,985
Marketable securities (Notes 1 and 2)		17,121	11,200
Accounts receivable trade, less allowances for doubtful accounts $230 (2020, $293)		15,283	13,576
Inventories (Notes 1 and 3)		10,387	9,344
Prepaid expenses and other receivables		3,701	3,132
Total current assets		**60,979**	**51,237**
Property, plant and equipment, net (Notes 1 and 4)		18,962	18,766
Intangible assets, net (Notes 1 and 5)		46,392	53,402
Goodwill (Notes 1 and 5)		35,246	36,393
Deferred taxes on income (Note 8)		10,223	8,534
Other assets		10,216	6,562
Total assets	**$**	**182,018**	**174,894**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	3,766	2,631
Accounts payable		11,055	9,505
Accrued liabilities		13,612	13,968
Accrued rebates, returns and promotions		12,095	11,513
Accrued compensation and employee related obligations		3,586	3,484
Accrued taxes on income (Note 8)		1,112	1,392
Total current liabilities		**45,226**	**42,493**
Long-term debt (Note 7)		29,985	32,635
Deferred taxes on income (Note 8)		7,487	7,214
Employee related obligations (Notes 9 and 10)		8,898	10,771
Long-term taxes payable (Note 1)		5,713	6,559
Other liabilities		10,686	11,944
Total liabilities		**107,995**	**111,616**
Commitments and Contingencies (Note 19)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(13,058)	(15,242)
Retained earnings		123,060	113,890
		113,122	101,768
Less: common stock held in treasury, at cost (Note 12) (490,878,000 shares and 487,331,000 shares)		39,099	38,490
Total shareholders' equity		**74,023**	**63,278**
Total liabilities and shareholders' equity	**$**	**182,018**	**174,894**

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)

		2021	2020	2019
Sales to customers	$	93,775	82,584	82,059
Cost of products sold		29,855	28,427	27,556
Gross profit		63,920	54,157	54,503
Selling, marketing and administrative expenses		24,659	22,084	22,178
Research and development expense		14,714	12,159	11,355
In-process research and development (Note 5)		900	181	890
Interest income		(53)	(111)	(357)
Interest expense, net of portion capitalized (Note 4)		183	201	318
Other (income) expense, net		489	2,899	2,525
Restructuring (Note 20)		252	247	266
Earnings before provision for taxes on income		22,776	16,497	17,328
Provision for taxes on income (Note 8)		1,898	1,783	2,209
Net earnings	**$**	**20,878**	**14,714**	**15,119**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**7.93**	**5.59**	**5.72**
Diluted	**$**	**7.81**	**5.51**	**5.63**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,632.1**	**2,632.8**	**2,645.1**
Diluted		**2,674.0**	**2,670.7**	**2,684.3**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2021	2020	2019
Net earnings	$ 20,878	14,714	15,119
Other comprehensive income (loss), net of tax			
Foreign currency translation	(1,079)	(233)	164
Securities:			
Unrealized holding gain (loss) arising during period	(4)	1	—
Reclassifications to earnings	—	—	—
Net change	(4)	1	—
Employee benefit plans:			
Prior service credit (cost), net of amortization	(169)	1,298	(18)
Gain (loss), net of amortization	4,318	(1,135)	(714)
Effect of exchange rates	106	(229)	(1)
Net change	4,255	(66)	(733)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(199)	1,000	(107)
Reclassifications to earnings	(789)	(53)	7
Net change	(988)	947	(100)
Other comprehensive income (loss)	2,184	649	(669)
Comprehensive income	$ 23,062	15,363	14,450

The tax effects in other comprehensive income for the fiscal years 2021, 2020 and 2019 respectively: Foreign Currency Translation; $346 million, $536 million and $19 million; Securities: $1 million in 2021, Employee Benefit Plans: $1,198 million, $21 million and $222 million, Derivatives & Hedges: $263 million, $252 million and $27 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 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)**
Net earnings	20,878	20,878			
Cash dividends paid ($4.19 per share)	(11,032)	(11,032)			
Employee compensation and stock option plans	2,171	(676)			2,847
Repurchase of common stock	(3,456)				(3,456)
Other comprehensive income (loss), net of tax	2,184		2,184		
Balance, January 2, 2022	**$ 74,023**	**123,060**	**(13,058)**	**3,120**	**(39,099)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in Millions) (Note 1)

	2021	2020	2019
Cash flows from operating activities			
Net earnings	$ 20,878	14,714	15,119
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,390	7,231	7,009
Stock based compensation	1,135	1,005	977
Asset write-downs	989	233	1,096
Contingent consideration reversal	—	(1,148)	—
Net gain on sale of assets/businesses	(617)	(111)	(2,154)
Deferred tax provision	(2,079)	(1,141)	(2,476)
Credit losses and accounts receivable allowances	(48)	63	(20)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
(Increase)/Decrease in accounts receivable	(2,402)	774	(289)
Increase in inventories	(1,248)	(265)	(277)
Increase in accounts payable and accrued liabilities	2,437	5,141	4,060
Increase in other current and non-current assets	(1,964)	(3,704)	(1,054)
(Decrease)/Increase in other current and non-current liabilities	(1,061)	744	1,425
Net cash flows from operating activities	**23,410**	**23,536**	**23,416**
Cash flows from investing activities			
Additions to property, plant and equipment	(3,652)	(3,347)	(3,498)
Proceeds from the disposal of assets/businesses, net	711	305	3,265
Acquisitions, net of cash acquired (Note 18)	(60)	(7,323)	(5,810)
Purchases of investments	(30,394)	(21,089)	(3,920)
Sales of investments	25,006	12,137	3,387
Credit support agreements activity, net	214	(987)	338
Other (primarily licenses and milestones)	(508)	(521)	44
Net cash used by investing activities	**(8,683)**	**(20,825)**	**(6,194)**
Cash flows from financing activities			
Dividends to shareholders	(11,032)	(10,481)	(9,917)
Repurchase of common stock	(3,456)	(3,221)	(6,746)
Proceeds from short-term debt	1,997	3,391	39
Repayment of short-term debt	(1,190)	(2,663)	(100)
Proceeds from long-term debt, net of issuance costs	5	7,431	3
Repayment of long-term debt	(1,802)	(1,064)	(2,823)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,036	1,114	954
Credit support agreements activity, net	281	(333)	100
Other	114	(294)	475
Net cash used by financing activities	**(14,047)**	**(6,120)**	**(18,015)**
Effect of exchange rate changes on cash and cash equivalents	(178)	89	(9)
Increase/(Decrease) in cash and cash equivalents	502	(3,320)	(802)
Cash and cash equivalents, beginning of year (Note 1)	13,985	17,305	18,107
Cash and cash equivalents, end of year (Note 1)	**$ 14,487**	**13,985**	**17,305**

Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 990	904	995
Interest, net of amount capitalized	941	841	925
Income taxes	4,768	4,619	4,191

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	$	1,811	1,937	1,736
Conversion of debt		—	27	1
Acquisitions				
Fair value of assets acquired	$	61	7,755	7,228
Fair value of liabilities assumed and noncontrolling interests		(1)	(432)	(1,418)
Net cash paid for acquisitions (Note 18)	**$**	**60**	**7,323**	**5,810**

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 141,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health, Pharmaceutical and 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, distributors, hospitals and healthcare 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 Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a new, publicly traded company. The Company is targeting completion of the planned separation in 18 to 24 months after initial announcement.

New Accounting Standards

Recently Adopted Accounting Standards

There were no new material accounting standards adopted in fiscal 2021.

Recently Issued Accounting Standards

Not Adopted as of January 2, 2022

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 January 3, 2021. There were no new material accounting standards issued in fiscal 2021 that impacted the Company.

ASU 2021-01: Reference Rate Reform

In mid- 2017, the Financial Conduct Authority (FCA) announced that it will no longer require banks to submit rates for the London Interbank Offered Rate (LIBOR) after 2021 hence market participants should work to transition to alternative reference rates (Reference Rate Reform) and should not rely on LIBOR being available after the end of 2021. Reference rate reform is the term used to refer to the efforts that have been undertaken by regulators and other market participants to introduce new reference rates that are based on a larger and more liquid population of observable transactions. The Company evaluated the implications of reference rate reform and applicable financial reporting guidance in ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting on its key financial and commercial contracts that referenced LIBOR including any hedging relationships. Most contracts reviewed will mature prior to the termination of LIBOR or will be modified to apply a new reference rate (primarily the Secured Overnight Financing Rate "SOFR" where applicable). The company also applied available practical expedients under ASC 848 to in scope financial and commercial contracts that previously referenced LIBOR when applicable. As a result, the Company's implementation of any reference rate reform provisions to commercial and financial contracts did not result in any material change for 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	
Land and leasehold improvements	
Machinery and equipment	

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

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

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

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.7 billion and $7.2 billion as of January 2, 2022 and January 3, 2021, 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 2021, 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 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 $1.1 billion, $1.0 billion and $1.0 billion in fiscal years 2021, 2020 and 2019, 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 2021 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 $0.9 billion and $1.0 billion in 2021 and 2020, respectively. The lease liability was $1.0 billion and $1.1 billion in 2021and 2020, respectively. The operating lease costs were $0.3 billion, $0.3 billion and $0.3 billion in 2021, 2020 and 2019, respectively. Cash paid for amounts included in the measurement of lease liabilities were $0.3 billion, $0.3 billion and $0.3 billion in 2021, 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 $2.7 billion, $2.1 billion and $2.2 billion in fiscal years 2021, 2020 and 2019, 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 2021 was approximately $6.9 billion, of which $6.1 billion is classified as noncurrent and reflected as “Long-term taxes payable” on the Company’s balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

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

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.7 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

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

Net Earnings Per Share

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

Use of Estimates

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

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

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 2, 2022 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 along with the Company's on-going vaccine development and distribution efforts. While there was not a material impact to the Company's consolidated financial statements as of and for the fiscal year ended January 2, 2022, 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 2021 and 2020, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2021				
	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,936	—	2,936	2,936	—
Non-U.S. Sovereign Securities[1]	1,006	—	1,006	90	916
U.S. Reverse repurchase agreements	1,659	—	1,659	1,659	—
Corporate debt securities[1]	3,479	(1)	3,478	200	3,279
Money market funds	1,901	—	1,901	1,901	—
Time deposits[1]	900	—	900	900	—
Subtotal	$ 11,881	(1)	11,880	7,686	4,195
U.S. Gov't Securities	$ 19,485	(4)	19,481	6,785	12,696
Other Sovereign Securities	1	—	1	1	—
Corporate debt securities	245	—	245	15	230
Subtotal available for sale[2]	$ 19,731	(4)	19,727	6,801	12,926
Total cash, cash equivalents and current marketable securities				**$ 14,487**	**17,121**

(Dollars in Millions)	2020				
	Carrying Amount	Unrecognized Gain	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,863	—	2,863	2,863	—
Non-U.S. Sovereign Securities[1]	690	—	690	—	690
U.S. Reverse repurchase agreements	1,937	—	1,937	1,937	—
Corporate debt securities[1]	2,674	—	2,674	1,451	1,223
Money market funds	2,102	—	2,102	2,102	—
Time deposits[1]	877	—	877	877	—
Subtotal	$ 11,143	—	11,143	9,230	1,913
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**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

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

The contractual maturities of the available for sale debt securities at January 2, 2022 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 19,709	19,705
Due after one year through five years	22	22
Due after five years through ten years	—	—
Total debt securities	$ 19,731	19,727

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 2021 and 2020, inventories were comprised of:

(Dollars in Millions)	**2021**	**2020**
Raw materials and supplies	$ 1,592	1,410
Goods in process	2,287	2,040
Finished goods	6,508	5,894
Total inventories	**$ 10,387**	**9,344**

4. Property, Plant and Equipment

At the end of fiscal years 2021 and 2020, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	**2021**	**2020**
Land and land improvements	$ 884	882
Buildings and building equipment	12,882	12,502
Machinery and equipment	29,774	29,104
Construction in progress	4,139	4,316
Total property, plant and equipment, gross	$ 47,679	46,804
Less accumulated depreciation	28,717	28,038
Total property, plant and equipment, net[(1)]	**$ 18,962**	**18,766**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2021, 2020 and 2019 was $49 million, $63 million and $70 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2021, 2020 and 2019 was $2.7 billion, $2.6 billion and $2.5 billion, respectively.

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

5. Intangible Assets and Goodwill

At the end of fiscal years 2021 and 2020, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2021	2020
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 38,572	39,990
Less accumulated amortization	(20,088)	(17,618)
Patents and trademarks — net	**$ 18,484**	**22,372**
Customer relationships and other intangibles — gross	$ 23,011	22,898
Less accumulated amortization	(11,925)	(10,912)
Customer relationships and other intangibles — net[1]	**$ 11,086**	**11,986**
Intangible assets with indefinite lives:		
Trademarks	$ 6,985	7,195
Purchased in-process research and development[2]	9,837	11,849
Total intangible assets with indefinite lives	**$ 16,822**	**19,044**
Total intangible assets — net	**$ 46,392**	**53,402**

[1]The majority is comprised of customer relationships

[2]In fiscal 2021, the Company recorded a partial IPR&D impairment charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The remaining reduction was driven by assets that reached commercialization and are now classified as having definite lives.

Goodwill as of January 2, 2022 and January 3, 2021, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	Medical Devices	Total
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
Goodwill, related to acquisitions	—	—	—	—
Goodwill, related to divestitures	(9)	—	—	(9)
Currency translation/other	(517)	(429)	(192)	(1,138)
Goodwill at January 2, 2022	**$ 9,810**	**10,580**	**14,856**	**35,246**

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, $4.7 billion and $4.5 billion before tax, for the fiscal years ended January 2, 2022, January 3, 2021 and December 29, 2019, 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)

2022	2023	2024	2025	2026
$4,600	4,600	4,400	3,600	3,000

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 2, 2022, the total amount of cash collateral paid by the Company under the CSA amounted to $570 million 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 2, 2022, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $45.8 billion, $37.4 billion and $10.0 billion, respectively. 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.

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

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

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

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 2, 2022, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $336 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts and net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended

(Dollars in Millions)	January 2, 2022 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Ja Sales	Cost of Products Sold
The effects of fair value, net investment and cash flow hedging:							
Gain (Loss) on fair value hedging relationship:							
Interest rate swaps contracts:							
Hedged items	$ —	—	—	(109)	—	—	—
Derivatives designated as hedging instruments	—	—	—	109	—	—	—
Gain (Loss) on net investment hedging relationship:							
Cross currency interest rate swaps contracts:							
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	$ —	—	—	174	—	—	—
Amount of gain or (loss) recognized in AOCI	—	—	—	174	—	—	—
Gain (Loss) on cash flow hedging relationship:							
Forward foreign exchange contracts:							
Amount of gain or (loss) reclassified							

As of January 2, 2022 and January 3, 2021, the following amounts were recorded on the consolidated balance sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
(Dollars in Millions)	January 2, 2022	January 3, 2021	January 2, 2022	January 3, 2021
Long-term Debt	$ 9,793	$ —	$ (142)	$ —

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended January 2, 2022 and January 3, 2021:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		January 2, 2022	January 3, 2021
Foreign Exchange Contracts	Other (income) expense	$ (70)	24

The following table is the effect of net investment hedges for the fiscal years ended January 2, 2022 and January 3, 2021:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	January 2, 2022	January 3, 2021		January 2, 2022	January 3, 2021
Debt	$ 387	(473)	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 548	65	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 2, 2022 and January 3, 2021:

	January 3, 2021			January 2, 2022	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,481	198	205	1,884	1,884
Equity Investments without readily determinable value	$ 738	394	(632)	500	500

	December 29, 2019			January 3, 2021	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,148	527	(194)	1,481	1,481
Equity Investments without readily determinable value	$ 712	(55)	81	738	738

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For the fiscal years ended January 2, 2022 and January 3, 2021 for equity investments without readily determinable market values, $28 million and $76 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were offsetting impacts of $422 million and $21 million, respectively, of changes in fair value reflected in net income due to changes in observable prices and gains on the disposal of investments. The impact in fiscal 2021 was driven by the gain on disposal of the Grail investment.

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 2, 2022 and January 3, 2021 were as follows:

	2021				2020
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	540	—	540	849
Interest rate contracts [2]	—	796	—	796	240
Total	$ —	**1,336**	—	**1,336**	**1,089**
Liabilities:					
Forward foreign exchange contracts	—	881	—	881	702
Interest rate contracts [2]	—	979	—	979	1,569
Total	$ —	**1,860**	—	**1,860**	**2,271**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	24	—	24	49
Liabilities:					
Forward foreign exchange contracts	—	28	—	28	38
Available For Sale Other Investments:					
Equity investments[3]	1,884	—	—	1,884	1,481
Debt securities[4]	—	19,727	—	19,727	14,042
Other Liabilities					
Contingent Consideration[5]	$		533	533	633

Gross to Net Derivative Reconciliation		2021	2020
(Dollars in Millions)			
Total Gross Assets	$	1,360	1,138
Credit Support Agreement (CSA)		(1,285)	(1,107)
Total Net Asset		75	31
Total Gross Liabilities		1,888	2,309
Credit Support Agreement (CSA)		(1,855)	(2,172)
Total Net Liabilities	$	33	137

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

		2021	2020	2019
(Dollars in Millions)				
Beginning Balance	$	633	1,715	397
Changes in estimated fair value [6]		(52)	(1,089)	151
Additions		—	106	1,246
Payments		(48)	(99)	(79)
Ending Balance	$	533	633	1,715

(1) 2020 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,481 million, which are classified as Level 1 and contingent consideration of $633 million, classified as Level 3.
(2) Includes cross currency interest rate swaps and interest rate swaps.
(3) Classified as non-current other assets.
(4) Classified as cash equivalents and current marketable securities.
(5) Includes $520 million, $594 million and $1,631 million, classified as non-current other liabilities as of January 2, 2022, January 3, 2021 and December 29, 2019, respectively. Includes $13 million, $39 million and $84 million classified as current liabilities as of January 2, 2022, January 3, 2021 and December 29, 2019, respectively.
(6) Ongoing fair value adjustment amounts are recorded primarily in Research and Development expense. The Company recorded a contingent consideration reversal of $1,148 million in 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. The reversal of the contingent consideration was recorded in Other income and expense.

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)	2021	Effective Rate %	2020	Effective Rate %
3.55% Notes due 2021	$ —	— %	$ 450	3.67 %
2.45% Notes due 2021	—	—	350	2.48
1.65% Notes due 2021	—	—	999	1.65
0.250% Notes due 2022 (1B Euro 1.1311)[2]/(1B Euro 1.2281)[3]	1,131 [2]	0.26	1,227 [3]	0.26
2.25% Notes due 2022	1,000	2.31	999	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	802	3.18	803	3.17
2.05% Notes due 2023	499	2.09	499	2.09
0.650% Notes due 2024 (750MM Euro 1.1311)[2]/(750MM Euro 1.2281)[3]	847 [2]	0.68	919 [3]	0.68
5.50% Notes due 2024 (500MM 1.3485 GBP)[2]/(500MM GBP 1.3654)[3]	672 [2]	6.75	679 [3]	6.75
2.625% Notes due 2025	749	2.63	748	2.63
0.55% Notes due 2025	983	0.57	996	0.57
2.45% Notes due 2026	1,995	2.47	1,994	2.47
2.95% Notes due 2027	978	2.96	997	2.96
0.95% Notes due 2027	1,478	0.96	1,494	0.96
1.150% Notes due 2028 (750MM Euro 1.1311)[2]/ (750MM Euro 1.2281)[3]	843 [2]	1.21	915 [3]	1.21
2.90% Notes due 2028	1,495	2.91	1,495	2.91
6.95% Notes due 2029	298	7.14	297	7.14
1.30% Notes due 2030	1,723	1.30	1,743	1.30
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	854	4.24	855	4.24
1.650% Notes due 2035 (1.5B Euro 1.1311)[2]/(1.5B Euro 1.2281)[3]	1,683 [2]	1.68	1,827 [3]	1.68
3.55% Notes due 2036	974	3.59	989	3.59
5.95% Notes due 2037	993	5.99	992	5.99
3.625% Notes due 2037	1,475	3.64	1,488	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	992	3.42	991	3.42
4.50% Debentures due 2040	540	4.63	539	4.63
2.10% Notes due 2040	974	2.14	986	2.14
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	496	4.52
3.70% Notes due 2046	1,975	3.74	1,974	3.74
3.75% Notes due 2047	971	3.76	991	3.76
3.500% Notes due 2048	743	3.52	742	3.52
2.250% Notes due 2050	983	2.29	984	2.29
2.450% Notes due 2060	1,222	2.49	1,228	2.49
Other	7	—	7	—
Subtotal	**32,116** [4]	**2.89 %**	**34,434** [4]	**2.85 %**
Less current portion	2,131		1,799	
Total long-term debt	**$ 29,985**		**$ 32,635**	

(1) Weighted average effective rate.
(2) Translation rate at January 2, 2022.
(3) Translation rate at January 3, 2021.
(4) The excess of the fair value over the carrying value of debt was $3.2 billion at the end of fiscal year 2021 and $5.4 billion at the end of fiscal year 2020.

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 2021, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 8, 2022. Interest charged on borrowings under the credit line agreement is based on either the Term SOFR Reference Rate or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal years 2021 and 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 $3.8 billion and $2.6 billion at the end of fiscal years 2021 and 2020, respectively. The current portion of the long term debt was $2.1 billion and $1.8 billion in 2021 and 2020, respectively, and the remainder is commercial paper and local borrowing by international subsidiaries.

The current debt balance as of January 2, 2022 includes $1.6 billion of commercial paper which has a weighted average interest rate of 0.11% and a weighted average maturity of approximately three months.

Aggregate maturities of long-term debt obligations commencing in 2022 are:

(Dollars in Millions)

2022	2023	2024	2025	2026	After 2026
$2,131	1,551	1,518	1,732	1,995	23,189

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2021	2020	2019
Currently payable:			
U.S. taxes	$ 1,525	1,026	1,941
International taxes	2,452	1,898	2,744
Total currently payable	3,977	2,924	4,685
Deferred:			
U.S. taxes	583	(76)	(814)
International taxes	(2,662)	(1,065)	(1,662)
Total deferred	(2,079)	(1,141)	(2,476)
Provision for taxes on income	**$ 1,898**	**1,783**	**2,209**

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2021, 2020 and 2019, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2021	2020	2019
U.S.	$ 6,110	4,312	3,543
International	16,666	12,185	13,785
Earnings before taxes on income:	$ 22,776	16,497	17,328
Tax rates:			
U.S. statutory rate	21.0 %	21.0	21.0
International operations [1]	(16.4)	(9.9)	(5.9)
U.S. taxes on international income [2]	6.7	2.7	1.8
Tax benefits from loss on capital assets	(1.3)	(1.2)	(0.3)
Tax benefits on share-based compensation	(1.0)	(1.5)	(0.5)
TCJA and related impacts	(0.5)	0.7	(3.9) [3]
All other	(0.2)	(1.0)	0.5
Effective Rate	8.3 %	10.8	12.7

(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 2021 amounts include the reorganization of international subsidiaries; the 2020 and 2019 amounts include the impact of the new tax legislation enactment in Switzerland, both of which are further described below.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code. The 2021 amounts include the reorganization of international subsidiaries; the 2020 and 2019 amounts include the impact of the new tax legislation enactment in Switzerland, both of which is further described below.
(3) Represents impact of adjustments to balances originally recorded as part of the 2017 TCJA provisional tax charge. Further information provided below.

The fiscal year 2021 tax rate decreased by 2.5% compared to the fiscal year 2020 tax rate, which was primarily driven by the following items. In fiscal year 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. The net impact of this restructuring was approximately $0.6 billion net benefit or 2.7% benefit to the Company's annual effective tax rate, comprised of the following items:

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

Also, in the fiscal fourth quarter of 2021, the Company recognized a loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2021 tax rate by approximately 1.3% which is reflected as a "Tax benefits from loss on capital assets" on the effective tax rate reconciliation. Additionally other fiscal 2021 impacts to the rate were primarily driven by litigation and acquisition related items as follows:

- the Company accrued additional legal expenses, of approximately $1.6 billion for talc at an effective tax rate of 23.5% and $0.8 billion for Risperdal settlements at an effective tax rate of 16.4% (See Note 19 to the Consolidated Financial Statements for more details).
- the Company recorded a partial IPR&D charge of $0.9 billion for the Ottava intangible asset (acquired with the Auris Health acquisition in 2019) at an effective rate of 22.4% (See Notes 5 and 18 to the Consolidated Financial Statements for more details).

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 year 2020, the Company recognized a capital loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2020 tax rate by approximately 1.2% which is reflected as a "Tax benefits from loss on capital assets" on the effective tax rate reconciliation. In addition, in the fiscal year 2020, the Company had lower income in higher tax jurisdictions, primarily driven by:

- the impact of the accrual of litigation costs related to talc for $4.0 billion which reduced the U.S. earnings before taxes at an effective tax rate of 23.5%;
- the accrual of additional legal costs, including an additional $1.0 billion associated with a revised agreement in principle to settle opioid litigation at an effective tax rate of 21.4%

The Company also reduced the contingent consideration liability related to the Auris Health acquisition (see Note 18) and reversed 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.

In fiscal year 2019, 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 following items also impacted the fiscal year 2019 effective tax rate:

- 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.

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.

Temporary differences and carryforwards at the end of fiscal years 2021 and 2020 were as follows:

	2021 Deferred Tax		2020 Deferred Tax[1]	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 1,244		2,434	
Stock based compensation	679		627	
Depreciation of property, plant and equipment		(876)		(823)
Goodwill and intangibles		(2,659)[2]		(5,023)
R&D capitalized for tax	1,664		1,517	
Reserves & liabilities	2,882		3,466	
Income reported for tax purposes	2,566		1,777	
Net realizable operating loss carryforward	1,073		990	
Undistributed foreign earnings	1,015	(1,461)	812	(1,435)
Global intangible low-taxed income		(4,853)		(3,606)
Miscellaneous international	1,006	(39)	854	(211)
Miscellaneous U.S.	495			(59)
Total deferred income taxes	**$ 12,624**	**(9,888)**	**12,477**	**(11,157)**

[1]Certain prior year amounts have been reclassified to conform to current year presentation
[2]Amount is inclusive of the $2.3 billion deferred tax asset established as part of the reorganized ownership structure of certain wholly-owned international subsidiaries, as previously described.

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

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

(Dollars in Millions)	2021	2020	2019
Beginning of year	$ 3,373	3,853	3,326
Increases related to current year tax positions	242	265	249
Increases related to prior period tax positions	23	668	408
Decreases related to prior period tax positions	(128)	(551)	(105)
Settlements	(187)	(839)	(9)
Lapse of statute of limitations	0	(23)	(16)
End of year	**$ 3,323**	**3,373**	**3,853**

The unrecognized tax benefits of $3.3 billion at January 2, 2022, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the IRS has completed its audit for the tax years through 2012 and is currently auditing tax years 2013 through 2016. In the fiscal year 2020, the Company made its final payments for approximately$0.7 billion to the U.S. Treasury related to the final settlement of 2010-2012 tax audit liability.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2008. 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 $44 million, $32 million and $50 million in fiscal years 2021, 2020 and 2019, respectively. The total amount of accrued interest was $512 million and $468 million in fiscal years 2021 and 2020, respectively.

9. Employee Related Obligations

At the end of fiscal 2021 and fiscal 2020, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2021	2020
Pension benefits	$ 4,088	5,761
Postretirement benefits	2,069	2,229
Postemployment benefits	3,117	3,078
Deferred compensation	181	250
Total employee obligations	9,455	11,318
Less current benefits payable	557	547
Employee related obligations — non-current	**$ 8,898**	**10,771**

Prepaid employee related obligations of $4,436 million and $656 million for 2021 and 2020, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

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

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits
accrued under the Final Average Pay formula for service before January 1, 2026. The impact of this change decreases the
Projected Benefit Obligation 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 healthcare benefits in advance and has the right to modify these plans in the future.

In 2021 and 2020 the Company used December 31, 2021 and December 31, 2020, 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 2021, 2020 and 2019 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**
Service cost	$ 1,421	1,380	1,163	309	287	274
Interest cost	770	955	1,096	81	133	185
Expected return on plan assets	(2,645)	(2,461)	(2,322)	(7)	(7)	(6)
Amortization of prior service cost	(181)	2	4	(31)	(31)	(31)
Recognized actuarial losses (gains)	1,257	891	579	151	142	129
Curtailments and settlements	1	23	73	—	—	—
Net periodic benefit cost	**$ 623**	**790**	**593**	**503**	**524**	**551**

The service cost component of net periodic benefit cost is presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported, including Cost of products sold, Research and development expense, and Selling, marketing and administrative expenses. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings.

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**
Net Periodic Benefit Cost						
Service cost discount rate	2.14 %	2.82	3.63	2.09	3.04	4.45
Interest cost discount rate	2.34 %	3.13	4.13	2.33	3.08	4.25
Rate of increase in compensation levels	4.01 %	4.00	3.99	4.25	4.25	4.29
Expected long-term rate of return on plan assets	7.71 %	8.12	8.31			
Benefit Obligation						
Discount rate	2.49 %	2.14	2.91	2.68	2.23	3.39
Rate of increase in compensation levels	4.01 %	4.00	4.01	4.21	4.27	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 healthcare cost trend rates, for all individuals:

Healthcare Plans	**2021**	**2020**
Healthcare cost trend rate assumed for next year	5.33 %	5.68 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	3.73 %	4.49 %
Year the rate reaches the ultimate trend rate	2046	2040

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2021 and 2020 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2021**	**2020**	**2021**	**2020**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 43,300	37,188	5,028	5,076
Service cost	1,421	1,380	309	287
Interest cost	770	955	81	133
Plan participant contributions	67	61	—	—
Amendments[(1)]	5	(1,780)	—	—
Actuarial (gains) losses[(2)]	(2,132)	5,716	(188)	(75)
Divestitures & acquisitions	(2)	(88)	—	—
Curtailments, settlements & restructuring	(7)	(24)	—	—
Benefits paid from plan	(1,157)	(1,111)	(348)	(396)
Effect of exchange rates	(683)	1,003	(4)	3
Projected benefit obligation — end of year	**$ 41,582**	**43,300**	**4,878**	**5,028**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 38,195	32,201	90	115
Actual return on plan assets	4,439	5,524	17	14
Company contributions	969	870	343	357
Plan participant contributions	67	61	—	—
Settlements	(7)	(13)	—	—
Divestitures & acquisitions	(2)	(84)	—	—
Benefits paid from plan assets	(1,157)	(1,111)	(348)	(396)
Effect of exchange rates	(574)	747	—	—
Plan assets at fair value — end of year	**$ 41,930**	**38,195**	**102**	**90**
Funded status — end of year	**$ 348**	**(5,105)**	**(4,776)**	**(4,938)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 4,436	656	—	—
Current liabilities	(115)	(125)	(438)	(418)
Non-current liabilities	(3,973)	(5,636)	(4,338)	(4,520)
Total recognized in the consolidated balance sheet — end of year	**$ 348**	**(5,105)**	**(4,776)**	**(4,938)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 5,539	10,860	1,113	1,463
Prior service cost (credit)[(1)]	(1,610)	(1,797)	(13)	(44)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 3,929**	**9,063**	**1,100**	**1,419**
Accumulated Benefit Obligations — end of year	**$ 39,049**	**40,356**		

[(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 gain for retirement plans in 2021 was primarily related to increases in discount rates; the actuarial losses for retirement plans in 2020 were primarily related to decreases in discount rates.

(Dollars in Millions)	Retirement Plans 2021	Retirement Plans 2020	Other Benefit Plans 2021	Other Benefit Plans 2020
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 623**	**790**	**503**	**524**
Net actuarial (gain) loss	(3,927)	2,616	(199)	(81)
Amortization of net actuarial loss	(1,257)	(891)	(151)	(142)
Prior service cost (credit)	5	(1,780)	—	—
Amortization of prior service (cost) credit	181	(2)	31	31
Effect of exchange rates	(136)	293	—	1
Total loss/(income) recognized in other comprehensive income, before tax	**$ (5,134)**	**236**	**(319)**	**(191)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ (4,511)**	**1,026**	**184**	**333**

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 2021, the Company contributed $102 million and $867 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, 2021 and December 31, 2020, respectively:

	U.S. Plans				
	Qualified Plans		Non-Qualified Plans		Funded
(Dollars in Millions)	2021	2020	2021	2020	2021
Plan Assets	$ 27,944	25,554	—	—	13,986
Projected Benefit Obligation	25,041	25,466	2,703	2,748	13,428
Accumulated Benefit Obligation	23,985	24,158	2,479	2,495	12,212
Over (Under) Funded Status					
Projected Benefit Obligation	$ 2,903	88	(2,703)	(2,748)	558
Accumulated Benefit Obligation	3,959	1,396	(2,479)	(2,495)	1,774

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $3.9 billion, $4.2 billion and $0.3 billion, respectively, at the end of 2021, and $8.8 billion, $9.8 billion and $4.4 billion, respectively, at the end of 2020.

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

(Dollars in Millions)	2022	2023	2024	2025	2026	2027-2031
Projected future benefit payments						
Retirement plans	$ 1,317	1,386	1,421	1,496	1,572	9,279
Other benefit plans	$ 447	459	472	485	434	2,379

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)	2022	2023	2024	2025	2026	2027-2031
Projected future contributions	$ 114	119	126	133	139	794

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 2021 and 2020 and target allocations for 2022 are as follows:

	Percent of Plan Assets		Target Allocation
	2021	2020	2022
Worldwide Retirement Plans			
Equity securities	65 %	66 %	61 %
Debt securities	35	34	39
Total plan assets	**100 %**	**100 %**	**100 %**

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

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

Valuation Hierarchy
The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.
The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

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

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

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.

- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.

- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2021 and December 31, 2020:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**
Short-term investment funds	$ 102	127	1,033	763	—	—	—	—	1,135	890
Government and agency securities	—	—	7,016	5,023	—	—	—	—	7,016	5,023
Debt instruments	—	—	3,505	3,931	—	—	—	—	3,505	3,931
Equity securities	14,107	14,375	2	2	—	—	—	—	14,109	14,377
Commingled funds	—	—	5,496	4,690	105	160	8,708	8,236	14,309	13,086
Other assets	—	—	34	11	15	21	1,807	856	1,856	888
Investments at fair value	**$14,209**	**14,502**	**17,086**	**14,420**	**120**	**181**	**10,515**	**9,092**	**41,930**	**38,195**

[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 $102 million and $90 million at December 31, 2021 and December 31, 2020, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $385 million (0.9% of total plan assets) at December 31, 2021 and $946 million (2.5% of total plan assets) at December 31, 2020.

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 $256 million, $243 million and $235 million in fiscal years 2021, 2020 and 2019, 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 30, 2018	457,519	$ 34,362
Employee compensation and stock option plans	(20,053)	(2,691)
Repurchase of common stock	49,870	6,746
Balance at December 29, 2019	487,336	38,417
Employee compensation and stock option plans	(21,765)	(3,148)
Repurchase of common stock	21,760	3,221
Balance at January 3, 2021	487,331	38,490
Employee compensation and stock option plans	(17,399)	(2,847)
Repurchase of common stock	20,946	3,456
Balance at January 2, 2022	490,878	$ 39,099

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2021, 2020 and 2019.

Cash dividends paid were $4.19 per share in fiscal year 2021, compared with dividends of $3.98 per share in fiscal year 2020, and $3.75 per share in fiscal year 2019.

On January 4, 2022, the Board of Directors declared a regular cash dividend of $1.06 per share, payable on March 8, 2022 to shareholders of record as of February 22, 2022.

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 30, 2018	$ (8,869)	—	(6,158)	(195)	(15,222)
Net 2019 changes	164	—	(733)	(100)	(669)
December 29, 2019	(8,705)	—	(6,891)	(295)	(15,891)
Net 2020 changes	(233)	1	(66)	947	649
January 3, 2021	(8,938)	1	(6,957)	652	(15,242)
Net 2021 changes	(1,079)	(4)	4,255	(988)	2,184
January 2, 2022	$ (10,017)	(3)	(2,702)	(336)	(13,058)

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 2021, 2020 and 2019 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $236 million, $209 million and $267 million in fiscal years 2021, 2020 and 2019, 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 2, 2022, January 3, 2021 and December 29, 2019:

(In Millions Except Per Share Amounts)	2021	2020	2019
Basic net earnings per share	$ 7.93	5.59	5.72
Average shares outstanding — basic	2,632.1	2,632.8	2,645.1
Potential shares exercisable under stock option plans	138.0	118.3	136.3
Less: shares repurchased under treasury stock method	(96.1)	(80.4)	(97.8)
Convertible debt shares	—	—	0.7
Adjusted average shares outstanding — diluted	2,674.0	2,670.7	2,684.3
Diluted net earnings per share	$ 7.81	5.51	5.63

The diluted net earnings per share calculation for fiscal year 2021 included all shares related to stock options, as the exercise price of these options was less than the average market value of the Company's stock. As of January 2, 2022, the Company did not have convertible debt.

The diluted net earnings per share calculation for fiscal year 2020 excluded 18 million shares related to stock options, as the exercise price of these options was greater than the average market value of the Company's stock. 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.

16. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 2, 2022, 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 240 million at the end of fiscal year 2021.

The compensation cost that has been charged against income for these plans was $1,135 million, $1,005 million and $977 million for fiscal years 2021, 2020 and 2019, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $218 million, $210 million and $227 million for fiscal years 2021, 2020 and 2019, respectively. The Company also recognized additional income tax benefits of

$223 million, $248 million and $209 million for fiscal years 2021, 2020 and 2019, respectively, for which options were exercised or restricted shares were vested. The total unrecognized compensation cost was $862 million, $804 million and $823 million for fiscal years 2021, 2020 and 2019,

respectively. The weighted average period for this cost to be recognized was 1.78 years, 1.76 years and 1.71 years for fiscal years 2021, 2020, and 2019, 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 2021, 2020 and 2019 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 $20.86, $16.42 and $17.80, in fiscal years 2021, 2020 and 2019, respectively. The fair value was estimated based on the weighted average assumptions of:

	2021	2020	2019
Risk-free rate	0.83 %	1.47 %	2.56 %
Expected volatility	18.59 %	15.33 %	16.27 %
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.50 %	2.60 %	2.80 %

A summary of option activity under the Plan as of January 2, 2022, January 3, 2021 and December 29, 2019, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 30, 2018	109,652	$ 98.29	$ 3,214
Options granted	19,745	131.94	
Options exercised	(14,785)	82.43	
Options canceled/forfeited	(2,975)	125.11	
Shares at December 29, 2019	111,637	105.63	4,478
Options granted	20,723	151.41	
Options exercised	(16,275)	86.05	
Options canceled/forfeited	(1,835)	137.62	
Shares at January 3, 2021	114,250	116.22	4,703
Options granted	18,525	164.62	
Options exercised	(13,248)	97.48	
Options canceled/forfeited	(2,166)	149.75	
Shares at January 2, 2022	**117,361**	**$ 125.36**	**$ 5,364**

The total intrinsic value of options exercised was $919 million, $1,021 million and $807 million in fiscal years 2021, 2020 and 2019, respectively.

The following table summarizes stock options outstanding and exercisable at January 2, 2022:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$65.08-$90.44	16,007	1.6	$81.92	16,007	$81.92
$100.06-$101.87	22,647	3.6	$101.07	22,647	$101.07
$115.67-$129.51	24,543	5.6	$122.59	23,972	$122.43
$131.94-$151.41	36,304	7.6	$142.23	100	$140.72
$151.42-$164.62	17,860	9.1	$164.62	16	$164.62
	117,361	**5.8**	**$125.36**	**62,742**	**$104.42**

[1] Average contractual life remaining in years.

Stock options outstanding at January 3, 2021 and December 29, 2019 were 114,250 and an average life of 6.0 years and 111,637 and an average life of 6.0 years, respectively. Stock options exercisable at January 3, 2021 and December 29, 2019 were 61,289 at an average price of $96.97 and 60,761 at an average price of $88.88, 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 2, 2022 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 3, 2021	14,998	2,236
Granted	4,981	741
Issued	(5,101)	(610)
Canceled/forfeited/adjusted	(756)	(55)
Shares at January 2, 2022	14,122	2,312

The average fair value of the restricted share units granted was $152.62, $139.58 and $121.31 in fiscal years 2021, 2020 and 2019, 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 $611 million, $650 million and $586 million in 2021, 2020 and 2019, respectively.

The weighted average fair value of the performance share units granted was $179.35, $160.54 and $124.67 in fiscal years 2021, 2020 and 2019, 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 $83 million, $91 million and $119 million in fiscal years 2021, 2020 and 2019, respectively.

17. Segments of Business* and Geographic Areas

(Dollars in Millions)	Sales to Customers			% Change	
	2021	2020	2019	'21 vs. '20	'20 vs. '19
Consumer Health					
OTC					
U.S.	$ 2,594	2,460	2,010	5.4 %	22.4
International	2,634	2,364	2,434	11.4	(2.9)
Worldwide	5,227	4,824	4,444	8.4	8.5
Skin Health/Beauty					
U.S.	2,400	2,350	2,392	2.1	(1.7)
International	2,141	2,100	2,201	1.9	(4.6)
Worldwide	4,541	4,450	4,593	2.0	(3.1)
Oral Care					
U.S.	637	683	621	(6.7)	9.9
International	1,008	958	906	5.1	5.7
Worldwide	1,645	1,641	1,528	0.2	7.4
Baby Care					
U.S.	378	376	362	0.5	3.7
International	1,188	1,141	1,313	4.1	(13.1)
Worldwide	1,566	1,517	1,675	3.2	(9.4)
Women's Health					
U.S.	13	13	12	(1.6)	8.2
International	905	888	974	1.8	(8.8)
Worldwide	917	901	986	1.8	(8.6)
Wound Care/Other					
U.S.	495	480	441	3.1	8.9
International	243	240	230	1.7	4.1
Worldwide	739	720	671	2.6	7.2
TOTAL CONSUMER HEALTH					
U.S.	6,516	6,362	5,839	2.4	9.0
International	8,119	7,691	8,059	5.6	(4.6)
Worldwide	14,635	14,053	13,898	4.1	1.1

PHARMACEUTICAL					
Immunology					
U.S.	10,843	10,175	9,641	6.6	5.5
International	5,907	4,880	4,309	21.0	13.2
Worldwide	16,750	15,055	13,950	11.3	7.9
REMICADE®					
U.S.	2,019	2,508	3,079	(19.5)	(18.5)
U.S. Exports	236	346	294	(31.9)	18.0
International	935	893	1,007	4.8	(11.4)
Worldwide	3,190	3,747	4,380	(14.9)	(14.4)
SIMPONI / SIMPONI ARIA®					
U.S.	1,127	1,155	1,159	(2.4)	(0.3)
International	1,148	1,088	1,029	5.5	5.8
Worldwide	2,276	2,243	2,188	1.4	2.6
STELARA®					
U.S.	5,938	5,240	4,346	13.3	20.6
International	3,196	2,467	2,015	29.6	22.4
Worldwide	9,134	7,707	6,361	18.5	21.1
TREMFYA®					
U.S.	1,503	926	764	62.3	21.3
International	624	421	248	48.2	69.9
Worldwide	2,127	1,347	1,012	57.9	33.2
OTHER IMMUNOLOGY					
U.S.	21	—	—	**	—
International	3	11	10	(73.3)	6.4
Worldwide	24	11	10	**	6.4
Infectious Diseases					
U.S.	2,249	1,735	1,597	29.7	8.6
International	3,612	1,839	1,815	96.3	1.3
Worldwide	5,861	3,574	3,413	64.0	4.7
COVID-19 VACCINE					
U.S.	634	—	—	**	**
International	1,751	—	—	**	**
Worldwide	2,385	—	—	**	**
EDURANT® / rilpivirine					
U.S.	41	44	50	(7.6)	(11.2)
International	953	920	812	3.6	13.3
Worldwide	994	964	861	3.1	11.9
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®					
U.S.	1,508	1,587	1,422	(4.9)	11.6
International	575	597	689	(3.6)	(13.4)
Worldwide	2,083	2,184	2,110	(4.6)	3.5
OTHER INFECTIOUS DISEASES					
U.S.	66	104	126	(36.0)	(17.6)
International	333	323	315	3.0	2.6
Worldwide	399	427	441	(6.5)	(3.2)

Neuroscience					
U.S.	3,347	3,091	2,919	8.3	5.9
International	3,664	3,457	3,409	6.0	1.4
Worldwide	7,011	6,548	6,328	7.1	3.5
CONCERTA® / methylphenidate					
U.S.	172	183	233	(5.8)	(21.4)
International	495	439	463	12.8	(5.1)
Worldwide	667	622	696	7.3	(10.6)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	2,550	2,314	2,107	10.2	9.8
International	1,472	1,339	1,224	10.0	9.4
Worldwide	4,022	3,653	3,330	10.1	9.7
RISPERDAL CONSTA®					
U.S.	287	296	314	(2.9)	(5.9)
International	305	346	374	(11.8)	(7.5)
Worldwide	592	642	688	(7.7)	(6.8)
OTHER NEUROSCIENCE					
U.S.	338	298	266	13.3	12.4
International	1,391	1,334	1,349	4.3	(1.1)
Worldwide	1,729	1,632	1,614	6.0	1.1
Oncology					
U.S.	5,958	5,092	4,299	17.0	18.5
International	8,590	7,275	6,393	18.1	13.8
Worldwide	14,548	12,367	10,692	17.6	15.7
DARZALEX®					
U.S.	3,169	2,232	1,567	42.0	42.4
International	2,854	1,958	1,430	45.8	36.9
Worldwide	6,023	4,190	2,998	43.8	39.8
ERLEADA®					
U.S.	813	583	297	39.3	96.1
International	478	176	35	* *	* *
Worldwide	1,291	760	332	70.0	* *
IMBRUVICA®					
U.S.	1,747	1,821	1,555	(4.0)	17.1
International	2,622	2,307	1,856	13.6	24.3
Worldwide	4,369	4,128	3,411	5.8	21.0
ZYTIGA® /abiraterone acetate					
U.S.	119	373	810	(68.1)	(54.0)
International	2,178	2,097	1,985	3.9	5.6
Worldwide	2,297	2,470	2,795	(7.0)	(11.6)
OTHER ONCOLOGY					
U.S.	110	83	70	31.7	18.6
International	458	738	1,087	(37.9)	(32.1)
Worldwide	568	821	1,158	(30.8)	(29.1)

Pulmonary Hypertension					
U.S.	2,365	2,133	1,684	10.9	26.6
International	1,085	1,015	939	6.9	8.2
Worldwide	3,450	3,148	2,623	9.6	20.0
OPSUMIT®					
U.S.	1,147	1,008	766	13.7	31.7
International	672	631	562	6.6	12.3
Worldwide	1,819	1,639	1,327	11.0	23.5
UPTRAVI®					
U.S.	1,056	955	714	10.5	33.8
International	181	138	105	31.1	30.9
Worldwide	1,237	1,093	819	13.1	33.5
OTHER					
U.S.	163	169	205	(3.7)	(17.6)
International	232	247	272	(5.9)	(9.2)
Worldwide	395	416	476	(5.0)	(12.8)
Cardiovascular / Metabolism / Other					
U.S.	3,192	3,509	3,734	(9.0)	(6.0)
International	1,268	1,369	1,458	(7.4)	(6.1)
Worldwide	4,460	4,878	5,192	(8.6)	(6.0)
XARELTO®					
U.S.	2,438	2,345	2,313	4.0	1.4
International	—	—	—	—	—
Worldwide	2,438	2,345	2,313	4.0	1.4
INVOKANA® / INVOKAMET®					
U.S.	308	564	536	(45.4)	5.2
International	254	231	199	9.9	16.3
Worldwide	563	795	735	(29.3)	8.2
PROCRIT® / EPREX®					
U.S.	223	277	505	(19.7)	(45.1)
International	256	274	285	(6.8)	(3.8)
Worldwide	479	552	790	(13.3)	(30.2)
OTHER					
U.S.	223	323	380	(31.0)	(15.1)
International	758	864	974	(12.2)	(11.3)
Worldwide	981	1,186	1,353	(17.3)	(12.4)
TOTAL PHARMACEUTICAL					
U.S.	27,954	25,735	23,874	8.6	7.8
International	24,126	19,837	18,324	21.6	8.3
Worldwide	52,080	45,572	42,198	14.3	8.0

MEDICAL DEVICES					
Interventional Solutions					
U.S.	1,836	1,452	1,443	26.4	0.6
International	2,135	1,594	1,554	34.0	2.6
Worldwide	3,971	3,046	2,997	30.4	1.6
Orthopaedics					
U.S.	5,126	4,779	5,319	7.3	(10.2)
International	3,462	2,984	3,520	16.0	(15.2)
Worldwide	8,588	7,763	8,839	10.6	(12.2)
HIPS					
U.S.	883	793	863	11.4	(8.2)
International	602	487	575	23.6	(15.3)
Worldwide	1,485	1,280	1,438	16.0	(11.0)
KNEES					
U.S.	787	743	889	5.9	(16.4)
International	538	427	591	26.1	(27.8)
Worldwide	1,325	1,170	1,480	13.3	(21.0)
TRAUMA					
U.S.	1,819	1,648	1,652	10.4	(0.2)
International	1,066	966	1,068	10.4	(9.6)
Worldwide	2,885	2,614	2,720	10.4	(3.9)
SPINE, SPORTS & OTHER					
U.S.	1,637	1,595	1,915	2.6	(16.7)
International	1,256	1,104	1,286	13.8	(14.1)
Worldwide	2,893	2,699	3,201	7.2	(15.7)
Surgery					
U.S.	3,867	3,249	3,828	19.0	(15.1)
International	5,945	4,983	5,673	19.3	(12.2)
Worldwide	9,812	8,232	9,501	19.2	(13.4)
ADVANCED					
U.S.	1,761	1,535	1,637	14.9	(6.2)
International	2,861	2,304	2,458	24.1	(6.2)
Worldwide	4,622	3,839	4,095	20.4	(6.2)
GENERAL					
U.S.	2,105	1,714	2,192	22.7	(21.8)
International	3,085	2,679	3,215	15.2	(16.7)
Worldwide	5,190	4,392	5,406	18.1	(18.8)
Vision					
U.S.	1,857	1,557	1,794	19.3	(13.2)
International	2,831	2,362	2,830	19.8	(16.5)
Worldwide	4,688	3,919	4,624	19.6	(15.2)
CONTACT LENSES / OTHER					
U.S.	1,398	1,213	1,304	15.2	(7.0)
International	2,043	1,781	2,088	14.7	(14.7)
Worldwide	3,440	2,994	3,392	14.9	(11.7)

SURGICAL					
U.S.	459	344	490	33.5	(29.7)
International	788	581	742	35.7	(21.7)
Worldwide	1,248	925	1,232	34.9	(24.9)
TOTAL MEDICAL DEVICES					
U.S.	12,686	11,036	12,384	14.9	(10.9)
International	14,374	11,923	13,579	20.6	(12.2)
Worldwide	27,060	22,959	25,963	17.9	(11.6)
WORLDWIDE					
U.S.	47,156	43,133	42,097	9.3	2.5
International	46,619	39,451	39,962	18.2	(1.3)
Worldwide	$ 93,775	82,584	82,059	13.6 %	0.6

*Certain prior year amounts have been reclassified to conform to current year presentation
**Percentage greater than 100% or not meaningful

	Income (Loss) Before Tax			Identifiable Assets	
(Dollars in Millions)	**2021 [3]**	**2020 [4]**	**2019 [5]**	**2021**	**2020**
Consumer Health	$ 1,294	(1,064)	2,061	$ 25,081	27,355
Pharmaceutical	18,181	15,462	8,816	64,376	66,158
Medical Devices	4,373	3,044	7,286	53,372	49,578
Total	23,848	17,442	18,163	142,829	143,091
Less: Expense not allocated to segments [1]	1,072	945	835		
General corporate [2]				39,189	31,803
Worldwide total	**$ 22,776**	**16,497**	**17,328**	**$ 182,018**	**174,894**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**
Consumer Health	$ 331	248	328	$ 759	785	765
Pharmaceutical	1,198	863	950	4,029	4,006	3,910
Medical Devices	1,933	1,980	1,912	2,286	2,140	2,014
Segments total	3,462	3,091	3,190	7,074	6,931	6,689
General corporate	190	256	308	316	300	320
Worldwide total	**$ 3,652**	**3,347**	**3,498**	**$ 7,390**	**7,231**	**7,009**

	Sales to Customers			Long-Lived Assets [6]	
(Dollars in Millions)	**2021**	**2020**	**2019**	**2021**	**2020**
United States	$ 47,156	43,133	42,097	$ 48,586	49,951
Europe	23,594	18,980	18,466	43,257	49,363
Western Hemisphere excluding U.S.	5,750	5,335	5,941	2,708	2,734
Asia-Pacific, Africa	17,275	15,136	15,555	5,035	5,484
Segments total	93,775	82,584	82,059	99,586	107,532
General corporate				1,014	1,029
Other non long-lived assets				81,418	66,333
Worldwide total	**$ 93,775**	**82,584**	**82,059**	**$ 182,018**	**174,894**

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

Export sales are not significant. In fiscal year 2021, the Company utilized three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In fiscal year 2020, the Company had three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0% and 12.0% of the total consolidated revenues. 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.

(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 $1.6 billion, primarily talc related reserves
- A restructuring related charge of $0.1 billion

Pharmaceutical includes:

- Litigation expense of $0.6 billion, primarily related to Risperdal
- Divestiture gains of $0.6 billion
- Gains on securities of $0.5 billion
- A restructuring related charge of $0.1 billion

Medical Devices includes:

- A restructuring related charge of $0.3 billion
- An in-process research and development expense of $0.9 billion
- A Medical Device Regulation charge of $0.2 billion
- Litigation expense of $0.1 billion

(4) 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

(5) 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

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2021, and 2020 of $18,962 and $18,766, respectively, and intangible assets and goodwill, net for fiscal years 2021 and 2020 of $81,638 and $89,795, respectively.

18. Acquisitions and Divestitures

During fiscal year 2021, the Company did not make any material acquisitions.

During fiscal year 2020, certain businesses were acquired for $7.3 billion in cash and $0.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $7.5 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2020 acquisitions primarily included: all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc. (XBiotech), Momenta Pharmaceuticals, Inc. (Momenta), a company that discovers and develops novel therapies for immune-mediated diseases and the outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion applying a probability of success factor that ranged from 20% to 60% to reflect inherent development, regulatory and commercial risk for the different indications. The discount rate applied was approximately 16%. 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. On January 28, 2022, subsequent to the fiscal year 2021, additional information regarding efficacy became available which led the Company to the decision to terminate the development of bermekimab for Atopic Dermatitis (AD). The Company recorded an intangible asset impairment charge of approximately $0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of AD and Hidradenitis Suppurativa (HS). The impairment charge is related to the AD indication and is a nonrecognized subsequent event and will be reflected in the first quarter 2022 financial statements. The Company acquired all rights to bermekimab from XBiotech, Inc. in fiscal year 2020.

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 U.S. 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 a U.S. 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. 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 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. In the fiscal third quarter of 2021, the Company recorded a partial IPR&D charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava). A probability of success factor ranging from 18% to 66% across Ottava sub-platforms, 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 9.5%.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2021, 2020 and 2019 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company’s results of operations, cash flows or financial position.

Divestitures

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

During fiscal year 2020, the Company sold 11.8 million shares of Idorsia LTD (Idorsia), or its 8.3% ownership in the company at that time. The transaction resulted in gross proceeds of approximately CHF 337 million ($357 million) based on a sales price of CHF 28.55/share and resulted in an immaterial net loss. At the end of fiscal 2020, the Company had rights to approximately 38.7 million shares through a convertible loan with a principal amount of CHF 445 million (due June 2027). During fiscal year 2021, the Company converted CHF 110 million ($120 million) of this loan into approximately 9.6 million shares of Idorsia which were reflected at fair value as of January 2, 2022. During the fiscal third quarter of 2021, the Company's undrawn credit facility with Idorsia was terminated.

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.

19. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; indemnification and other matters; governmental investigations; and

other legal proceedings that arise from time to time in the ordinary course of their business. 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 and in person trials resume.

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 2, 2022, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

PRODUCT LIABILITY

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 JOHNSON'S® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of January 2, 2022, in the United States there were approximately 250 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 5,300 with respect to the PINNACLE® Acetabular Cup System; 10,100 with respect to pelvic meshes; 8,800 with respect to RISPERDAL®; 5,500 with respect to XARELTO®; 40,400 with respect to body powders containing talc; 100 with respect to INVOKANA®; and 4,700 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System (ASR Hip) used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 2013. DePuy reached additional agreements in February 2015 and March 2017, which further

extended the settlement program to include ASR Hip patients who had revision surgeries after August 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, thereby bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional

costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and ASR Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and 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 also has 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. In March 2021, the MDL Court entered an order closing the MDL. The MDL Court has remanded cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved the majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and class actions in Israel, Australia and Canada. 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 issued a decision and entered damages awards to the three Lead Applicants. The Company appealed the decision to the intermediate appellate court, the Full Court. The appeal was heard in February 2021 and, in March 2021, the Full Court entered a judgment dismissing the appeal. An application for special leave to the High Court of Australia was filed in April 2021, and the High Court heard oral argument on the application in November 2021. Special leave was refused. While this brings an end to the appellate process, there will now be an individual case assessment process for the remaining group member claims. The parties currently are in discussions with the Court to determine the form and mechanism of that individual case assessment process. The next hearing is scheduled for late February 2022. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases and an agreement to resolve the Israeli class action was reached in May 2021. The parties in the Israeli class action are currently negotiating the wording and some of the terms thereof and once finalized, the settlement will be subject to court approval. The parties are due to update the court on the status of the finalization of the settlement negotiations by the end of February 2022. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh (Physiomesh), claims for personal injury have been made against Ethicon, Inc. (Ethicon) and 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) also has been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., one multi-plaintiff lawsuit pending in Oklahoma state court and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement (MSA) was entered into in September 2021 and includes 3,729 cases in the MDL and MCL. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. The deadline for issuance of Individual Allocation amounts by the Special Master is March 2022. The costs associated with this proposed settlement are reflected in the Company's accruals. Post-Settlement cases in the Physiomesh MDL and MCL are subject to docket control orders requiring early expert reports and discovery requirements. As of February 2022, there are approximately 90 active cases subject to these orders which are being reviewed and evaluated.

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 United States, and in jurisdictions outside the United States. Discovery is underway in the MCL proceedings.

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

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 primarily have been filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to $6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO®, Bayer Healthcare AG, and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases 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 Johnson & Johnson announced an agreement in principle to settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, the settlement became final in December 2019, and the settlement was funded in January 2020. This resolved the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

A significant number of personal injury claims alleging that talc causes cancer were made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of these personal injury lawsuits, filed in state and federal courts in the United States as well as outside of the United States, continued to increase through fiscal year 2021.

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

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

injury, except for any liabilities for which the exclusive remedy is provided under a workers' compensation statute or act (the Talc-Related Liabilities).

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Case). As a result of the LTL Bankruptcy Case, the Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. On November 15, 2021, the North

Carolina Bankruptcy Court confirmed the scope of the stay, issuing a Preliminary Injunction (PI) prohibiting and enjoining the commencement and prosecution of talc-related claims against LTL, Old JJCI, New JJCI, Johnson & Johnson, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties. The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey in November 2021, and that court subsequently extended the PI through the end of February 2022. Claimants have filed a motion to dismiss the LTL Bankruptcy Case. The court commenced a hearing on February 14, 2022 regarding the motion to dismiss and on whether the PI should be extended. While the PI effectively stays all of the Company's talc-related personal injury litigation, LTL has agreed to lift the automatic stay on a small number of appeals where appeal bonds have been filed.

The Company has agreed to provide funding to LTL for the payment of amounts the Bankruptcy Court determines are owed by LTL through the establishment of a $2 billion trust in furtherance of this purpose. The Company has established a reserve for approximately $2 billion in connection with the aforementioned trust. Subsequent to the fiscal third quarter of 2021, the Company de-consolidated LTL, which is a related party, as a result of the bankruptcy filing. The impact of the de-consolidation is not material to the Company. The parties have not yet been able to reach a resolution of all matters related to talc, and while certain amounts under various scenarios have recently been referred to in testimony as part of the LTL bankruptcy proceedings, the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary petition under chapter 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. In May 2020, Imerys, its parent Imerys S.A., the Tort Claimants' Committee (TCC), and the Future Claimants' Representative (FCR) (collectively, the Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto. The Plan Proponents have since filed numerous amendments to the Plan and Disclosure Statement. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement, allowing Imerys to proceed with soliciting votes on the Plan. In March 2021, the Company voted to reject the Plan and opted out of the consensual releases in the Plan. In April 2021, the Plan Proponents announced the Plan had received the requisite number of accepting votes to confirm the Plan. The Company challenged certain improprieties with respect to portions of the vote and sought to disqualify those votes. In October 2021, the Bankruptcy Court issued a ruling deeming thousands of votes as withdrawn as improperly voted. In October 2021, Imerys cancelled the confirmation hearing on the Plan. Imerys, the TCC, the FCR, and certain of Imerys's insurers (the Mediation Parties) have since agreed to engage in mediation.

In July 2021, Imerys commenced an adversary proceeding against the Company in the Imerys Bankruptcy (the Imerys adversary proceeding). The Imerys adversary proceeding sought, among other things, certain declarations with respect to the indemnification obligations allegedly owed by the Company to Imerys. The TCC and FCR simultaneously filed a motion for temporary restraining order and preliminary injunction seeking to enjoin the Company from undergoing a corporate restructuring that would separate the Company's talc liabilities from its other assets. The Bankruptcy Court denied the motion. The Company thereafter filed a motion to dismiss the adversary proceeding. The Bankruptcy Court has not yet decided the motion to dismiss. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Imerys adversary proceeding.

In June 2020, Cyprus Mines Corporation and its parent (together, Cyprus), which had owned certain Imerys talc mines, filed an adversary proceeding against the Company and Imerys in the Imerys Bankruptcy seeking a declaration of indemnity rights under certain contractual agreements (the Cyprus adversary proceeding). The Company denies such indemnification is owed, and filed a motion to dismiss the adversary complaint. In February 2021, Cyprus filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan. The Plan contemplates a settlement with Imerys and talc claimants where Cyprus would make a monetary contribution to a trust established under the Imerys Plan in exchange for an injunction against Talc Claims asserted against it. Cyprus has not yet sought approval of its Disclosure Statement and Plan. Cyprus, along with the TCC and FCR appointed in the Cyprus chapter 11 case, have agreed to participate in the mediation with the Mediation Parties. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Cyprus adversary proceeding.

In February 2021, several of the Company's insurers involved in coverage litigation in New Jersey State Court (the Coverage Action) filed a motion in the Imerys Bankruptcy Court proceeding seeking a determination that the automatic stay does not apply to the Coverage Action and, in the alternative, seeking relief from the automatic stay to allow them to continue to litigate their claims in the Coverage Action. In March 2021, the Company filed a limited response and reservation of rights with respect to the motion. The Court entered an agreed order modifying the stay to allow the litigation in the Coverage Action to continue. In October 2021, LTL filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Coverage Action.

In 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, the Company answered the complaint. In April 2021, briefing on Plaintiffs' motion for class certification was completed. In July 2021, the Company filed a notice of supplemental authority in opposition to Plaintiff's motion for class certification, and Plaintiff filed a response. In December 2021, the Company filed a motion to supplement the class certification record, and in January 2022, Plaintiff responded. Discovery is ongoing.

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. In February 2022, the Court granted Johnson & Johnson's cross motion to dismiss. 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 and demanding that suit be brought against certain Directors. 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 March 2021, Plaintiffs filed a motion for discovery. The Court temporarily terminated Johnson & Johnson's motion to dismiss pending a decision on Plaintiff's motion for discovery. In November 2021, at the Court's request, the parties submitted supplemental briefing on Plaintiff's motion for discovery.

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. In February 2021, the Court granted Defendants' motion, and granted Plaintiffs leave to amend. In April 2021, Plaintiffs informed the Court that they did not intend to file an amended complaint, and the Court dismissed the case with prejudice. In May 2021, Plaintiffs filed a notice of appeal with the Third Circuit. In July 2021, Plaintiffs filed their opening brief in the Third Circuit and in September 2021, Defendants filed their response brief, and in October 2021, Plaintiffs filed their reply brief. In January 2022, the Third Circuit heard oral argument.

A lawsuit was brought against the Company in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act (CLRA) relating to JOHNSON'S® Baby Powder. In that lawsuit, the plaintiffs allege that 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 February 2021, Plaintiffs filed a Notice of Appeal with the Ninth Circuit. Plaintiffs filed their opening brief in July 2021. The company filed its responsive brief in October 2021. In October 2021, Notice of Suggestion of Bankruptcy was filed

with the Ninth Circuit. A bankruptcy stay was imposed in December 2021, and the Court held the reply deadline in abeyance.

In addition, the Company has received inquiries, subpoenas, and requests to produce documents regarding talc matters, including from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the Subcommittee on Economic and Consumer Policy of the House Committee on Oversight and Reform, the Senate

Committee on the Judiciary, the House Committee on Oversight and Reform, and individual Members of Congress. The Company has produced documents and responded to inquiries, and will continue to cooperate with government inquiries.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and 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, lawsuits filed in federal courts in the United States, including putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases also have been filed in various state courts. 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 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 began in October 2021, and shortly thereafter, the parties reached an agreement to settle the case. Plaintiff's motion to dismiss with prejudice was filed in October 2021. The case was dismissed with prejudice in November 2021.

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 U.S. Patent and Trademark Office (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. In March 2021, the USPTO ruled that the challenged claims of the '447 and '906 patents are not invalid. Auris has appealed that decision. Auris filed a request for reexamination

of the ’276 patent in November 2021, and in January 2022, the USPTO granted the reexamination request. Trial is scheduled to begin in January 2023.

In August 2019, RSB Spine LLC (RSB Spine) filed a patent infringement suit against DePuy Synthes, Inc. in the United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of 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. A stay that had been entered pending Inter Partes Review at the U.S. Patent & Trademark Office has been lifted, and trial is scheduled to begin in December 2022.

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. In June 2021, Osteoplastics admitted that the PROPLAN CMF® Virtual Surgical Planning Services do not infringe any asserted patents. Trial was scheduled for October 2022. In October 2021, the case was settled and dismissed.

In October 2020, Rasmussen Instruments, LLC (Rasmussen) filed a patent infringement suit against DePuy Synthes Products, Inc., DePuy Synthes Sales, Inc. and Medical Device Business Services, Inc. (collectively, DePuy) in the United States District Court for the District of Massachusetts. Rasmussen alleges that DePuy willfully infringes U.S. Patent Nos. 9,492,180 and 10,517,583 ('583) by making and selling the Attune® Balanced Sizer. In April 2021, Rasmussen sought permission to amend its infringement contentions to allege that DePuy also willfully infringes the '583 patent by making and selling the Attune® Balancing Blocks. Rasmussen seeks treble damages for willful infringement. Trial is scheduled for February 2022.

Pharmaceutical

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits the Company's subsidiaries have brought against generic companies that have filed ANDAs with the U.S. FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of 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 Company's subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the generic companies involved would have the ability, upon approval of the U.S. FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, the Company's subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. 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®

Beginning in January 2019, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations in Canada against Apotex Inc. (Apotex), Pharmascience Inc. (Pharmascience) and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in response to those parties' filing of Abbreviated New Drug Submissions (ANDS) seeking approval to market generic versions of ZYTIGA® before the expiration of the Canadian Patent No. 2,661,422 ('422). The trial in these actions concluded in November 2020, and the Court issued a decision holding the '422 patent invalid in January 2021. In February 2021, Janssen appealed the decision.

XARELTO®

In March 2021, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer AG (collectively, Bayer) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Lupin Limited and

Lupin Pharmaceuticals, Inc. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of U.S. Patent No. 10,828,310 ('310).

In May 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the '310 patent.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent. In August 2021, the court entered a joint stipulation dismissing Teva Pharmaceutical Industries Ltd.

In October 2021, the court consolidated the Delaware lawsuits for all purposes, including trial. Trial for the consolidated Delaware lawsuits is scheduled to begin in May 2023.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the Northern District of West Virginia against Mylan Pharmaceuticals Inc. and Mylan Inc. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent. In August 2021, JPI and Bayer filed a motion before the United States Judicial Panel on Multidistrict Litigation (the MDL panel) to transfer this lawsuit to the United States District Court for the District of Delaware for coordinated and consolidated pretrial proceedings. In December 2021, the MDL panel granted the motion. No trial date has been set in this lawsuit.

In each of these lawsuits, JPI and Bayer are seeking an order enjoining defendants from marketing their generic version of XARELTO® before the expiration of the ’310 patent.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

In October 2019, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (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 MTPC’s United States Patent No. 7,943,788 (’788) relating to INVOKAMET®. 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 MTPC’s United States Patent Nos. 7,943,582 (’582) and/or 8,513,202 (’202) relating to INVOKAMET XR®.

In each of these U.S. lawsuits, Janssen and MTPC are seeking an order enjoining the defendant from marketing their generic versions of 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. 2,799,204, 2,534,024 and 2,671,357. 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. The trial is scheduled to begin in August 2022.

OPSUMIT®

In May 2020, Janssen Inc. (Janssen) and Actelion Pharmaceuticals Ltd (Actelion) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz’s filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of Canadian Patent No. 2,659,770 (’770). Trial is ongoing.

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 October 2021, the court issued a decision in Janssen's favor. Teva has appealed the decision.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent. Pursuant to an agreement by the parties, judgment in favor of Janssen was entered in December 2021. Mylan has filed an appeal.

In December 2019, Janssen initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallinckrodt PLC and Specgx LLC (collectively, Pharmascience), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent.

In November 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Tolmar, Inc., Tolmar Therapeutics, Inc., Tolmar Pharmaceuticals, Inc. and Tolmar Holding, Inc. (collectively, Tolmar), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent.

In each of these U.S. lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen Canada) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva Canada) in response to Teva's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 ('629) and 2,655,335 ('335). Janssen subsequently discontinued the portion of the lawsuit relating to the '629 patent. In May 2020, the Canadian Federal Court issued a Public Judgment and Reasons declaring that Teva Canada's generic version of INVEGA SUSTENNA®, if approved, would infringe certain claims of the '335 patent and that the claims of the '335 patent are not invalid 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. A summary trial on the issue of infringement took place in November 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. A trial on the issue of validity 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. A summary trial on the issue of infringement took place in December 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. Apotex has not contested validity.

In each of these Canadian lawsuits, Janssen Canada is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

INVEGA TRINZA®

In September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan

Institutional LLC (collectively, Mylan). Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (546 mg) before expiration of United States Patent No. 10,143,693 (’693) relating to INVEGA TRINZA® (546 mg). Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® before the expiration of the ’693 patent. Trial is scheduled to begin in October 2022.

In August 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (819 mg) before expiration of the ’693 patent. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® (819 mg) before the expiration of the ’693 patent.

In October 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (273 mg and 410 mg) before expiration of the ’693 patent. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® (273 mg and 410 mg) before the expiration of the ’693 patent.

In January 2022, the court consolidated the three cases into the case filed in September 2020.

IMBRUVICA®

In March 2019, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen), which filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of 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 June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386. Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

Trial against Alvogen took place in October 2020. In August 2021, the District Court issued a decision in favor of Pharmacyclics and Janssen finding the asserted claims against Alvogen to be infringed and not invalid. Alvogen has appealed that decision.

In September 2021, Pharmacyclics and Janssen Inc. (Janssen Canada) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Natco Pharma (Canada) Inc. (Natco) in response to Natco’s filing of two ANDSs seeking approval to market generic versions of IMBRUVICA® capsules before the expiration of Canadian Patent Nos. 2,663,116; 2,928,721; 2,800,913; 3,007,787; 3,007,788; 2,875,986; and 3,022,256. The trial is scheduled to begin in July 2023. Pharmacyclics and Janssen are seeking an order enjoining Natco from marketing its 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 Zydus Pharmaceuticals (USA), Inc. and Zydus Worldwide DMCC (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of UPTRAVI® before expiration of Nippon Shinyaku’s United States Patent Nos. 7,205,302 (’302); relating to UPTRAVI®. Actelion is the exclusive licensee of the ’302 patent. In January 2022, Actelion, Nippon Shinyaku and Zydus entered into a confidential settlement agreement and the lawsuit was dismissed.

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 approximately 3,400 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 manufacturers, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are over 380 cases pending in various state courts. There are close to 3,000 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio. In addition, the Province of British Columbia filed suit against Johnson & Johnson and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against Johnson & Johnson and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. In October 2019, an antitrust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

In 2019, the trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $465 million. Johnson & Johnson and JPI appealed the judgment, and in November 2021, the Oklahoma Supreme Court reversed the trial court's 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. In April 2021, three California counties and the City of Oakland commenced a trial in California state court against Johnson & Johnson and JPI, and other affiliates, as well as three other pharmaceutical manufacturers. The trial concluded in October 2021, and in December 2021, the Court entered a final trial judgment in favor of Defendants on all claims. In February 2022, Plaintiffs' motion to set aside and vacate the judgment was denied.

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.

In June 2021, the Company and JPI announced a settlement agreement with the State of New York and its participating subdivisions, including Nassau County and Suffolk County, resolving their opioid-related claims against the Company on terms consistent with the Company's previously announced agreement in principle to contribute up to $5 billion to all-in settlement of opioid-related claims by states, cities, counties, and tribal governments. The settlement provides New York and its participating subdivisions with up to $263 million to address opioid-related issues, reimburses attorney fees and costs, and removes the

Company and Janssen from a multi-defendant trial of opioid-related claims that commenced in Suffolk County in June 2021. In exchange, the Company and JPI receive releases from the claims asserted by New York and the participating parties, including NYDFS.
In October 2021, the Company and JPI announced a settlement agreement with the State of Texas and its participating subdivisions, including Dallas County, Bexar County, and Tarrant County, resolving their opioid-related claims against the Company on terms consistent with the Company's previously announced agreement to contribute up to $5 billion to all-in settlement of opioid-related claims by states, cities, counties, and tribal governments. The settlement provides Texas and its participating subdivisions with up to $297 million to address opioid-related issues and reimburse attorney fees and costs, and removes the Company and Janssen from multi-defendant bellwether trials of opioid-related claims scheduled to commence in Texas state courts in early 2022. In exchange, the Company and JPI will receive releases from the claims asserted by Texas and the participating subdivisions.

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. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims have been finalized and up to one-third of the all-in settlement is expected to be paid within the next 12 months, depending upon the level of participation by the states and their subdivisions. The terms provide a period of time for states to elect to participate in the agreement and, thereafter, a period for the subdivisions of the participating states to opt-in. As of January 2022, 45 states, five territories, and the District of Columbia had elected to participate in the settlement. The subdivision opt-in period expired in January 2022. The Company retains the right to opt-out of the agreement until late February 2022 if, in its sole discretion, there is insufficient participation. Based on expected participation, the Company has committed in advance to proceed with the settlement in five of the participating states (New York, Texas, Florida, Nevada, and New Mexico) and with tribal governments, whose cases were scheduled for trial in 2021, 2022, or 2023.

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. In February 2021, the Court held oral argument on Johnson & Johnson's motion. In February 2022, the Court granted Johnson & Johnson's motion to dismiss the amended complaint. 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 Court granted the shareholders motion to voluntarily dismiss the

consolidated action without prejudice, and the shareholders' counsel then filed a notice of association in the first-filed derivative action pending in the Superior Court of New Jersey.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies concerning the hip devices. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the District Court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. In March 2021, DePuy filed its motion to strike and dismiss the relators' second amended complaint; the District Court denied DePuy's motion to strike and dismiss in July 2021. DePuy filed a motion for reconsideration of the District Court's July 2021 ruling. In November 2021, the District Court granted DePuy's motion for reconsideration and dismissed the case with prejudice. The District Court's order was unsealed in December 2021. The Relators filed several post-dismissal motions, including a January 2022 omnibus motion for reconsideration. Following the District Court's order dismissing the case with prejudice, DePuy filed a December 2021 motion seeking the recovery of attorneys' fees.

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. 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 case. In October 2020, the Company settled with the Attorney General of Oregon. Trial in the Kentucky matter is scheduled for May 2023.

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.) (collectively, JJCI). The complaint alleges that JJCI violated the Mississippi Consumer Protection Act by failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. Johnson & Johnson and JJCI moved for summary judgment on the grounds that the State's claim was barred by preemption, which the trial court denied. The Mississippi Supreme Court granted Johnson & Johnson and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019. Briefing and oral argument were completed. Thereafter, the Court rejected the interlocutory appeal in April 2021 and remanded the matter to the trial court. Thereafter, the State moved for a trial setting. JJCI objected to any trial setting due to the LTL Bankruptcy and that any decision on whether the stay applied should be deferred to the LTL Bankruptcy court. The State opposed any stay and argued that the trial court should decide issues concerning the stay. The motion for trial setting and JJCI's objections were heard in November 2021 and in January 2022, the Court granted plaintiff's motion for trial setting and directed the parties to consult with the Court administrator to secure a trial date. That process is underway. In August 2021, JJCI filed a Petition for Writ of Certiorari in the United States Supreme Court as to the Mississippi Supreme Court's ruling of April 2021, the State responded to the Petition for Writ of Certiorari in November 2021, the JJCI filed a reply in November 2021, and the United States Supreme Court denied the Petition for Writ of Certiorari in December 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, which was denied. The Company made its first document production in February 2021 and discovery is currently scheduled to close on April 25, 2022.

Forty-two states and the District of Columbia have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona,

North Carolina, Texas, and Washington and entered into confidentiality agreements. The Company has not received any follow up requests from those states.

In March 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. The Court denied summary judgment on all claims in December 2021. *Daubert* motions were granted in part and denied in part in January 2022, and the case is proceeding to trial.

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

In April and September 2017, 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.(DePuy) 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 have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

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

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

GENERAL LITIGATION

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 are complete. Trial is scheduled to begin in March 2022.

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. This matter was settled in January 2022.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand.

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

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals U.S., Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy required by the Food and Drug Administration, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland. In October 2019, the Court granted Actelion's motion to dismiss the amended complaint. In April 2021, the United States Court of Appeals for the Fourth Circuit reversed and remanded. Discovery is ongoing.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. Janssen's motion to dismiss was denied in December 2021.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson in the United States District Court for the Northern District of California. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers Squibb and Japan Tobacco. In March 2020, the Court granted in part and denied in part defendants' motions to dismiss. Plaintiffs filed an amended complaint in April 2020. Defendants moved to dismiss the amended complaint. In July 2020, the Court granted in part and denied in part the renewed motion to dismiss. In December 2021, several insurance companies and other payers filed individual "Opt-Out" complaints containing allegations similar to the original complaint. 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. In December 2021, BWI filed a motion for summary judgment. The trial is set for April 2022.

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 Johnson & Johnson 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 2021, the Court granted in part and denied in part defendants' motion to dismiss certain causes of action. All claims against the individual defendants were dismissed.

Beginning in May 2021, multiple putative class actions were filed in state and federal courts (California, Florida, New York, and New Jersey) against various Johnson & Johnson entities alleging violations of state consumer fraud statutes based on nondisclosure of alleged benzene contamination of certain Neutrogena and Aveeno sunscreen products and the affirmative promotion of those products as "safe"; and, in at least one case, alleging a strict liability manufacturing defect and failure to warn claims, asserting that the named plaintiffs suffered unspecified injuries as a result of alleged exposure to benzene. The Judicial Panel on Multi-District Litigation has consolidated all pending actions, except one product liability case and one case pending in New Jersey state court, in the United States District Court for the Southern District of Florida, Fort Lauderdale Division. In October 2021, the Company reached an agreement in principle for the settlement of a nationwide class, encompassing the claims of the consolidated actions, subject to approval by the Florida federal Court. In December 2021, plaintiffs in the consolidated actions filed a motion for preliminary approval of a nationwide class settlement.

Johnson & Johnson (subsequently substituted by Johnson & Johnson Consumer Inc. (JJCI)) along with more than 120 other companies, is a defendant in a cost recovery and contribution action brought by Occidental Chemical Corporation in June 2018 in the United States District Court for the District of New Jersey, related to the clean-up of a section of the Lower Passaic River in New Jersey.

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. In fiscal year 2021, the Company recorded a pre-tax charge of $0.5 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.8 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by the end of 2022. The program is set to be completed at the end of 2022. The Company expects to record pre-tax restructuring charges of approximately $2.1 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 2021:

(Dollars in Millions)	Severance	Asset Write-offs/ Sales	Other[2]	Total
Reserve balance, December 29, 2019	$ 164	—	16	180
2020 activity	(29)	—	(7)	(36)
Reserve balance, January 3, 2021	135	—	9	144
Current year activity:				
Charges	—	53	420	473
Cash settlements	(23)		(404)	(427)
Settled non cash	—	(53)		(53)
Reserve balance, January 2, 2022[1]	$ 112	—	25	137

[1] Cash outlays for severance are expected to be substantially paid out over the next year 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.

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 2, 2022 and January 3, 2021, 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 2, 2022, 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 2, 2022, 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 2, 2022 and January 3, 2021, and the results of its operations and its cash flows for each of the three fiscal years in the period ended January 2, 2022 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 2, 2022, 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 $7.7 billion as of January 2, 2022. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation Contingencies – Talc
As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse awards, judgments, or verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. Management continues to believe that the Company has strong legal grounds to contest the talc verdicts it has appealed. Notwithstanding management's confidence in the safety of the Company's talc products, in certain circumstances the Company has settled cases. In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI), a wholly-owned subsidiary of Johnson & Johnson, implemented a corporate restructuring and created a subsidiary, LTL Management LLC (LTL), which became solely responsible for the talc-related liabilities, and another subsidiary, New JJCI, which became responsible for the remaining business of Old JJCI. LTL filed a voluntary petition, seeking relief under chapter 11 of the Bankruptcy Code. As a result of the LTL bankruptcy case, the Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. On November 15, 2021, the North Carolina Bankruptcy Court confirmed the scope of the stay, issuing a Preliminary Injunction (PI) prohibiting and enjoining the commencement and prosecution of talc-related claims against LTL, Old JJCI, New JJCI, Johnson & Johnson, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties. Claimants have filed a motion to dismiss the LTL bankruptcy case. The court commenced a hearing on February 14, 2022 regarding the motion to dismiss and on whether the PI should be extended. The Company has agreed to provide funding to LTL for the

payment of amounts the Bankruptcy Court determines are owed by LTL through the establishment of a $2 billion trust in furtherance of this purpose. The Company has established a reserve for approximately $2 billion in connection with the aforementioned trust. The parties have not yet been able to reach a resolution of all matters related to talc, and while certain amounts under various scenarios have recently been referred to in testimony as part of the LTL bankruptcy proceedings, the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred and when determining whether a reasonable estimate of the loss or range of loss for the future and existing talc claims can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation and the ongoing LTL bankruptcy proceedings with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

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 awards, judgments, or verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; 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, including tribal governments, related to opioids matters. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of the 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. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims have been finalized, depending upon the level of participation by the various parties. The terms provide a period of time for states to elect to participate in the agreement and, thereafter, a period for the subdivisions of the participating states to opt-in. The subdivision opt-in period expired in January 2022. The Company retains the right to opt-out of the agreement until late February 2022 if, in its sole discretion, there is insufficient participation.

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 determining whether a reasonable estimate of the range of loss for the agreement to settle the 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 17, 2022
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 2, 2022. 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 2, 2022, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 2, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ J. Duato	/s/ Joseph J. Wolk
Joaquin Duato	Joseph J. Wolk
Director	Executive Vice President, Chief Financial Officer
Chief Executive 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 2, 2022, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2016 and December 31, 2011 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

jnj-20220102_g10.jpg

	2016	2017	2018	2019	2020	2021
Johnson & Johnson	$100.00	$124.40	$118.02	$137.15	$152.03	$169.43
S&P 500 Index	$100.00	$121.82	$116.47	$153.13	$181.29	$233.28
S&P Pharmaceutical Index	$100.00	$112.57	$121.68	$140.04	$150.58	$189.36
S&P Healthcare Equipment Index	$100.00	$130.90	$152.15	$196.77	$231.46	$276.26

10 Year Shareholder Return Performance J&J vs. Indices

jnj-20220102_g11.jpg

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2
Johnson & Johnson	$100.00	$110.83	$149.19	$175.05	$177.08	$204.21	$254.05	$241.00	$280.07	$310.46	$3
S&P 500 Index	$100.00	$115.99	$153.55	$174.55	$176.95	$198.10	$241.33	$230.73	$303.35	$359.13	$4
S&P Pharmaceutical Index	$100.00	$114.43	$154.74	$189.12	$200.06	$196.93	$221.69	$239.63	$275.78	$296.54	$3
S&P Healthcare Equipment Index	$100.00	$117.27	$149.74	$189.09	$200.39	$213.38	$279.31	$324.67	$419.87	$493.90	$5

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Joaquin Duato, Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Duato and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective.

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 2, 2022, 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 many of its employees have worked 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.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and, if applicable, "Stock Ownership and Section 16 Compliance – Delinquent Section 16(a) Reports" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to

the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation & Benefits Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation & Benefits Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 2, 2022 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]	133,794,708	$109.96	240,344,013
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	133,794,708	$109.96	240,344,013

(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 2021 and 2020

Consolidated Statements of Earnings for Fiscal Years 2021, 2020 and 2019

Consolidated Statements of Comprehensive Income for Fiscal Years 2021, 2020 and 2019

Consolidated Statements of Equity for Fiscal Years 2021, 2020 and 2019

Consolidated Statements of Cash Flows for Fiscal Years 2021, 2020 and 2019

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 17, 2022

JOHNSON & JOHNSON

(Registrant)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ J. Duato J. Duato	Director Chief Executive Officer (Principal Executive Officer)	February 17, 2022
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 17, 2022
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 17, 2022
/s/ A. Gorsky A. Gorsky	Executive Chairman, Board of Directors	February 17, 2022
/s/ M. C. Beckerle M. C. Beckerle	Director	February 17, 2022
/s/ D. S. Davis D. S. Davis	Director	February 17, 2022
/s/ I. E. L. Davis I. E. L. Davis	Director	February 17, 2022
/s/ J. A. Doudna J. A. Doudna	Director	February 17, 2022

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 17, 2022
/s/ H. Joly H. Joly	Director	February 17, 2022
/s/ M. B. McClellan M. B. McClellan	Director	February 17, 2022
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 17, 2022
/s/ C. Prince C. Prince	Director	February 17, 2022
/s/ A. E. Washington A. E. Washington	Director	February 17, 2022
/s/ M. A. Weinberger M. A. Weinberger	Director	February 17, 2022
/s/ N.Y. West N. Y. West	Director	February 17, 2022
/s/ R. A. Williams R. A. Williams	Director	February 17, 2022

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2017.*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 31, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)	Amended and Restated Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (Amended and restated effective January 1, 2020, except as otherwise provided) incorporated herein by reference to Exhibit 10(n) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2021*
10(o)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(p)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(q)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(r)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(s)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(t)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

*	Management contract or compensatory plan.
**	Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE 1934**

For the fiscal year ended January 3, 2021

or

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

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

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

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.250% Notes Due January 2022	JNJ22	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant’s most recently completed second fiscal quarter was approximately $363 billion.

On February 16, 2021, there were 2,628,679,824 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

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

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

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

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

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

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates.
- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics, including the outbreak of the novel coronavirus (COVID-19) pandemic;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

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

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

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

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

Segments of Business

The Company is organized into three business segments: Consumer Health, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer Health

The Consumer Health segment includes a broad range of products focused on personal healthcare used in the skin health/beauty, over-the-counter medicines, baby care, oral care, women's health and wound care markets. Major brands in skin health/beauty include the AVEENO®; CLEAN & CLEAR®; DR. CI:LABO®; NEUTROGENA® and OGX® product lines. Over-the-counter (OTC) medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; NICORETTE® smoking cessation products outside the U.S.; ZARBEE'S NATURALS® and the PEPCID® line of acid reflux products. Baby Care includes the JOHNSON'S® and AVEENO Baby® line of products. Oral Care includes the LISTERINE® product line. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV;

CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the

maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; ERLEADA® (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the Interventional Solutions, Orthopaedics, Surgery, and Vision fields. Medical Devices in Interventional Solutions include Electrophysiology products (Biosense Webster) to treat cardiovascular diseases, Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke; the Orthopaedics portfolio (DePuy Synthes) is comprised of products in support of Hips, Knees, Trauma, and Spine, Sports & Other; the Surgery portfolios (Ethicon) include advanced and general surgery offerings, solutions that focus on Breast Aesthetics (Mentor) and Ear, Nose and Throat (Acclarent) procedures; and Johnson & Johnson Vision products such as ACUVUE® Brand disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

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

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

Raw Materials

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

Patents

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

covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19, “Legal Proceedings—Intellectual Property” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company’s largest product, STELARA® (ustekinumab), accounted for approximately 9.3% of the Company's total revenues for fiscal 2020. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA®. The latest expiring United States patent expires in 2023. The latest expiring European patent expires in 2024.

Sales of the Company’s second largest product, DARZALEX® (daratumumab) and DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj), accounted for approximately 5.1% of the Company's total revenues for fiscal 2020.
Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns patents related to DARZALEX®, and Janssen Biotech, Inc. has an exclusive license to those patents. The latest expiring licensed United States patent expires in 2029. The latest expiring licensed European patent expires in 2031. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO™.

Sales of the Company’s third largest product, IMBRUVICA® (ibrutinib), accounted for approximately 5.0% of the Company's total revenues for fiscal 2020. Accordingly, patents related to this product are believed to be material to the Company. Pharmacyclics LLC (an AbbVie company) owns the patents related to IMBRUVICA®, and Janssen Biotech, Inc. has an exclusive license to those patents. The Pharmacyclics patents and their expiration dates are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmacyclics LLC and Janssen Biotech, Inc. have entered into confidential settlement agreements with certain generic companies granting licenses to market their generic ibrutinib products in the United States before the expiration of certain patents.

Trademarks

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

Seasonality

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

Competition

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

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company’s compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

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

a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe and in other countries are examples of such increased regulation.

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

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

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and congress on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and health care providers. Various transparency laws and regulations require disclosures of payments and other transfers of value made to physicians and teaching hospitals and, beginning with disclosures in 2022, to certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue efforts to repeal, modify, or invalidate provisions of the Patient Protection and Affordable Care Act (the ACA) which passed in 2010. For example, federal legislation repealed the ACA's individual mandate tax penalty as well as the tax on generous employer-sponsored healthcare plans; the Center for Medicare & Medicaid Services (CMS) began permitting states to impose work requirements on persons covered by Medicaid expansion plans; certain federal subsidies to insurers have ended; and certain short-term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U.S. courts and so their long-term impact remains uncertain. The ACA has also been subject to judicial challenge. In November 2020, the U.S. Supreme Court heard argument in *Texas v. Azar*, which challenges the constitutionality of the ACA. Pending resolution of the litigation, all of the ACA but the individual mandate to buy health insurance remains in effect. The U.S. government also continues to propose and implement changes to the Medicare Part D benefit including the size of manufacturer discounts in the coverage gap and catastrophic phases of the benefit. There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing in the Medicare and Medicaid programs. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from the COVID-19 pandemic and Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

The global regulatory landscape is also subject to change as the COVID-19 pandemic continues to affect the U.S. and global economies. The U.S. FDA and other health authorities have shifted resources and priorities to meet the many challenges presented by the pandemic. Pandemic-related disruptions could negatively impact the

processing of regulatory submissions and slow agency review times necessary for the approval or clearance of new drugs and devices. The duration and severity of the COVID-19 pandemic is unpredictable and difficult to assess.

Employees and Human Capital Management

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

	2020	2019
Employees[1]	136,400	133,200
Full-time equivalent (FTE) positions[2]	134,500	132,200

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

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

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Strategy

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

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

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

Culture and Employee Engagement

At Johnson & Johnson, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide are further guided by the Company's Code of Business Conduct which sets basic requirements for business conduct and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2020, 93% of global employees across 78 countries participated in Our Credo Survey which is offered in 36 languages.

Growth and Development

To continue to lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources

are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. In 2020, 44.6% of employees in Manager and above job categories took advantage of career opportunities by moving across functions, country or business segment lines (including upward promotion or lateral transfer and excluding employees in the research and development organizations). The Company's voluntary turnover rate was 5.2%.

Diversity, Equity, and Inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. Enabling employees to perform at their best while being themselves is fundamental to the Company's continued success. The Company's DEI vision is: *Be yourself, change the world*. The Company's DEI strategy focuses on three pillars that reflect the strategic priorities identified to enable the Company to address the challenges and opportunities presented by this evolving understanding of diversity:

- Accelerate the Company's efforts to advance a culture of inclusion and innovation
- Build a diverse workforce for the future
- Enhance business results and reputation

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

Compensation and Benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' financial, physical, and mental well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs.

Health, Wellness and Safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal mind and body health goals. The programs and practices the Company advances covers three core dimensions: Healthy Eating, Healthy Movement and Healthy Mind.

Available Information

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

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

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the

Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

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

Risks Related to Our Business, Industry and Operations

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

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer health businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

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

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 90 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

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

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

Other risks associated with our reliance on third parties, including the Company's strategic partnership with Jabil in the Medical Devices segment, to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third party manufacturers suffer any damage to facilities, lose benefits under material agreements, experience power outages, encounter financial difficulties, are unable to secure necessary raw materials from their suppliers or suffer any other reduction in efficiency, the Company may

experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

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

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

The COVID-19 pandemic has adversely impacted certain aspects of the Company's business and could cause disruptions or future impact to the Company's business, results of operations and financial condition.
We are subject to risks associated with global health crises and pandemics, including the global outbreak of the novel coronavirus and its mutations (COVID-19). The COVID-19 pandemic has adversely impacted, and is expected to continue to adversely impact, certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The spread of COVID-19 has caused the Company to modify its business practices (including instituting remote work for many of the Company's employees), and the Company may take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners. The Company continues to monitor the situation and while we have robust business continuity plans in place across our global supply chain network to help mitigate the impact of COVID-19, these efforts may not completely prevent our business from being adversely affected and future impacts remain uncertain.

While the U.S. and other countries have begun or will begin to reopen their economies, the extent to which COVID-19 will impact the Company's future operations will depend on many factors which cannot be predicted with confidence, including the duration of the outbreak. Any resurgence in COVID-19 infections could result in the imposition of new mandates and prolonged restrictive measures implemented in order to control the spread of the disease. The continued global spread of COVID-19 could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, including third-party suppliers, sales and marketing and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

We also face uncertainties related to our efforts to develop a COVID-19 vaccine candidate, including uncertainties related to the risk that our development programs may not be successful, commercially viable or receive approval or Emergency Use Authorization from regulatory authorities; risks associated with clinical trial data, including further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the JNJ-78436735 vaccine candidate and dose level for the Phase 3 (ENSEMBLE) trial; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; disruptions in the relationships between us, our third-party suppliers and external manufacturers; the risk that other companies may produce superior or competitive products; the risk that demand for any products we may develop may no longer exist; risks related to the availability of raw materials to manufacture any such products; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts and risks associated with any changes in the way we approach or provide additional research funding for potential drug development related to COVID-19; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis, that we may experience manufacturing delays once a manufacturing site is activated, or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine or product candidate, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods indicated, and other

challenges and risks associated with the pace of our vaccine development program; and pricing and access challenges for such products, including in the U.S.

In addition, to the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section and those incorporated by reference herein, including risks relating to the Company’s effective tax rate as a result of changes in consumption as well as changes in

laws relating to supply of the Company's products. Given that developments concerning the COVID-19 pandemic have been constantly evolving, additional impacts and risks may arise, including litigation, that are not presently known to the Company.

Risk Related to the Government Regulation and Legal Proceedings

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU, United Kingdom and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

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

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

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

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

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

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate

Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of health care industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and

litigation brought by government agencies are described in Note 19, “Legal Proceedings-Government Proceedings” under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company’s operating results.
Changes in tax laws or regulations around the world could negatively impact the Company’s effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company’s deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company’s Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

See Note 8 on income taxes for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with the 2015 Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company’s expectations, which could result in tax liabilities in excess of reserves.

Risks Related to Our Intellectual Property

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

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

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

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

Risks Related to Product Development, Regulatory Approval and Commercialization

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

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2020 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

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

Risk Related to Financial and Economic Market Conditions

The Company faces a variety of risks associated with conducting business internationally.
The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2020, approximately 48% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 7% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

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

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose

of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities;

therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets;
- political or social upheavals, economic instability, repression, or human rights issues; and
- geopolitical events, including natural disasters, disruptions to markets due to war, armed conflict, terrorism, epidemics or pandemics.

Failure to maintain a satisfactory credit rating could adversely affect our liquidity, capital position, borrowing costs and access to capital markets.

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

Other Risks

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

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

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

To meet business objectives, the Company relies on both internal technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and

sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and

regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 90 manufacturing facilities occupying approximately 15.2 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer Health	4,684
Pharmaceutical	5,559
Medical Devices	4,951
Worldwide Total	15,194

Within the U.S., five facilities are used by the Consumer Health segment, five by the Pharmaceutical segment and 19 by the Medical Devices segment. Outside of the U.S., 24 facilities are used by the Consumer Health segment, 14 by the Pharmaceutical segment and 23 by the Medical Devices segment.

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

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	29	4,351
Europe	25	5,992
Western Hemisphere, excluding U.S.	10	1,777
Africa, Asia and Pacific	26	3,074
Worldwide Total	90	15,194

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition of this Report.

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

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

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production restarted in 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. A third-party expert continued to reassess the sites at various times through 2020. McNEIL-PPC is awaiting FDA inspections of the facilities which have been delayed due to COVID-19.

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

Item 3. LEGAL PROCEEDINGS

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

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned “Item 1. Election of Directors” in the Proxy Statement.

Name	Age	Position
Joaquin Duato	58	Vice Chairman, Executive Committee[a]
Peter M. Fasolo, Ph.D.	58	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	60	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	50	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Thibaut Mongon	51	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer Health[d]
Michael E. Sneed	61	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[e]
Paulus Stoffels, M.D.	58	Vice Chairman, Executive Committee; Chief Scientific Officer[f]
Jennifer L. Taubert	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[g]
Michael H. Ullmann	62	Member, Executive Committee; Executive Vice President, General Counsel[h]
Kathryn E. Wengel	55	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[i]
Joseph J. Wolk	54	Member, Executive Committee; Executive Vice President, Chief Financial Officer[j]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer Health sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. Ms. McEvoy has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the Consumer Health sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer Health, and became a member of the Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

(e) Mr. M. E. Sneed joined the Company in 1983 as Marketing Assistant for Personal Products Company, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the Company's global marketing, communication, design and philanthropy functions.

(f) Dr. P. Stoffels rejoined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company's innovation agenda across the Pharmaceutical, Medical Devices and Consumer Health sectors, product safety strategy, and the Company's global public health strategy.

(g) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions of increasing responsibility in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert has responsibility for the Immunology, Infectious Diseases, Neuroscience, Oncology, Cardiovascular and Metabolism, and Pulmonary Hypertension businesses throughout Janssen.

(h) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr.

Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation, health care compliance, global brand protection and privacy.

(i) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In

July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(j) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 16, 2021, there were 132,376 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information."

Issuer Purchases of Equity Securities

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2020. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 28, 2020 through October 25, 2020	350,000	$ 145.57	-	-
October 26, 2020 through November 22, 2020	369,000	148.53	-	-
November 23, 2020 through January 3, 2021	1,432,333	150.50	-	-
Total	2,151,333			

(1) During the fiscal fourth quarter of 2020, the Company repurchased an aggregate of 2,151,333 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

Item 6. Reserved

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health (previously referred to as Consumer), Pharmaceutical and Medical Devices. The Consumer Health segment includes a broad range of products used in the baby care, oral care, skin health/beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer Health, Pharmaceutical and Medical Devices business segments.

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

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2020 sales. In 2020, $12.2 billion was invested in research and development and $7.3 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the 134,500 diverse employees worldwide. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

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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.

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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®	Rapid Reduction				

Medical Devices Segment

The Medical Devices segment sales in 2020 were $23.0 billion, a decrease of 11.6% from 2019, which included an operational decrease of 11.4% and a negative currency impact of 0.2%. U.S. sales were $11.0 billion, a decrease of 10.9% as compared to the prior year. International sales were $11.9 billion, a decrease of 12.2% as compared to the prior year, with an operational decrease of 11.8% and a negative currency impact of 0.4%. In 2020, the net impact of acquisitions and divestitures on the Medical Devices segment worldwide operational sales growth was a negative 0.9% of which, the divestiture of Advanced Sterilization Products (ASP) had an impact of approximately 0.8%. Growth was negatively impacted by COVID-19 and associated deferral of medical procedures.

Major Medical Devices Franchise Sales*:

(Dollars in Millions)	2020	2019	% Change '20 vs. '19
Surgery	**$ 8,232**	**9,501**	**(13.4)%**
Advanced	3,839	4,095	(6.2)
General[(1)]	4,392	5,406	(18.8)
Orthopaedics	**7,763**	**8,839**	**(12.2)**
Hips	1,280	1,438	(11.0)
Knees	1,170	1,480	(21.0)
Trauma	2,614	2,720	(3.9)
Spine, Sports & Other[(2)]	2,699	3,201	(15.7)
Vision	**3,919**	**4,624**	**(15.2)**
Contact Lenses/Other	2,994	3,392	(11.7)
Surgical	925	1,232	(24.9)
Interventional Solutions	**3,046**	**2,997**	**1.6**
Total Medical Devices Sales	**$ 22,959**	**25,963**	**(11.6)%**

*Certain prior year amounts have been reclassified to conform to current year presentation

(1) Includes Specialty Surgery which was previously disclosed separately

(2) Previously referred to as Spine & Other

The Surgery franchise sales were $8.2 billion in 2020, a decrease of 13.4% from 2019. The decline in Advanced Surgery was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S. This was partially offset by the success of new products outside the U.S. and the recovery of an isolated supply disruption in the prior year related to SURGIFLO® . The decline in General Surgery was primarily driven by the negative impact of COVID-19 and the ASP divestiture.

The Orthopaedics franchise sales were $7.8 billion in 2020, a decrease of 12.2% from 2019. The decline in hips was driven by the negative impact of COVID-19 partially offset by a leadership position in the Anterior approach, strong market demand for the ACTIS® stem and enabling technologies – KINCISE™ and VELYS™ Hip Navigation. The decline in knees was driven by the negative impact of COVID-19. The decline in Trauma was driven by the negative impact of COVID-19 partially offset by strength from new products. The decline in Spine, Sports & Other was driven by the negative impact of COVID-19 partially offset by the uptake of new products.

The Vision franchise sales were of $3.9 billion in 2020, a decrease of 15.2% from 2019. The Contact Lenses/ Other operational decline was due to the negative impact of COVID-19. The Surgical operational decline was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S.

The Interventional Solutions franchise achieved sales of $3.0 billion in 2020, an increase of 1.6% from 2019. Growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth coupled with strength from new products and market recovery offsetting negative impacts from COVID-19.

Analysis of Consolidated Earnings Before Provision for Taxes on Income
Consolidated earnings before provision for taxes on income was $16.5 billion and $17.3 billion for the years 2020 and 2019, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 20.0% and 21.1%, in 2020 and 2019, respectively.

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

Cost of Products Sold and Selling, Marketing and Administrative Expenses:

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

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

- Medical Device idle capacity costs associated with COVID-19 related production slow downs
- Establishment of obsolescence reserves and fixed cost deleveraging associated with the impact of COVID-19 in the Medical Devices business
- Supply chain costs associated with the development of the COVID-19 vaccine in the Pharmaceutical business partially offset by:
- Favorable mix within the Pharmaceutical business
- Favorable product mix with a higher percentage of sales coming from the Pharmaceutical business

The intangible asset amortization expense included in cost of products sold was $4.7 billion and $4.5 billion, for the years 2020 and 2019, respectively.

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

- Leveraging in the Pharmaceutical and Consumer Health businesses
- Portfolio and investment optimization including execution of the ongoing SKU rationalization program in the Consumer Health business

- Favorable segment mix with a higher percentage of sales coming from the Pharmaceutical business

partially offset by:

- The negative impact on sales resulting from COVID-19 in the Medical Devices business

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

	2020		2019	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*
Consumer Health	$ 422	3.0 %	$ 493	3.5 %
Pharmaceutical	9,563	21.0	8,834	20.9
Medical Devices	2,174	9.5	2,028	7.8
Total research and development expense	$ 12,159	14.7 %	$ 11,355	13.8 %
Percent increase/(decrease) over the prior year	7.1 %		5.4 %	

*As a percent to segment sales

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

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

- Segment mix driven by a higher percentage of sales generated by the Pharmaceutical business versus the prior year
- The negative COVID-19 impact on Medical Devices sales
- Increased investment in the Medical Devices business related to robotics and digital programs
- Portfolio progression including the COVID-19 vaccine in the Pharmaceutical business, net of governmental reimbursements

Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In fiscal year 2020, the Company recorded an IPR&D charge of $0.2 billion primarily related to a partial impairment due to timing and progression of one of the digital surgery platforms acquired with the Auris Health acquisition. In the fiscal year 2019, the Company recorded an IPR&D charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176.

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

Other (income) expense, net for the fiscal year 2020 was unfavorable by $0.4 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2020	2019	Change
Litigation expense[1]	$ 5.1	5.1	—
Acquisition and Integration related[2]	(1.1)	0.3	(1.4)
Unrealized (gains)/losses on securities	(0.5)	(0.6)	0.1
Equity step-up gain related to DR. CI:LABO	0.0	(0.3)	0.3
Divestiture Gains[3]	(0.2)	(2.2)	2.0
Restructuring related	0.1	0.2	(0.1)
Other	(0.5)	0.0	(0.5)
Total Other (Income) Expense, Net	$ 2.9	2.5	0.4

[1]2020 litigation expense primarily associated with Talc related reserves and certain settlements ($4.0 billion). 2019 litigation expense primarily related to the agreement in principle to settle opioid litigation ($4.0 billion).
[2]2020 is primarily driven by a contingent consideration reversal of approximately $1.1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
[3] 2019 included the divestiture of ASP

Interest (Income) Expense: The fiscal year 2020 included net interest expense of $90 million as compared to income of $39 million in the fiscal year 2019. This was primarily due to reduced interest income resulting from lower rates of interest earned on cash balances and a higher average debt balance. This was partially offset by a lower average debt interest rate and a higher average cash balance. Cash, cash equivalents and marketable securities totaled $25.2 billion at the end of 2020, and averaged $22.2 billion as compared to the cash, cash equivalents and marketable securities total of $19.3 billion and $19.5 billion average cash balance in 2019. The total debt balance at the end of 2020 was $35.3 billion with an average debt balance of $31.5 billion as compared to $27.7 billion at the end of 2019 and an average debt balance of $29.1 billion. In the fiscal third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end. In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion.

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

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**
Consumer Health	$ (1,064)	2,061	14,053	13,898	(7.6)%	14.8
Pharmaceutical	15,462	8,816	45,572	42,198	33.9	20.9
Medical Devices	3,044	7,286	22,959	25,963	13.3	28.1
Total [1]	17,442	18,163	82,584	82,059	21.1	22.1
Less: Net expense not allocated to segments [2]	945	835				
Earnings before provision for taxes on income	$ 16,497	17,328	82,584	82,059	20.0 %	21.1

(1) See Note 17 to the Consolidated Financial Statements for more details.
(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Health Segment:
In 2020, the Consumer Health segment loss before tax as a percent of sales was (7.6)% versus income before tax of 14.8% in 2019. The decrease in the income before tax as a percent of sales was primarily driven by the following:

- Higher litigation expense of $3.9 billion in 2020 vs. $0.4 billion in 2019 (primarily associated with talc related reserves and certain settlements)
- The fiscal year 2019 included a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO

partially offset by:

- Portfolio and investment optimization including execution of the ongoing SKU rationalization program

Pharmaceutical Segment:
In 2020, the Pharmaceutical segment income before tax as a percent to sales was 33.9% versus 20.9% in 2019. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Lower litigation expense of $0.8 billion in 2020 vs. $4.3 billion in 2019 (primarily related to the agreement in principle to settle opioid litigation, of which $1.0 billion is in 2020 and $4.0 billion is in 2019)
- An in-process research and development charge of $0.9 billion in fiscal 2019 related to Alios
- Lower acquisition and integration related costs in fiscal 2020
- Leveraging in selling, marketing and administrative expense

Medical Devices Segment: In 2020, the Medical Devices segment income before tax as a percent to sales was 13.3% versus 28.1% in 2019. The decrease in the income before tax as a percent to sales was primarily driven by the following:

- A gain of $2.0 billion related to the ASP divestiture recorded in the fiscal 2019
- Idle capacity costs associated with COVID-19 related production slow downs in fiscal 2020

- Establishment of obsolescence reserves and fixed cost deleveraging associated with the impact of COVID-19 in fiscal 2020
- The negative impact of COVID-19 on sales in fiscal 2020

- An in-process research and development charge of $0.2 billion in fiscal 2020 primarily related to the Auris Health acquisition

partially offset by:

- A contingent consideration reversal of approximately $1.1 billion in fiscal 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition
- Litigation expense was $0.3 billion in 2020 vs. $0.4 billion in 2019

Restructuring: In the fiscal second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2020, the Company recorded a pre-tax charge of $0.4 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.2 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.3 billion have been recorded since the restructuring was announced.

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

Provision for Taxes on Income: The worldwide effective income tax rate was 10.8% in 2020 and 12.7% in 2019. During the fiscal first quarter of 2021, the Internal Revenue Service published final regulations addressing the requirements for tax deductibility of settlement payments. The Company recorded a pre-tax reserve for $4.0 billion in the fiscal year 2019 based on the agreement in principle to settle opioid litigation and recorded an additional pre-tax $1.0 billion in the fiscal third quarter of 2020 upon which an effective rate of 21.4% has been applied.

For discussion related to the fiscal 2020 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $14.0 billion at the end of 2020 as compared to $17.3 billion at the end of 2019. The primary sources and uses of cash that contributed to the $3.3 billion decrease were:

(Dollars In Billions)	
$ 17.3	Q4 2019 Cash and cash equivalents balance
23.5	cash generated from operating activities
(20.8)	net cash used by investing activities
(6.1)	net cash used by financing activities
0.1	effect of exchange rate and rounding
$ 14.0	Q4 2020 Cash and cash equivalents balance

In addition, the Company had $11.2 billion in marketable securities at the end of fiscal year 2020 and $2.0 billion at the end of fiscal year 2019. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $23.5 billion was the result of:

(Dollars In Billions)	
$ 14.7	Net Earnings
7.3	non-cash expenses and other adjustments primarily stock-based compensation, asset write-downs and cr allowances partially offset by the deferred tax provis businesses
0.8	decrease in accounts receivable
5.9	an increase in accounts payable and accrued liabiliti current liabilities
(4.0)	an increase in inventories and other current and non-
(1.2)	contingent consideration reversal (related to the timi milestones associated with the Auris Health acquisit
$ 23.5	Cash Flow from operations

Investing activities use of $20.8 billion of cash was primarily used for:

(Dollars In Billions)	
$ (7.3)	primarily related to the acquisitions of Momenta, be XBiotech Inc. as well as the acquisition of all outsta
(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 wi
(0.3)	Credit support agreements activity, net
(0.3)	other
$ (6.1)	Net cash used for financing activities

As of January 3, 2021, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of January 3, 2021, the net debt position was $10.1 billion as compared to the prior year of $8.4 billion. There was an increase in the net debt position due to increased borrowings in the fiscal third quarter of 2020. The debt balance at the end of 2020 was $35.3 billion as compared to $27.7 billion in 2019. Considering recent market conditions and the on-going COVID-19 crisis, the Company has evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the talc litigation and agreement in principle to settle opioid litigation of which the

majority may be paid over the next two to three years. In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. In the fiscal

third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end. In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements. The net proceeds from this offering were used to fund the Momenta Pharmaceuticals, Inc. acquisition which closed on October 1, 2020 and for general corporate purposes. Additionally, as a result of the Tax Cuts and Jobs Act (TCJA), the Company has access to its cash outside the U.S. at a significantly reduced cost.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of January 3, 2021: To satisfy these obligations, the Company intends to use cash from operations.

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Total
2021	$ 812	1,799	949	3,560
2022	812	2,226	908	3,946
2023	1,522	1,552	880	3,954
2024	2,029	1,598	842	4,469
2025	2,536	1,744	789	5,069
After 2025	—	25,515	9,503	35,018
Total	**$ 7,711**	**34,434**	**13,871**	**56,016**

For tax matters, see Note 8 to the Consolidated Financial Statements. The table does not include activity related to business combinations or the Company's approximate $0.9 billion in contractual supply commitments associated with its development of a COVID-19 vaccine.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 3, 2021 market rates would increase the unrealized value of the Company's forward contracts by $121 million. Conversely, a 10% depreciation of the U.S. Dollar from the January 3, 2021 market rates would decrease the unrealized value of the Company's forward contracts by $148 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1,667 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

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

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $36 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2020, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion,

which expires on September 9, 2021. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, London Interbank Offered Rates (LIBOR), Secured Overnight Financing Rate (SOFR) Swap Curve or other applicable market
rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2020 and 2019 were $35.3 billion and $27.7 billion, respectively. The increase in borrowings was the issuance of notes in 2020 when market conditions were favorable. In 2020, net debt (cash and current marketable securities, net of debt) was $10.1 billion compared to net debt of $8.4 billion in 2019. Total debt represented 35.8% of total capital (shareholders' equity and total debt) in 2020 and 31.8% of total capital in 2019. Shareholders' equity per share at the end of 2020 was $24.04 compared to $22.59 at year-end 2019.

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

Dividends

The Company increased its dividend in 2020 for the 58th consecutive year. Cash dividends paid were $3.98 per share in 2020 and $3.75 per share in 2019.

On January 4, 2021, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on March 9, 2021 to shareholders of record as of February 23, 2021.

Other Information

Critical Accounting Policies and Estimates

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

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to, the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of January 3, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, inventory and related reserves, accrued rebates and associated reserves, and the carrying value of the goodwill and other long-lived assets. While there was not a material impact to the Company's consolidated financial statements as of and for the year ended January 3, 2021, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

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

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost

exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal years 2020 and 2019.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 3.0% of the total revenues and are included in sales to customers.

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

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

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 3, 2021 and December 29, 2019.

Consumer Health Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2020				
Accrued rebates [1]	$ 284	793	(788)	289
Accrued returns	63	138	(125)	76
Accrued promotions	487	1,988	(2,047)	428
Subtotal	$ 834	2,919	(2,960)	793
Reserve for doubtful accounts	35	7	(3)	39
Reserve for cash discounts	17	201	(206)	12
Total	$ 886	3,127	(3,169)	844
2019				
Accrued rebates[1]	$ 271	841	(828)	284
Accrued returns	57	128	(122)	63
Accrued promotions	497	2,119	(2,129)	487
Subtotal	$ 825	3,088	(3,079)	834
Reserve for doubtful accounts	32	21	(18)	35
Reserve for cash discounts	23	198	(204)	17
Total	$ 880	3,307	(3,301)	886

[1] Includes reserve for customer rebates of $66 million at January 3, 2021 and $54 million at December 29, 2019, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2020				
Accrued rebates [1]	$ 9,013	32,415	(31,591)	9,837
Accrued returns	500	233	(273)	460
Accrued promotions	5	10	(9)	6
Subtotal	$ 9,518	32,658	(31,873)	10,303
Reserve for doubtful accounts	36	24	(8)	52
Reserve for cash discounts	65	1,034	(1,029)	70
Total	$ 9,619	33,716	(32,910)	10,425
2019				
Accrued rebates [1]	$ 7,510	26,868	(25,365)	9,013
Accrued returns	436	354	(290)	500
Accrued promotions	13	17	(25)	5
Subtotal	$ 7,959	27,239	(25,680)	9,518
Reserve for doubtful accounts	47	2	(13)	36
Reserve for cash discounts	53	936	(924)	65
Total	$ 8,059	28,177	(26,617)	9,619

(1) Includes reserve for customer rebates of $174 million at January 3, 2021 and $93 million at December 29, 2019, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2020				
Accrued rebates[1]	$ 1,013	5,144	(4,983)	1,174
Accrued returns	118	578	(558)	138
Accrued promotions	46	118	(112)	52
Subtotal	$ 1,177	5,840	(5,653)	1,364
Reserve for doubtful accounts	155	95	(48)	202
Reserve for cash discounts	10	88	(89)	9
Total	$ 1,342	6,023	(5,790)	1,575
2019				
Accrued rebates[1]	$ 1,218	5,487	(5,692)	1,013
Accrued returns	114	673	(669)	118
Accrued promotions	42	106	(102)	46
Subtotal	$ 1,374	6,266	(6,463)	1,177
Reserve for doubtful accounts	169	30	(44)	155
Reserve for cash discounts	—	106	(96)	10
Total	$ 1,543	6,402	(6,603)	1,342

(1) Includes reserve for customer rebates of $707 million at January 3, 2021 and $499 million at December 29, 2019, recorded as a contra asset.

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

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

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

During the fiscal first quarter of 2021, the Internal Revenue Service published final regulations addressing the requirements for tax deductibility of settlement payments. The Company recorded a pre-tax reserve for $4.0 billion in fiscal 2019 based on the agreement in principle to settle opioid litigation and recorded an additional pre-tax $1.0 billion in the fiscal third quarter of 2020 upon which an effective rate of 21.4% has been applied.

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

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

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

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

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. Prior to fiscal 2020, for performance share units, the fair market value was calculated for each of the three component goals at the date of grant: operational sales, adjusted operational earnings per share and relative total shareholder return. Beginning in fiscal 2020, for performance share units, the fair market value is calculated for the two component goals at the date of grant: adjusted operational earnings per share and relative total shareholder return. The fair values for the earnings per share goal of each performance share unit was estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 16 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 3, 2021.

Economic and Market Factors

COVID-19 considerations and business continuity
The Company has considered various internal and external factors in assessing the potential impact of COVID-19 on its business and financial results based upon information available at this time, as follows:

- *Operating Model:* The Company has a diversified business model across the healthcare industry with flexibility designed into its manufacturing, research and development clinical operations and commercial capabilities.
- *Supply Chain:* The Company continues to leverage its global manufacturing footprint and dual-source capabilities while closely monitoring and maintaining critical inventory at major distribution centers away from high-risk areas to ensure adequate and effective distribution.
- *Business Continuity:* The robust, active business continuity plans across the Company's network have been instrumental in preparing the Company for events like COVID-19 and the ability to meet the majority of patient and consumer needs remains uninterrupted.
- *Workforce:* The Company has put procedures in place to protect its essential workforce in manufacturing, distribution, commercial and research operations while ensuring appropriate remote working protocols have been established for other employees.
- *Liquidity:* The Company's high-quality credit rating allows the Company superior access to the financial capital markets for the foreseeable future. In the fiscal third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end, for additional liquidity. Additionally, in the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion. The net proceeds from this offering were used to fund the Momenta Pharmaceuticals, Inc. acquisition on October 1, 2020 and for general corporate purposes.
- *Domestic and Foreign Legislation:* The Company will continue to assess and evaluate the on-going global legislative efforts to combat the COVID-19 impact on economies and the sectors in which it participates. Currently, the recent legislative acts put in place are not expected to have a material impact on the Company’s operations.

In fiscal 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid and contractually obligated to be paid to these contract manufacturing organizations of approximately $0.9 billion are reflected in the prepaid expenses and other, other assets, accrued liabilities and other liabilities accounts in the Company's consolidated balance sheet upon execution of each agreement. Additionally, the Company has entered into certain vaccine development cost sharing arrangements with government related organizations.

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2010 - 2020, in the U.S., the weighted average compound annual growth rate of the Company’s net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as “Brexit”. The U.K. officially exited the E.U. on January 31, 2020, however, there was a transition period to allow time to agree the terms of a new trade deal. On December 30, 2020, the U.K., E.U. and the European Atomic Energy Community (Euratom) signed the EU–UK Trade and Cooperation Agreement (TCA). Over the last few years, Brexit has created global political and economic uncertainty and has led to volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. While the UK and EU have now agreed on a future trade and cooperation agreement, it is still unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. However, the Company currently does not believe that these and other related effects will have a material

impact on the Company’s consolidated financial position or operating results. As of January 3, 2021, the business of the Company’s U.K. subsidiaries represented less than 6% of the Company’s consolidated assets and less than 3% of the Company's fiscal twelve months revenues.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2020 would have increased or decreased the translation of foreign sales by approximately $384 million and net income by approximately $115 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

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

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

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

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2021, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

See Note 19 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 16, 2021, there were 132,376 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to “Item 7. Management’s Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk” of this Report; and Note 1 “Summary of Significant Accounting Policies - Financial Instruments” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 3, 2021 and December 29, 2019
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2020	2019
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	13,985	17,305
Marketable securities (Notes 1 and 2)		11,200	1,982
Accounts receivable trade, less allowances for doubtful accounts $293 (2019, $226)		13,576	14,481
Inventories (Notes 1 and 3)		9,344	9,020
Prepaid expenses and other receivables		3,132	2,392
Assets held for sale (Note 18)		—	94
Total current assets		**51,237**	**45,274**
Property, plant and equipment, net (Notes 1 and 4)		18,766	17,658
Intangible assets, net (Notes 1 and 5)		53,402	47,643
Goodwill (Notes 1 and 5)		36,393	33,639
Deferred taxes on income (Note 8)		8,534	7,819
Other assets		6,562	5,695
Total assets	**$**	**174,894**	**157,728**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	2,631	1,202
Accounts payable		9,505	8,544
Accrued liabilities		13,968	9,715
Accrued rebates, returns and promotions		11,513	10,883
Accrued compensation and employee related obligations		3,484	3,354
Accrued taxes on income (Note 8)		1,392	2,266
Total current liabilities		**42,493**	**35,964**
Long-term debt (Note 7)		32,635	26,494
Deferred taxes on income (Note 8)		7,214	5,958
Employee related obligations (Notes 9 and 10)		10,771	10,663
Long-term taxes payable (Note 1)		6,559	7,444
Other liabilities		11,944	11,734
Total liabilities		**111,616**	**98,257**
Commitments and Contingencies (Note 19)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,242)	(15,891)
Retained earnings		113,890	110,659
		101,768	97,888
Less: common stock held in treasury, at cost (Note 12) (487,331,000 shares and 487,336,000 shares)		38,490	38,417
Total shareholders' equity		**63,278**	**59,471**
Total liabilities and shareholders' equity	**$**	**174,894**	**157,728**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2020	2019	2018
Sales to customers	$	82,584	82,059	81,581
Cost of products sold		28,427	27,556	27,091
Gross profit		54,157	54,503	54,490
Selling, marketing and administrative expenses		22,084	22,178	22,540
Research and development expense		12,159	11,355	10,775
In-process research and development (Note 5)		181	890	1,126
Interest income		(111)	(357)	(611)
Interest expense, net of portion capitalized (Note 4)		201	318	1,005
Other (income) expense, net		2,899	2,525	1,405
Restructuring (Note 20)		247	266	251
Earnings before provision for taxes on income		16,497	17,328	17,999
Provision for taxes on income (Note 8)		1,783	2,209	2,702
Net earnings	**$**	**14,714**	**15,119**	**15,297**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**5.59**	**5.72**	**5.70**
Diluted	**$**	**5.51**	**5.63**	**5.61**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,632.8**	**2,645.1**	**2,681.5**
Diluted		**2,670.7**	**2,684.3**	**2,728.7**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2020	2019	2018
Net earnings	$ 14,714	15,119	15,297
Other comprehensive income (loss), net of tax			
Foreign currency translation	(233)	164	(1,518)
Securities:			
Unrealized holding gain (loss) arising during period	1	—	(1)
Reclassifications to earnings	—	—	1
Net change	1	—	—
Employee benefit plans:			
Prior service credit (cost), net of amortization	1,298	(18)	(44)
Gain (loss), net of amortization	(1,135)	(714)	(56)
Effect of exchange rates	(229)	(1)	92
Net change	(66)	(733)	(8)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	1,000	(107)	(73)
Reclassifications to earnings	(53)	7	(192)
Net change	947	(100)	(265)
Other comprehensive income (loss)	649	(669)	(1,791)
Comprehensive income	$ 15,363	14,450	13,506

The tax effects in other comprehensive income for the fiscal years 2020, 2019 and 2018 respectively: Foreign Currency Translation; $536 million, $19 million and $236 million; Employee Benefit Plans: $21 million, $222 million and $4 million, Derivatives & Hedges: $252 million, $27 million and $70 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 31, 2017	**$ 60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment[1]	(486)	(254)	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	15,119	15,119			
Cash dividends paid ($3.75 per share)	(9,917)	(9,917)			
Employee compensation and stock option plans	1,933	(758)			2,691
Repurchase of common stock	(6,746)				(6,746)
Other	(1)	(1)			
Other comprehensive income (loss), net of tax	(669)		(669)		
Balance, December 29, 2019	**59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**
Net earnings	14,714	14,714			
Cash dividends paid ($3.98 per share)	(10,481)	(10,481)			
Employee compensation and stock option plans	2,217	(931)			3,148
Repurchase of common stock	(3,221)				(3,221)
Other	(71)	(71)			
Other comprehensive income (loss), net of tax	649		649		
Balance, January 3, 2021	**$ 63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**

[1] See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

	2020	2019	2018
Cash flows from operating activities			
Net earnings	$ 14,714	15,119	15,297
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,231	7,009	6,929
Stock based compensation	1,005	977	978
Asset write-downs	233	1,096	1,258
Contingent consideration reversal	(1,148)	—	—
Net gain on sale of assets/businesses	(111)	(2,154)	(1,217)
Deferred tax provision	(1,141)	(2,476)	(1,016)
Credit losses and accounts receivable allowances	63	(20)	(31)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Decrease/(Increase) in accounts receivable	774	(289)	(1,185)
Increase in inventories	(265)	(277)	(644)
Increase in accounts payable and accrued liabilities	5,141	4,060	3,951
Increase in other current and non-current assets	(3,704)	(1,054)	(275)
Increase/(Decrease) in other current and non-current liabilities	744	1,425	(1,844)
Net cash flows from operating activities	**23,536**	**23,416**	**22,201**
Cash flows from investing activities			
Additions to property, plant and equipment	(3,347)	(3,498)	(3,670)
Proceeds from the disposal of assets/businesses, net	305	3,265	3,203
Acquisitions, net of cash acquired (Note 18)	(7,323)	(5,810)	(899)
Purchases of investments	(21,089)	(3,920)	(5,626)
Sales of investments	12,137	3,387	4,289
Credit support agreements activity, net	(987)	338	—
Other (primarily licenses and milestones)	(521)	44	(464)
Net cash used by investing activities	**(20,825)**	**(6,194)**	**(3,167)**
Cash flows from financing activities			
Dividends to shareholders	(10,481)	(9,917)	(9,494)
Repurchase of common stock	(3,221)	(6,746)	(5,868)
Proceeds from short-term debt	3,391	39	80
Repayment of short-term debt	(2,663)	(100)	(2,479)
Proceeds from long-term debt, net of issuance costs	7,431	3	5
Repayment of long-term debt	(1,064)	(2,823)	(1,555)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,114	954	949
Credit support agreements activity, net	(333)	100	25
Other	(294)	475	(173)
Net cash used by financing activities	**(6,120)**	**(18,015)**	**(18,510)**
Effect of exchange rate changes on cash and cash equivalents	89	(9)	(241)
(Decrease)/Increase in cash and cash equivalents	(3,320)	(802)	283
Cash and cash equivalents, beginning of year (Note 1)	17,305	18,107	17,824
Cash and cash equivalents, end of year (Note 1)	**$ 13,985**	**17,305**	**18,107**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 904	995	1,049
Interest, net of amount capitalized	841	925	963
Income taxes	4,619	4,191	4,570

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	1,937	1,736	2,095
Conversion of debt		27	1	6
Acquisitions				
Fair value of assets acquired	$	7,755	7,228	1,047
Fair value of liabilities assumed and noncontrolling interests		(432)	(1,418)	(148)
Net cash paid for acquisitions (Note 18)	**$**	**7,323**	**5,810**	**899**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

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

Description of the Company and Business Segments

The Company has approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health (previously referred to as Consumer), Pharmaceutical and Medical Devices. The Consumer Health segment includes a broad range of products used in the baby care, oral care, skin health/beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2018-18: Collaborative Arrangements

The Company adopted this standard as of the beginning of the fiscal year 2020. This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses

The Company adopted this standard as of the beginning of the fiscal year 2020. This update introduces the current expected credit loss (CECL) model, which requires an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2018-14: Compensation - Defined Benefit Plans

The Company adopted this standard in the fiscal year ended 2020. This standard revised the financial statement note disclosure requirements of ASC 715-20 for defined benefit plan sponsors. The adoption of this standard had no impact on the Company's consolidated financial statements. See Note 10 to the Consolidated Financial Statements for defined benefit plan disclosures.

Accounting Standards adopted in the fiscal 2018 with a cumulative effect to the 2018 opening balance of Retained Earnings

The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of these accounting standards in 2018:

(Dollars in Millions)		Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$	(47)
ASU 2016-01 - Financial Instruments		232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers		(439)
Total	$	(254)

Recently Issued Accounting Standards
Not Adopted as of January 3, 2021

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019. There were no new material accounting standards issued in fiscal 2020 that impacted the Company.

Cash Equivalents

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

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

Investments

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

Property, Plant and Equipment and Depreciation

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

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

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

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between

the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

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

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.2 billion and $7.0 billion as of January 3, 2021 and December 29, 2019, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during each of the fiscal years 2020, 2019 and 2018.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 3.0% of the total revenues and are included in sales to customers.

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

Shipping and Handling

Shipping and handling costs incurred were $1.0 billion, $1.0 billion and $1.1 billion in fiscal years 2020, 2019 and 2018, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

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

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2020 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

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

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

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

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

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

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to operating leases was $1.0 billion and $1.0 billion in 2020 and 2019, respectively. The lease liability was $1.1 billion and $1.0 billion in 2020 and 2019, respectively. The operating lease costs were $0.3 billion, $0.3 billion and $0.3 billion in 2020, 2019 and 2018, respectively. Cash paid for amounts included in the measurement of lease liabilities were $0.3 billion and $0.3 billion in 2020 and 2019, respectively.

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

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

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

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically

involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development.

Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

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

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

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

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

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

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.1 billion, $2.2 billion and $2.6 billion in fiscal years 2020, 2019 and 2018, respectively.

Income Taxes

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

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

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the 2020 was approximately $7.7 billion, of which $6.9 billion is classified as noncurrent and reflected as "Long-term taxes payable" on the Company's balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of

GILTI inclusion in future years upon reversal (i.e., “deferred method”). In 2018, the Company elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company

intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

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

Net Earnings Per Share

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

Use of Estimates

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

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

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of January 3, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, inventory and related reserves, accrued rebates and associated reserves, and the carrying value of the goodwill and other long-lived assets. While there was not a material impact to the Company's consolidated financial statements as of and for the fiscal year ended January 3, 2021, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

Annual Closing Date

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

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of the fiscal year 2020 and 2019, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2020				
	Carrying Amount	Unrecognized Gain	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,863	—	2,863	2,863	—
Non-U.S. Sovereign Securities[1]	690	—	690	—	690
U.S. Reverse repurchase agreements	1,937	—	1,937	1,937	—
Corporate debt securities[1]	2,674	—	2,674	1,451	1,223
Money market funds	2,102	—	2,102	2,102	—
Time deposits[1]	877	—	877	877	—
Subtotal	$ 11,143	—	11,143	9,230	1,913
U.S. Gov't Securities	$ 13,777	1	13,778	4,731	9,047
Other Sovereign Securities	14	—	14	—	14
Corporate debt securities	250	—	250	24	226
Subtotal available for sale[2]	$ 14,041	1	14,042	4,755	9,287
Total cash, cash equivalents and current marketable securities				**$ 13,985**	**11,200**

(Dollars in Millions)	2019		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,637	2,637	—
Non-U.S. Sovereign Securities[1]	439	149	290
U.S. Reverse repurchase agreements	6,375	6,375	—
Other Reverse repurchase agreements	375	375	—
Corporate debt securities[1]	1,323	889	434
Money market funds	2,864	2,864	—
Time deposits[1]	906	906	—
Subtotal	$ 14,919	14,195	724
Gov't Securities	$ 4,102	3,095	1,007
Corporate debt securities	266	15	251
Subtotal available for sale[2]	$ 4,368	3,110	1,258
Total cash, cash equivalents and current marketable securities		**$ 17,305**	**1,982**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

At the end of fiscal year 2019, the carrying amount was the same as the estimated fair value.

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

The contractual maturities of the available for sale debt securities at January 3, 2021 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 14,026	14,027
Due after one year through five years	15	15
Due after five years through ten years	—	—
Total debt securities	$ 14,041	14,042

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

3. Inventories

At the end of fiscal years 2020 and 2019, inventories were comprised of:

(Dollars in Millions)	**2020**	**2019**
Raw materials and supplies	$ 1,410	1,117
Goods in process	2,040	1,832
Finished goods	5,894	6,071
Total inventories [1]	**$ 9,344**	**9,020**

[1] See Note 18 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures for the fiscal year ended December 29, 2019. There were no assets held for sale at January 3, 2021.

4. Property, Plant and Equipment

At the end of fiscal years 2020 and 2019, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	**2020**	**2019**
Land and land improvements	$ 882	854
Buildings and building equipment	12,502	11,877
Machinery and equipment	29,104	26,964
Construction in progress	4,316	3,637
Total property, plant and equipment, gross	$ 46,804	43,332
Less accumulated depreciation	28,038	25,674
Total property, plant and equipment, net[1]	**$ 18,766**	**17,658**

[1] See Note 18 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures for the fiscal year ended December 29, 2019. There were no assets held for sale at January 3, 2021.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2020, 2019 and 2018 was $63 million, $70 million and $86 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2020, 2019 and 2018 was $2.6 billion, $2.5 billion and $2.6 billion, respectively.

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

5. Intangible Assets and Goodwill

At the end of fiscal years 2020 and 2019, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2020	2019
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 39,990	36,634
Less accumulated amortization	17,618	13,154
Patents and trademarks — net	**$ 22,372**	**23,480**
Customer relationships and other intangibles — gross	$ 22,898	22,056
Less accumulated amortization	10,912	9,462
Customer relationships and other intangibles — net*	**$ 11,986**	**12,594**
Intangible assets with indefinite lives:		
Trademarks	$ 7,195	6,922
Purchased in-process research and development[(1)]	11,849	4,647
Total intangible assets with indefinite lives	**$ 19,044**	**11,569**
Total intangible assets — net	**$ 53,402**	**47,643**

*The majority is comprised of customer relationships

[(1)] In fiscal year 2020, the Company completed multiple acquisitions and recorded in-process research and development intangible assets of $6.0 billion from Momenta Pharmaceuticals, Inc., $0.8 billion for bermekimab and certain related assets from XBiotech, Inc., and $0.4 billion from the acquisition of all outstanding shares in Verb Surgical, Inc.

Goodwill as of January 3, 2021 and December 29, 2019, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	Medical Devices	Total
Goodwill at December 30, 2018	$ 8,670	9,063	12,720	30,453
Goodwill, related to acquisitions	1,188	75	2,018	3,281
Currency translation/other	(122)	31	(4)	(95)
Goodwill at December 29, 2019	$ 9,736	9,169	14,734	33,639
Goodwill, related to acquisitions	—	1,222	238	1,460
Currency translation/other	600	618	76	1,294
Goodwill at January 3, 2021	**$ 10,336**	**11,009**	**15,048**	**36,393**

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in cost of products sold was $4.7 billion, $4.5 billion and $4.4 billion before tax, for the fiscal years ended January 3, 2021, December 29, 2019 and December 30, 2018, respectively. Intangible asset write-downs are included in Other (income) expense, net.

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

(Dollars in Millions)

2021	2022	2023	2024	2025
$4,600	4,200	4,100	3,900	3,200

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

6. Fair Value Measurements

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

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

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of January 3, 2021, the total amount of cash collateral paid by the Company under the CSA amounted to $1.1 billion net, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 3, 2021, the Company had notional amounts outstanding for forward foreign exchange contracts, and cross currency interest rate swaps of $37.8 billion and $30.6 billion, respectively. As of December 29, 2019, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $45.3 billion and $20.1 billion, respectively.

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

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

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. The effect of which are immaterial for the fiscal years ended January 3, 2021 and December 29, 2019. Gains and losses on net investment hedge are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

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

As of January 3, 2021, the balance of deferred net gain on derivatives included in accumulated other comprehensive income was $652 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended January 3, 2021 and December 29, 2019, net of tax:

(Dollars in Millions)	January 3, 2021 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	De Sales	Cost of Product Sold
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	—	—	—
Amount of gain or (loss) recognized in AOCI	—	—	—	153	—	—	—
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)
Amount of gain or (loss) recognized in AOCI	44	298	(191)	—	(52)	(20)	(606)
Cross currency interest rate swaps contracts:							
Amount of gain or							

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended January 3, 2021 and December 29, 2019:

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

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

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	January 3, 2021	December 29, 2019		January 3, 2021	December 29, 2019
Debt	$ (473)	121	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 65	488	Interest (income) expense	—	—

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

The following table is a summary of the activity related to equity investments for the fiscal years ended January 3, 2021 and December 29, 2019:

	December 29, 2019			January 3, 2021	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,148	527	(194)	1,481	1,481
Equity Investments without readily determinable value	$ 712	(55)	81	738	738

	December 30, 2018			December 29, 2019	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 511	533	104	1,148	1,148
Equity Investments without readily determinable value	$ 681	(38)	69	712	712

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For the fiscal years ended January 3, 2021 and December 29, 2019 for equity investments without readily determinable market values, $76 million and $57 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were $21 million and $19 million, respectively, of changes in fair value reflected in net income due to changes in observable prices.

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

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or

that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended January 3, 2021 and December 29, 2019 were as follows:

	2020				2019
(Dollars in Millions)	**Level 1**	**Level 2**	**Level 3**	**Total**	**Total [1]**
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	849	—	849	209
Interest rate contracts [2][3]	—	240	—	240	693
Total	$ —	**1,089**	—	**1,089**	**902**
Liabilities:					
Forward foreign exchange contracts	—	702	—	702	426
Interest rate contracts [3]	—	1,569	—	1,569	193
Total	$ —	**2,271**	—	**2,271**	**619**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	49	—	49	23
Liabilities:					
Forward foreign exchange contracts	—	38	—	38	33
Available For Sale Other Investments:					
Equity investments[4]	1,481	—	—	1,481	1,148
Debt securities[5]	—	14,042	—	14,042	4,368
Other Liabilities					
Contingent Consideration[6]	$		633	633	1,715

Gross to Net Derivative Reconciliation		2020	2019
(Dollars in Millions)			
Total Gross Assets	$	1,138	925
Credit Support Agreement (CSA)		(1,107)	(841)
Total Net Asset		31	84
Total Gross Liabilities		2,309	652
Credit Support Agreement (CSA)		(2,172)	(586)
Total Net Liabilities	$	137	66

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

		2020	2019	2018
(Dollars in Millions)				
Beginning Balance	$	1,715	397	600
Changes in estimated fair value [7]		(1,089)	151	(156)
Additions		106	1,246	125
Payments		(99)	(79)	(172)
Ending Balance	$	633	1,715	397

(1) 2019 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,148 million, which are classified as Level 1 and contingent consideration of $1,715 million, classified as Level 3.
(2) Includes $1 million of non-current assets as of December 29, 2019.
(3) Includes cross currency interest rate swaps and interest rate swaps.
(4) Classified as non-current other assets.
(5) Classified as cash equivalents and current marketable securities.
(6) Includes $594 million, $1,631 million (primarily related to Auris Health) and $397 million, classified as non-current other liabilities as of January 3, 2021, December 29, 2019 and December 30, 2018, respectively. Includes $39 million and $84 million classified as current liabilities as of January 3, 2021 and December 29, 2019, respectively.
(7) Ongoing fair value adjustment amounts are recorded primarily in Research and Development expense. The Company recorded a contingent consideration reversal of $1,148 million in 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. The reversal of the contingent consideration was recorded in Other income and expense

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

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2020	Effective Rate %	2019	Effective Rate %
3% Zero Coupon Convertible Subordinated Debentures due 2020	$ —	—	51	3.00
2.95% Debentures due 2020	—	—	549	3.15
1.950% Notes due 2020	—	—	500	1.99
3.55% Notes due 2021	450	3.67	449	3.67
2.45% Notes due 2021	350	2.48	349	2.48
1.65% Notes due 2021	999	1.65	999	1.65
0.250% Notes due 2022 (1B Euro 1.2281)[2]/ (1B Euro 1.1096)[3]	1,227 [2]	0.26	1,108 [3]	0.26
2.25% Notes due 2022	999	2.31	998	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	803	3.17	804	3.17
2.05% Notes due 2023	499	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.2281)[2]/(750MM Euro 1.1096)[3]	919 [2]	0.68	829 [3]	0.68
5.50% Notes due 2024 (500MM 1.3654 GBP)[2]/(500MM GBP 1.2987)[3]	679 [2]	6.75	645 [3]	6.75
2.625% Notes due 2025	748	2.63	748	2.63
0.55% Notes due 2025[5]	996	0.57	—	—
2.45% Notes due 2026	1,994	2.47	1,993	2.47
2.95% Notes due 2027	997	2.96	996	2.96
0.95% Notes due 2027[5]	1,494	0.96	—	—
1.150% Notes due 2028 (750MM Euro 1.2281)[2]/(750MM Euro 1.1096)[3]	915 [2]	1.21	825 [3]	1.21
2.90% Notes due 2028	1,495	2.91	1,494	2.91
6.95% Notes due 2029	297	7.14	297	7.14
1.30% Notes due 2030[5]	1,743	1.30	—	—
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	855	4.24	855	4.24
1.650% Notes due 2035 (1.5B Euro 1.2281) [2]/(1.5B Euro 1.1096)[3]	1,827 [2]	1.68	1,649 [3]	1.68
3.55% Notes due 2036	989	3.59	989	3.59
5.95% Notes due 2037	992	5.99	992	5.99
3.625% Notes due 2037	1,488	3.64	1,487	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	991	3.42	991	3.42
4.50% Debentures due 2040	539	4.63	539	4.63
2.10% Notes due 2040[5]	986	2.14	—	—
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	495	4.52
3.70% Notes due 2046	1,974	3.74	1,973	3.74
3.75% Notes due 2047	991	3.76	991	3.76
3.500% Notes due 2048	742	3.52	742	3.52
2.250% Notes due 2050[5]	984	2.29	—	—

2.450% Notes due 2060[5]	1,228	2.49	—	—
Other	7	—	18	—
Subtotal	**34,434** [4]	**2.85 %** [1]	**27,594** [4]	**3.19** [1]
Less current portion	1,799		1,100	
Total long-term debt	**$ 32,635**		**26,494**	

(1) Weighted average effective rate.
(2) Translation rate at January 3, 2021.
(3) Translation rate at December 29, 2019.
(4) The excess of the fair value over the carrying value of debt was $5.4 billion at the end of fiscal year 2020 and $3.0 billion at the end of fiscal year 2019.
(5) In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion.

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

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2020, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 9, 2021. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, London Interbank Offered Rates (LIBOR), Secured Overnight Financing Rate (SOFR) Swap Curve or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal year 2020, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.6 billion at the end of fiscal year 2020, of which $1.8 billion is the current portion of the long-term debt, and the remainder is commercial paper and local borrowings by international subsidiaries.

Throughout fiscal year 2019, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $1.2 billion at the end of fiscal year 2019, of which $1.1 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term debt obligations commencing in 2021 are:

(Dollars in Millions)

2021	2022	2023	2024	2025	After 2025
$1,799	2,226	1,552	1,598	1,744	25,515

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2020	2019	2018
Currently payable:			
U.S. taxes	$ 1,026	1,941	1,284
International taxes	1,898	2,744	2,434
Total currently payable	2,924	4,685	3,718
Deferred:			
U.S. taxes	(76)	(814)	1,210 [1]
International taxes	(1,065)	(1,662)	(2,226)
Total deferred	(1,141)	(2,476)	(1,016)
Provision for taxes on income	**$ 1,783**	**2,209**	**2,702**

(1) Includes $1.4 billion of deferred tax expense for the adoption of the deferred method to account for GILTI.

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2020, 2019 and 2018, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2020	2019	2018
U.S.	$ 4,312	3,543	5,575
International	12,185	13,785	12,424
Earnings before taxes on income:	$ 16,497	17,328	17,999
Tax rates:			
U.S. statutory rate	21.0 %	21.0	21.0
International operations [1]	(9.9)	(5.9)	(3.7)
U.S. taxes on international income [2]	2.7	1.8	1.4
Tax benefits on Capital Loss	(1.2)	(0.3) [4]	—
Tax benefits on share-based compensation	(1.5)	(0.5)	(1.5)
TCJA and related impacts	0.7	(3.9) [3]	(1.9) [3]
All other	(1.0)	0.5 [4]	(0.3)
Effective Rate	10.8 %	12.7	15.0

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2020 and 2019 amounts include the impact of the new tax legislation enactment in Switzerland, which is further described below.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to balances originally recorded as part of the 2017 TCJA provisional tax charge. Further information provided below.
(4) Certain prior year amounts have been reclassified to conform to current year presentation.

The fiscal year 2020 tax rate decreased by 1.9% compared to the fiscal year 2019 tax rate, which was primarily driven by the following items. In fiscal year 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF) which became effective on January 1, 2020. The Federal transitional provisions of TRAF allow companies, under certain conditions, to adjust the tax basis in certain assets to fair value (i.e., "step-up") to be depreciated and amortized resulting in an incremental Swiss tax deduction over the transitional period.

TRAF also provides for parameters which enable the Swiss cantons to establish localized tax rates and regulations for companies. The new cantonal tax parameters include favorable tax benefits for patents and additional research and development tax deductions. The cantonal transitional provisions of TRAF allowed companies to elect either 1) tax basis step-up similar to the Federal transition benefit or 2) alternative statutory tax rate for a period not to exceed 5 years. The Company currently has operations located in various Swiss cantons. During the fiscal year 2019, as described in further detail below, the Company recorded the impacts of the TRAF that were enacted in that period.

During the fiscal year 2020, the final canton where the Company maintains significant operations enacted TRAF legislation. Additionally, the Company received rulings from the Swiss Federal and cantonal tax authorities in the remaining jurisdictions where it has significant operations. These rulings resulted in the Company revising its estimate on the tax basis adjustment (i.e., "step-up") for its assets and as a result, the Company recorded additional deferred tax benefits in 2020. The Company recognized a net benefit in the fiscal year 2020 for Swiss Tax Reform of approximately $0.4 billion or 2.6% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $0.3 billion tax benefit relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred in the fiscal year 2020; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $450 million deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets as described above; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.

- approximately $0.3 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities in the fiscal year 2020. This benefit has been reflected as “U.S. tax on international income” on the Company’s effective tax rate reconciliation.

The Company does not expect to receive future rulings regarding the transitional provisions of TRAF.

Also, in the fiscal fourth quarter of 2020, the Company recognized a capital loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2020 tax rate by approximately 1.2% which is

reflected as a “Tax Benefits on Capital Loss” on the effective tax rate reconciliation. In addition in the fiscal year 2020, the Company had lower income in higher tax jurisdictions, primarily driven by:

- the impact of the accrual of litigation costs related to Talc for $4.0 billion which reduced the U.S. earnings before taxes at an effective tax rate of 23.5%;
- the accrual of additional legal costs, including an additional $1.0 billion associated with a revised agreement in principle to settle opioid litigation at an effective tax rate of 21.4%

The Company also generated additional tax benefits from stock-based compensation that were either exercised or vested; reduced the contingent consideration liability related to the Auris Health acquisition (see Note 18); and reversal of some of its unrecognized tax benefits due to the completion of several years of tax examinations in certain jurisdictions during the fiscal year 2020.

The fiscal year 2019 tax rate decreased by 2.3% compared to the fiscal year 2018 tax rate. In addition to the impact of TRAF discussed in more detail below, the primary drivers of the net decrease were as follows:

- The Company reorganized the ownership structure of certain wholly-owned international subsidiaries in the fiscal fourth quarter of 2019, which resulted in a reduction of certain withholding and local taxes that it had previously recognized as part of the provisional Tax Cuts and Jobs Act (TCJA) tax charge in the fiscal year 2017 and finalized in the fiscal year 2018. Following the completion of this restructuring and approval by the applicable local authorities, the Company reversed a deferred tax liability of $0.6 billion and a related deferred tax asset of $0.2 billion for U.S. foreign tax credits, for a net deferred tax benefit of $0.4 billion decreasing the annual effective tax rate by 2.2%. This benefit has been reflected as “TCJA and related impacts” on the Company’s effective tax rate reconciliation.
- The impact of the agreement in principle to settle opioid litigation for $4 billion (see Note 19 to the Consolidated Financial Statements) which reduced the U.S. earnings before taxes at an effective tax rate of 23.5% and decreased the Company’s annual effective tax rate by approximately 2.1%.
- In December of fiscal year 2019, the U.S. Treasury issued final foreign tax credit regulations, which resulted in the Company revising the amount of foreign tax credits that were initially recorded in the fiscal year 2017 as part of the provisional TCJA tax charge. As a result, the Company recorded an increased deferred tax asset related to these foreign tax credits of approximately $0.3 billion or 1.7% to the annual effective tax rate. This benefit has been reflected as “TCJA and related impacts” on the Company’s effective tax rate reconciliation.
- The Company reassessed its uncertain tax positions related to the current IRS audit and increased its unrecognized tax benefit by $0.3 billion liability which increased the annual effective tax rate by approximately 1.5% (see section on Unrecognized Tax Benefits for additional information). As these positions were related to uncertain tax regarding international transfer pricing, this expense has been classified as “International Operations” on the Company’s effective tax rate reconciliation. Subsequent to December 29, 2019, the Company received and agreed to Notices of Proposed Adjustments (NOPAs) from the IRS. The Company believes it is adequately reserved for potential exposures.
- There were several one-time tax impacts that resulted in a cumulative net tax benefit to the 2018 annual effective tax rate of 1.2%. These items included the LifeScan divestiture, the adjustment to the 2017 provisional TCJA tax charge and the acceleration of certain tax deductions as part of the 2017 tax return.
- More income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2018.

As described above for the Swiss tax legislation, in the fiscal year 2019, the Company recorded a net tax expense of $0.1 billion which increased the effective tax rate for the fiscal year 2019 by approximately 0.6%. This net tax expense related to federal and certain cantonal enactments in the fiscal year 2019 consisting of the following provisions:

- approximately $0.6 billion tax expense relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred by December 29, 2019; this expense has been reflected as “International Operations” on the Company’s effective tax rate reconciliation.
- a $0.9 billion deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company’s Swiss subsidiaries’ assets; this benefit has been reflected as “International Operations” on the Company’s effective tax rate reconciliation.
- approximately $450 million of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities and the new deferred tax asset for the

Federal step-up. This benefit has been reflected as “U.S. tax on international income” on the Company’s effective tax rate reconciliation.

In the fiscal year 2018, the Company completed its full assessment and finalized the accounting for the impact of the TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This charge was primarily related to additional deferred tax liabilities for foreign local and withholding taxes for the remaining balance of undistributed foreign earnings as of December 31, 2017 that were not provided for in the 2017 provisional charge.

As described in Note 1, in the fiscal year 2018, the Company elected to treat GILTI as a period expense under the deferred method and recorded a deferred tax cost of approximately $1.4 billion in the fiscal year 2018 related to facts and circumstances that existed on the date of TCJA enactment. During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. This benefit has been reflected as “TCJA and related impacts” on the Company’s effective tax rate reconciliation.

Temporary differences and carryforwards at the end of fiscal years 2020 and 2019 were as follows:

	2020 Deferred Tax		2019 Deferred Tax*	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,434		2,473	
Stock based compensation	627		595	
Depreciation & amortization	721		1,122	
Non-deductible intangibles		(6,567)		(5,835)
International R&D capitalized for tax	1,517		1,189	
Reserves & liabilities	3,466		2,337	
Income reported for tax purposes	1,705		1,605	
Net operating loss carryforward international	990		838	
Undistributed foreign earnings	812	(1,435)	765	(1,289)
Global intangible low-taxed income		(3,606)		(2,965)
Miscellaneous international	854	(211)	696	(81)
Miscellaneous U.S.	12		411	
Total deferred income taxes	**$ 13,138**	**(11,819)**	**12,031**	**(10,170)**

*Certain prior year amounts have been reclassified to conform to current year presentation

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

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

(Dollars in Millions)	**2020**	**2019**	**2018**
Beginning of year	$ 3,853	3,326	3,151
Increases related to current year tax positions	265	249	242
Increases related to prior period tax positions	668	408	145
Decreases related to prior period tax positions	(551)	(105)	(137)
Settlements	(839)	(9)	(40)
Lapse of statute of limitations	(23)	(16)	(35)
End of year	**$ 3,373**	**3,853**	**3,326**

The unrecognized tax benefits of $3.4 billion at January 3, 2021, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2012. As of December 29, 2019, the Company classified unrecognized tax benefits and related interest

of approximately $0.9 billion as a current liability on the “Accrued taxes on Income” line of the Consolidated Balance Sheet. In the fiscal year 2020, the Company made its final payments for approximately $0.7 billion to the U.S. Treasury related to the final settlement of 2010-2012 tax audit liability.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities, except as previously noted on amounts related to the current United States IRS audit. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $32 million, $50 million and $53 million in fiscal years 2020, 2019 and 2018, respectively. The total amount of accrued interest was $468 million and $559 million in fiscal years 2020 and 2019, respectively.

9. Employee Related Obligations

At the end of fiscal 2020 and fiscal 2019, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2020	2019
Pension benefits	$ 5,761	5,538
Postretirement benefits	2,229	2,297
Postemployment benefits	3,078	3,004
Deferred compensation	250	338
Total employee obligations	11,318	11,177
Less current benefits payable	547	514
Employee related obligations — non-current	**$ 10,771**	**10,663**

Prepaid employee related obligations of $656 million and $551 million for 2020 and 2019, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

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

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits
accrued under the Final Average Pay formula for service before January 1, 2026. The impact of this change decreases the
PBO as of January 3, 2021 by approximately $1.8 billion and is included in the "Amendments" line in the Change in Benefit Obligation.

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

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

In 2020 and 2019 the Company used December 31, 2020 and December 31, 2019, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2020, 2019 and 2018 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Service cost	$ 1,380	1,163	1,283	287	274	269
Interest cost	955	1,096	996	133	185	148
Expected return on plan assets	(2,461)	(2,322)	(2,212)	(7)	(6)	(7)
Amortization of prior service cost	2	4	3	(31)	(31)	(31)
Recognized actuarial losses (gains)	891	579	852	142	129	123
Curtailments and settlements	23	73	1	—	—	—
Net periodic benefit cost	**$ 790**	**593**	**923**	**524**	**551**	**502**

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Net Periodic Benefit Cost						
Service cost discount rate	2.82 %	3.63	3.20	3.04	4.45	3.85
Interest cost discount rate	3.13 %	4.13	3.60	3.08	4.25	3.62
Rate of increase in compensation levels	4.00 %	3.99	3.98	4.25	4.29	4.29
Expected long-term rate of return on plan assets	8.12 %	8.31	8.46			
Benefit Obligation						
Discount rate	2.14 %	2.91	3.76	2.23	3.39	4.40
Rate of increase in compensation levels	4.00 %	4.01	3.97	4.27	4.29	4.29

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

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

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

Health Care Plans	**2020**	**2019**
Health care cost trend rate assumed for next year	5.68 %	5.87 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.49 %	4.50 %
Year the rate reaches the ultimate trend rate	2040	2040

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2020 and 2019 for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	Retirement Plans 2020	Retirement Plans 2019	Other Benefit Plans 2020	Other Benefit Plans 2019
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 37,188	31,670	5,076	4,480
Service cost	1,380	1,163	287	274
Interest cost	955	1,096	133	185
Plan participant contributions	61	63	—	—
Amendments[1]	(1,780)	—	—	—
Actuarial (gains) losses[2]	5,716	5,178	(75)	562
Divestitures & acquisitions	(88)	(278)	—	—
Curtailments, settlements & restructuring	(24)	(172)	—	—
Benefits paid from plan	(1,111)	(1,555)[3]	(396)	(431)
Effect of exchange rates	1,003	23	3	6
Projected benefit obligation — end of year	**$ 43,300**	**37,188**	**5,028**	**5,076**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 32,201	26,818	115	180
Actual return on plan assets	5,524	6,185	14	19
Company contributions	870	908	357	347
Plan participant contributions	61	63	—	—
Settlements	(13)	(16)	—	—
Divestitures & acquisitions	(84)	(274)	—	—
Benefits paid from plan assets	(1,111)	(1,555)[3]	(396)	(431)
Effect of exchange rates	747	72	—	—
Plan assets at fair value — end of year	**$ 38,195**	**32,201**	**90**	**115**
Funded status — end of year	**$ (5,105)**	**(4,987)**	**(4,938)**	**(4,961)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 656	551	—	—
Current liabilities	(125)	(113)	(418)	(397)
Non-current liabilities	(5,636)	(5,425)	(4,520)	(4,564)
Total recognized in the consolidated balance sheet — end of year	**$ (5,105)**	**(4,987)**	**(4,938)**	**(4,961)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 10,860	8,835	1,463	1,685
Prior service cost (credit)[1]	(1,797)	(8)	(44)	(75)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 9,063**	**8,827**	**1,419**	**1,610**
Accumulated Benefit Obligations — end of year	**$ 40,356**	**33,416**		

[1]In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026.
[2]The actuarial losses for retirement plans in 2020 and 2019 was primarily related to decreases in discount rates.
[3]In 2019, the Company offered a voluntary lump-sum payment option for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2019. The amount distributed in 2019 was approximately $514 million.

(Dollars in Millions)	Retirement Plans 2020	Retirement Plans 2019	Other Benefit Plans 2020	Other Benefit Plans 2019
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 790**	**593**	**524**	**551**
Net actuarial (gain) loss	2,616	1,084	(81)	550
Amortization of net actuarial loss	(891)	(579)	(142)	(129)
Prior service cost (credit)	(1,780)	—	—	—
Amortization of prior service (cost) credit	(2)	(4)	31	31
Effect of exchange rates	293	1	1	1
Total loss/(income) recognized in other comprehensive income, before tax	**$ 236**	**502**	**(191)**	**453**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,026**	**1,095**	**333**	**1,004**

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

In 2020, the Company contributed $441 million and $429 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2020 and December 31, 2019, respectively:

	U.S. Plans				
	Qualified Plans		Non-Qualified Plans		Funded
(Dollars in Millions)	2020	2019	2020	2019	2020
Plan Assets	$ 25,554	21,398	—	—	12,641
Projected Benefit Obligation	25,466	22,034	2,748	2,544	14,541
Accumulated Benefit Obligation	24,158	19,831	2,495	2,115	13,210
Over (Under) Funded Status					
Projected Benefit Obligation	$ 88	(636)	(2,748)	(2,544)	(1,900)
Accumulated Benefit Obligation	1,396	1,567	(2,495)	(2,115)	(569)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $8.8 billion, $9.8 billion and $4.4 billion, respectively, at the end of 2020, and $4.3 billion, $5.2 billion and $0.9 billion, respectively, at the end of 2019.

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

(Dollars in Millions)	2021	2022	2023	2024	2025	2026-2030
Projected future benefit payments						
Retirement plans	$ 1,257	1,292	1,388	1,424	1,494	8,795
Other benefit plans	$ 427	440	453	465	417	2,273

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

(Dollars in Millions)	2021	2022	2023	2024	2025	2026-2030
Projected future contributions	$ 110	116	121	130	136	787

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

The Company's retirement plan asset allocation at the end of 2020 and 2019 and target allocations for 2021 are as follows:

	Percent of Plan Assets		Target Allocation
	2020	2019	2021
Worldwide Retirement Plans			
Equity securities	66 %	74 %	67 %
Debt securities	34	26	33
Total plan assets	**100 %**	**100 %**	**100 %**

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

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

Valuation Hierarchy
The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.
The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

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

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

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.

- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.

- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2020 and December 31, 2019:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**
Short-term investment funds	$ 127	119	763	405	—	—	—	—	890	524
Government and agency securities	—	—	5,023	4,140	—	—	—	—	5,023	4,140
Debt instruments	—	—	3,931	3,452	—	—	—	—	3,931	3,452
Equity securities	14,375	12,483	2	2	—	—	—	—	14,377	12,485
Commingled funds	—	—	4,690	3,338	160	181	8,236	7,580	13,086	11,099
Other assets	—	—	11	9	21	19	856	473	888	501
Investments at fair value	**$14,502**	**12,602**	**14,420**	**11,346**	**181**	**200**	**9,092**	**8,053**	**38,195**	**32,201**

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

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $90 million and $84 million at December 31, 2020 and December 31, 2019, respectively and U.S. short-term investment funds (Level 2) of $31 million at December 31, 2019.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $946 million (2.5% of total plan assets) at December 31, 2020 and $984 million (3.1% of total plan assets) at December 31, 2019.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee’s contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $243 million, $235 million and $242 million in fiscal years 2020, 2019 and 2018, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock	
	Shares	Amount
Balance at December 31, 2017	437,318	$ 31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	34,362
Employee compensation and stock option plans	(20,053)	(2,691)
Repurchase of common stock	49,870	6,746
Balance at December 29, 2019	487,336	38,417
Employee compensation and stock option plans	(21,765)	(3,148)
Repurchase of common stock	21,760	3,221
Balance at January 3, 2021	487,331	$ 38,490

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2020, 2019 and 2018.

Cash dividends paid were $3.98 per share in fiscal year 2020, compared with dividends of $3.75 per share in fiscal year 2019, and $3.54 per share in fiscal year 2018.

On January 4, 2021, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on March 9, 2021 to shareholders of record as of February 23, 2021.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed as of September 29, 2019.

13. Accumulated Other Comprehensive Income (Loss)

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

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 31, 2017	$ (7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings		(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	(8,869)	—	(6,158)	(195)	(15,222)
Net 2019 changes	164	—	(733)	(100)	(669)
December 29, 2019	(8,705)	—	(6,891)	(295)	(15,891)
Net 2020 changes	(233)	1	(66)	947	649
January 3, 2021	$ (8,938)	1	(6,957)	652	(15,242)

[1] Per the adoption of ASU 2016-01- Financial Instruments

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

Details on reclassifications out of Accumulated Other Comprehensive Income:

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

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

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

14. International Currency Translation

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

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

A rollforward of the changes during fiscal years 2020, 2019 and 2018 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $209 million, $267 million and $265 million in fiscal years 2020, 2019 and 2018, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 3, 2021, December 29, 2019 and December 30, 2018:

(In Millions Except Per Share Amounts)	2020	2019	2018
Basic net earnings per share	$ 5.59	5.72	5.70
Average shares outstanding — basic	2,632.8	2,645.1	2,681.5
Potential shares exercisable under stock option plans	118.3	136.3	139.0
Less: shares repurchased under treasury stock method	(80.4)	(97.8)	(92.5)
Convertible debt shares	—	0.7	0.7
Adjusted average shares outstanding — diluted	2,670.7	2,684.3	2,728.7
Diluted net earnings per share	$ 5.51	5.63	5.61

The diluted net earnings per share calculation for fiscal year 2020 excluded 18 million shares related to stock options, as the exercise price of these options was greater than their average market value. As of January 3, 2021, the Company did not have convertible debt.

The diluted net earnings per share calculation for fiscal year 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than the average market value of the Company’s stock. The diluted net earnings per share calculation for fiscal year 2019 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense of $1 million after-tax.

The diluted net earnings per share calculation for fiscal year 2018 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock. The diluted net earnings per share calculation for fiscal year 2018 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense of $1 million after-tax.

16. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 3, 2021, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 277 million at the end of fiscal year 2020.

The compensation cost that has been charged against income for these plans was $1,005 million, $977 million and $978 million for fiscal years 2020, 2019 and 2018, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $210 million, $227 million and $192 million for fiscal

years 2020, 2019 and 2018, respectively. The Company also recognized additional income tax benefits of $248 million, $209 million and $264 million for fiscal years 2020, 2019 and 2018, respectively, for which options were exercised or restricted shares were vested. The total

unrecognized compensation cost was $804 million, $823 million and $827 million for fiscal years 2020, 2019 and 2018, respectively. The weighted average period for this cost to be recognized was 1.76 years, 1.71 years and 1.73 years for fiscal years 2020, 2019, and 2018, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

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

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2020, 2019 and 2018 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $16.42, $17.80 and $17.98, in fiscal years 2020, 2019 and 2018, respectively. The fair value was estimated based on the weighted average assumptions of:

	2020	2019	2018
Risk-free rate	1.47 %	2.56 %	2.77 %
Expected volatility	15.33 %	16.27 %	15.77 %
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.60 %	2.80 %	2.70 %

A summary of option activity under the Plan as of January 3, 2021, December 29, 2019 and December 30, 2018, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 31, 2017	111,306	$ 90.48	$ 5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	109,652	98.29	3,214
Options granted	19,745	131.94	
Options exercised	(14,785)	82.43	
Options canceled/forfeited	(2,975)	125.11	
Shares at December 29, 2019	111,637	105.63	4,478
Options granted	20,723	151.41	
Options exercised	(16,275)	86.05	
Options canceled/forfeited	(1,835)	137.62	
Shares at January 3, 2021	**114,250**	**$ 116.22**	**$ 4,703**

The total intrinsic value of options exercised was $1,021 million, $807 million and $1,028 million in fiscal years 2020, 2019 and 2018, respectively.

The following table summarizes stock options outstanding and exercisable at January 3, 2021:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$62.20-$72.54	11,111	1.8	$70.79	11,111	$70.79
$90.44-$100.06	22,304	3.6	$95.36	22,304	$95.36
$100.48-$115.67	28,180	5.6	$108.64	27,695	$108.51
$129.51-$131.94	32,553	7.6	$130.85	145	$130.53
$141.06-$151.41	20,102	9.1	$151.41	34	$151.41
	114,250	**6.0**	**$116.22**	**61,289**	**$96.97**

[1] Average contractual life remaining in years.

Stock options outstanding at December 29, 2019 and December 30, 2018 were 111,637 and an average life of 6.0 years and 109,652 and an average life of 6.2 years, respectively. Stock options exercisable at December 29, 2019 and December 30, 2018 were 60,761 at an average price of $88.88 and 54,862 at an average price of $82.03, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. Beginning in fiscal 2020, performance shares were granted with two equally-weighted goals that directly align with or help drive long-term total shareholder return: adjusted operational earnings per share and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 3, 2021 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 29, 2019	16,769	2,174
Granted	5,051	816
Issued	(6,042)	(702)
Canceled/forfeited/adjusted	(780)	(52)
Shares at January 3, 2021	14,998	2,236

The average fair value of the restricted share units granted was $139.58, $121.31 and $119.67 in fiscal years 2020, 2019 and 2018, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $650 million, $586 million and $614 million in 2020, 2019 and 2018, respectively.

The weighted average fair value of the performance share units granted was $160.54, $124.67 and $120.64 in fiscal years 2020, 2019 and 2018, calculated using the weighted average fair market value for each of the component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation

model. The fair value of performance share units issued was $91 million, $119 million and $129 million in fiscal years 2020, 2019 and 2018, respectively.

17. Segments of Business* and Geographic Areas

(Dollars in Millions)	Sales to Customers			% Change	
	2020	2019	2018	'20 vs. '19	'19 vs. '18
Consumer Health)[1]					
OTC					
U.S.	$ 2,460	2,010	1,850	22.4 %	8.6
International	2,364	2,434	2,484	(2.9)	(2.0)
Worldwide	4,824	4,444	4,334	8.5	2.5
Skin Health/Beauty[2]					
U.S.	2,350	2,392	2,403	(1.7)	(0.4)
International	2,100	2,201	1,979	(4.6)	11.2
Worldwide	4,450	4,593	4,382	(3.1)	4.8
Oral Care					
U.S.	683	621	637	9.9	(2.5)
International	958	906	918	5.7	(1.2)
Worldwide	1,641	1,528	1,555	7.4	(1.7)
Baby Care					
U.S.	376	362	422	3.7	(14.2)
International	1,141	1,313	1,436	(13.1)	(8.6)
Worldwide	1,517	1,675	1,858	(9.4)	(9.9)
Women's Health					
U.S.	13	12	13	8.2	(5.5)
International	888	974	1,036	(8.8)	(6.0)
Worldwide	901	986	1,049	(8.6)	(6.0)
Wound Care/Other					
U.S.	480	441	436	8.9	1.2
International	240	230	239	4.1	(3.9)
Worldwide	720	671	675	7.2	(0.6)
TOTAL CONSUMER HEALTH					
U.S.	6,362	5,839	5,761	9.0	1.4
International	7,691	8,059	8,092	(4.6)	(0.4)
Worldwide	14,053	13,898	13,853	1.1	0.3

[1]Previously referred to as Consumer
[2]Previously referred to as Beauty

PHARMACEUTICAL					
Immunology					
U.S.	10,175	9,641	9,073	5.5	6.3
International	4,880	4,309	4,047	13.2	6.5
Worldwide	15,055	13,950	13,120	7.9	6.3
REMICADE®					
U.S.	2,508	3,079	3,664	(18.5)	(16.0)
U.S. Exports	346	294	436	18.0	(32.7)
International	893	1,007	1,226	(11.4)	(17.8)
Worldwide	3,747	4,380	5,326	(14.4)	(17.8)
SIMPONI / SIMPONI ARIA®					
U.S.	1,155	1,159	1,051	(0.3)	10.2
International	1,088	1,029	1,033	5.8	(0.4)
Worldwide	2,243	2,188	2,084	2.6	5.0
STELARA®					
U.S.	5,240	4,346	3,469	20.6	25.3
International	2,467	2,015	1,687	22.4	19.4
Worldwide	7,707	6,361	5,156	21.1	23.4
TREMFYA®					
U.S.	926	764	453	21.3	68.5
International	421	248	91	69.9	**
Worldwide	1,347	1,012	544	33.2	85.9
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	11	10	10	6.4	4.5
Worldwide	11	10	10	6.4	4.5
Infectious Diseases					
U.S.	1,735	1,597	1,378	8.6	15.9
International	1,839	1,815	1,926	1.3	(5.7)
Worldwide	3,574	3,413	3,304	4.7	3.3
EDURANT® / rilpivirine					
U.S.	44	50	58	(11.2)	(13.7)
International	920	812	758	13.3	7.1
Worldwide	964	861	816	11.9	5.6
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®					
U.S.	1,587	1,422	1,169	11.6	21.6
International	597	689	786	(13.4)	(12.3)
Worldwide	2,184	2,110	1,955	3.5	8.0
OTHER INFECTIOUS DISEASES					
U.S.	104	126	151	(17.6)	(16.5)
International	323	315	382	2.6	(17.6)
Worldwide	427	441	533	(3.2)	(17.3)

Neuroscience					
U.S.	3,091	2,919	2,574	5.9	13.4
International	3,457	3,409	3,503	1.4	(2.7)
Worldwide	6,548	6,328	6,077	3.5	4.1
CONCERTA® / methylphenidate					
U.S.	183	233	229	(21.4)	1.7
International	439	463	434	(5.1)	6.6
Worldwide	622	696	663	(10.6)	4.9
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	2,314	2,107	1,791	9.8	17.6
International	1,339	1,224	1,137	9.4	7.7
Worldwide	3,653	3,330	2,928	9.7	13.7
RISPERDAL CONSTA®					
U.S.	296	314	315	(5.9)	(0.3)
International	346	374	422	(7.5)	(11.4)
Worldwide	642	688	737	(6.8)	(6.7)
OTHER NEUROSCIENCE					
U.S.	298	266	239	12.4	11.4
International	1,334	1,349	1,510	(1.1)	(10.7)
Worldwide	1,632	1,614	1,749	1.1	(7.7)
Oncology					
U.S.	5,092	4,299	4,331	18.5	(0.7)
International	7,275	6,393	5,513	13.8	16.0
Worldwide	12,367	10,692	9,844	15.7	8.6
DARZALEX®					
U.S.	2,232	1,567	1,203	42.4	30.3
International	1,958	1,430	822	36.9	73.9
Worldwide	4,190	2,998	2,025	39.8	48.0
ERLEADA®					
U.S.	583	297	124	96.1	**
International	176	35	—	* *	**
Worldwide	760	332	124	* *	**
IMBRUVICA®					
U.S.	1,821	1,555	1,129	17.1	37.7
International	2,307	1,856	1,486	24.3	24.9
Worldwide	4,128	3,411	2,615	21.0	30.4
VELCADE®					
U.S.	—	—	—	—	—
International	408	751	1,116	(45.7)	(32.7)
Worldwide	408	751	1,116	(45.7)	(32.7)
ZYTIGA® /abiraterone acetate					
U.S.	373	810	1,771	(54.0)	(54.3)
International	2,097	1,985	1,727	5.6	15.0
Worldwide	2,470	2,795	3,498	(11.6)	(20.1)

OTHER ONCOLOGY					
U.S.	83	70	104	19.2	(32.7)
International	330	336	362	(1.9)	(7.2)
Worldwide	413	407	466	1.7	(12.7)
Pulmonary Hypertension					
U.S.	2,133	1,684	1,651	26.6	2.0
International	1,015	939	922	8.2	1.9
Worldwide	3,148	2,623	2,573	20.0	1.9
OPSUMIT®					
U.S.	1,008	766	700	31.7	9.4
International	631	562	515	12.3	9.0
Worldwide	1,639	1,327	1,215	23.5	9.2
UPTRAVI®					
U.S.	955	714	598	33.8	19.3
International	138	105	65	30.9	62.4
Worldwide	1,093	819	663	33.5	23.5
OTHER					
U.S.	169	205	353	(17.6)	(41.9)
International	247	272	342	(9.2)	(20.5)
Worldwide	416	476	695	(12.8)	(31.5)
Cardiovascular / Metabolism / Other					
U.S.	3,509	3,734	4,279	(6.0)	(12.7)
International	1,369	1,458	1,537	(6.1)	(5.2)
Worldwide	4,878	5,192	5,816	(6.0)	(10.7)
XARELTO®					
U.S.	2,345	2,313	2,477	1.4	(6.6)
International	—	—	—	—	—
Worldwide	2,345	2,313	2,477	1.4	(6.6)
INVOKANA® / INVOKAMET®					
U.S.	564	536	711	5.2	(24.6)
International	231	199	170	16.3	17.3
Worldwide	795	735	881	8.2	(16.5)
PROCRIT® / EPREX®					
U.S.	277	505	674	(45.1)	(25.1)
International	274	285	314	(3.8)	(9.2)
Worldwide	552	790	988	(30.2)	(20.0)
OTHER					
U.S.	323	380	417	(15.1)	(9.1)
International	864	974	1,053	(11.3)	(7.6)
Worldwide	1,186	1,353	1,470	(12.4)	(8.0)
TOTAL PHARMACEUTICAL					
U.S.	25,735	23,874	23,286	7.8	2.5
International	19,837	18,324	17,448	8.3	5.0
Worldwide	45,572	42,198	40,734	8.0	3.6

MEDICAL DEVICES					
Diabetes Care					
U.S.	—	—	371	—	**
International	—	—	638	—	**
Worldwide	—	—	1,009	—	**
Interventional Solutions					
U.S.	1,452	1,443	1,283	0.6	12.5
International	1,594	1,554	1,363	2.6	14.0
Worldwide	3,046	2,997	2,646	1.6	13.3
Orthopaedics					
U.S.	4,779	5,319	5,281	(10.2)	0.7
International	2,984	3,520	3,604	(15.2)	(2.3)
Worldwide	7,763	8,839	8,885	(12.2)	(0.5)
HIPS					
U.S.	793	863	841	(8.2)	2.6
International	487	575	577	(15.3)	(0.3)
Worldwide	1,280	1,438	1,418	(11.0)	1.4
KNEES					
U.S.	743	889	911	(16.4)	(2.4)
International	427	591	591	(27.8)	0.0
Worldwide	1,170	1,480	1,502	(21.0)	(1.4)
TRAUMA					
U.S.	1,648	1,652	1,599	(0.2)	3.3
International	966	1,068	1,100	(9.6)	(2.9)
Worldwide	2,614	2,720	2,699	(3.9)	0.8
SPINE, SPORTS & OTHER[3]					
U.S.	1,595	1,915	1,930	(16.7)	(0.8)
International	1,104	1,286	1,336	(14.1)	(3.8)
Worldwide	2,699	3,201	3,266	(15.7)	(2.0)
Surgery					
U.S.	3,249	3,828	4,125	(15.1)	(7.2)
International	4,983	5,673	5,776	(12.2)	(1.8)
Worldwide	8,232	9,501	9,901	(13.4)	(4.0)
ADVANCED					
U.S.	1,535	1,637	1,657	(6.2)	(1.2)
International	2,304	2,458	2,345	(6.2)	4.8
Worldwide	3,839	4,095	4,002	(6.2)	2.3
GENERAL					
U.S.	1,714	2,192	2,468	(21.8)	(11.2)
International	2,679	3,215	3,431	(16.7)	(6.3)
Worldwide	4,392	5,406	5,899	(18.8)	(8.4)
Vision					
U.S.	1,557	1,794	1,777	(13.2)	0.9
International	2,362	2,830	2,776	(16.5)	2.0
Worldwide	3,919	4,624	4,553	(15.2)	1.6

CONTACT LENSES / OTHER					
U.S.	1,213	1,304	1,237	(7.0)	5.4
International	1,781	2,088	2,065	(14.7)	1.1
Worldwide	2,994	3,392	3,302	(11.7)	2.7
SURGICAL					
U.S.	344	490	540	(29.7)	(9.4)
International	581	742	711	(21.7)	4.4
Worldwide	925	1,232	1,251	(24.9)	(1.6)
TOTAL MEDICAL DEVICES					
U.S.	11,036	12,384	12,837	(10.9)	(3.5)
International	11,923	13,579	14,157	(12.2)	(4.1)
Worldwide	22,959	25,963	26,994	(11.6)	(3.8)
WORLDWIDE					
U.S.	43,133	42,097	41,884	2.5	0.5
International	39,451	39,962	39,697	(1.3)	0.7
Worldwide	$ 82,584	82,059	81,581	0.6 %	0.6

[3]Previously referred to as Spine & Other
*Certain prior year amounts have been reclassified to conform to current year presentation
**Percentage greater than 100% or not meaningful

	Income (Loss) Before Tax			Identifiable Assets	
(Dollars in Millions)	**2020 [3]**	**2019 [4]**	**2018 [5]**	**2020**	**2019**
Consumer Health	$ (1,064)	2,061	2,320	$ 27,355	26,618
Pharmaceutical	15,462	8,816	12,568	66,158	56,292
Medical Devices	3,044	7,286	4,397	49,578	49,462
Total	17,442	18,163	19,285	143,091	132,372
Less: Expense not allocated to segments [1]	945	835	1,286		
General corporate [2]				31,803	25,356
Worldwide total	**$ 16,497**	**17,328**	**17,999**	**$ 174,894**	**157,728**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Consumer Health	$ 248	328	438	$ 785	765	688
Pharmaceutical	863	950	1,012	4,006	3,910	3,802
Medical Devices	1,980	1,912	1,843	2,140	2,014	2,103
Segments total	3,091	3,190	3,293	6,931	6,689	6,593
General corporate	256	308	377	300	320	336
Worldwide total	**$ 3,347**	**3,498**	**3,670**	**$ 7,231**	**7,009**	**6,929**

(Dollars in Millions)	Sales to Customers 2020	2019	2018	Long-Lived Assets [6] 2020	2019
United States	$ 43,133	42,097	41,884	$ 49,951	41,528
Europe	18,980	18,466	18,753	49,363	48,015
Western Hemisphere excluding U.S.	5,335	5,941	6,113	2,734	2,862
Asia-Pacific, Africa	15,136	15,555	14,831	5,484	5,486
Segments total	82,584	82,059	81,581	107,532	97,891
General corporate				1,029	1,049
Other non long-lived assets				66,333	58,788
Worldwide total	**$ 82,584**	**82,059**	**81,581**	**$ 174,894**	**157,728**

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

Export sales are not significant. In fiscal year 2020, the Company utilized three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0% and 12.0% of the total consolidated revenues. In fiscal year 2019, the Company had three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In fiscal year 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0%, and 11.0% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

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

(3) Consumer Health includes:

- Litigation expense of $3.9 billion, primarily talc related reserves and certain settlements.

Pharmaceutical includes:

- Litigation expense of $0.8 billion, primarily related to the agreement in principle to settle opioid litigation
- An unrealized gain on securities of $0.5 billion
- A restructuring related charge of $0.1 billion

Medical Devices includes:

- A contingent consideration reversal of $1.1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
- Litigation expense of $0.3 billion
- A restructuring related charge of $0.3 billion
- An in-process research and development expense of $0.2 billion
- A Medical Device Regulation charge of $0.1 billion

(4) Consumer Health includes:

- A gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO
- Litigation expense of $0.4 billion
- A restructuring related charge of $0.1 billion

Pharmaceutical includes:

- Litigation expense of $4.3 billion of which $4.0 billion is related to the agreement in principle to settle opioid litigation
- An in-process research and development expense of $0.9 billion related to the Alios asset
- A research and development expense of $0.3 billion for an upfront payment related to argenx
- An unrealized gain on securities of $0.6 billion
- Actelion acquisition and integration related costs of $0.2 billion
- A restructuring charge of $0.1 billion

Medical Devices includes:

- A gain of $2.0 billion from the divestiture of the ASP business

- A restructuring related charge of $0.4 billion
- Litigation expense of $0.4 billion
- Auris Health acquisition and integration related costs of $0.1 billion

(5) Consumer Health includes:

- A gain of $0.3 billion from the divestiture of NIZORAL®
- Litigation expense of $0.3 billion

Pharmaceutical includes:

- An in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion
- Actelion acquisition and integration related costs of $0.2 billion
- An unrealized loss on securities of $0.2 billion
- A gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products

Medical Devices includes:

- Litigation expense of $1.7 billion
- A restructuring related charge of $0.6 billion
- AMO acquisition and integration related costs of $0.1 billion
- A gain of $0.5 billion from the divestiture of the LifeScan business

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2020, and 2019 of $18,766 and $17,658, respectively, and intangible assets and goodwill, net for fiscal years 2020 and 2019 of $89,795 and $81,282, respectively.

18. Acquisitions and Divestitures

Certain businesses were acquired for $7.3 billion in cash and $0.4 billion of liabilities assumed during fiscal year 2020. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $7.5 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2020 acquisitions primarily included: all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc. (XBiotech), Momenta Pharmaceuticals, Inc. (Momenta), a company that discovers and develops novel therapies for immune-mediated diseases and the outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion applying a probability of success factor that ranged from 20% to 60% to reflect inherent development, regulatory and commercial risk for the different indications. The discount rate applied was approximately 16%. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

Additionally, in the fiscal first quarter of 2020, the Company completed the acquisition of all outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities, including those shares previously held by Verily. The transaction was accounted for as a business combination and included in the Medical Devices segment. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.4 billion, goodwill for $0.2 billion, other assets of $0.2 billion and liabilities assumed of $0.3 billion. The fair value of the Company's previously held equity investment in Verb Surgical Inc. was $0.4 billion.

On October 1, 2020, the Company completed the acquisition of Momenta for a purchase price of approximately $6.1 billion, net of cash acquired. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets (IPR&D) of $6.0 billion, goodwill of $1.2 billion, other assets of $0.5 billion and liabilities of

$1.6 billion. The assets acquired are intended to address substantial unmet medical need in maternal-fetal disorders, neuro-inflammatory disorders, rheumatology, dermatology and autoimmune hematology. Depending on the asset, probability of success factors ranging from 20% to 77% were used in the fair value calculation to reflect inherent development and regulatory risk of the IPR&D. The discount rate applied was approximately 13%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

During fiscal year 2019 certain businesses were acquired for $5.8 billion in cash and $1.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $6.8 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2019 acquisitions primarily included DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products and Auris Health, Inc. a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures.

On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer Health segment. During the fiscal first quarter of 2020, the Company finalized the purchase price allocation. The final fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities of $0.4 billion. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On April 1, 2019 the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above. During the fiscal second quarter of 2020, the Company finalized the purchase price allocation. During fiscal 2020, the Company recorded Other income of approximately $1.1 billion for the reversal of all of the contingent consideration related to the timing of certain developmental and commercial milestones, which are not expected to be met based on the Company’s current timelines. During the fiscal third quarter of 2020, the Company recorded a partial IPR&D impairment charge of $0.1 billion related to timing and progression of the digital surgery platforms. A probability of success factor ranging from 55% to 95% was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied was approximately 10%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

During fiscal year 2018 certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2020, 2019 and 2018 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company’s results of operations, cash flows or financial position.

Divestitures

Subsequent to fiscal 2020, in separate transactions, the Company divested two brands outside the U.S. within the Pharmaceutical segment and received combined proceeds of approximately $0.6 billion. The Company will reflect these brand divestitures in its 2021 financial results.

During fiscal year 2020, the Company sold 11.8 million shares of Idorsia LTD (Idorsia), or its 8.3% ownership in the company. The transaction resulted in gross proceeds of approximately CHF 337 million ($357 million) based on a sales price of CHF 28.55/share and an immaterial net loss. The Company currently has rights to at least an additional 38.7 million shares (or approximately 20% of Idorsia equity) through a convertible loan with a principal amount of CHF 445 million (due June 2027). Idorsia also has access to an approximate CHF 243 million credit facility with the Company. As of January 3, 2021, Idorsia has not made any draw-downs under the credit facility.

During fiscal year 2019, the Company divested its ASP business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

During fiscal year 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in fiscal year 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion.

In fiscal year 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. The transfers were completed in fiscal year 2020. As of January 3, 2021, there were no assets held for sale on the Consolidated Balance Sheet. As of December 29, 2019, the assets held for sale on the Consolidated Balance Sheet were $0.1 billion of inventory and property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 20 to the Consolidated Financial Statements.

19. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business. Due to the ongoing impacts of the COVID-19 pandemic, certain trials have been rescheduled or delayed. The Company continues to monitor its legal proceedings as the situation evolves.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2021, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

PRODUCT LIABILITY

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

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of January 3, 2021, in the United States there were approximately 560 plaintiffs with direct claims in pending lawsuits regarding

injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 7,800 with respect to the PINNACLE® Acetabular Cup System; 14,900 with respect to pelvic meshes; 9,300 with respect to RISPERDAL®; 12,600 with respect to XARELTO®; 25,000 with respect to body powders containing talc; 300 with respect to INVOKANA®; and 4,200 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System and the related settlement program.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. The MDL Court is remanding cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved a majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In March 2020, the Court entered damages awards to the three Lead Applicants. The Company is appealing the decision. With respect to other group members, there will be an individual case assessment process which will require proof of use and causally related loss. The form of the individual case assessment process has not yet been determined by the Court. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending outside the United States. Discovery is proceeding in these cases and certain of the cases are in preparation for trials.

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

In September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of 107 PROLENE™ Polypropylene Hernia System ("PHS") cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those cases have also been transferred to an MCL in Atlantic County Superior Court. Discovery is underway in these cases.

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

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one single plaintiff which was subsequently reduced in January 2020 to $6.8 million by the trial judge. The Company and plaintiff are each appealing this judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson (J&J); and JPI's collaboration partner for XARELTO®, Bayer AG and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases were consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and J&J announced an agreement in principle to the settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, the settlement became final in December 2019, and the settlement was funded in January 2020. This resolved the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of pending personal injury lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California, and suits have also been filed outside the United States. The majority of cases are pending in federal court, organized into a multi-district litigation (MDL) in the United States District Court for the District of New Jersey. In the MDL, the parties sought to exclude experts through Daubert motions. In April 2020, the Court issued rulings that limit the scope of testimony, including some theories and testing methods, for certain plaintiff expert witnesses and denied plaintiffs' attempt to limit the scope of testimony of certain of the Company's witnesses. With this ruling made, case-specific discovery has begun per the Court's directive.

In talc cases that have previously gone to trial, the Company has obtained defense verdicts in a number of them, but there have also been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in *Ingham v. Johnson & Johnson, et al.,* No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion and, with additional interest as of January 3, 2021, as the Company pursues further appeal, is currently $2.5 billion (the *Ingham* decision). An application for transfer of the case to the Missouri Supreme Court was subsequently denied, and the Company is currently seeking review by the United States Supreme Court. The Company continues to believe that it has strong legal grounds for the appeal of this verdict, as well as other verdicts that it has appealed. Notwithstanding

the Company's confidence in the safety of its talc products, in certain circumstances the Company has and may settle cases. The Company has established an accrual for defense costs and reserves for the resolution of certain cases and claims, including the *Ingham* decision currently on appeal, in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under

the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. The Company previously proposed to resolve Imerys' (and the Company's) obligations arising out of the Talc Claims by agreeing to assume the defense of litigation of all Talc Claims involving the Company's products, waiving the Company's indemnification claims against Imerys, and lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys. In May 2020, Imerys and the asbestos claimants' committee (Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto agreeing to put its North American operations up for auction which was subsequently amended. The Company has objected to the Disclosure Statement and intends to object to the Plan of Reorganization as currently structured. Additionally, in June 2020, Cyprus Mines Corporation and its parent (Cyprus) filed an adversary proceeding against the Company as well as Imerys seeking a declaration of indemnity under certain contractual agreements. The Company denies such indemnification is owed and filed a motion to dismiss the adversary complaint arguing, among other things, that the Court does not have subject matter jurisdiction over Cyprus's claims against the Company. The Plan Proponents filed numerous amendments to the Plan and Disclosure Statement to which the Company objected. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement for the Ninth Amended Joint Chapter 11 Plan of Reorganization of Imerys Talc America, Inc. and its Debtor Affiliates allowing Debtors to proceed with soliciting votes on the Plan. The Company intends to continue to object to the Plan. A hearing to consider confirmation of the Plan has been scheduled for June 2021.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiff is seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss. In March 2020, Defendants answered the complaint. Discovery is underway.

In June 2019, a shareholder filed a complaint initiating a summary proceeding in New Jersey state court for a books and records inspection. In August 2019, Johnson & Johnson responded to the books and records complaint and filed a cross motion to dismiss. In September 2019, Plaintiff replied and the Court heard oral argument. The Court has not yet ruled in the books and records action. In October 2019, December 2019, and January 2020, four shareholders filed four separate derivative lawsuits against Johnson & Johnson as the nominal defendant and its current directors and certain officers as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In February 2020, the four cases were consolidated into a single action under the caption *In re Johnson & Johnson Talc Stockholder Derivative Litigation*.

In July 2020, a report was delivered to the Company's Board of Directors by independent counsel retained by the Board to investigate the allegations in the derivative lawsuits and in a series of shareholder letters that the Board received raising similar issues. Four of the shareholders who sent demands are plaintiffs in the *In re Johnson & Johnson Talc Stockholder Derivative Litigation*. The independent counsel recommended that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of the derivative lawsuits. The Board unanimously adopted the recommendations of the independent counsel's report. In October 2020, the shareholders filed a consolidated complaint, and in January 2021, Johnson & Johnson moved to dismiss the consolidated complaint.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. In September 2019, Defendants filed a motion to dismiss. In April 2020, the Court granted Defendants' motion but granted leave to amend. In June 2020, Plaintiffs filed an amended complaint, and in July 2020, Defendants moved to dismiss the amended complaint. As of October 2020, briefing on Defendants' motion was complete.

A lawsuit pending in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act relating to JOHNSON'S® Baby Powder has been resolved in the Company's favor. In

that lawsuit, the plaintiffs allege that Johnson & Johnson violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice.

In January 2020, the Abtahi Law Group filed an action under Proposition 65 against Johnson & Johnson and Johnson & Johnson Consumer Inc. as well as a number of other alleged talcum powder manufacturers and distributors, including one California company. In that action, the plaintiff alleges contamination of talcum powder products with unsafe levels of arsenic, hexavalent chromium and lead. The plaintiff seeks civil penalties and injunctive relief. Defendants filed a motion for summary judgment in January 2021, and a hearing has been scheduled for April 2021. Limited informal discovery is continuing.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the Securities and Exchange Commission (SEC) and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company produced documents as required in response and will continue to cooperate with government inquiries. In November 2020, the SEC terminated its investigation.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. In December 2016, lawsuits filed in federal courts in the United States were organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of ELMIRON®, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON® contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, the federal cases, including two putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. In addition, three class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense costs associated with ELMIRON® related product liability litigation.

INTELLECTUAL PROPERTY

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

Medical Devices

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants (collectively, DePuy). MedIdea alleged infringement of United States Patent Nos. 6,558,426 (’426); 8,273,132 (’132); 8,721,730 (’730) and 9,492,280 (’280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. In November

2019, judgment was entered in favor of DePuy. In January 2021, the U.S. Court of Appeals for the Federal Circuit affirmed.

In December 2016, Dr. Ford Albritton sued Acclarent, Inc. (Acclarent) in United States District Court for the Northern District of Texas alleging that Acclarent's RELIEVA® Spin and RELIEVEA SpinPlus® products infringe U.S. Patent No. 9,011,412. Dr. Albritton also alleges breach of contract, fraud and that he is the true owner of Acclarent's U.S. Patent No. 8,414,473. Trial is scheduled to begin in October 2021.

In November 2017, Board of Regents, The University of Texas System and TissueGen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC (collectively, Ethicon) alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® PDS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 ('296) and 7,033,603 ('603) directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the United States Patent and Trademark Office (USPTO), seeking Inter Partes Review (IPR) of both asserted patents. In June 2020, the USPTO denied institution of the '296 patent IPR and granted institution of the '603 patent IPR. UT dismissed the '603 patent from the suit and no longer accuses PDS® Plus Antibacterial Sutures or STRATAFIX® PDS® Plus Antibacterial Sutures of infringement. The previously scheduled district court trial has been postponed.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. (collectively, Intuitive) filed a patent infringement suit against Auris Health, Inc. (Auris) in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,246,200 ('200); 6,491,701 ('701); 6,522,906 ('906); 6,800,056 ('056); 8,142,447 ('447); 8,620,473 ('473); 8,801,601 ('601); and 9,452,276 ('276) based on Auris' Monarch™ Platform. Auris filed IPR Petitions with the USPTO regarding the '200, '056, '601 '701, '447, '276 and '906 patents. Intuitive subsequently dropped the '200, '473 and '701 patents from the suit. In December 2019, the USPTO instituted review of the '601 patent and denied review of the '056 patent. In February and March 2020, the USPTO instituted review of the '200, '447, '701 and '906 patents and denied review of the '276 patent. In December 2020, the USPTO declared all of the challenged claims in the '601 patent to be invalid. Intuitive has appealed that decision. The district court trial is scheduled to begin in June 2021.

In August 2019, RSB Spine LLC (RSB Spine) filed a patent infringement suit against DePuy Synthes, Inc. in United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of United States Patent Nos. 6,984,234 and 9,713,537 by one or more of the following products: ZERO-P-VA™ Spacer, ZERO-P® Spacer, ZERO-P NATURAL™ Plate, SYNFIX® LR Spacer and SYNFIX® Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., and Precision Spine, Inc. In June 2020, the case was stayed pending IPR proceedings filed by the Consolidated Defendants involving the asserted patents.

In March 2020, Osteoplastics, LLC filed a patent infringement suit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., Medical Device Business Services, Inc., and Synthes, Inc. (collectively, DePuy Synthes) in the United States District Court for the District of Delaware. In the suit, Osteoplastics alleges willful infringement of U.S. Patent Nos. 8,781,557; 9,929,920; 9,330,206; 9,626,756; 9,672,617; 9,672,302; and 9,275,191 based on the PROPLAN CMF® Virtual Surgical Planning Services and the TruMatch® CMF Personalize Solutions. In April 2020, Osteoplastics filed an amended complaint to substitute U.S. Patent No. 9,292,920 for U.S. Patent No. 9,929,920. Osteoplastics seeks monetary damages and injunctive relief. In June 2020, DePuy Synthes filed a motion to dismiss the complaint. In October 2020, the Court dismissed Medical Device Business Services, Inc. from the case but otherwise denied the motion. Trial is scheduled for October 2022.

Pharmaceutical

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed ANDAs with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for

substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the

USPTO, created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In November 2017, Janssen Inc. and Janssen Oncology Inc. (collectively, Janssen) initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422 ('422). The final hearing concluded in May 2019. In October 2019, the Court issued an order prohibiting the Canadian Minister of Health from approving Apotex's ANDS until the expiration of the '422 patent. In November 2019, Apotex filed an appeal.

Beginning in January 2019, Janssen initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations in Canada against Apotex, Pharmascience Inc. (Pharmascience) and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in response to those parties' filing of Abbreviated New Drug Submissions (ANDS) seeking approval to market generic versions of ZYTIGA® before the expiration of the '422 patent. The final hearing in these actions concluded in November 2020, and the Court issued a decision holding the '422 patent invalid in January 2021. In February 2021, Janssen appealed the decision.

In August 2020, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (Jamp) in Canada in response to Jamp's filing of an ANDS seeking approval to market a generic version of ZYTIGA® before the expiration of the '422 patent. The final hearing is scheduled to begin in May 2022.

In each of these Canadian actions, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the '422 patent.

XARELTO®

In August 2020, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, DRL) which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of U.S. Patent No. 9,539,218 ('218). In this lawsuit, JPI and Bayer were seeking an order enjoining DRL from marketing their generic versions of XARELTO® before the expiration of the relevant patents. In November 2020, JPI and Bayer entered into a confidential settlement agreement with DRL, and the case was voluntarily dismissed.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against a number of generic companies that filed ANDAs seeking approval to market generic versions of INVOKANA®, INVOKAMET® and/or INVOKAMET® XR before expiration of MTPC's United States Patent Nos. 7,943,582 ('582) and/or 8,513,202 ('202) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR. Janssen is the exclusive licensee of the asserted patents. Named defendants include MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (MSN); Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin). These cases were consolidated into one action (Polymorph Main Action), which has been scheduled for trial starting in April 2021. In December 2020, Janssen and MTPC entered into a confidential settlement with Sandoz and in January 2021, Janssen and MTPC entered into a confidential settlement with Lupin. The cases against Sandoz and Lupin were voluntarily dismissed.

In July 2017, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus which filed ANDAs seeking approval to market generic versions of INVOKANA® and IVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 ('788), 8,222,219 ('219) and/or 8,785,403 ('403) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR (Compounds Main Action). Janssen is the exclusive licensee of the asserted patents. Trial concluded in October 2020.

In July 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, which filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the ’582 patent and ’202 patent relating to INVOKAMET XR®. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, which filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the ’788 patent. In

October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd (DRL), who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the '788 patent. In January 2021, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®. In February 2021, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of United States Patent No. 10,617,668 relating to INVOKANA®. These lawsuits have not been consolidated with the Main Actions.

In each of these U.S. lawsuits, Janssen and MTPC are seeking an order enjoining the defendant from marketing their generic versions of INVOKANA®, INVOKAMET® and/or, INVOKAMET XR® before the expiration of the relevant patents.

In October 2020, Janssen Inc., Janssen Pharmaceutica NV and MTPC initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of INVOKANA® before the expiration of the Canadian Patent Nos. 2,534,024 and 2,671,357. The final hearing is scheduled to begin in August 2022.

Janssen Inc., Janssen Pharmaceutica NV and MTPC are seeking an order enjoining Sandoz from marketing its generic version of INVOKANA® before the expiration of the relevant patents.

OPSUMIT®

ln October 2020, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Laurus Labs Limited and PharmaQ, Inc. (collectively, Laurus), which filed an ANDA seeking approval to market generic versions of OPSUMIT® before the expiration of U.S. Patent No. 7,094,781 ('781). Actelion was seeking an order enjoining Laurus from marketing generic versions of OPSUMIT® before the expiration of the '781 patent. In January 2021, Actelion entered into a settlement agreement with Laurus.

In May 2020, Janssen Inc. (Janssen) and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of Canadian Patent No. 2,659,770 ('770). Trial is scheduled to begin in January 2022.

In May 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in Canada in response to Apotex's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of the '770 patent. Trial is scheduled to begin in February 2022.

In July 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (JAMP) in Canada in response to JAMP's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg before the expiration of the '770 patent and Canadian Patent No. 2,621,273 ('273). Trial is scheduled to begin in April 2022.

In each of these Canadian actions, Janssen and Actelion are seeking an order enjoining the defendants from marketing their generic versions of OPSUMIT® before the expiration of the relevant patents.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906 ('906). Trial concluded in October 2020.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’906 patent. In February 2020, Mylan filed a Petition for Inter Partes Review with the USPTO seeking to invalidate the ’906 patent. The USPTO denied the Petition in September 2020, and Mylan appealed.

In December 2019, Janssen initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallinckrodt PLC and Specgx LLC (collectively, Pharmascience), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’906 patent.

In each of these U.S. lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen Canada) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva Canada) in response to Teva's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 (’629) and 2,655,335 (’335). Janssen subsequently discontinued the portion of the lawsuit relating to the ’629 patent. In May 2020, the Canadian Federal Court issued a Public Judgment and Reasons declaring that Teva Canada’s generic version of INVEGA SUSTENNA®, if approved, would infringe claims of the ’335 patent and that the claims of the ’335 patent are not invalid for obviousness. Teva Canada appealed.

In November 2020, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. in response to Pharmascience Inc.'s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’335 patent. The Final Hearing is scheduled to begin in July 2022.

In January 2021, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in response to Apotex's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’335 patent. The Final Hearing is scheduled to begin in September 2022.

In each of these Canadian lawsuits, Janssen Canada is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies that filed ANDAs seeking approval to market generic versions of IMBRUVICA® 140 mg capsules before expiration of Pharmacyclics’ United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The named defendants include the following generic companies: Cipla Limited and Cipla USA Inc. (collectively, Cipla); Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, Sandoz).

In January 2019, Pharmacyclics and JBI amended their complaint against Sandoz to allege infringement of United States Patent Nos. 10,125,140 and 10,106,548.

In February 2019, Pharmacyclics and JBI amended their complaint against Cipla to allege infringement of United States Patent Nos. 10,106,548, and 10,125,140.

In March 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen), which filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, and 10,125,140.

In May 2019, Pharmacyclics and JBI amended their complaint against Cipla to further allege infringement of United States Patent No. 10,016,435. In June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386.

In August 2019, Pharmacyclics and JBI amended their complaints against Cipla and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232. In August 2019, the Court granted a joint stipulation to stay the litigation against Cipla.

Trial in the actions against Sandoz and Alvogen took place in October 2020.

In March 2019, Sandoz filed an IPR Petition with the USPTO, seeking to invalidate United States Patent No. 9,795,604. In September 2020, the USPTO issued a final decision in the IPR invalidating certain claims of the ’604 patent and upholding the validity of certain claims in the ’604 patent. The final decision was not appealed by the parties.

In March 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen and Sandoz asserting infringement of United States Patent No. 10,478,439. In April 2020, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent No. 10,463,668. In October 2020, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent Nos. 10,752,634 and 10,695,350 and amended their complaint against Alvogen to further allege infringement of U.S. Patent No. 10,653,696. In December 2020 the Court entered a joint stipulation dismissing the complaint against Sandoz.

In April 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus Worldwide DMCC and Cadila Healthcare Limited (collectively, Zydus), which filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,008,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, 10,125,140, 10,213,386 and 10,478,439.

Trials in the actions against Alvogen and Zydus are scheduled to begin in March 2022.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

UPTRAVI®

In April 2020, Actelion Pharmaceuticals Ltd (Actelion) and Nippon Shinyaku Co., Ltd. (Nippon Shinyaku) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies that filed ANDAs seeking approval to market generic versions of UPTRAVI® before expiration of Nippon Shinyaku’s United States Patent Nos. 7,205,302; 8,791,122; and 9,284,280 relating to UPTRAVI® . Actelion is the exclusive licensee of the asserted patents. The defendants include Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc. (collectively, Alembic); MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (collectively, MSN);); VGYAAN Pharmaceuticals LLC (VGYAAN); and Zydus Pharmaceuticals (USA), Inc. and Zydus Worldwide DMCC (collectively, Zydus). In January 2021, the Court entered joint stipulations dismissing VGYAAN and MSN from suit.

Actelion and Nippon Shinyaku are seeking an order enjoining the defendants from marketing generic versions of UPTRAVI® before the expiration of the relevant patents.

INVEGA TRINZA®

In September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LCC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan Institutional LLC (collectively, Mylan). Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® before expiration of United States Patent No. 10,143,693 relating to INVEGA TRINZA®. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® before the expiration of the relevant patent.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer health and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. Such regulation has been the basis of government investigations and litigations. The most significant litigation brought by, and investigations conducted by,

government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations

that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 3,100 lawsuits related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children suffering from Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina; Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are more than 370 cases pending in various state courts. There are over 2,800 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In addition, the Province of British Columbia filed suit in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $572 million, subject to a final order to be issued by the Court. The Court issued a final judgment reducing the amount to $465 million. Johnson & Johnson and JPI have appealed the judgment. The Company believes that it has strong grounds to overturn this judgment. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these matters. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by

states, cities and counties. The Company cannot predict if or when the agreement will be finalized and individual cases are ongoing.

In August 2019, Johnson & Johnson received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its

opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Johnson & Johnson received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. In September 2020, the Company learned that NYDFS filed a statement of charges related to this investigation.

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

In November 2019, one of the shareholders who sent a demand filed a derivative complaint against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In May 2020, the shareholder filed an amended complaint challenging the Board's rejection of his demand. In August 2020, Johnson & Johnson moved to dismiss the amended complaint, and as of December 2020, that motion was fully briefed. In August 2020, another shareholder who sent a demand filed a separate derivative complaint in the same court making similar allegations. In October 2020, the Court granted defendants' request to reassign the second-filed case to the division where the first-filed case is pending.

In December 2019, two additional shareholders who sent demands filed two separate derivative complaints making similar allegations against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the United States District for the District of New Jersey. In April 2020, the two federal cases were consolidated into a single action captioned *In re Johnson & Johnson Opioid Stockholder Derivative Litigation*. In July 2020, the shareholders filed a consolidated complaint. In September 2020, Johnson & Johnson moved to dismiss the consolidated complaint, and in December 2020, the shareholders opposed Johnson & Johnson's motion. Johnson & Johnson filed its reply in February 2021. In July 2020, an additional shareholder who sent a demand filed a derivative complaint in the same federal court making similar allegations against the same defendants named in the consolidated action. In January 2021, pursuant to an order in the consolidated action, the third case was consolidated into the consolidated action. In February 2021, the shareholders in the consolidated action filed a motion for voluntary dismissal.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court. In July 2020, the Court ordered the relators to complete discovery by August 2020; the Relators have requested an extension of the August 2020 deadline that DePuy opposed and additional discovery-related motions have been filed by both parties. Additionally, DePuy has requested a schedule for the filing of a motion to strike and to dismiss the relators' second amended complaint.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by the following states: Kentucky, Mississippi, West Virginia and Oregon. In April 2019, Johnson & Johnson and Ethicon settled the Washington case. The California case started trial in July 2019 and concluded in September 2019. The trial date for the Kentucky case

was scheduled for September 2019 but has been adjourned and no new trial date has been scheduled. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia. In January 2020, the Court in California issued a statement of decision, finding in favor of the State of California, and awarded civil penalties in the amount of $344 million. In April 2020, the Court in California denied the Company's motion for a new trial. In August 2020, the Court entered judgment with respect to the penalties of $344 million, but denied the Attorney General’s request for injunctive relief. The Company is appealing the penalty judgment. In April 2020, the

Company settled the West Virginia. In October 2020, the Company settled with the Attorney General of Oregon. In November 2020, the Company settled with the Attorney General of Mississippi.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retained OCD's portion of any liability resulting from the investigation for activity that occurred prior to the sale of Therakos. Following production of documents to and settlement discussions with the U.S. Attorney's Office, J&J affiliate Medical Device Business Services, Inc. agreed to resolve claims under the federal False Claims Act and analogous state laws in a settlement announced in November 2020. In the settlement agreement, Medical Device Business Services expressly denied any wrongful conduct. As a result of the settlement, a qui tam complaint filed by two relators pending in the U.S. District Court for the Eastern District of Pennsylvania will be dismissed. Separate settlement agreements with the states participating in the settlement are in the process of being finalized.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants violated the Mississippi Consumer Protection Act by
failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The matter is stayed pending interlocutory appeal of a December 2018 denial of Johnson & Johnson and JJCI's motion for summary judgment. The Mississippi Supreme Court granted J&J and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019. Briefing is complete and oral argument was held in February 2021.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. The State of New Mexico filed an Amended Complaint in March 2020. The Company moved to dismiss certain of the claims in the Amended Complaint, which was granted. The Company then filed a motion for partial judgment on the pleadings in December 2020.

Forty-one states have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Several states have issued Civil Investigative Demands seeking documents and other information.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act. The Company has provided documents in response to the demand.

In July 2016, Johnson & Johnson and Janssen Products LP were served with a *qui tam* complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA® and INTELENCE®, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators. In February 2021, the Court stayed the case and ordered mediation.

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

August 2019. The Company filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies. The Company has provided documents in response to the subpoenas.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. We continue to actively respond to inquiries regarding the Foreign Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

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

GENERAL LITIGATION

In March 2018, a purported class action was filed in the Circuit Court Third Judicial District Madison County, Illinois against Johnson & Johnson Consumer, Inc. (JJCI), alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder. The complaint seeks damages but does not allege personal injury. In October 2020, JJCI moved to dismiss the complaint.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In August 2020, US CBP formally rejected Janssen's Supplemental Petition challenging the penalties assessment and demanded payment of the mitigated penalty. In October 2020, US CBP agreed to not refer the matter to the Office of Chief Counsel at this time, pending resolution of the related Classification Litigation. In December 2013, Janssen Ortho sued the United States in the United States Court of International Trade (the Classification Litigation) seeking a determination that darunavir ethanolate is exempt from duties upon importation into the United States. In February 2020, the Court ruled that darunavir ethanolate is eligible for duty free treatment. In April 2020, the United States appealed to the United States Court of Appeals for the Federal Circuit.

In September 2020, Genmab A/S brought an arbitration against Janssen Biotech, Inc. pursuant to a 2012 License Agreement between the parties. The arbitration relates to royalties for certain Janssen daratumumab products.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. Discovery and pre-trial motion practice is complete. No trial date has been set.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages. In November 2020, Defendants moved to dismiss the complaint.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that

Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. Discovery is ongoing.

Beginning in September 2017, multiple purported class actions were filed on behalf of indirect purchasers of REMICADE® against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The cases were consolidated for pre-trial purposes as *In re REMICADE® Antitrust Litigation* in United States District Court for the Eastern District of Pennsylvania. The consolidated complaint seeks damages and injunctive relief. Discovery is ongoing.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In March 2019, summary judgment was granted in favor of Janssen. In February 2020, the United States Court of Appeals for the Third Circuit reversed the District Court's decision. Discovery is ongoing.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company produced documents and information responsive to the Civil Investigative Demand.
In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries in United States District Court for the District of Columbia, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In July 2020, the District Court dismissed the complaint. In January 2021, plaintiffs appealed the District Court's decision to the United States Court of Appeals for the District of Columbia Circuit.

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

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. In September 2019, Janssen moved to dismiss the complaint.

In April 2019, Blue Cross & Blue Shield of Louisiana and HMO Louisiana, Inc. filed a class action complaint against Janssen Biotech, Inc, Janssen Oncology, Inc, Janssen Research & Development, LLC and BTG International Limited in the United States District Court for the Eastern District of Virginia on behalf of indirect purchasers of ZYTIGA®. Several additional complaints were filed thereafter in Virginia and New Jersey. The indirect purchaser complaints generally allege that the defendants violated the antitrust and consumer protections laws of several states and the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry and seek damages. The Virginia cases have been transferred to the United States District Court for the District of New Jersey and consolidated with the New Jersey case for pretrial purposes. In May 2020, a class action complaint was filed against Janssen Biotech Inc., Janssen Oncology, Inc., Janssen Research & Development LLC and BTG International Limited in the United States District Court for the District of New Jersey, on behalf of direct purchasers of ZYTIGA®. The direct purchaser complaint alleges that defendants violated the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry, and seek damages and injunctive relief.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson in the United States District Court for the Northern District of California. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the

development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers Squibb and Japan Tobacco. In March 2020, the Court granted in part and denied in part defendants' motions to dismiss. Plaintiffs filed an amended complaint in April 2020. Defendants moved to dismiss the amended complaint. In July 2020, the Court granted in part and denied in part the renewed motion to dismiss. Discovery is ongoing.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. In January 2020, BWI filed a motion to dismiss the complaint. In August 2020, the Court granted in part and denied in part BWI's motion to dismiss. Discovery is ongoing.

In November 2019, Johnson & Johnson received a demand for indemnification from Pfizer Inc., pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer. Also in November 2019, Johnson & Johnson, Inc. received a demand for indemnification from Sanofi Consumer Health, Inc., pursuant to the 2016 Asset Purchase Agreement between J&J, Inc. and Sanofi. In January 2020, Johnson & Johnson received a demand for indemnification from Boehringer Ingelheim Pharmaceuticals, Inc., pursuant to the 2006 Asset Purchase Agreement among the Company, Pfizer, and Boehringer Ingelheim. The notices seek indemnification for legal claims related to over-the-counter Zantac (ranitidine) products. Plaintiffs in the underlying actions allege that Zantac and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, and seek injunctive and monetary relief.

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against Johnson & Johnson, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2020, Ethicon moved to dismiss certain causes of action in the complaint.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

20. Restructuring

In the fiscal second quarter of 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the Global Supply Chain restructuring strategic collaborations see Note 18 to the Consolidated Financial Statements. In fiscal year 2020, the Company recorded a pre-tax charge of $0.4 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.2 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.3 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2020:

(Dollars in Millions)	Severance	Asset Write-offs/Sales	Other[2]	Total
Reserve balance, December 30, 2018	$ 194	—	48	242
2019 activity	(30)	—	(32)	(62)
Reserve balance, December 29, 2019	164	—	16	180
Current year activity:				
Charges	—	43	405	448
Cash settlements	(29)	24 [4]	(399)	(404)
Settled non cash	—	(67)	(13) [3]	(80)
Reserve balance, January 3, 2021[1]	$ 135	—	9	144

[1] Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Relates to pension related net actuarial losses associated with the transfer of employees to Jabil Inc. as part of the strategic collaboration.
[4] Represents gain on sale of an asset

The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of January 3, 2021 and December 29, 2019, and the related consolidated statements of earnings, of comprehensive income, of equity and of cash flows for each of the three fiscal years in the period ended January 3, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of January 3, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of January 3, 2021 and December 29, 2019, and the results of its operations and its cash flows for each of the three fiscal years in the period ended January 3, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 3, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. Pharmaceutical Rebate Reserves – Managed Care, Medicare and Medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.2 billion as of January 3, 2021. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.
Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation Contingencies – Talc

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. There have been verdicts against the Company for this matter, including a verdict in July 2018 of $4.7 billion, which was reversed in part and affirmed in part by the Missouri Court of Appeals in June 2020, reducing the overall award to $2.1 billion and, with additional interest as of January 3, 2021, as the Company pursues further appeal, is currently $2.5 billion. An application for transfer of the case to the Missouri Supreme Court was subsequently denied, and the Company is currently seeking review by the United States Supreme Court. As described by management, the Company continues to believe that it has strong legal grounds for the appeal of this verdict, as well as other verdicts it has appealed. Notwithstanding the Company's

confidence in the safety of its talc products, in certain circumstances the Company has and may settle cases. The Company has established an accrual for defense costs and reserves for settlement of certain cases and claims, as well as one case currently on appeal, in connection with product liability litigation associated with body powders containing talc.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred and when

determining whether a reasonable estimate of the loss or range of loss for each claim can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

Litigation – Opioids

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including opioids, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. The Company has been named in numerous lawsuits brought by certain state and local governments related to opioids matters. The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against the Company in the amount of $572 million which was subsequently reduced to $465 million. The Company has appealed the judgment and, as described by management, believes that it has strong grounds to overturn this judgment. Separately in October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of the lawsuits. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. As described by management, this agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties.

The principal considerations for our determination that performing procedures relating to the opioids litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred for the judgment against the Company in Oklahoma and when determining whether a reasonable estimate of the range of loss for the proposed agreement in principle to settle opioids litigation can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the opioid litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the opioids litigation; (ii) discussing the status of significant known actual and potential litigation and ongoing settlement negotiations with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 22, 2021
We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 3, 2021. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 3, 2021, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 3, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending January 3, 2021, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2015 and December 31, 2010 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

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	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

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	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 60l of Regulation S-K*

The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 22, 2021

JOHNSON & JOHNSON

(Registrant)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 22, 2021
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 22, 2021
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 22, 2021
/s/ M. C. Beckerle M. C. Beckerle	Director	February 22, 2021
/s/ D. S. Davis D. S. Davis	Director	February 22, 2021
/s/ I. E. L. Davis I. E. L. Davis	Director	February 22, 2021
/s/ J. A. Doudna J. A. Doudna	Director	February 22, 2021

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

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2017.*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 31, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)	Amended and Restated Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (Amended and restated effective January 1, 2020, except as otherwise provided) — Filed with this document.*
10(o)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(p)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(q)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(r)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(s)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(t)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

*	Management contract or compensatory plan.
**	Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

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

FORM 10-K

☑

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

For the fiscal year ended December 29, 2019

or

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

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

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

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.250% Notes Due January 2022	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ	New York Stock Exchange
5.50% Notes Due November 2024	JNJ	New York Stock Exchange
1.150% Notes Due November 2028	JNJ	New York Stock Exchange
1.650% Notes Due May 2035	JNJ	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $368 billion.

On February 10, 2020, there were 2,634,721,257 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;

- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;

- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;

- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;

- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;

- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;

- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and

- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;

- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;

- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;

- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and

- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;

- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;

- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;

- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and

- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;

- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;

- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;

-

Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;

- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;

- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company’s products; and

- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain, including the Company's transaction with Jabil, may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

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

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

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

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products focused on personal healthcare used in the beauty, over-the-counter pharmaceutical, baby care, oral care, women's health and wound care markets. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DR. CI:LABO®; NEUTROGENA® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; NICORETTE® smoking cessation products outside the U.S.; ZARBEE'S NATURALS® and the PEPCID® line of acid reflux products. Baby Care includes the JOHNSON'S® and AVEENO Baby® line of products. Oral Care includes the LISTERINE® product line. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold online and to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity

disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the

maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; and vision products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

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

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

Raw Materials

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

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company’s largest product, STELARA® (ustekinumab), accounted for approximately 7.8% of the Company's total revenues for fiscal 2019. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA®. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the U.S. In the U.S., the latest projected expiration date for patents in this set is 2023 due to patent term extension and adjustment. In most of Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplementary Protection Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021.

In addition to competing in the immunology market with STELARA®, the Company is currently marketing SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products. Patents related to these products are in force and the latest projected U.S. expiration date is 2024 due to patent term extension and adjustment. The Company also markets REMICADE® (infliximab) in the immunology market which is the Company's 2nd largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

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

Seasonality

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

Competition

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

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

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

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

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

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and congress on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. There is increased focus on interactions between healthcare companies and health care providers and various transparency laws and regulations require disclosures of financial relationships between companies and health care providers. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue efforts to repeal and modify provisions of the Patient Protection and Affordable Care Act (the ACA) which passed in 2010. For example, federal legislation repealed the ACA's individual mandate tax penalty as well as the tax on generous employer-sponsored healthcare plans; CMS began permitting states to impose work requirements on persons covered by Medicaid expansion plans; certain federal subsidies to insurers have ended; and certain short-term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U.S. courts and so their long-term impact remains uncertain. The U.S. government also continues to propose and implement changes to the Medicare Part D benefit including the size of manufacturer discounts in the coverage gap and catastrophic phases of the benefit. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Available Information

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

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

In addition, the Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business

Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as

provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

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

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs or may be determined to be class actions and may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

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

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

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

Changes in tax laws or regulations around the world could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is

enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

In fiscal year 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF) which became effective on January 1, 2020. As of December 29, 2019, certain cantons where the Company operates have not yet enacted portions of the tax reform as stipulated in the Swiss Federal law. These enactments and future possible guidance from the applicable taxing authorities may have a material impact on the Company's operating results.

See Note 8 on income taxes for additional information.

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

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

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

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

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

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could

negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

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

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2019 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

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

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

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2019, approximately 49% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 7% in the Western Hemisphere, excluding the U.S., and 19% in the Asia-Pacific

and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows,

unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

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

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

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

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

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 97 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

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

The Company relies on third parties to manufacture certain of our products. We depend on these third party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality

and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 97 manufacturing facilities occupying approximately 15.2 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	4,832
Pharmaceutical	5,496
Medical Devices	4,825
Worldwide Total	15,153

Within the U.S., five facilities are used by the Consumer segment, five by the Pharmaceutical segment and 22 by the Medical Devices segment. Outside of the U.S., 25 facilities are used by the Consumer segment, 14 by the Pharmaceutical segment and 26 by the Medical Devices segment.

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

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	32	4,480
Europe	27	5,939
Western Hemisphere, excluding U.S.	11	1,833
Africa, Asia and Pacific	27	2,901
Worldwide Total	97	15,153

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition of this Report.

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

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

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted in 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 “Legal Proceedings” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned “Item 1. Election of Directors” in the Proxy Statement.

Name	Age	Position
Joaquin Duato	57	Vice Chairman, Executive Committee[a]
Peter M. Fasolo, Ph.D.	57	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	59	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	49	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Thibaut Mongon	50	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer[d]
Michael E. Sneed	60	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[e]
Paulus Stoffels, M.D.	57	Vice Chairman, Executive Committee; Chief Scientific Officer[f]
Jennifer L. Taubert	56	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[g]
Michael H. Ullmann	61	Member, Executive Committee; Executive Vice President, General Counsel[h]
Kathryn E. Wengel	54	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[i]
Joseph J. Wolk	53	Member, Executive Committee; Executive Vice President, Chief Financial Officer[j]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. Ms. McEvoy has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the consumer sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer, and became a member of the Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

(e) Mr. M. E. Sneed joined the Company in 1983 as Marketing Assistant for Personal Products Company, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the Company's global marketing, communication, design and philanthropy functions.

(f) Dr. P. Stoffels rejoined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company's innovation agenda across the Pharmaceutical, Medical Devices and Consumer sectors, product safety strategy, and the Company's global public health strategy.

(g) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions of increasing responsibility in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert has responsibility for the Immunology, Infectious Diseases, Neuroscience, Oncology, Cardiovascular and Metabolism, and Pulmonary Hypertension businesses throughout Janssen.

(h) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical

Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

(i) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(j) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 12, 2020, there were 135,953 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases take place from time to time on the open market or through privately negotiated transactions. The repurchase program was completed in the fiscal third quarter of 2019.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2019. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 30, 2019 through October 27, 2019	—	$ —	-	-
October 28, 2019 through November 24, 2019	734,409	130.60	-	-
November 25, 2019 through December 29, 2019	2,327,205	141.91	-	-
Total	3,061,614			

[1] During the fiscal fourth quarter of 2019, the Company repurchased an aggregate of 3,061,614 shares of Johnson & Johnson Common Stock in open-market transactions, of which 3,061,614 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

[2] As of September 29, 2019, the share repurchase program was completed with an aggregate of 37,181,268 shares purchased for a total of $5.0 billion since the inception of the repurchase program announced on December 17, 2018.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2009-2019

(Dollars in Millions Except Per Share Amounts)	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
Sales to customers — U.S.	$42,097	41,884	39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889
Sales to customers — International	39,962	39,697	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008
Total sales	82,059	81,581	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897
Cost of products sold	27,556	27,091	25,439	21,789	21,426	22,684	22,181	21,515	20,219	18,688	18,380
Selling, marketing and administrative expenses	22,178	22,540	21,520	20,067	21,079	21,887	21,650	20,697	20,800	19,296	19,712
Research and development expense	11,355	10,775	10,594	9,143	8,999	8,471	8,119	7,602	7,486	6,796	6,949
In-process research and development	890	1,126	408	29	224	178	580	1,163	—	—	—
Interest income	(357)	(611)	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)
Interest expense, net of portion capitalized	318	1,005	934	726	552	533	482	532	571	455	451
Other (income) expense, net	2,525	1,405	(42)	210	(1,783)	82	2,903	2,004	3,115	(488)	(333)
Restructuring	266	251	309	491	509	—	—	—	569	—	1,073
	64,731	63,582	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142
Earnings before provision for taxes on income	$17,328	17,999	17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755
Provision for taxes on income	2,209	2,702	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489
Net earnings	15,119	15,297	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	—	—	339	—	—	—
Net earnings attributable to Johnson & Johnson	15,119	15,297	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266
Percent of sales to customers	18.4%	18.8	1.7	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8
Diluted net earnings per share of common stock [1]	$5.63	5.61	0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40
Percent return on average shareholders' equity	25.4%	25.5	2.0	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4
Percent increase (decrease) over previous year:											
Sales to customers	0.6%	6.7	6.3	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)
Diluted net earnings per share	0.4%	N/M	(92.1)	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)

Supplementary balance sheet data:											
Property, plant and equipment, net	17,658	17,035	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759
Additions to property, plant and equipment	3,498	3,670	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365
Total assets	157,728	152,954	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682
Long-term debt	26,494	27,684	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223
Operating cash flow	23,416	22,201	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571
Common stock information											
Dividends paid per share	3.75	3.54	3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93
Shareholders' equity per share	22.59	22.44	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37
Market price per share (year-end close)	$145.75	127.27	139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41
Average shares outstanding (millions)											
— basic	2,645.1	2,681.5	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5
— diluted	2,684.3	2,728.7	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1
Employees (thousands)	132.2	135.1	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5

(1) Attributable to Johnson & Johnson

N/M = Not Meaningful

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 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

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

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2019 sales. In 2019, $11.4 billion was invested in research and development and $5.8 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the 132,200 diverse employees worldwide. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

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Results of Operations
Analysis of Consolidated Sales
For discussion on results of operations and financial condition pertaining to the fiscal years 2018 and 2017 see the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition.

In 2019, worldwide sales increased 0.6% to $82.1 billion as compared to an increase of 6.7% in 2018. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2019	2018
Volume	3.7 %	8.5 %
Price	(0.9)	(2.2)
Currency	(2.2)	0.4
Total	**0.6 %**	**6.7 %**

The net impact of acquisitions and divestitures on the worldwide sales growth was a negative impact of 1.7% in 2019 and a positive impact of 0.8% in 2018.

Sales by U.S. companies were $42.1 billion in 2019 and $41.9 billion in 2018. This represents increases of 0.5% in 2019 and 5.1% in 2018. Sales by international companies were $40.0 billion in 2019 and $39.7 billion in 2018. This represents an increase of 0.7% in 2019 and 8.5% in 2018.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.0%, 3.9% and 0.2%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.9%, 3.1% and 2.6%, respectively.

In 2019, sales by companies in Europe experienced a sales decline of 1.5% as compared to the prior year, which included operational growth of 3.8% offset by a negative currency impact of 5.3%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a sales decline of 2.8% as compared to the prior year, which included operational growth of 5.7% offset by a negative currency impact of 8.5%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 4.9% as compared to the prior year, including operational growth of 6.9% partially offset by a negative currency impact of 2.0%.

In 2019, the Company utilized three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues.

chart-035f7b06f212532ca24.jpgchart-1ac36ca0d1a4503ca1c.jpg

Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2019 were $13.9 billion, an increase of 0.3% from 2018, which included 3.0% operational growth and a negative currency impact of 2.7%. U.S. Consumer segment sales were $5.8 billion, an increase of 1.4%. International sales were $8.1 billion, a decrease of 0.4%, which included 4.2% operational growth and a negative currency impact of 4.6%. In 2019, acquisitions and divestitures had a net positive impact of 1.6% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Beauty	$ 4,593	4,382	4.8 %
OTC	4,444	4,334	2.5
Baby Care	1,675	1,858	(9.9)
Oral Care	1,528	1,555	(1.7)
Women's Health	986	1,049	(6.0)
Wound Care/Other	671	675	(0.6)
Total Consumer Sales	**$ 13,898**	**13,853**	**0.3 %**

The Beauty franchise sales of $4.6 billion increased 4.8% as compared to the prior year. Growth was primarily driven by incremental sales from the acquisition of Ci:z Holdings Co., Ltd., (DR.CI:LABO) in Japan as well as market growth and share gains of NEUTROGENA® and AVEENO® products. Growth was partially offset by the divestitures of RoC® and NIZORAL® in the fiscal year 2018.

The Over-the-Counter (OTC) franchise sales of $4.4 billion increased 2.5% as compared to the prior year. Growth was primarily driven by incremental sales from the acquisition of ZARBEES®. Additional contributors to the growth were TYLENOL®, Children's MOTRIN®, digestive health products and anti-smoking aids.

The Baby Care franchise sales were $1.7 billion in 2019, a decrease of 9.9% compared to the prior year, primarily due to JOHNSON's® competitive pressures coupled with comparisons to prior year relaunch activities and the Baby Center divestiture.

The Oral Care franchise sales of $1.5 billion decreased 1.7% as compared to the prior year. Growth in LISTERINE® Mouthwash and Ready Tabs outside the U.S. was offset by share declines and retailer destocking in the U.S. and the negative impact of currency.

The Women's Health franchise sales were $1.0 billion in 2019, a decrease of 6.0% as compared to the prior year. The decline was primarily driven by the negative impact of currency and weakness in liners partially offset by strength in napkins in Asia Pacific and Latin America.

The Wound Care/Other franchise sales were $0.7 billion in 2019, a decrease of 0.6% as compared to the prior year. The decline was primarily driven by the divestiture of COMPEED® outside the U.S. and the negative impact of currency.

Pharmaceutical Segment

Pharmaceutical segment sales in 2019 were $42.2 billion, an increase of 3.6% from 2018, which included operational growth of 5.8% and a negative currency impact of 2.2%. U.S. sales were $23.9 billion, an increase of 2.5%. International sales were $18.3 billion, an increase of 5.0%, which included 10.1% operational growth and a negative currency impact of 5.1%. In 2019, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was negligible. Adjustments to previous reserve estimates, as compared to the prior year, positively impacted the Pharmaceutical segment operational growth by approximately 1.3%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Total Immunology	**$ 13,950**	**13,120**	**6.3 %**
REMICADE®	4,380	5,326	(17.8)
SIMPONI®/SIMPONI ARIA®	2,188	2,084	5.0
STELARA®	6,361	5,156	23.4
TREMFYA®	1,012	544	85.9
Other Immunology	10	10	4.5
Total Infectious Diseases	**3,413**	**3,304**	**3.3**
EDURANT®/rilpivirine	861	816	5.6
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	2,110	1,955	8.0
Other Infectious Diseases	441	533	(17.3)
Total Neuroscience	**6,328**	**6,077**	**4.1**
CONCERTA®/methylphenidate	696	663	4.9
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/ TREVICTA®	3,330	2,928	13.7
RISPERDAL CONSTA®	688	737	(6.7)
Other Neuroscience	1,614	1,749	(7.7)
Total Oncology	**10,692**	**9,844**	**8.6**
DARZALEX®	2,998	2,025	48.0
IMBRUVICA®	3,411	2,615	30.4
VELCADE®	751	1,116	(32.7)
ZYTIGA® /abiraterone acetate	2,795	3,498	(20.1)
Other Oncology	739	590	25.0
Total Pulmonary Hypertension	**2,623**	**2,573**	**1.9**
OPSUMIT®	1,327	1,215	9.2
TRACLEER® /bosentan	341	546	(37.5)
UPTRAVI®	819	663	23.5
Other Pulmonary Hypertension	135	149	(9.4)
Total Cardiovascular / Metabolism / Other	**5,192**	**5,816**	**(10.7)**
XARELTO®	2,313	2,477	(6.6)
INVOKANA®/ INVOKAMET®	735	881	(16.5)
PROCRIT®/EPREX®	790	988	(20.0)
Other	1,353	1,470	(8.0)
Total Pharmaceutical Sales	**$ 42,198**	**40,734**	**3.6 %**

Immunology products sales were $14.0 billion in 2019, representing an increase of 6.3% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease, and TREMFYA® (guselkumab) in Psoriasis, expanded indications of SIMPONI®/SIMPONI ARIA® (golimumab), and the U.S. immunology market growth. Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the U.S., resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the U.S., a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.4 billion in 2019, representing an increase of 3.3% as compared to the prior year. Strong sales of SYMTUZA® and the launch of JULUCA® (dolutegravir/rilpivirine) were partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA® in certain countries outside the U.S.

Neuroscience products sales were $6.3 billion, representing an increase of 4.1% as compared to the prior year. Strong sales of long-acting injectables INVEGA TRINZA®/TREVICTA®(paliperidone palmitate) and INVEGA SUSTENNA®/XEPLION® were partially offset by cannibalization of RISPERDAL CONSTA® (risperidone).

Oncology products achieved sales of $10.7 billion in 2019, representing an increase of 8.6% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) with continued market growth and share gain, IMBRUVICA® (ibrutinib) due to increased patient uptake globally. Additionally, sales from the launch of ERLEADA™ (apalutamide) contributed to the growth. Growth was negatively impacted from a decline in U.S. sales of ZYTIGA® (abiraterone acetate) driven by generic competition partially offset by increased sales outside the U.S. Lower sales of VELCADE® (bortezomib) were also due to generic competition.

Pulmonary Hypertension products achieved sales of $2.6 billion, representing an increase of 1.9% as compared to the prior year. Sales of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to continued market growth and increased share gains while sales of TRACLEER® (bosentan) were negatively impacted by generics and cannibalization from OPSUMIT®.

Cardiovascular/Metabolism/Other products sales were $5.2 billion, a decline of 10.7% as compared to the prior year. XARELTO® (rivaroxaban) sales volume growth was offset by higher discounts and rebates. Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) were due to share loss from competitive pressure and a safety label update in the U.S. and lower sales of PROCRIT®/ EPREX® (epoetin alfa) were due to biosimilar competition.

During 2019, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
BALVERSA™ (erdafitinib)	Treatment of locally advanced or metastatic urothelial cancer	Ÿ			
DARZALEX® (daratumumab)	Combination Regimen for Newly Diagnosed, Transplant-eligible Patients with Multiple Myeloma	Ÿ			Ÿ
	Newly diagnosed patients with Multiple Myeloma in combination with Lenalidomide and Dexamethasone	Ÿ			
	Split-dosing regimen	Ÿ			
	Combination therapy for transplant ineligible Multiple Myeloma patients		Ÿ	Ÿ	
	Subcutaneous Formulation in Multiple Myeloma			Ÿ	Ÿ
ERLEADA™ (apalutamide)	Treatment of Metastatic Castration-Sensitive Prostate Cancer	Ÿ			
	Treatment of Metastatic Hormone-Sensitive Prostate Cancer				Ÿ
IMBRUVICA® (ibrutinib)	Expanded Use in Combination with Obinutuzumab in Adult Patients with Previously Untreated Chronic Lymphocytic Leukemia and in Combination with Rituximab in Waldenström's Macroglobulinemia		Ÿ		
	Treatment for Chronic Lymphocytic Leukemia in combination with obinutuzumab	Ÿ			
INVOKANA® (canagliflozin)	Treatment of Diabetic Kidney Disease	Ÿ			
rilpivirine and cabotegravir	For Monthly, Injectable, Two Drug Regimen for Treatment of HIV			Ÿ	Ÿ
SPRAVATO® (esketamine)	Treatment-resistant depression	Ÿ	Ÿ		
	Rapid Reduction of Depressive Symptoms in Adults with Major Depressive Disorder who have Active Suicidal Ideation with Intent			Ÿ	
STELARA® (ustekinumab)	Extended Use for the Treatment of Moderately to Severely Active Ulcerative Colitis	Ÿ	Ÿ		
	Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis			Ÿ	
TREMFYA® (guselkumab)	One-press patient-controlled injector	Ÿ			
	Treatment of Adults with Active Psoriatic Arthritis			Ÿ	Ÿ
XARELTO® (rivaroxaban)	For the prevention of Blood Clots in Acutely Ill Medical Patients	Ÿ			

Medical Devices Segment

The Medical Devices segment sales in 2019 were $26.0 billion, a decrease of 3.8% from 2018, which included an operational decrease of 1.7% and a negative currency impact of 2.1%. U.S. sales were $12.4 billion, a decrease of 3.5% as compared to the prior year. International sales were $13.6 billion, a decrease of 4.1% as compared to the prior year, with an operational decrease of 0.1% and a negative currency impact of 4.0%. In 2019, the net impact of acquisitions and divestitures on the Medical Devices segment worldwide operational sales growth was a negative 5.6% of which, the divestitures of LifeScan and Advanced Sterilization Products (ASP) had an impact of approximately 3.8% and 1.6%, respectively.

Major Medical Devices Franchise Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Surgery	**$ 9,501**	**9,901**	**(4.0)%**
Advanced	4,095	4,002	2.3
General	4,480	4,557	(1.7)
Specialty	926	1,342	(31.0)
Orthopaedics	**8,839**	**8,885**	**(0.5)**
Hips	1,438	1,418	1.4
Knees	1,480	1,502	(1.4)
Trauma	2,720	2,699	0.8
Spine & Other	3,201	3,266	(2.0)
Vision	**4,624**	**4,553**	**1.6**
Contact Lenses/Other	3,392	3,302	2.7
Surgical	1,232	1,251	(1.6)
Interventional Solutions	**2,997**	**2,646**	**13.3**
Diabetes Care[1]	**—**	**1,009**	*
Total Medical Devices Sales	**$ 25,963**	**26,994**	**(3.8)%**

[1]LifeScan was divested in the fiscal fourth quarter of 2018.

*Percentage greater than 100% or not meaningful

The Surgery franchise sales were $9.5 billion in 2019, a decrease of 4.0% from 2018. Growth in Advanced Surgery was primarily driven by endocutter, biosurgery and energy products. The decline in General Surgery was primarily driven by the negative impact of currency partially offset by growth of wound closure products. The decline in Specialty Surgery was primarily driven by the divestiture of the sterilization business (ASP) partially offset by growth of aesthetic products.

The Orthopaedics franchise sales were $8.8 billion in 2019, a decrease of 0.5%, including operational growth of 1.2% offset by a negative currency impact of 1.7% as compared to the prior year. The growth in hips was driven by leadership position in the anterior approach, strong market demand for the ACTIS® stem and the KINCISE™ surgical automated system. Knees grew outside the U.S. from new products coupled with continued global uptake of ATTUNE® Revision, offset by a negative currency impact. Growth in trauma was due to strong market growth coupled with continued uptake of new products. The decline in Spine & Other was primarily driven by base business declines in Spine partially offset by growth in Sports which was led by new products, MONOVISC® in the U.S. and growth in Asia Pacific.

The Vision franchise achieved sales of $4.6 billion in 2019, an increase of 1.6% from 2018. Growth was primarily driven by the strength of daily disposable lenses in the ACUVUE® OASYS contact lenses category. The Surgical operational growth was primarily driven by the strength of cataracts outside the U.S. partially offset by competitive pressures in the U.S.

The Interventional Solutions franchise achieved sales of $3.0 billion in 2019, an increase of 13.3% from 2018. Strong growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth and with strong THERMOCOOL SMARTTOUCH® SF Contact Force Sensing Catheter and diagnostic catheter sales.

Analysis of Consolidated Earnings Before Provision for Taxes on Income
Consolidated earnings before provision for taxes on income was $17.3 billion and $18.0 billion for the fiscal years ended 2019 and 2018, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 21.1% and 22.1%, in 2019 and 2018, respectively.

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Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2019	2018
Cost of products sold	33.6%	33.2
Percent point increase/(decrease) over the prior year	0.4	(0.1)
Selling, marketing and administrative expenses	27.0%	27.6
Percent point increase/(decrease) over the prior year	(0.6)	(0.5)

In 2019, cost of products sold as a percent to sales increased to 33.6% from 33.2% as compared to the same period a year ago primarily driven by the negative impact of currency in the Pharmaceutical business as well as increased intangible asset amortization expense. Intangible asset amortization expense of $4.5 billion was included in cost of products sold for 2019 as compared to $4.4 billion in 2018. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2019 as compared to the prior year, primarily due to favorable segment mix with a higher percentage of sales coming from the Pharmaceutical business, planned prioritization and reduced brand marketing expense in the Consumer business partially offset by increased selling and marketing investments in the Medical Devices business.

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

	2019		2018	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 493	3.5%	565	4.1
Pharmaceutical	8,834	20.9	8,446	20.7
Medical Devices	2,028	7.8	1,764	6.5
Total research and development expense	$ 11,355	13.8%	10,775	13.2
Percent increase/(decrease) over the prior year	5.4%		1.7	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2019, worldwide costs of research and development activities increased by 5.4% compared to 2018 primarily driven by increased investment in the Medical Devices business related to robotics and digital surgery platforms along with higher upfront and developmental milestone payments, primarily from the argenx collaboration in the Pharmaceutical business.

Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In the fiscal first quarter of 2019, the Company recorded an IPR&D charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176. In the fiscal third quarter of 2018, the Company recorded an impairment charge of $1.1 billion which included a partial impairment charge of $0.8 billion related to the development program of AL-8176 and an impairment charge of $0.3 billion for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1 Limited.

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

The change in other (income) expense, net for the fiscal year 2019 was additional net expense of $1.1 billion primarily attributable to litigation expense of $5.1 billion in 2019, primarily related to the agreement in principle to settle opioid litigation of $4.0 billion, as compared to litigation expense of $2.0 billion in 2018. This was partially offset by divestiture gains in 2019 of $2.2 billion of which $2.0 billion related to the divestiture of the ASP business. In addition, the fiscal year 2019 included higher unrealized gains on securities of $0.7 billion, an equity step-up gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO, and lower restructuring related expense of $0.2 billion as compared to the same period a year ago. Divestiture gains were approximately $1.2 billion in 2018 and included the LifeScan business, NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. Additionally, 2018 included a reversal of a contingent liability of $0.2 billion.

Interest (Income) Expense: The fiscal year 2019 included net interest income as compared to an expense in the fiscal year 2018. This was primarily due to the positive effect of net investment hedging arrangements and certain cross currency swaps, and a lower average debt balance. Cash, cash equivalents and marketable securities totaled $19.3 billion at the end of 2019, and averaged $19.5 billion as compared to the cash, cash equivalents and marketable securities total of $19.7 billion and $19.0 billion average cash balance in 2018. The total debt balance at the end of 2019 was $27.7 billion with an average debt balance of $29.1 billion as compared to $30.5 billion at the end of 2018 and an average debt balance of $32.5 billion. The decrease in debt was due to the retirement of long-term debt.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**
Consumer	$ 2,061	2,320	13,898	13,853	14.8%	16.7
Pharmaceutical	8,816	12,568	42,198	40,734	20.9	30.9
Medical Devices	7,286	4,397	25,963	26,994	28.1	16.3
Total [1]	18,163	19,285	82,059	81,581	22.1	23.6
Less: Net expense not allocated to segments [2]	835	1,286				

Earnings before provision for taxes on income	$ 17,328	17,999	82,059	81,581	21.1%	22.1

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Segment: In 2019, the Consumer segment income before tax as a percent to sales was 14.8%, versus 16.7% in 2018. The decrease in the income before tax as a percent of sales in 2019 as compared to 2018 was primarily attributable to higher expenses for litigation of $0.1 billion, intangible asset amortization of $0.1 billion and restructuring of $0.1 billion in the fiscal year 2019 as compared to the fiscal year 2018. This was partially offset by planned prioritization and brand marketing expense reductions. The fiscal year 2019 included a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO. Divestiture gains for the fiscal year of 2018 included a gain of $0.3 billion from the divestiture of NIZORAL®.

Pharmaceutical Segment: In 2019, the Pharmaceutical segment income before tax as a percent to sales was 20.9% versus 30.9% in 2018. The decrease in the income before tax as a percent of sales was primarily due to higher litigation expense of $4.3 billion, primarily due to the agreement in principle to settle opioid litigation of $4.0 billion, increased spending in research and development, including a $0.3 billion upfront payment to argenx. This was partially offset by $0.8 billion of higher unrealized gains on securities, a lower in-process research and development charge of $0.2 billion, and lower Actelion acquisition and integration related costs as compared to the fiscal year 2018. In addition, the fiscal year 2018 included a contingent liability reversal of $0.2 billion and higher divestiture gains of $0.2 billion.

Medical Devices Segment: In 2019, the Medical Devices segment income before tax as a percent to sales was 28.1% versus 16.3% in 2018. The increase in the income before tax as a percent to sales was primarily attributable to higher divestiture gains in 2019. Divestiture gains in the fiscal 2019 included a gain of $2.0 billion related to the ASP business. Divestiture gains for the fiscal year of 2018 included a gain of $0.5 billion related to LifeScan. Additionally, the fiscal year 2019 included lower litigation expense of $1.3 billion, lower restructuring charges of $0.2 billion and lower intangible asset amortization expense of $0.1 billion as compared to the fiscal year 2018. This was partially offset by increased investment in robotics and digital solutions.

Restructuring: In the fiscal second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2019, the Company recorded a pre-tax charge of $0.6 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.2 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $0.8 billion have been recorded since the restructuring was announced.

See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 12.7% in 2019 and 15.0% in 2018.

For discussion related to the fiscal 2019 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (TRAF). On May 19, 2019 a public referendum was held in Switzerland that approved the federal reform proposals. In the fiscal third quarter of 2019, the Swiss Federal Council enacted TRAF which became effective on January 1, 2020. On February 9, 2020 a public referendum on the legislative change was held in the last remaining canton where the Company has significant operations. The legislation was approved by the voters and formal enactment is expected in the fiscal first half of 2020. The Company has not yet elected the transitional provision in this canton. However, the net financial benefit is estimated to be between $0.2 billion and $0.5 billion in the fiscal first half of 2020. The Company does not believe that TRAF will have a material impact to the Company’s ongoing consolidated effective tax rate beginning in fiscal year 2020.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $17.3 billion at the end of 2019 as compared to $18.1 billion at the end of 2018. The primary sources and uses of cash that contributed to the $0.8 billion decrease were approximately $23.4 billion of cash generated from operating activities. This was offset by $6.2 billion net cash used by investing activities and $18.0 billion net cash used by financing activities. In addition, the Company had $2.0 billion in marketable securities at the end of 2019 and $1.6 billion at the end of 2018. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $23.4 billion was the result of $15.1 billion of net earnings and $9.1 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation, assets write-downs (primarily related to the Alios IPR&D asset), and favorable increases in accounts payable, accrued liabilities and other liabilities of $5.5 billion. This was reduced by $1.6 billion related to an increase in accounts receivable, inventories, other current and non-current assets. as well as non-cash expenses and other adjustments of $2.5 billion for the increase in the deferred tax provision and a net gain on sale of assets/businesses of $2.2 billion (primarily related to the ASP divestiture).

Investing activities use of $6.2 billion of cash was primarily used for acquisitions of $5.8 billion primarily related to the acquisitions of Auris Health, Inc. and DR. CI:LABO, additions to property, plant and equipment of $3.5 billion and $0.5 billion from the net purchases of investments. Investing activities also included a source of $3.3 billion of proceeds from the disposal of assets/businesses, primarily the ASP divestiture, and proceeds from credit support agreements of $0.3 billion.

Financing activities use of $18.0 billion of cash was primarily used for dividends to shareholders of $9.9 billion, the repurchase of common stock of $6.7 billion and the net retirement of short and long term debt of $2.9 billion. Financing activities also included sources of $1.5 billion from proceeds of stock options exercised/employee withholding tax on stock awards, and other financing activities.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. Shares acquired are available for general corporate purposes. The Company financed the share repurchase program through available cash. As of September 29, 2019, $5.0 billion was repurchased under the program and the program was completed.

As of December 29, 2019, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 29, 2019, the net debt position was $8.4 billion as compared to the prior year of $10.8 billion. There was a decrease in the net debt position due to retirement of debt. The debt balance at the end of 2019 was $27.7 billion as compared to $30.5 billion in 2018. In 2019, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the agreement in principle to settle opioid litigation to be potentially paid over the next two to three years. As discussed in Note 8 to the Consolidated Financial Statements, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit and settlement of the related tax liabilities in the fiscal year 2020. As of December 29, 2019, the Company has classified unrecognized tax benefits and related interest of approximately $0.9 billion as a current liability in the “Accrued taxes on Income” line in the Consolidated Balance Sheet. This is the amount expected to be paid over the next 12 months with respect to the IRS audit. Subsequent to December 29, 2019, the Company made a payment for approximately $0.6 billion to the U.S. Treasury related to the estimated 2010-2012 tax audit liability in anticipation of the final settlement later in fiscal 2020. The completion of this tax audit may result in additional adjustments to the Company’s unrecognized tax benefit liability that may have a material impact on the Company’s future operating results or cash flows in the period that the audit is substantially completed.

The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a shelf registration on February 27, 2017, which will enable it to issue debt securities on a timely basis and will be updated as required. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 29, 2019 market rates would increase the unrealized value of the Company's forward contracts by $271 million. Conversely, a

10% depreciation of the U.S. Dollar from the December 29, 2019 market rates would decrease the unrealized value of the Company's forward contracts by $331 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1,043 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $7 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2019, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 10, 2020. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR), or other applicable market rate as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2019 and 2018 were $27.7 billion and $30.5 billion, respectively. The decrease in borrowings was due to the retirement of debt in 2019. In 2019, net debt (cash and current marketable securities, net of debt) was $8.4 billion compared to net debt of $10.8 billion in 2018. Total debt represented 31.8% of total capital (shareholders' equity and total debt) in 2019 and 33.8% of total capital in 2018. Shareholders' equity per share at the end of 2019 was $22.59 compared to $22.44 at year-end 2018.

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

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 29, 2019 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Leases	Total
2020	$ 528	1,100	886	103	215	2,832
2021	812	1,797	841	107	254	3,811
2022	812	2,106	796	113	197	4,024
2023	1,522	1,552	764	118	141	4,097
2024	2,029	1,474	729	127	86	4,445
After 2024	2,536	19,565	8,121	749	201	31,172
Total	**$ 8,239**	**27,594**	**12,137**	**1,317**	**1,094**	**50,381**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends
The Company increased its dividend in 2019 for the 57th consecutive year. Cash dividends paid were $3.75 per share in 2019 and $3.54 per share in 2018.

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

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which was adopted in 2018.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately
1.0% of annual net trade sales during the fiscal reporting years 2019 and 2018.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were approximately 2.0% of the total revenues and are included in sales to customers.

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

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

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 29, 2019 and December 30, 2018.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2019				
Accrued rebates [1]	$ 271	841	(828)	284
Accrued returns	57	128	(122)	63
Accrued promotions	497	2,119	(2,129)	487
Subtotal	$ 825	3,088	(3,079)	834
Reserve for doubtful accounts	32	21	(18)	35
Reserve for cash discounts	23	198	(204)	17
Total	$ 880	3,307	(3,301)	886
2018				
Accrued rebates[1]	$ 186	836	(751)	271
Accrued returns	68	98	(109)	57
Accrued promotions	481	2,233	(2,217)	497
Subtotal	$ 735	3,167	(3,077)	825
Reserve for doubtful accounts	31	10	(9)	32
Reserve for cash discounts	23	204	(204)	23
Total	$ 789	3,381	(3,290)	880

(1) Includes reserve for customer rebates of $54 million at December 29, 2019 and $57 million at December 30, 2018, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2019				
Accrued rebates [1]	$ 7,510	26,868	(25,365)	9,013
Accrued returns	436	354	(290)	500
Accrued promotions	13	17	(25)	5
Subtotal	$ 7,959	27,239	(25,680)	9,518
Reserve for doubtful accounts	47	2	(13)	36
Reserve for cash discounts	53	936	(924)	65
Total	$ 8,059	28,177	(26,617)	9,619
2018				
Accrued rebates [1]	$ 4,862	22,644	(19,996)	7,510
Accrued returns	362	385	(311)	436
Accrued promotions	35	46	(68)	13
Subtotal	$ 5,259	23,075	(20,375)	7,959
Reserve for doubtful accounts	77	37	(67)	47
Reserve for cash discounts	55	860	(862)	53

Total	$ 5,391	23,972	(21,304)	8,059

(1) Includes reserve for customer rebates of $93 million at December 29, 2019 and $89 million at December 30, 2018, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2019				
Accrued rebates[1]	$ 1,218	5,487	(5,692)	1,013
Accrued returns	114	673	(669)	118
Accrued promotions	42	106	(102)	46
Subtotal	$ 1,374	6,266	(6,463)	1,177
Reserve for doubtful accounts	169	30	(44)	155
Reserve for cash discounts	—	106	(96)	10
Total	$ 1,543	6,402	(6,603)	1,342
2018[2]				
Accrued rebates[1]	$ 1,620	6,344	(6,746)	1,218
Accrued returns	152	750	(788)	114
Accrued promotions	83	116	(157)	42
Subtotal	$ 1,855	7,210	(7,691)	1,374
Reserve for doubtful accounts	183	29	(43)	169
Reserve for cash discounts	15	140	(155)	—
Total	$ 2,053	7,379	(7,889)	1,543

(1) Includes reserve for customer rebates of $499 million at December 29, 2019 and $632 million at December 30, 2018, recorded as a contra asset.

(2) Certain prior period amounts have been reclassified to conform to current year presentation.

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

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

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.8 billion under current enacted tax laws and regulations and at current currency exchange rates.

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

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

insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

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

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 29, 2019.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2009 - 2019, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and on January 31, 2020, the U.K. formally exited the E.U. Given the lack of comparable precedent, it is unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 29, 2019, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2019 would have increased or decreased the translation of foreign sales by approximately $390 million and net income by approximately $120 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate

may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted. For discussion on Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform) see Provision for Taxes on Income in Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company’s businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company’s key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on “REMICADE® Related Cases” and “Litigation Against Filers of Abbreviated New Drug Applications” in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 29, 2019, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company’s Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 12, 2020, there were 135,953 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to “Item 7. Management’s Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk” of this Report; and Note 1 “Summary of Significant Accounting Policies - Financial Instruments” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 29, 2019 and December 30, 2018
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2019	2018
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	17,305	18,107
Marketable securities (Notes 1 and 2)		1,982	1,580
Accounts receivable trade, less allowances for doubtful accounts $226 (2018, $248)		14,481	14,098
Inventories (Notes 1 and 3)		9,020	8,599
Prepaid expenses and other receivables		2,392	2,699
Assets held for sale (Note 20)		94	950
Total current assets		**45,274**	**46,033**
Property, plant and equipment, net (Notes 1 and 4)		17,658	17,035
Intangible assets, net (Notes 1 and 5)		47,643	47,611
Goodwill (Notes 1 and 5)		33,639	30,453
Deferred taxes on income (Note 8)		7,819	7,640
Other assets		5,695	4,182
Total assets	**$**	**157,728**	**152,954**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	1,202	2,796
Accounts payable		8,544	7,537
Accrued liabilities		9,715	7,601
Accrued rebates, returns and promotions		10,883	9,380
Accrued compensation and employee related obligations		3,354	3,098
Accrued taxes on income (Note 8)		2,266	818
Total current liabilities		**35,964**	**31,230**
Long-term debt (Note 7)		26,494	27,684
Deferred taxes on income (Note 8)		5,958	7,506
Employee related obligations (Notes 9 and 10)		10,663	9,951
Long-term taxes payable (Note 8)		7,444	8,242
Other liabilities		11,734	8,589
Total liabilities		**98,257**	**93,202**
Commitments and Contingencies (Note 21)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,891)	(15,222)
Retained earnings		110,659	106,216
		97,888	94,114
Less: common stock held in treasury, at cost (Note 12) (487,336,000 shares and 457,519,000 shares)		38,417	34,362
Total shareholders' equity		**59,471**	**59,752**
Total liabilities and shareholders' equity	**$**	**157,728**	**152,954**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2019	2018	2017
Sales to customers	$ 82,059	81,581	76,450
Cost of products sold	27,556	27,091	25,439
Gross profit	54,503	54,490	51,011
Selling, marketing and administrative expenses	22,178	22,540	21,520
Research and development expense	11,355	10,775	10,594
In-process research and development (Note 5)	890	1,126	408
Interest income	(357)	(611)	(385)
Interest expense, net of portion capitalized (Note 4)	318	1,005	934
Other (income) expense, net	2,525	1,405	(42)
Restructuring (Note 22)	266	251	309
Earnings before provision for taxes on income	17,328	17,999	17,673
Provision for taxes on income (Note 8)	2,209	2,702	16,373
Net earnings	**$ 15,119**	**15,297**	**1,300**
Net earnings per share (Notes 1 and 15)			
Basic	**$ 5.72**	**5.70**	**0.48**
Diluted	**$ 5.63**	**5.61**	**0.47**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,645.1**	**2,681.5**	**2,692.0**
Diluted	**2,684.3**	**2,728.7**	**2,745.3**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2019	2018	2017
Net earnings	$ 15,119	15,297	1,300
Other comprehensive income (loss), net of tax			
Foreign currency translation	164	(1,518)	1,696
Securities:			
Unrealized holding gain (loss) arising during period	—	(1)	159
Reclassifications to earnings	—	1	(338)
Net change	—	—	(179)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(18)	(44)	2
Gain (loss), net of amortization	(714)	(56)	29
Effect of exchange rates	(1)	92	(201)
Net change	(733)	(8)	(170)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(107)	(73)	(4)
Reclassifications to earnings	7	(192)	359
Net change	(100)	(265)	355
Other comprehensive income (loss)	(669)	(1,791)	1,702
Comprehensive income	$ 14,450	13,506	3,002

The tax effects in other comprehensive income for the fiscal years ended 2019, 2018 and 2017 respectively: Foreign Currency Translation; $19 million in 2019 and $236 million in 2018; Securities: $96 million in 2017, Employee Benefit Plans: $222 million, $4 million and $83 million, Derivatives & Hedges: $27 million, $70 million and $191 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 1, 2017	**$ 70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid ($3.32 per share)	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment	(486)	(254) [1]	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	15,119	15,119			
Cash dividends paid ($3.75 per share)	(9,917)	(9,917)			
Employee compensation and stock option plans	1,933	(758)			2,691
Repurchase of common stock	(6,746)				(6,746)
Other	(1)	(1)			
Other comprehensive income (loss), net of tax	(669)		(669)		
Balance, December 29, 2019	**$ 59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**

(1) See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2019	2018	2017
Cash flows from operating activities				
Net earnings	$	15,119	15,297	1,300
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		7,009	6,929	5,642
Stock based compensation		977	978	962
Asset write-downs		1,096	1,258	795
Gain on sale of assets/businesses		(2,154)	(1,217)	(1,307)
Deferred tax provision		(2,476)	(1,016)	2,406
Accounts receivable allowances		(20)	(31)	17
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(289)	(1,185)	(633)
(Increase)/Decrease in inventories		(277)	(644)	581
Increase in accounts payable and accrued liabilities		4,060	3,951	2,725
Increase in other current and non-current assets		(1,054)	(275)	(411)
Increase/(Decrease) in other current and non-current liabilities		1,425	(1,844)	8,979
Net cash flows from operating activities		**23,416**	**22,201**	**21,056**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,498)	(3,670)	(3,279)
Proceeds from the disposal of assets/businesses, net		3,265	3,203	1,832
Acquisitions, net of cash acquired (Note 20)		(5,810)	(899)	(35,151)
Purchases of investments		(3,920)	(5,626)	(6,153)
Sales of investments		3,387	4,289	28,117
Proceeds from credit support agreements		338	—	—
Other		44	(464)	(234)
Net cash used by investing activities		**(6,194)**	**(3,167)**	**(14,868)**
Cash flows from financing activities				
Dividends to shareholders		(9,917)	(9,494)	(8,943)
Repurchase of common stock		(6,746)	(5,868)	(6,358)
Proceeds from short-term debt		39	80	869
Repayment of short-term debt		(100)	(2,479)	(1,330)
Proceeds from long-term debt, net of issuance costs		3	5	8,992
Repayment of long-term debt		(2,823)	(1,555)	(1,777)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		954	949	1,062
Other		575	(148)	(188)
Net cash used by financing activities		**(18,015)**	**(18,510)**	**(7,673)**
Effect of exchange rate changes on cash and cash equivalents		(9)	(241)	337
(Decrease)/Increase in cash and cash equivalents		(802)	283	(1,148)
Cash and cash equivalents, beginning of year (Note 1)		18,107	17,824	18,972
Cash and cash equivalents, end of year (Note 1)	**$**	**17,305**	**18,107**	**17,824**

Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	995	1,049	960

Interest, net of amount capitalized	925	963	866
Income taxes	4,191	4,570	3,312

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	1,736	2,095	2,062
Conversion of debt		1	6	16

Acquisitions				
Fair value of assets acquired	$	7,228	1,047	36,937
Fair value of liabilities assumed and noncontrolling interests		(1,418)	(148)	(1,786)
Net cash paid for acquisitions (Note 20)	**$**	**5,810**	**899**	**35,151**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

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

Description of the Company and Business Segments

The Company has approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2016-02: Leases

The Company adopted this standard as of the beginning of fiscal year 2019, on a prospective basis. This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for arrangements that are classified as operating leases. The Company's operating leases resulted in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheet, however it did not have a material impact on the consolidated financial statements.

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration.

Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term.

The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

For additional disclosures see Note 16 to the Consolidated Financial Statements.

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

This update allows a Company to elect to reclassify stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017 from accumulated other comprehensive income to retained earnings. The Company has elected not to reclassify the income tax effects of this standard and therefore this standard will not impact the Company's consolidated financial statements.

ASU 2018-16: Derivatives and Hedging (Topic ASC 815)
This update adds the Overnight Index Swap (OIS) rate based on the Secured Overnight Financing Rate (SOFR) as an eligible benchmark interest rate permitted in the application of hedge accounting. The guidance was effective for the Company as of the fiscal fourth quarter of 2018, due to the previous adoption of ASU 2017-12. The impact of the adoption of this guidance did not have a material impact on the Company's consolidated financial statements and related disclosures. The standard may have an impact in the future as the market for SOFR derivatives develops over time and if SOFR is used to hedge the Company's financial instruments.

Accounting Standards adopted in the fiscal 2018 with a cumulative effect to the 2018 opening balance of Retained Earnings
The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of the new accounting standards mentioned below:

(Dollars in Millions)	Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$ (47)
ASU 2016-01 - Financial Instruments	232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers	(439)
Total	$ (254)

Recently Issued Accounting Standards
Not Adopted as of December 29, 2019
ASU 2018-18: Collaborative Arrangements
This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses
This update introduces the current expected credit loss (CECL) model, which will require an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity will be required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. This update will be effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

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

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure

that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

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

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

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

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

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

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

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.0 billion and $5.8 billion as of December 29, 2019 and December 30, 2018, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately
1.0% of annual net trade sales during the fiscal reporting years 2019, 2018 and 2017.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in

sales to customers. For all years presented, profit-share payments were approximately 2.0% of the total revenues and are included in sales to customers.

See Note 18 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and Handling
Shipping and handling costs incurred were $1.0 billion, $1.1 billion and $1.0 billion in 2019, 2018 and 2017, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

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

Intangible Assets and Goodwill
The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2019 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

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

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

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

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

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

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

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically

involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit

share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

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

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

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

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

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

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.2 billion, $2.6 billion and $2.5 billion in 2019, 2018 and 2017, respectively.

Income Taxes

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

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

In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of the global intangible low-taxed income (GILTI) in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). In fiscal 2018, the Company elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.8 billion under current enacted tax laws and regulations and at current currency exchange rates.

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

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

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

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

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of the fiscal year 2019 and 2018, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2019		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,637	2,637	—
Non-U.S. Sovereign Securities[1]	439	149	290
U.S. Reverse repurchase agreements	6,375	6,375	—
Other Reverse repurchase agreements	375	375	—
Corporate debt securities[1]	1,323	889	434
Money market funds	2,864	2,864	—
Time deposits[1]	906	906	—
Subtotal	$ 14,919	14,195	724
U.S. Gov't Securities	$ 4,102	3,095	1,007
Corporate debt securities	266	15	251
Subtotal available for sale[2]	$ 4,368	3,110	1,258
Total cash, cash equivalents and current marketable securities		**$ 17,305**	**1,982**

(Dollars in Millions)	2018		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,619	2,619	—
U.S. Reverse repurchase agreements	3,009	3,009	—
Other Reverse repurchase agreements	443	443	—
Money market funds	3,397	3,397	—
Time deposits[1]	485	485	—
Subtotal	$ 9,953	9,953	—
Gov't Securities	$ 9,474	8,144	1,330
Corporate debt securities	260	10	250
Subtotal available for sale[2]	$ 9,734	8,154	1,580
Total cash, cash equivalents and current marketable securities		**$ 18,107**	**1,580**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.
In 2019 and 2018, the carrying amount was the same as the estimated fair value.

The contractual maturities of the available for sale debt securities at December 29, 2019 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 4,322	4,322
Due after one year through five years	46	46
Due after five years through ten years	—	—
Total debt securities	$ 4,368	4,368

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

3. Inventories

At the end of 2019 and 2018, inventories were comprised of:

(Dollars in Millions)	2019	2018
Raw materials and supplies	$ 1,117	1,114
Goods in process	1,832	2,109
Finished goods	6,071	5,376
Total inventories [1]	**$ 9,020**	**8,599**

[1] See Note 20 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures.

4. Property, Plant and Equipment

At the end of 2019 and 2018, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2019	2018
Land and land improvements	$ 854	807
Buildings and building equipment	11,877	11,176
Machinery and equipment	26,964	25,992
Construction in progress	3,637	3,876
Total property, plant and equipment, gross	$ 43,332	41,851
Less accumulated depreciation	25,674	24,816
Total property, plant and equipment, net[1]	**$ 17,658**	**17,035**

[1] See Note 20 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2019, 2018 and 2017 was $70 million, $86 million and $94 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2019, 2018 and 2017 was $2.5 billion, $2.6 billion and $2.6 billion, respectively.

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

5. Intangible Assets and Goodwill

At the end of 2019 and 2018, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2019	2018
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 36,634	35,194
Less accumulated amortization	13,154	9,784
Patents and trademarks — net	**$ 23,480**	**25,410**
Customer relationships and other intangibles — gross	$ 22,056	21,334
Less accumulated amortization	9,462	8,323
Customer relationships and other intangibles — net*	**$ 12,594**	**13,011**
Intangible assets with indefinite lives:		
Trademarks	$ 6,922	6,937
Purchased in-process research and development[1]	4,647	2,253
Total intangible assets with indefinite lives	**$ 11,569**	**9,190**
Total intangible assets — net	**$ 47,643**	**47,611**

*The majority is comprised of customer relationships

[1] In the fiscal year 2019, the Company completed the acquisition of Auris Health, Inc. and recorded an in-process research and development intangible asset of $2.9 billion. Additionally, in the fiscal first quarter of 2019, the Company recorded an IPR&D impairment charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176. A partial impairment charge of $0.8 billion was previously recorded in the fiscal third quarter 2018 related to the development program of AL-8176.

Goodwill as of December 29, 2019 and December 30, 2018, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at December 31, 2017	$ 8,875	9,109	13,922	31,906
Goodwill, related to acquisitions	168	51	184	403
Goodwill, related to divestitures	—	—	(1,348) [1]	(1,348)
Currency translation/other	(373)	(97)	(38)	(508)
Goodwill at December 30, 2018	$ 8,670	9,063	12,720	30,453
Goodwill, related to acquisitions	1,188	75	2,018	3,281
Currency translation/other	(122)	31	(4)	(95)
Goodwill at December 29, 2019	**$ 9,736**	**9,169**	**14,734**	**33,639**

[1] Goodwill of $1.0 billion is related to the divestiture of the LifeScan business. Goodwill of $0.3 billion is related to the divestiture of the Advanced Sterilization Products business which closed in 2019, and was pending and classified as assets held for sale on the Consolidated Balance Sheet as of December 30, 2018.

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in cost of products sold was $4.5 billion, $4.4 billion and $3.0 billion before tax, for the fiscal years ended December 29, 2019, December 30, 2018 and December 31, 2017, respectively. Intangible asset write-downs are included in Other (income) expense, net.

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

(Dollars in Millions)

2020	2021	2022	2023	2024
$4,500	4,300	4,100	4,100	4,000

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

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

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

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 29, 2019, the total amount of cash collateral held by the Company under the credit support agreements (CSA) amounted to $255 million net, primarily related to net investment hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment

grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 29, 2019, the Company had notional amounts outstanding for forward foreign exchange contracts, and cross currency interest rate swaps of $45.3 billion, and $20.1 billion respectively. As of December 30, 2018, the Company

had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.1 billion, $7.3 billion, and $0.5 billion respectively.

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

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

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. The effect of which are immaterial for the fiscal years ended December 29, 2019 and December 30, 2018. Gains and losses on net investment hedge are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

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

As of December 29, 2019, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $295 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 29, 2019 and December 30, 2018, net of tax:

	December 29, 2019					December 30, 2018				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	159	—	—	—	—	56	—
Amount of gain or (loss) recognized in AOCI	—	—	—	159	—	—	—	—	56	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(54)	(321)	(105)	—	22	47	200	(220)	—	(24)
Amount of gain or (loss) recognized in AOCI	(20)	(606)	(94)	—	39	(32)	(17)	(193)	—	(4)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	292	—	—	—	—	133	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	415	—	—	—	—	117	—

For the fiscal years ended December 29, 2019 and December 30, 2018, the following amounts were recorded on the Consolidated Balance Sheet

Line item in the Consolidated Balance Sheet in which the hedged item is included	**Carrying Amount of the Hedged Liability**		**Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability**	
(Dollars in Millions)	December 29, 2019	December 30, 2018	December 29, 2019	December 30, 2018
Current Portion of Long-term Debt	$ —	494	—	5

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 29, 2019 and December 30, 2018:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 29, 2019	December 30, 2018
Foreign Exchange Contracts	Other (income) expense	(144)	(68)

The following table is the effect of net investment hedges for the fiscal years ended December 29, 2019 and December 30, 2018:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	December 29, 2019	December 30, 2018		December 29, 2019	December 30, 2018
Debt	$ 121	218	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 488	150	Interest (income) expense	—	—

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

The following table is a summary of the activity related to equity investments for the fiscal years ended December 29, 2019 and December 30, 2018:

	December 30, 2018			December 29, 2019	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 511	533	104	1,148	1,148
Equity Investments without readily determinable value	$ 681	(38)	69	712	712

	December 31, 2017			December 30, 2018	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 751	(247)	7	511	511
	$ 510	13	158	681	681

Equity Investments without readily determinable value

(1) Recorded in Other Income/Expense
(2) Other includes impact of currency

For the fiscal years ended December 29, 2019 and December 30, 2018 for equity investments without readily determinable market values, $57 million and $54 million respectively, of the changes in fair value reflected in net income were the result of impairments. There were $19 million and $67 million respectively, of changes in fair value reflected in net income due to changes in observable prices.

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

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

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended December 29, 2019 and December 30, 2018 were as follows:

	2019				2018
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	209	—	209	501
Interest rate contracts [2][4]	—	693	—	693	161
Total	—	**902**	—	**902**	**662**
Liabilities:					
Forward foreign exchange contracts	—	426	—	426	548
Interest rate contracts [3][4]	—	193	—	193	292
Total	—	**619**	—	**619**	**840**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	23	—	23	32
Liabilities:					
Forward foreign exchange contracts	—	33	—	33	32
Available For Sale Other Investments:					
Equity investments[5]	1,148	—	—	1,148	511
Debt securities[6]	$ —	4,368	—	4,368	9,734
Other Liabilities					

Contingent Consideration[7]	1,715	1,715	397

Gross to Net Derivative Reconciliation		2019	2018
(Dollars in Millions)			
Total Gross Assets	$	925	694
Credit Support Agreement (CSA)		(841)	(423)
Total Net Asset		84	271
Total Gross Liabilities		652	872
Credit Support Agreement (CSA)		(586)	(605)
Total Net Liabilities	$	66	267

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

	2019	2018	2017
(Dollars in Millions)			
Beginning Balance	397	600	378
Changes in estimated fair value [8]	151	(156)	87
Additions	1,246	125	160
Payments	(79)	(172)	(25)
Ending Balance	1,715	397	600

(1) 2018 assets and liabilities are all classified as Level 2 with the exception of equity investments of $511 million, which are classified as Level 1 and contingent consideration of $397 million, classified as Level 3.

(2) Includes $1 million and $6 million of non-current assets for the fiscal years ending December 29, 2019 and December 30, 2018, respectively.

(3) Includes $3 million of non-current liabilities for the fiscal years ending December 30, 2018.

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

(5) Classified as non-current other assets.

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

(7) Includes $1,631 million (primarily related to Auris Health), $397 million and $600 million, classified as non-current other liabilities as of December 29, 2019, December 30, 2018 and December 31, 2017 respectively. Includes $84 million classified as current liabilities as of December 29, 2019.

(8) Amounts are recorded primarily in Research and Development expense.

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

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2019	Effective Rate %	2018	Effective Rate %
4.75% Notes due 2019 (1B Euro 1.1096)[2]/ (1B Euro 1.14)[3]	$ —	—	1,139 [2]	5.83
1.875% Notes due 2019	—	—	494	1.93
0.89% Notes due 2019	—	—	300	1.32
1.125% Notes due 2019	—	—	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	51	3.00	51	3.00
2.95% Debentures due 2020	549	3.15	548	3.15
1.950% Notes due 2020	500	1.99	499	1.99
3.55% Notes due 2021	449	3.67	449	3.67
2.45% Notes due 2021	349	2.48	349	2.48
1.65% Notes due 2021	999	1.65	998	1.65
0.250% Notes due 2022 (1B Euro 1.1096)[2]/ (1B Euro 1.14)[3]	1,108 [2]	0.26	1,137 [3]	0.26
2.25% Notes due 2022	998	2.31	996	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	804	3.17	805	3.17
2.05% Notes due 2023	498	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.1096)[2]/(750MM Euro 1.14)[3]	829 [2]	0.68	851 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.2987) [2]/(500MM GBP 1.2636)[3]	645 [2]	6.75	627 [3]	6.75
2.625% Notes due 2025	748	2.63	748	2.63
2.45% Notes due 2026	1,993	2.47	1,992	2.47
2.95% Notes due 2027	996	2.96	996	2.96
1.150% Notes due 2028 (750MM Euro 1.1096)[2]/(750MM Euro 1.14)[3]	825 [2]	1.21	847 [3]	1.21
2.900% Notes due 2028	1,494	2.91	1,493	2.91
6.95% Notes due 2029	297	7.14	297	7.14
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	855	4.24	856	4.24
1.650% Notes due 2035 (1.5B Euro 1.1096) [2]/(1.5B Euro 1.14)[3]	1,649 [2]	1.68	1,693 [3]	1.68
3.55% Notes due 2036	989	3.59	988	3.59
5.95% Notes due 2037	992	5.99	991	5.99
3.625% Notes due 2037	1,487	3.64	1,486	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	991	3.42	990	3.42
4.50% Debentures due 2040	539	4.63	538	4.63
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	495	4.52	495	4.52
3.70% Notes due 2046	1,973	3.74	1,972	3.74
3.75% Notes due 2047	991	3.76	991	3.76
3.500% Notes due 2048	742	3.52	742	3.52
Other	18	—	24	—

Subtotal	**27,594** [4]	**3.19 %** [1]	**30,320** [4]	**3.19** [1]
Less current portion	1,100		2,636	
Total long-term debt	**$ 26,494**		**27,684**	

[1] Weighted average effective rate.

[2] Translation rate at December 29, 2019.

[3] Translation rate at December 30, 2018.

[4] The excess of the fair value over the carrying value of debt was $3.0 billion in 2019 and $0.3 billion in 2018.

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

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2019, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 10, 2020. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR) or other applicable market rate as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2019, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $1.2 billion at the end of 2019, of which $1.1 billion is the current portion of the long-term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2018, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.8 billion at the end of 2018, of which $2.6 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term debt obligations commencing in 2020 are:

(Dollars in Millions)

2020	2021	2022	2023	2024	After 2024
$1,100	1,797	2,106	1,552	1,474	19,565

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2019	2018	2017
Currently payable:			
U.S. taxes	$ 1,941	1,284	12,095
International taxes	2,744	2,434	1,872
Total currently payable	4,685	3,718	13,967
Deferred:			
U.S. taxes	(814)	1,210 [1]	(1,956)
International taxes	(1,662)	(2,226)	4,362
Total deferred	(2,476)	(1,016)	2,406
Provision for taxes on income	**$ 2,209**	**2,702**	**16,373**

[1] Includes $1.4 billion of deferred tax expense for the adoption of the deferred method to account for GILTI.

A comparison of income tax expense at the U.S. statutory rate of 21% in 2019 and 2018 and 35% in 2017, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2019	2018	2017
U.S.	$ 3,543	5,575	4,865
International	13,785	12,424	12,808
Earnings before taxes on income:	$ 17,328	17,999	17,673
Tax rates:			
U.S. statutory rate	21.0 %	21.0	35.0
International operations [1]	(5.9)	(3.7)	(12.8)
U.S. taxes on international income [2]	1.8	1.4	0.7
Tax benefits on share-based compensation	(0.5)	(1.5)	(2.1)
All other	0.2	(0.3)	(1.5)
TCJA and related impacts	(3.9) [3]	(1.9) [3]	73.3 [4]
Effective Rate	12.7 %	15.0	92.6

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to balances originally recorded as part of the 2017 TCJA provisional tax charge. Further information provided below.
(4) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate.

The 2019 tax rate decreased by 2.3% compared to the fiscal year 2018 tax rate. In addition to the impact of Swiss tax reform discussed in more detail below, the primary drivers of the net decrease were as follows:

- The Company reorganized the ownership structure of certain wholly-owned international subsidiaries in the fiscal fourth quarter of 2019, which resulted in a reduction of certain withholding and local taxes that it had previously recognized as part of the provisional Tax Cuts and Jobs Act (TCJA) tax charge in the fiscal year 2017 and finalized in the fiscal year 2018. Following the completion of this restructuring and approval by the applicable local authorities, the Company reversed a deferred tax liability of $0.6 billion and a related deferred tax asset of $0.2 billion for U.S. foreign tax credits, for a net deferred tax benefit of $0.4 billion decreasing the annual effective tax rate by 2.2%. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The impact of the agreement in principle to settle opioid litigation for $4 billion (see Note 21 to the Consolidated Financial Statements) which reduced the U.S. earnings before taxes at an effective tax rate of 23.5% and decreased the Company's annual effective tax rate by approximately 2.1%.
- In December of fiscal year 2019, the U.S. Treasury issued final foreign tax credit regulations, which resulted in the Company revising the amount of foreign tax credits that were initially recorded in the fiscal year 2017 as part of the provisional TCJA tax charge. As a result, the Company recorded an increased deferred tax asset related to these foreign tax credits of approximately $0.3 billion or 1.7% to the annual effective tax rate. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The Company reassessed its uncertain tax positions related to the current IRS audit and increased its unrecognized tax benefit by $0.3 billion liability which increased the annual effective tax rate by approximately 1.5% (see section on Unrecognized Tax Benefits for additional information). As these positions were related to uncertain tax regarding international transfer pricing, this expense has been classified as "International Operations" on the Company's effective tax rate reconciliation. Subsequent to December 29, 2019, the Company received and agreed to Notices of Proposed Adjustments (NOPAs) from the IRS. The Company believes it is adequately reserved for potential exposures.

- There were several one-time tax impacts that resulted in a cumulative net tax benefit to the 2018 annual effective tax rate of 1.2%. These items included the LifeScan divestiture, the adjustment to the 2017 provisional TCJA tax charge and the acceleration of certain tax deductions as part of the 2017 tax return.
- More income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2018.

On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (TRAF). On May 19, 2019 a public referendum was held in Switzerland that approved the federal reform proposals. In the fiscal third quarter of 2019, the Swiss Federal Council enacted TRAF which became effective on January 1, 2020. The Federal transitional provisions

of TRAF allow companies, under certain conditions, to adjust their tax basis adjustments to fair value (i.e., "step-up") which is used for tax depreciation and amortization purposes resulting in a deduction over the transitional period. The subsequent adjustment to the Company's asset tax basis will require review and approval by the tax authorities.

TRAF also provides for parameters which enable the Swiss cantons to establish localized tax rates and regulations for companies. The new cantonal tax parameters include favorable tax benefits for patents and additional research and development tax deductions. The cantonal transitional provisions of TRAF are also expected to allow companies to elect either 1) tax basis step-up similar to the Federal transition benefit or 2) alternative statutory tax rate for a period not to exceed 5 years. The Company currently has operations located in various Swiss cantons and enactment may not be uniform in both the substantive nature of the legislation and the timing of enactment.

The Company recorded a net tax expense of $0.1 billion which increased the effective tax rate for the fiscal year 2019 by approximately 0.6%. This net tax expense related to federal and certain cantonal enactments in the fiscal year 2019 consisting of the following provisions:

- approximately $0.6 billion tax expense relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred by December 29, 2019; this expense has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $0.9 billion deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $450 million of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities and the new deferred tax asset for the Federal step-up. this benefit has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

In the fiscal fourth quarter of 2019, the Swiss Federal Tax Administration issued authoritative guidance that required the Company to decrease the estimated value of the Federal tax basis step-up by approximately $0.3 billion from the determination made in the fiscal third quarter of 2019. Further authoritative guidance from the relevant Swiss tax authorities may be issued in the future and additional revisions may be required in the fiscal period that they are issued.

The Company is currently assessing and applying for approval for the elective transition provisions in several cantons which includes discussions with local tax authorities on the application of the new law. The Company has recorded an estimated impact of the transitional provisions based on the best available information for cantons where enactment has occurred but the Company has not yet received a final tax ruling.

As of December 29, 2019, the one canton where the Company maintains significant operations has not yet enacted TRAF legislation and the amounts recorded in the fiscal year 2019 do not include estimates for unenacted legislation. On February 9, 2020 a public referendum on the legislative change was held in this canton and the legislation was approved by the voters; formal enactment is expected in the fiscal first half of 2020. The Company has not yet elected the transitional provision in this canton. However, the net financial benefit is estimated to be between $0.2 billion and $0.5 billion in the fiscal first half of 2020.

U.S. Tax Cuts and Jobs Act (TCJA) (2018 and 2017)
In the fiscal year 2017, the United States enacted into law new U.S. tax legislation, the TCJA. This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the fiscal year 2019 was approximately $8.2 billion, of which $7.7 billion is classified as noncurrent and reflected as "Long-term taxes payable" on the Company's balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

In the fourth quarter of 2017, the Company recorded a provisional tax cost of approximately $13.0 billion which consisted primarily of the following components:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings

- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on unrecognized tax benefits
- a $0.1
  billion charge for U.S. state and local taxes on the repatriation of these foreign earnings

In the fiscal year 2018, the Company completed its full assessment and finalized the accounting for the impact of the TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This charge was primarily related to additional deferred tax liabilities for foreign local and withholding taxes for the remaining balance of undistributed foreign earnings as of December 31, 2017 that were not provided for in the 2017 provisional charge.

The TCJA also includes provisions for a tax on GILTI. GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In the fiscal year 2018, the Company elected to treat GILTI as a period expense under the deferred method and recorded a deferred tax cost of approximately $1.4 billion in the fiscal year 2018 related to facts and circumstances that existed on the date of TCJA enactment. See Note 1 for further information regarding income taxes accounting policies.

During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.

The 2018 effective tax rate decreased by 77.6% compared to 2017. The 2017 effective tax rate was primarily driven by the approximately $13 billion provisional tax charge recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. Additional drivers of the 2018 annual effective tax were:

- the reduction of the U.S. statutory corporate tax rate including the effects of tax elections which resulted in the acceleration of certain deductions into the 2017 tax return. The impact of these accelerated deductions decreased the annual effective tax rate by approximately 1.7%
- the impact of the adjustments to the 2017 provisional TCJA charge, including both Staff Accounting Bulletin (SAB) 118 adjustments and the internal restructuring, decreased the effective tax rate by approximately 1.9%
- GILTI tax which increased the annual effective tax rate by approximately 1.6%, which excludes the impact of the SAB 118 adjustment for the adoption of the deferred method for GILTI
- tax benefits received from stock-based compensation during fiscal 2018 and 2017, reduced the effective tax rate by 1.5% and 2.0%, respectively
- in the fourth quarter of 2018, the Company completed the divestiture of its LifeScan business (See Note 20 to the Consolidated Financial Statements), which increased the Company's annual effective tax rate by approximately 0.8%
- more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2017

Temporary differences and carryforwards for 2019 and 2018 were as follows:

	2019 Deferred Tax		2018 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,393		2,398	
Stock based compensation	546		639	
Depreciation & amortization	1,122		1,784	
Non-deductible intangibles		(5,752)		(5,967)
International R&D capitalized for tax	1,189		1,282	
Reserves & liabilities	2,384		1,647	
Income reported for tax purposes	1,605		1,104	
Net operating loss carryforward international	838		786	
Undistributed foreign earnings	765	(1,289)	693	(2,240)
Global intangible low-taxed income		(2,965)		(2,971)
Miscellaneous international	696	(81)	603	(93)
Miscellaneous U.S.	410		469	
Total deferred income taxes	**$ 11,948**	**(10,087)**	**11,405**	**(11,271)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

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

(Dollars in Millions)	**2019**	**2018**	**2017**
Beginning of year	$ 3,326	3,151	3,041
Increases related to current year tax positions	249	242	332
Increases related to prior period tax positions	408	145	232
Decreases related to prior period tax positions	(105)	(137)	(416) [(1)]
Settlements	(9)	(40)	(2)
Lapse of statute of limitations	(16)	(35)	(36)
End of year	**$ 3,853**	**3,326**	**3,151**

[(1)] In 2017, $347 million of this decrease is related to the TCJA.

The unrecognized tax benefits of $3.9 billion at December 29, 2019, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit and settlement of the related tax liabilities in the fiscal year 2020. As of the December 29, 2019, the Company has classified unrecognized tax benefits and related interest of approximately $0.9 billion as a current liability on the "Accrued taxes on Income" line of the Consolidated Balance Sheet. This is the amount expected to be paid over the next 12 months with respect to the IRS audit. Subsequent to December 29, 2019, the Company made a payment for approximately $0.6 billion to the U.S. Treasury related to the estimated 2010-2012 tax audit liability in anticipation of the final settlement later in fiscal 2020. The completion of this tax audit may result in additional adjustments to the Company's unrecognized tax benefit liability. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities, except as previously noted on amounts related to the current United States IRS audit. Interest expense and penalties related to

unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $50 million, $53 million and $60 million in 2019, 2018 and 2017, respectively. The total amount of accrued interest was $559 million and $503 million in 2019 and 2018, respectively.

9. Employee Related Obligations

At the end of 2019 and 2018, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2019	2018
Pension benefits	$ 5,538	5,327
Postretirement benefits	2,297	2,283
Postemployment benefits	3,004	2,330
Deferred compensation	338	410
Total employee obligations	11,177	10,350
Less current benefits payable	514	399
Employee related obligations — non-current	**$ 10,663**	**9,951**

Prepaid employee related obligations of $551 million and $475 million for 2019 and 2018, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit Plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

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

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2019 and 2018 the Company used December 31, 2019 and December 31, 2018, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2019, 2018 and 2017 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2019	2018	2017	2019	2018	2017
Service cost	$ 1,163	1,283	1,080	274	269	247
Interest cost	1,096	996	927	185	148	159
Expected return on plan assets	(2,322)	(2,212)	(2,041)	(6)	(7)	(6)
Amortization of prior service cost (credit)	4	3	2	(31)	(31)	(30)
Recognized actuarial losses	579	852	609	129	123	138
Curtailments and settlements	73	1	17	—	—	—
Net periodic benefit cost	**$ 593**	**923**	**594**	**551**	**502**	**508**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	1,022
Amortization of prior service credit	29

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2019**	**2018**	**2017**	**2019**	**2018**	**2017**
Net Periodic Benefit Cost						
Service cost discount rate	3.63 %	3.20	3.59	4.45	3.85	4.63
Interest cost discount rate	4.13 %	3.60	3.98	4.25	3.62	3.94
Rate of increase in compensation levels	3.99 %	3.98	4.01	4.29	4.29	4.31
Expected long-term rate of return on plan assets	8.31 %	8.46	8.43			
Benefit Obligation						
Discount rate	2.91 %	3.76	3.30	3.39	4.40	3.78
Rate of increase in compensation levels	4.01 %	3.97	3.99	4.29	4.29	4.30

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

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

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

Health Care Plans	**2019**	**2018**
Health care cost trend rate assumed for next year	5.87 %	6.12 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50 %	4.55 %
Year the rate reaches the ultimate trend rate	2040	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		

Total interest and service cost	$	21	(17)
Post-retirement benefit obligation	$	296	(246)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2019 and 2018 for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	Retirement Plans 2019	Retirement Plans 2018	Other Benefit Plans 2019	Other Benefit Plans 2018
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 31,670	33,221	4,480	4,582
Service cost	1,163	1,283	274	269
Interest cost	1,096	996	185	148
Plan participant contributions	63	66	—	—
Amendments	—	26	—	—
Actuarial (gains) losses	5,178	(2,326)	562	(119)
Divestitures & acquisitions	(278)	(29)	—	—
Curtailments, settlements & restructuring	(172)	(21)	—	—
Benefits paid from plan assets*	(1,555)	(1,018)	(431)	(383)
Effect of exchange rates	23	(528)	6	(17)
Projected benefit obligation — end of year	**$ 37,188**	**31,670**	**5,076**	**4,480**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 26,818	28,404	180	281
Actual return on plan assets	6,185	(1,269)	19	—
Company contributions	908	1,140	347	282
Plan participant contributions	63	66	—	—
Settlements	(16)	(13)	—	—
Divestitures & acquisitions	(274)	(17)	—	—
Benefits paid from plan assets*	(1,555)	(1,018)	(431)	(383)
Effect of exchange rates	72	(475)	—	—
Plan assets at fair value — end of year	**$ 32,201**	**26,818**	**115**	**180**
Funded status — end of year	**$ (4,987)**	**(4,852)**	**(4,961)**	**(4,300)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 551	475	—	—
Current liabilities	(113)	(98)	(397)	(281)
Non-current liabilities	(5,425)	(5,229)	(4,564)	(4,019)
Total recognized in the consolidated balance sheet — end of year	**$ (4,987)**	**(4,852)**	**(4,961)**	**(4,300)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,835	8,323	1,685	1,263
Prior service cost (credit)	(8)	2	(75)	(106)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,827**	**8,325**	**1,610**	**1,157**
Accumulated Benefit Obligations — end of year	**$ 33,416**	**28,533**		

*In 2019, the Company offered a voluntary lump-sum payment option for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2019. The amount distributed in 2019 was approximately $514 million.

(Dollars in Millions)	Retirement Plans 2019	Retirement Plans 2018	Other Benefit Plans 2019	Other Benefit Plans 2018
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 593**	**923**	**551**	**502**
Net actuarial (gain) loss	1,084	1,153	550	(111)
Amortization of net actuarial loss	(579)	(852)	(129)	(123)
Prior service cost (credit)	—	26	—	—
Amortization of prior service (cost) credit	(4)	(3)	31	31
Effect of exchange rates	1	(114)	1	(3)
Total loss/(income) recognized in other comprehensive income, before tax	**$ 502**	**210**	**453**	**(206)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,095**	**1,133**	**1,004**	**296**

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

In 2019, the Company contributed $489 million and $419 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2019 and December 31, 2018, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2019	2018	2019	2018	2019	2018	2019	2018
Plan Assets	$ 21,398	17,725	—	—	10,803	9,093	—	—
Projected Benefit Obligation	22,034	18,609	2,544	2,176	12,132	10,467	478	418
Accumulated Benefit Obligation	19,831	16,851	2,115	1,793	11,040	9,510	430	379
Over (Under) Funded Status								
Projected Benefit Obligation	$ (636)	(884)	(2,544)	(2,176)	(1,329)	(1,374)	(478)	(418)
Accumulated Benefit Obligation	1,567	874	(2,115)	(1,793)	(237)	(417)	(430)	(379)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $4.3 billion, $5.2 billion and $0.9 billion, respectively, at the end of 2019, and $7.5 billion, $8.8 billion and $4.3 billion, respectively, at the end of 2018.

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

(Dollars in Millions)	2020	2021	2022	2023	2024	2025-2029
Projected future benefit payments						
Retirement plans	$ 1,126	1,172	1,234	1,323	1,359	7,945
Other benefit plans	$ 437	450	466	479	494	2,356

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

(Dollars in Millions)	2020	2021	2022	2023	2024	2025-2029
Projected future contributions	$ 103	107	113	118	127	749

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

The Company's retirement plan asset allocation at the end of 2019 and 2018 and target allocations for 2020 are as follows:

	Percent of Plan Assets		Target Allocation
	2019	2018	2020
Worldwide Retirement Plans			
Equity securities	74 %	71 %	69 %
Debt securities	26	29	31
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of Fair Value of Plan Assets

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

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

Valuation Hierarchy

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

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

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

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

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.

- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.

- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar

characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.

- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.

- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2019 and December 31, 2018:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**
Short-term investment funds	$ 119	122	405	529	—	—	—	—	524	651
Government and agency securities	—	—	4,140	3,595	—	—	—	—	4,140	3,595
Debt instruments	—	—	3,452	3,105	—	—	—	—	3,452	3,105
Equity securities	12,483	11,298	2	4	—	—	—	—	12,485	11,302
Commingled funds	—	—	3,338	2,304	181	133	7,580	5,201	11,099	7,638
Insurance contracts	—	—	—	—	19	193	—	—	19	193
Other assets	—	—	9	33	—	—	473	301	482	334
Investments at fair value	**$ 12,602**	**11,420**	**11,346**	**9,570**	**200**	**326**	**8,053**	**5,502**	**32,201**	**26,818**

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

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $84 million and $72 million and U.S. short-term investment funds (Level 2) of $31 million and $108 million at December 31, 2019 and December 31, 2018, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $984 million (3.1% of total worldwide plan assets) at December 31, 2019 and $876 million (3.3% of total worldwide plan assets) at December 31, 2018.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee’s contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $235 million, $242 million and $214 million in 2019, 2018 and 2017, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock	
	Shares	Amount
Balance at January 1, 2017	413,332	$ 28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	34,362
Employee compensation and stock option plans	(20,053)	(2,691)
Repurchase of common stock	49,870	6,746
Balance at December 29, 2019	487,336	$ 38,417

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2019, 2018 and 2017.

Cash dividends paid were $3.75 per share in 2019, compared with dividends of $3.54 per share in 2018, and $3.32 per share in 2017.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed as of September 29, 2019.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

13. Accumulated Other Comprehensive Income (Loss)

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

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 1, 2017	$ (9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	(7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings	—	(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	(8,869)	—	(6,158)	(195)	(15,222)
Net 2019 changes	164	—	(733)	(100)	(669)
December 29, 2019	$ (8,705)	—	(6,891)	(295)	(15,891)

[1] Per the adoption of ASU 2016-01- Financial Instruments

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

Details on reclassifications out of Accumulated Other Comprehensive Income:

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

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

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

14. International Currency Translation

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

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies, (Argentina and Venezuela). The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2019, 2018 and 2017 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $267 million, $265 million and $216 million in 2019, 2018 and 2017, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 29, 2019, December 30, 2018 and December 31, 2017:

(In Millions Except Per Share Amounts)	2019	2018	2017
Basic net earnings per share	$ 5.72	5.70	0.48
Average shares outstanding — basic	2,645.1	2,681.5	2,692.0
Potential shares exercisable under stock option plans	136.3	139.0	139.7
Less: shares repurchased under treasury stock method	(97.8)	(92.5)	(87.3)
Convertible debt shares	0.7	0.7	0.9
Adjusted average shares outstanding — diluted	2,684.3	2,728.7	2,745.3
Diluted net earnings per share	$ 5.63	5.61	0.47

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for 2019, 2018 and 2017.

The diluted net earnings per share calculation for 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than the average market value of the Company’s stock. The diluted net earnings per share calculation for 2018 and 2017 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Lease Commitments

The Company primarily has operating leases for space, vehicles, manufacturing equipment and data processing equipment. Leases have remaining lease terms ranging from 1 year to 55 years, some of which could include options to extend the leases when they are reasonably certain.

The operating lease costs were approximately $307 million, $332 million and $372 million in 2019, 2018 and 2017, respectively. Cash paid for amounts included in the measurement of lease liabilities in 2019 were $308 million. Commitments under finance leases are not significant. Other supplemental information related to these leases are as follows:

The Weighted Average Remaining Lease Term and discount rate:

Operating leases 5.8 years

Weighted Average Discount Rate 3%

Maturity of Lease Liabilities related to Operating Lease

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 29, 2019 are:

(Dollars in Millions)	Operating Leases
2020	$ 215
2021	254
2022	197
2023	141
2024	86
After 2024	201
Total lease payments	1,094
Less: Interest	109
Present Value of lease liabilities	$ 985

Supplemental information for comparative periods:

As of December 30, 2018, prior to the adoption of ASU 2016-02, the approximate future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year were:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023	Total
$223	188	154	116	76	139	896

Supplemental balance sheet information related to leases as of December 29, 2019 were as follows:

(Dollars in Millions)		
Non-current operating lease right-of-use assets	$	957
Current operating lease liabilities		269
Non-current Operating lease liabilities		716
Total operating lease liabilities	$	985

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 29, 2019, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 315 million at the end of 2019.

The compensation cost that has been charged against income for these plans was $977 million, $978 million and $962 million for 2019, 2018 and 2017, respectively. The total income tax benefit recognized in the income statement

for share-based compensation costs was $227 million, $192 million and $275 million for 2019, 2018 and 2017, respectively. The total unrecognized compensation cost was $823 million, $827 million and $798 million for 2019, 2018 and 2017, respectively. The weighted average period for this cost to be recognized was 1.71 years, 1.73 years and 1.76 years for 2019, 2018, and 2017, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

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

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2019, 2018 and 2017 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $17.80, $17.98 and $13.38, in 2019, 2018 and 2017, respectively. The fair value was estimated based on the weighted average assumptions of:

	2019	2018	2017
Risk-free rate	2.56%	2.77%	2.25%
Expected volatility	16.27%	15.77%	15.30%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.80%	2.70%	2.90%

A summary of option activity under the Plan as of December 29, 2019, December 30, 2018 and December 31, 2017, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 1, 2017	113,455	$ 83.16	$ 3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	111,306	90.48	5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	109,652	98.29	3,214
Options granted	19,745	131.94	
Options exercised	(14,785)	82.43	
Options canceled/forfeited	(2,975)	125.11	
Shares at December 29, 2019	**111,637**	**$ 105.63**	**$ 4,478**

The total intrinsic value of options exercised was $807 million, $1,028 million and $1,060 million in 2019, 2018 and 2017, respectively.

The following table summarizes stock options outstanding and exercisable at December 29, 2019:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$58.65-$66.07	7,752	1.3	$63.71	7,752	$63.71

$72.54-$90.44	23,837	3.6	$82.08	23,837	$82.08
$100.06-$101.87	29,586	5.6	$101.07	29,083	$101.05
$115.67-$129.51	31,810	7.6	$122.32	84	$120.76
$131.94-$141.06	18,652	9.1	$131.94	5	$131.94
	111,637	**6.0**	**$105.63**	**60,761**	**$88.88**

[1] Average contractual life remaining in years.

Stock options outstanding at December 30, 2018 and December 31, 2017 were 109,652 and an average life of 6.2 years and 111,306 and an average life of 6.3 years, respectively. Stock options exercisable at December 30, 2018 and December 31, 2017 were 54,862 at an average price of $82.03 and 52,421 at an average price of $73.61, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that were scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 29, 2019 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 30, 2018	18,460	2,494
Granted	5,769	932
Issued	(6,261)	(996)
Canceled/forfeited/adjusted	(1,199)	(256)
Shares at December 29, 2019	16,769	2,174

The average fair value of the restricted share units granted was $121.31, $119.67 and $107.69 in 2019, 2018 and 2017, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $585.9 million, $613.7 million and $596.5 million in 2019, 2018 and 2017, respectively.

The weighted average fair value of the performance share units granted was $124.67, $120.64 and $114.13 in 2019, 2018 and 2017, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $119.1 million, $128.8 million and $132.5 million in 2019, 2018 and 2017, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers			% Change	
	2019	2018	2017	'19 vs. '18	'18 vs. '17
CONSUMER					
Baby Care					
U.S.	$ 362	422	449	(14.2)%	(6.0)
International	1,313	1,436	1,467	(8.6)	(2.1)
Worldwide	1,675	1,858	1,916	(9.9)	(3.0)
Beauty					
U.S.	2,392	2,403	2,335	(0.4)	2.9
International	2,201	1,979	1,865	11.2	6.1
Worldwide	4,593	4,382	4,200	4.8	4.3
Oral Care					
U.S.	621	637	616	(2.5)	3.4
International	906	918	915	(1.2)	0.3
Worldwide	1,528	1,555	1,531	(1.7)	1.6
OTC					
U.S.	2,010	1,850	1,716	8.6	7.8
International	2,434	2,484	2,410	(2.0)	3.1
Worldwide	4,444	4,334	4,126	2.5	5.0
Women's Health					
U.S.	12	13	12	(5.5)	8.3
International	974	1,036	1,038	(6.0)	(0.2)
Worldwide	986	1,049	1,050	(6.0)	(0.1)
Wound Care/Other					
U.S.	441	436	437	1.2	(0.2)
International	230	239	342	(3.9)	(30.1)
Worldwide	671	675	779	(0.6)	(13.4)
TOTAL CONSUMER					
U.S.	5,839	5,761	5,565	1.4	3.5
International	8,059	8,092	8,037	(0.4)	0.7
Worldwide	13,898	13,853	13,602	0.3	1.8

PHARMACEUTICAL					
Immunology					
U.S.	9,641	9,073	8,871	6.3	2.3
International	4,309	4,047	3,373	6.5	20.0
Worldwide	13,950	13,120	12,244	6.3	7.2
REMICADE®					
U.S.	3,079	3,664	4,525	(16.0)	(19.0)
U.S. Exports	294	436	563	(32.7)	(22.6)
International	1,007	1,226	1,227	(17.8)	(0.1)
Worldwide	4,380	5,326	6,315	(17.8)	(15.7)
SIMPONI / SIMPONI ARIA®					
U.S.	1,159	1,051	954	10.2	10.2
International	1,029	1,033	879	(0.4)	17.5
Worldwide	2,188	2,084	1,833	5.0	13.7
STELARA®					
U.S.	4,346	3,469	2,767	25.3	25.4
International	2,015	1,687	1,244	19.4	35.6
Worldwide	6,361	5,156	4,011	23.4	28.5
TREMFYA®					
U.S.	764	453	62	68.5	*
International	248	91	1	*	*
Worldwide	1,012	544	63	85.9	*
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	10	10	22	4.5	(54.5)
Worldwide	10	10	22	4.5	(54.5)
Infectious Diseases					
U.S.	1,597	1,378	1,358	15.9	1.5
International	1,815	1,926	1,796	(5.7)	7.2
Worldwide	3,413	3,304	3,154	3.3	4.8
EDURANT® / rilpivirine					
U.S.	50	58	58	(13.7)	0.0
International	812	758	656	7.1	15.5
Worldwide	861	816	714	5.6	14.3
PREZISTA® / PREZCOBIX® / SYMTUZA® REZOLSTA® /					
U.S.	1,422	1,169	1,109	21.6	5.4
International	689	786	712	(12.3)	10.4
Worldwide	2,110	1,955	1,821	8.0	7.4
OTHER INFECTIOUS DISEASES					
U.S.	126	151	191	(16.5)	(20.9)
International	315	382	428	(17.6)	(10.7)
Worldwide	441	533	619	(17.3)	(13.9)

Neuroscience					
U.S.	2,919	2,574	2,630	13.4	(2.1)
International	3,409	3,503	3,356	(2.7)	4.4
Worldwide	6,328	6,077	5,986	4.1	1.5
CONCERTA® / Methylphenidate					
U.S.	233	229	384	1.7	(40.4)
International	463	434	407	6.6	6.6
Worldwide	696	663	791	4.9	(16.2)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	2,107	1,791	1,590	17.6	12.6
International	1,224	1,137	979	7.7	16.1
Worldwide	3,330	2,928	2,569	13.7	14.0
RISPERDAL CONSTA®					
U.S.	314	315	360	(0.3)	(12.5)
International	374	422	445	(11.4)	(5.2)
Worldwide	688	737	805	(6.7)	(8.4)
OTHER NEUROSCIENCE					
U.S.	266	239	296	11.4	(19.3)
International	1,349	1,510	1,525	(10.7)	(1.0)
Worldwide	1,614	1,749	1,821	(7.7)	(4.0)
Oncology					
U.S.	4,299	4,331	3,098	(0.7)	39.8
International	6,393	5,513	4,160	16.0	32.5
Worldwide	10,692	9,844	7,258	8.6	35.6
DARZALEX®					
U.S.	1,567	1,203	884	30.3	36.1
International	1,430	822	358	73.9	*
Worldwide	2,998	2,025	1,242	48.0	63.0
IMBRUVICA®					
U.S.	1,555	1,129	841	37.7	34.2
International	1,856	1,486	1,052	24.9	41.3
Worldwide	3,411	2,615	1,893	30.4	38.1
VELCADE®					
U.S.	—	—	—	—	—
International	751	1,116	1,114	(32.7)	0.2
Worldwide	751	1,116	1,114	(32.7)	0.2
ZYTIGA® /abiraterone acetate					
U.S.	810	1,771	1,228	(54.3)	44.2
International	1,985	1,727	1,277	15.0	35.2
Worldwide	2,795	3,498	2,505	(20.1)	39.6
OTHER ONCOLOGY					
U.S.	367	228	145	61.0	57.2
International	371	362	359	2.4	0.8
Worldwide	739	590	504	25.0	17.1

Pulmonary Hypertension					
U.S.	1,684	1,651	773	2.0	*
International	939	922	554	1.9	66.4
Worldwide	2,623	2,573	1,327	1.9	93.9
OPSUMIT®					
U.S.	766	700	320	9.4	*
International	562	515	253	9.0	*
Worldwide	1,327	1,215	573	9.2	*
TRACLEER® / bosentan					
U.S.	131	268	161	(51.1)	66.5
International	210	278	242	(24.3)	14.9
Worldwide	341	546	403	(37.5)	35.5
UPTRAVI®					
U.S.	714	598	238	19.3	*
International	105	65	25	62.4	*
Worldwide	819	663	263	23.5	*
OTHER					
U.S.	74	85	54	(13.7)	57.4
International	62	64	34	(3.7)	88.2
Worldwide	135	149	88	(9.4)	69.3
Cardiovascular / Metabolism / Other					
U.S.	3,734	4,279	4,744	(12.7)	(9.8)
International	1,458	1,537	1,543	(5.2)	(0.4)
Worldwide	5,192	5,816	6,287	(10.7)	(7.5)
XARELTO®					
U.S.	2,313	2,477	2,500	(6.6)	(0.9)
International	—	—	—	—	—
Worldwide	2,313	2,477	2,500	(6.6)	(0.9)
INVOKANA® / INVOKAMET®					
U.S.	536	711	944	(24.6)	(24.7)
International	199	170	167	17.3	1.8
Worldwide	735	881	1,111	(16.5)	(20.7)
PROCRIT® / EPREX®					
U.S.	505	674	675	(25.1)	(0.1)
International	285	314	297	(9.2)	5.7
Worldwide	790	988	972	(20.0)	1.6
OTHER					
U.S.	380	417	625	(9.1)	(33.3)
International	974	1,053	1,079	(7.6)	(2.4)
Worldwide	1,353	1,470	1,704	(8.0)	(13.7)
TOTAL PHARMACEUTICAL					
U.S.	23,874	23,286	21,474	2.5	8.4
International	18,324	17,448	14,782	5.0	18.0
Worldwide	42,198	40,734	36,256	3.6	12.4

MEDICAL DEVICES					
Diabetes Care					
U.S.	—	371	612	*	(39.4)
International	—	638	1,003	*	(36.4)
Worldwide	—	1,009	1,615	*	(37.5)
Diagnostics					
U.S.	—	—	—	—	—
International	—	—	1	—	*
Worldwide	—	—	1	—	*
Interventional Solutions					
U.S.	1,443	1,283	1,148	12.5	11.8
International	1,554	1,363	1,148	14.0	18.7
Worldwide	2,997	2,646	2,296	13.3	15.2
Orthopaedics					
U.S.	5,319	5,281	5,404	0.7	(2.3)
International	3,520	3,604	3,654	(2.3)	(1.4)
Worldwide	8,839	8,885	9,058	(0.5)	(1.9)
HIPS					
U.S.	863	841	827	2.6	1.7
International	575	577	567	(0.3)	1.8
Worldwide	1,438	1,418	1,394	1.4	1.7
KNEES					
U.S.	889	911	948	(2.4)	(3.9)
International	591	591	575	0.0	2.8
Worldwide	1,480	1,502	1,523	(1.4)	(1.4)
TRAUMA					
U.S.	1,652	1,599	1,576	3.3	1.5
International	1,068	1,100	1,040	(2.9)	5.8
Worldwide	2,720	2,699	2,616	0.8	3.2
SPINE & OTHER					
U.S.	1,915	1,930	2,053	(0.8)	(6.0)
International	1,286	1,336	1,472	(3.8)	(9.2)
Worldwide	3,201	3,266	3,525	(2.0)	(7.3)
Surgery					
U.S.	3,828	4,125	4,085	(7.2)	1.0
International	5,673	5,776	5,474	(1.8)	5.5
Worldwide	9,501	9,901	9,559	(4.0)	3.6
ADVANCED					
U.S.	1,637	1,657	1,620	(1.2)	2.3
International	2,458	2,345	2,136	4.8	9.8
Worldwide	4,095	4,002	3,756	2.3	6.5
GENERAL					
U.S.	1,762	1,751	1,728	0.6	1.3
International	2,718	2,806	2,735	(3.1)	2.6
Worldwide	4,480	4,557	4,463	(1.7)	2.1

SPECIALTY					
U.S.	430	717	737	(40.1)	(2.7)
International	497	625	603	(20.5)	3.6
Worldwide	926	1,342	1,340	(31.0)	0.1
Vision					
U.S.	1,794	1,777	1,575	0.9	12.8
International	2,830	2,776	2,488	2.0	11.6
Worldwide	4,624	4,553	4,063	1.6	12.1
CONTACT LENSES / OTHER					
U.S.	1,304	1,237	1,122	5.4	10.2
International	2,088	2,065	1,914	1.1	7.9
Worldwide	3,392	3,302	3,036	2.7	8.8
SURGICAL					
U.S.	490	540	453	(9.4)	19.2
International	742	711	574	4.4	23.9
Worldwide	1,232	1,251	1,027	(1.6)	21.8
TOTAL MEDICAL DEVICES					
U.S.	12,384	12,837	12,824	(3.5)	0.1
International	13,579	14,157	13,768	(4.1)	2.8
Worldwide	25,963	26,994	26,592	(3.8)	1.5
WORLDWIDE					
U.S.	42,097	41,884	39,863	0.5	5.1
International	39,962	39,697	36,587	0.7	8.5
Worldwide	$ 82,059	81,581	76,450	0.6 %	6.7

*Percentage greater than 100% or not meaningful

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	**2019** [3]	**2018** [4]	**2017** [5]	**2019**	**2018**
Consumer	$ 2,061	2,320	2,524	$ 26,618	25,877
Pharmaceutical	8,816	12,568	11,083	56,292	56,636
Medical Devices	7,286	4,397	5,392	49,462	46,254
Total	18,163	19,285	18,999	132,372	128,767
Less: Expense not allocated to segments [1]	835	1,286	1,326		
General corporate [2]				25,356	24,187
Worldwide total	**$ 17,328**	**17,999**	**17,673**	**$ 157,728**	**152,954**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2019**	**2018**	**2017**	**2019**	**2018**	**2017**
Consumer	$ 328	438	485	$ 765	688	674
Pharmaceutical	950	1,012	936	3,910	3,802	2,416
Medical Devices	1,912	1,843	1,566	2,014	2,103	2,216
Segments total	3,190	3,293	2,987	6,689	6,593	5,306
General corporate	308	377	292	320	336	336
Worldwide total	**$ 3,498**	**3,670**	**3,279**	**$ 7,009**	**6,929**	**5,642**

(Dollars in Millions)	Sales to Customers			Long-Lived Assets [6]	
	2019	2018	2017	2019	2018
United States	$ 42,097	41,884	39,863	$ 41,528	37,117
Europe	18,466	18,753	17,126	48,015	51,433
Western Hemisphere excluding U.S.	5,941	6,113	6,041	2,862	2,752
Asia-Pacific, Africa	15,555	14,831	13,420	5,486	2,733
Segments total	82,059	81,581	76,450	97,891	94,035
General corporate				1,049	1,064
Other non long-lived assets				58,788	57,855
Worldwide total	**$ 82,059**	**81,581**	**76,450**	**$ 157,728**	**152,954**

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

Export sales are not significant. In 2019, the Company utilized three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

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

(3) The Consumer segment includes a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO, litigation expense of $0.4 billion and a restructuring charge of $0.1 billion. The Pharmaceutical segment includes litigation expense of $4.3 billion including $4.0 billion related to the agreement in principle to settle opioid litigation (see Note 21 to the Consolidated Financial Statements for additional information regarding the opioid litigation), an in-process research and development expense of $0.9 billion related to the Alios asset, a research and development expense of $0.3 billion for an upfront payment related to argenx, an unrealized gain on securities of $0.6 billion, Actelion acquisition related costs of $0.2 billion and a restructuring charge of $0.1 billion. The Medical Devices segment includes a gain of $2.0 billion from the divestiture of the ASP business, a restructuring related charge of $0.4 billion, litigation expense of $0.4 billion and Auris Health acquisition related costs of $0.1 billion.

(4) The Consumer segment includes a gain of $0.3 billion from the divestiture of NIZORAL® and litigation expense of $0.3 billion. The Pharmaceutical segment includes an in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion, Actelion acquisition related costs of $0.2 billion, unrealized loss on securities of $0.2 billion and a gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products. The Medical Devices segment includes net litigation expense of $1.7 billion, a restructuring related charge of $0.6 billion, AMO acquisition related costs of $0.1 billion and a gain of $0.5
billion from the divestiture of the LifeScan business.

(5) The Pharmaceutical segment includes $0.8 billion for Actelion acquisition and integration related costs, an in-process research and development expense of $0.4 billion and litigation expense of $0.1 billion. The Medical Devices segment includes litigation expense of $1.1 billion, a restructuring related charge of $0.8 billion, an asset impairment of $0.2 billion primarily related to the insulin pump business and $0.1 billion for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(6) Long-lived assets include property, plant and equipment, net for 2019, and 2018 of $17,658 and $17,035, respectively, and intangible assets and goodwill, net for 2019 and 2018 of $81,282 and $78,064, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2019 and 2018 are summarized below:

(Dollars in Millions Except Per Share Data)	2019				2018			
	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,318	3,544	3,469	3,567	3,398	3,504	3,415	3,536
Pharmaceutical	10,244	10,529	10,877	10,548	9,844	10,354	10,346	10,190
Medical Devices	6,459	6,489	6,383	6,632	6,767	6,972	6,587	6,668
Total sales	20,021	20,562	20,729	20,747	20,009	20,830	20,348	20,394
Gross profit	13,406	13,622	13,862	13,613	13,395	13,903	13,759	13,433
Earnings before provision for taxes on income	4,422	7,041	1,647	4,218	5,481	4,973	4,423	3,122
Net earnings	3,749	5,607	1,753	4,010	4,367	3,954	3,934	3,042
Basic net earnings per share	$ 1.41	2.11	0.67	1.52	1.63	1.47	1.47	1.14
Diluted net earnings per share	$ 1.39	2.08	0.66	1.50	1.60	1.45	1.44	1.12

(1) The first quarter of 2019 includes a gain of $0.3 billion after-tax ($0.3 billion before-tax) related to the Company's previously held equity investment in DR. CI:LABO, an in-process research and development expense of $703 million after-tax ($890 million before-tax) related to the Alios asset, a litigation expense of $342 million after-tax ($423 million before-tax), an unrealized gain on securities of $125 million after-tax ($158 million before-tax), a restructuring related charge of $75 million after-tax ($90 million before-tax), and acquisition related costs of $60 million after-tax ($67 million before-tax).

(2) The second quarter of 2019 includes a gain of $1.5 billion after-tax ($2.0 billion before-tax) from the divestiture of the ASP business, a litigation expense of $342 million after-tax ($409 million before-tax), an unrealized gain on securities of $117 million after-tax ($148 million before-tax), a restructuring related charge of $116 million after-tax ($142 million before-tax) and acquisition related costs of $50 million after-tax ($55 million before-tax).

(3) The third quarter of 2019 includes a litigation expense of $3,080 million after-tax ($4,000 million before-tax) related to the agreement in principle to settle opioid litigation, a restructuring related charge of $106 million after-tax ($128 million before-tax), acquisition related costs of $88 million after-tax ($107 million before-tax), a $391 million benefit after-tax from the impact of tax legislation, and an unrealized loss on securities of $71 million after-tax ($89 million before-tax).

(4) The fourth quarter of 2019 includes a litigation expense of $251 million after-tax ($264 million before-tax), an unrealized gain on securities of $277 million after-tax ($350 million before-tax), a restructuring related charge of $214 million after-tax ($251 million before-tax), a $184 million benefit after-tax from the impact of tax legislation, and acquisition related costs of $82 million after-tax ($90 million before-tax).

(5) The first quarter of 2018 includes an Actelion acquisition related cost of $92 million after-tax ($96 million before-tax) and a restructuring related charge of $81 million after-tax ($107 million before-tax).

(6) The second quarter of 2018 includes a litigation expense of $609 million after-tax ($703 million before-tax) and a restructuring related charge of $152 million after-tax ($176 million before-tax).

(7) The third quarter of 2018 includes an in-process research and development expense of $859 million after-tax ($1,126 million before-tax) related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $184 million after and before tax, a restructuring related charge of $162 million after-tax ($190 million before-tax) and a $265 million benefit after-tax from the impact of tax legislation.

(8)

The fourth quarter of 2018 includes a litigation expense of $1,113 million after-tax ($1,288 million before-tax), a restructuring related charge of $190 million after-tax ($227 million before-tax) and a $137 million benefit after-tax from the impact of tax legislation.

20. Acquisitions and Divestitures

Certain businesses were acquired for $5.8 billion in cash and $1.4 billion of liabilities assumed during 2019. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2019 acquisitions primarily included: DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products; Auris Health, Inc. a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures and Taris Biomedical LLC a company specializing in the development of a novel drug delivery technology for the treatment of bladder diseases including cancer. The Company also acquired the assets of JointPoint, Inc., a privately held company, with navigation software to improve surgical outcomes in hip replacement.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $6.8 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. The acquisition was completed through a series of transactions that included an all-cash tender offer to acquire the publicly held shares not already held by the Company for ¥5,900 per share. The Company previously held a 20% ownership in DR. CI:LABO. As of June 2019, the Company became the legal owner of DR. CI:LABO with the completion of the tender offer procedure in Japan. The acquired company was then delisted from the Tokyo Stock Exchange. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer segment. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. At December 29, 2019, the fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities of $0.4 billion subject to any subsequent valuation adjustments within the measurement period. The adjustments made since the date of acquisition were $0.1 billion to intangible assets, accrued liabilities, deferred taxes on income and property, plant and equipment with the offset to goodwill. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On April 1, 2019 the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above, subject to any subsequent valuation adjustments within the measurement period. As of December 29, 2019 there were no valuation adjustments. The fair value of the contingent consideration was $1.1 billion. A probability of success factor ranging from 55% to 95% was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied was approximately 10%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On December 20, 2019, the Company announced the agreement to acquire Verily's stake in Verb Surgical Inc. The transaction closed in the fiscal first quarter of 2020 and Verb Surgical Inc. is now a subsidiary of Johnson & Johnson.

On December 30, 2019, subsequent to the fiscal year end, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction will be accounted for as a business combination and included in the Pharmaceutical segment.

During 2018 certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed during 2018. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2018 acquisitions primarily included: Zarbee's, Inc., a privately held company that is a leader in naturally-based consumer healthcare products; BeneVir Biopharm, Inc. (BeneVir), a privately-held, biopharmaceutical company specializing in the development of oncolytic immunotherapies and Orthotaxy, a privately-held developer of software-enabled surgery technologies, including a differentiated robotic-assisted surgery solution. The Company also acquired the assets of Medical Enterprises Distribution LLC, a privately held healthcare technology firm focused on surgical procedure innovation.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

During 2017 certain businesses were acquired for $35.2 billion in cash and $1.8 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd, an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34.4 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1.1 billion has been identified as the value of IPR&D, primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). In 2017 the Company held 9.9% of the shares of Idorsia and had rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. As a result of Idorsia raising additional capital in July 2018, the Company currently holds 9.0% of the shares of Idorsia and has rights to an additional 20.8% of Idorsia equity through a convertible loan with a carrying value and a principal amount of approximately $0.5 billion. The convertible loan may be converted into 38,715,114 Idorsia shares, subject to certain restrictions, as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. At the maturity of the loan, if the remaining amount has not yet been converted, Idorsia may elect to settle the remaining amount in cash or in ordinary shares of Idorsia. The equity investment in Idorsia and the convertible loan are recorded in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 3 of clinical development. The Company has also entered into an agreement to provide Idorsia with a Swiss franc denominated credit facility of approximately $250 million. As of December 29, 2019, Idorsia has not made any draw-downs under the credit facility. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion’s specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

During the fiscal second quarter of 2018, the Company finalized the purchase price allocation for Actelion to the individual assets acquired and liabilities assumed using the acquisition method. The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through the second quarter of 2018:

(Dollars in Millions)	
Cash & Cash equivalents	469
Inventory[1]	759
Accounts Receivable	485
Other current assets	93
Property, plant and equipment	104
Goodwill	6,161
Intangible assets	25,010
Deferred Taxes	99
Other non-current assets	19
Total Assets Acquired	33,199
Current liabilities	956
Deferred Taxes	1,776
Other non-current liabilities	413
Total Liabilities Assumed	3,145
Net Assets Acquired	30,054

[1] Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

The adjustments made since the date of acquisition were $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill. The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks*	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

*Includes $0.4 billion related to VALCHLOR®, one of the acquired products, which was divested in the fiscal second quarter of 2018.

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017, total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase

accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Actelion.

Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

(Dollars in Millions Except Per Share Data)	Unaudited Pro forma Consolidated Results 2017
Net Sales	77,681
Net Earnings	1,509
Diluted Net Earnings per Common Share	0.55

The Company recorded Actelion acquisition related costs before tax of approximately $0.2 billion, $0.2 billion and $0.8 billion in 2019, 2018 and 2017, respectively, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2019, 2018 and 2017 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

Divestitures

During 2019, the Company divested its Advanced Sterilization Products (ASP) business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.2 billion of inventory, $0.1 billion of property, plant and equipment, net and $0.3 billion of goodwill. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

During 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion.

In 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. The majority of the transfers were completed in 2019 with a minor amount remaining in 2020. As of December 29, 2019, the assets held for sale on the Consolidated Balance Sheet were $0.1 billion of inventory and property, plant and equipment, net. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.3 billion of inventory and $0.1 billion of property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 22 to the Consolidated Financial Statements.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

21. Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 29, 2019, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

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

PRODUCT LIABILITY

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

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of December 29, 2019, in the United States there were approximately 1,100 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 10,300 with respect to the PINNACLE® Acetabular Cup System; 17,600 with respect to pelvic meshes; 11,900 with respect to RISPERDAL®; 29,000 with respect to XARELTO®; 17,900 with respect to body powders containing talc; 400 with respect to INVOKANA®; and 3,300 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern

District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after

August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System and the related settlement program.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. The MDL Court is remanding cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved a majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. Orders determining the damages amounts to be awarded to the three Lead Applicants are expected in the first quarter of 2020. With respect to other group members, there will be an individual case assessment process which will require proof of use and causally related loss. The class actions in Canada are expected to be discontinued in 2020 as a result of a settlement of a group of cases, subject to court approval of the discontinuance. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending outside the United States.

Along with ETHICON PHYSIOMESH® lawsuits, there were a number of filings related to the PROCEED® Mesh and PROCEED® Ventral Patch products. In March 2019, the New Jersey Supreme Court entered an order consolidating all PROCEED® and PROCEED® Ventral Patch cases as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the US, and in jurisdictions outside the US. The Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch products. In

September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of 107 PROLENE™ Polypropylene Hernia System cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those will be transferred to an MCL in Atlantic County Superior Court.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent verdict in October 2019 of $8 billion of punitive damages related to one single plaintiff which was subsequently reduced in January 2020 to $6.8 million by the trial judge. The Company will appeal the final judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson (J&J); and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and J&J announced an agreement in principle to the settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, and the settlement became final in December 2019. This will resolve the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California, as well as outside the United States. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. In the multi-district litigation, the parties have moved to exclude experts, known as Daubert motions. The Court held Daubert hearings in mid-July 2019 and a final round of briefing has been submitted to the Court. The parties are awaiting a decision. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in July 2018 of $4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual primarily for defense costs in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. Based on such claims as well as indemnity and insurance claims the Company has against Imerys, the Company petitioned the United States District Court for the District of Delaware to establish federal jurisdiction of the state court talc lawsuits under the Bankruptcy Code. The Company's petition was denied and the state court talc lawsuits that have been removed to federal court on such basis have been remanded. The Company formally proposed to resolve Imerys' and the Company's obligations arising out of the Talc Claims by agreeing to assume the defense of litigation of all Talc Claims involving the Company's products, lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys, and waiving the Company's indemnification claims against Imerys. Discussions between Imerys and the Company on this issue remain ongoing.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily

JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss.

In October 2018, a shareholder derivative lawsuit was filed against Johnson & Johnson as the nominal defendant and its current directors as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In June 2019, the shareholder filed an additional

complaint initiating a summary proceeding in New Jersey state court for a books and records inspection. In August 2019, Johnson & Johnson responded to the books and records complaint and filed a cross motion to dismiss. In September 2019, Plaintiff replied and the Court heard oral argument. The Court has not yet ruled in the books and records action. In September 2019, the United States District Court for the District of New Jersey granted defendants' motion to dismiss the shareholder derivative lawsuit, and dismissed the complaint without prejudice. In October 2019, the shareholder filed a notice of appeal with the United States Court of Appeals for the Third Circuit. In January 2020, the shareholder voluntarily dismissed his appeal, with prejudice. Four additional shareholder derivative lawsuits have been filed in New Jersey making similar allegations against the Company and its current directors and certain officers.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. Defendants have filed a motion to dismiss.

A lawsuit is pending in the United States District Court for the Central District of California alleging violations of Proposition 65, California's Unfair Competition Law and False Advertising Law concerning JOHNSON'S® Baby Powder. In June 2019, plaintiffs filed a motion for voluntary dismissal of this Proposition 65 action and the Company opposed such motion to the extent it would allow plaintiffs' counsel to refile such claims with new plaintiffs. The Court granted plaintiff's motion conditioned upon payment of attorneys' fees and costs. The Court entered its award of attorneys' fees and costs in October 2019 and the case was dismissed without prejudice. Another lawsuit alleging violations of Proposition 65, California's Consumer Legal Remedies Act relating to JOHNSON'S® Baby Powder was filed in the Superior Court of California for the County of San Diego. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted, primarily on the basis that the plaintiffs failed to comply with Proposition 65's mandatory pre-suit notice requirement, which applies even when a plaintiff asserts only an indirect Proposition 65 claim. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the Securities and Exchange Commission and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company is cooperating with government inquiries and continues to produce documents in response.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

INTELLECTUAL PROPERTY

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

damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After the trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial. In March 2019, the district court denied Medinol's motion for a new trial. In April 2019, Medinol filed a notice of appeal.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants (collectively, DePuy). MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In January 2019, the district court stayed the case pending a decision in the Inter Partes Review proceeding on the '426 patent (see below). In December 2017, DePuy Synthes Products, Inc. filed a petition for Inter Partes Review with the United States Patent and Trademark Office (USPTO), seeking to invalidate the two claims of the '426 patent asserted in the district court litigation, and in June 2018, the USPTO instituted review of those claims. A hearing was held in March 2019, and in April 2019, the USPTO issued its decision upholding the validity of the patent. In May 2019, DePuy filed a motion for summary judgment of non-infringement of the claims of the '426 patent. In November 2019, judgment was entered in favor of Depuy. In December 2019, MedIdea filed a notice of appeal.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310 (the '310 patent); 9,084,608; 9,241,759 (the '759 patent) and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in October 2017. The parties have entered joint stipulations such that only the '310 patent and the '759 patent remain in dispute. Trial began in September 2019, and closing arguments will be heard in March 2020.

In December 2016, Dr. Ford Albritton sued Acclarent, Inc. (Acclarent) in United States District Court for the Northern District of Texas alleging that Acclarent's RELIEVA® Spin and RELIEVEA SpinPlus® products infringe U.S. Patent No. 9,011,412 (the '412 patent). Dr. Albritton also alleges breach of contract, fraud and that he is the true owner of Acclarent's U.S. Patent No. 8,414,473. In December 2016, Acclarent filed a petition for Inter Partes Review (IPR) with the United States Patent and Trademark Office (USPTO) challenging the validity of the '412 patent. The USPTO instituted the IPR in July 2017. In July 2018, the USPTO ruled in favor of Albritton in the IPR, finding that Acclarent had not met its burden of proof that the challenged claims were invalid. In October 2019, the Court of Appeals affirmed the USPTO's Patent Trial and Appeal Board. In June 2019, the parties filed cross motions for summary judgment in the district court and the parties are awaiting a decision. The district court trial is scheduled for April 2020.

In November 2017, Board of Regents, The University of Texas System and TissueGen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® PDS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 and 7,033,603 (the '603 patent) directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the USPTO, seeking Inter Partes Review (IPR) of both asserted patents. Those petitions have been stayed by the USPTO pending a decision by the U.S. Supreme Court in an unrelated case. UT dismissed the '603 patent from

the suit and no longer accuses PDS® Plus Antibacterial Sutures or STRATAFIX® PDS® Plus Antibacterial Sutures of infringement. The district court trial is scheduled for June 2020.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. ("Intuitive") filed a patent infringement suit against Auris Health, Inc. ("Auris") in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,246,200 ('200 patent); 6,491,701 ('701 patent); 6,522,906 ('906 patent); 6,800,056 ('056 patent); 8,142,447 ('447 patent); 8,620,473 ('473 patent); 8,801,601 ('601 patent); and 9,452,276 ('276 patent) based on Auris' Monarch™ Platform. Auris filed Petitions for Inter Partes Review with the USPTO regarding the '200, '056, '601 '701, '447, '276 and '906 patents. In December 2019, the USPTO instituted review of the '601 patent and denied review of the '056 patent. The district court trial is scheduled to begin in January 2021.

In August 2019, RSB Spine LLC ("RSB Spine") filed a patent infringement suit against DePuy Synthes, Inc. in United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of United States Patent Nos. 6,984,234 and 9,713, 537 by one or more of the following products: ZERO-P-VA™ Spacer, ZERO-P® Spacer, ZERO-P NATURAL™ Plate, SYNFIX® LR Spacer and SYNFIX® Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., Precision Spine, Inc., and Xtant Medical Holdings, Inc.

Pharmaceutical

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC, a Pfizer company (Searle) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the court's decision and the injunction is stayed pending the appeal. In January 2018, the court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU's ruling on the issue. In December 2019, the parties entered into a settlement agreement.

In April 2018, Acerta Pharma B.V., AstraZeneca UK Ltd and AstraZeneca Pharmaceuticals LP filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Pharmacyclics LLC and Abbvie Inc. (collectively, Abbvie), alleging that the manufacture and sale of IMBRUVICA® infringes U.S. Patent No. 7,459,554. Janssen Biotech, Inc., which commercializes IMBRUVICA® jointly with Abbvie, intervened in the action in November 2018. In October 2019, the parties entered into a settlement agreement.

REMICADE® Related Cases

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, Janssen Biotech, Inc. (JBI) filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the '471 patent) and United States Patent No. 7,598,083 (the '083 patent) directed to the cell culture media used to make Celltrion's biosimilar. In August 2016, the district court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the '471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of a decision by the USPTO's Patent Trial and Appeal Board affirming invalidity of the '471 patent.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the ’083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. JBI seeks monetary damages and other relief. In October 2017, the district court in the Massachusetts

action denied Celltrion and Hospira's motion to dismiss for lack of standing. In July 2018, the district court in the Massachusetts action granted Celltrion's motion for summary judgment of non-infringement and entered an order dismissing the '083 lawsuit against Celltrion and Hospira. JBI appealed to the United States Court of Appeals for the Federal Circuit, and Celltrion and Hospira cross-appealed on the standing issue. A hearing on the appeal and cross-appeal is scheduled for March 2020. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved the first infliximab biosimilar for sale in the United States in 2016, and a number of such products have been launched.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit (the main action) in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the '438 patent). The generic companies include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma).

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. (Glenmark) in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the '438 patent. These lawsuits were consolidated with the main action.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the '438 patent. This lawsuit has been consolidated with the main action.

In December 2017, Janssen and BTG entered into a settlement agreement with Glenmark.

In February 2018, Janssen and BTG filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively, MSN) in United States District Court for the District of New Jersey based on its ANDA seeking approval for a generic version of ZYTIGA® prior to the expiration of the '438 patent. In February 2019, the action was stayed pending the outcome of the main action.

In April 2018, Janssen and BTG entered into a settlement agreement with Apotex.

In October 2018, the United States District Court for the District of New Jersey issued a ruling invalidating all asserted claims of the ’438 patent. The court held that the patent claims would be infringed if the patent were valid. Janssen appealed the court’s decision.

In November 2018, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, Qilu), who filed an ANDA seeking approval to market a generic version of ZYTIGA® before the expiration of the ’438 patent. Janssen is seeking an order enjoining Qilu from marketing its generic version of ZYTIGA® before the expiration of the ’438 patent.

In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions finding the ’438 patent claims unpatentable, and Janssen requested rehearing. In December 2018, the USPTO denied Janssen’s request for rehearing of the IPR decisions. Janssen filed an appeal, which was consolidated with the above-mentioned appeal of the decision of the United States District Court for the District of New Jersey. In May 2019, the Federal Circuit issued a decision affirming the USPTO's decision in the Wockhardt IPR that the ’438 patent claims are unpatentable and dismissed the remaining appeals as moot. Subsequently, Janssen dismissed its lawsuits against MSN and Qilu.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422 (the ’422 patent). The final hearing concluded in May 2019. In October 2019, the court issued an order prohibiting the Canadian Minister of Health from approving Apotex’s ANDS until the expiration of the ’422 patent. In November 2019, Apotex filed an appeal.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA® before the expiration of the ’422 patent.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. (Pharmascience) and the Minister of Health in Canada in response to Pharmascience’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® 250 mg, before the expiration of the ’422 patent. The final hearing is scheduled to begin in October 2020.

In November 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience and the Minister of Health in Canada in response to Pharmascience’s filing of an ANDS seeking approval to market a generic version of ZYTIGA®, 500 mg, before the expiration of the ’422 patent. The final hearing is scheduled to begin in October 2020.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) and the Minister of Health in Canada in response to Sandoz’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. In July 2019, the parties entered into a settlement agreement.

In June 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. The final hearing is scheduled to begin in October 2020.

In each of these Canadian actions, Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to the defendants' ANDSs before the expiration of Janssen's patent.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). The trial concluded in April 2018. In July 2018 the district court entered judgment against Mylan and Sigmapharm, holding that the asserted compound patent is valid and infringed. In September 2018, the district court entered judgment against the remaining defendants. None of the defendants appealed the judgment.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (Alembic); Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin counterclaimed for declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent, Micro, Breckenridge, InvaGen, Sigmapharm, Lupin and Alembic have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The '218 cases have been consolidated for discovery and trial. The trial began in April 2019 and closing arguments were heard in June 2019.

In December 2018, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of Bayer AG's '218 patent. The case against Teva has been consolidated with the other '218 cases for all purposes, and Teva has agreed to have its case stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants.

In May 2018, Mylan filed a Petition for Inter Partes Review with the USPTO, seeking to invalidate the '218 patent. In December 2018, the USPTO issued a decision denying institution of Mylan's Petition for Inter Partes Review.

In May 2019, JPI and Bayer filed suit against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, Macleods) alleging infringement of the '218 patent. The case against Macleods has been consolidated with the other '218 cases for all purposes, and Macleods has agreed to have its case stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants.

In June 2019, JPI and Bayer filed suit against Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd. (collectively, Accord) alleging infringement of the '218 patent.

In August 2019, JPI and Bayer filed suit against Sunshine Lake Pharma Co., Ltd. and HEC Pharm USA Inc. alleging infringement of the '218 patent.

In October 2019, JPI and Bayer entered into a settlement agreement with Mylan. In November 2019, JPI and Bayer entered into a settlement agreement with Breckenridge. In December 2019, JPI and Bayer entered into settlement agreements with each of Accord, Micro, Sigmapharm, Sunshine, and Torrent. In January 2020, JPI and Bayer entered into a settlement agreement with Macleods.

The consolidated ’218 cases involving Alembic, Aurobindo, InvaGen, Lupin, Taro, and Teva, and have been stayed until March 2020.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

PREZISTA®

In May 2018, Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddys Laboratories, Inc., Dr. Reddys Laboratories, Ltd., Laurus Labs, Ltd. and Pharmaq, Inc. (collectively, DRL) who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. In February 2019, the parties entered into a settlement agreement.

In December 2018, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt Ltd., and Raks Pharma Pvt. Ltd. (collectively, Amneal), who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. In April 2019, the parties entered into a settlement agreement.

In January 2020, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of PREZISTA® before the expiration of United States Patent Nos. 7,700,645, 8,518,987, 7,126,015 and 7,595,408. Janssen is seeking an order enjoining Zydus from marketing its generic version of PREZISTA® before the expiration of the relevant patents.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent Nos. 7,943,582 (the '582 patent) and/or 8,513,202 (the '202 patent) relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin).

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent) relating to INVOKANA® and INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the '788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC's United States Patent No. 8,785,403 relating to INVOKAMET® (the '403 patent), and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent and the '219 patent relating to INVOKANA®. Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In April 2018, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Prinston, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent relating to INVOKANA®.

In February 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Lupin, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®.

In July 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the ’582 patent and ’202 patent relating to INVOKAMET XR®.

In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the ’788 patent. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against DRL, who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the ’788 patent.

Janssen and MTPC entered into settlement agreements with Prinston and InvaGen (June 2019), Hetero (July 2019) and Apotex and Teva (August 2019).

A trial on the ’582 and ’202 patents is scheduled to begin in April 2020, and a trial on the ’788, ’219 and ’403 patents is scheduled to begin in May 2020.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA®, INVOKAMET® and/or, INVOKAMET XR® before the expiration of the relevant patents.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), each of whom filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781 (the ’781 patent). In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent. Amneal and Zydus have stipulated to infringement. In February 2019, Actelion and Amneal entered into a settlement agreement. The trial against Zydus is scheduled to commence in October 2020.

In July 2019, Actelion Pharmaceuticals Ltd. filed suit against Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited (Aurobindo). Aurobindo filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of the ’781 patent. Actelion is seeking an order enjoining Defendants from marketing a generic version of OPSUMIT® before the expiration of the ’781 patent. Trial against Aurobindo is scheduled to commence in July 2021.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. Trial is scheduled to begin in June 2020.

In August 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the patent.

In December 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallincrodt PLC and Specgx LLC (collectively, Pharmascience), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 and 2,655,335. Janssen is seeking an order prohibiting the Minister of Health from issuing a

Notice of Compliance with respect to Teva's ANDS before the expiration of these patents. The final hearing is scheduled to begin in February 2020.

In each of these lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® 140 mg capsules before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). The trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting United States Patent No. 10,004,746.

In November 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Hetero Labs Limited, Hetero Labs Limited Unit-1, Hetero Labs Limited Unit-V, and Hetero USA Inc. (Hetero), who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 140 mg capsules, asserting infringement of United States Patent Nos. 8,754,090, 9,296,753, 9,540,382, 9,713,617 and 9,725,455.

In January 2019, Pharmacyclics and JBI amended their complaints against Fresenius Kabi, Zydus, Teva and Sandoz to further allege infringement of U.S. Patent Nos. 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the expiration of U.S. Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,540,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Hetero asserting infringement of United States Patent No. 10,106,548.

In February 2019, Pharmacyclics and JBI amended their complaints against Cipla, Shilpa, and Sun to allege infringement of United States Patent Nos. 10,106,548, and 10,125,140.

In February 2019, Pharmacyclics and JBI entered into settlement agreements with Teva and Hetero. In March 2019, Pharmacyclics and JBI entered into a settlement agreement with Shilpa.

In March 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (Alvogen), who filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, and 10,125,140.

In May 2019, Pharmacyclics and JBI amended their complaints against Cipla to further allege infringement of United States Patent No. 10,016,435. In June 2019, Pharmacyclics and JBI amended their complaints against Alvogen to further allege infringement of United States Patent No. 10,213,386.

In August 2019, Pharmacyclics and JBI amended their complaints against Cipla, Fresenius, and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232 and amended their complaint against Sun to further allege infringement of U.S. Patent No. 10,294,232.

In March 2019, Sandoz filed an Inter Partes Review (IPR) in the USPTO, seeking to invalidate United States Patent No. 9,795,604.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

TRACLEER®

In May 2019, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Natco Pharma Limited and Syneos Health LLC (collectively, Natco), who filed an ANDA seeking approval to market a generic version of TRACLEER®, 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). In the lawsuit, Actelion is seeking an order enjoining Natco from marketing its generic version of TRACLEER® before the expiration of the '126 patent. In November 2019, the parties entered into a settlement agreement.

In December 2019, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of TRACLEER®, 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). Actelion is seeking an order enjoining Zydus from marketing its generic version of TRACLEER® before the expiration of the '126 patent.

RISPERDAL CONSTA®

In July 2019, Janssen Pharmaceuticals, Inc., Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Luye Pharma Group Ltd., Luye Pharma (USA), Ltd., Nanjing Luye Pharmaceutical Co., Ltd. and Shandong Luye Pharmaceutical Co., Ltd. (collectively, Luye), who filed an ANDA seeking approval to market a generic version of RISPERDAL CONSTA® before the expiration of United States Patent No. 6,667,061. In November 2019, the parties entered into a settlement.

In this lawsuit, Janssen is seeking an order enjoining Luye from marketing a generic version of RISPERDAL CONSTA® before the expiration of the patent.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 2,800 lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA®

ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). Similar lawsuits have also been filed by the following groups of plaintiffs: individual plaintiffs on behalf of children suffering from Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, New

Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina; Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are more than 350 cases pending in various state courts. There are over 2,500 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In addition, the Province of British Columbia filed suit in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $572 million, subject to a final order to be issued by the court. The court issued a final judgment reducing the amount to $465 million. Johnson & Johnson and JPI have appealed the judgment. The Company believes that it has strong grounds to overturn this judgment. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these lawsuits, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties. The Company cannot predict if or when the agreement will be finalized and individual cases are ongoing, including a trial in New York scheduled to commence in March 2020.

In August 2019, Johnson & Johnson received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Johnson & Johnson received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. The Company is cooperating and producing documents in response to the various subpoenas and requests for information.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court, and fact discovery is currently scheduled to close in March 2020.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological

purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. In April 2019, Johnson & Johnson and Ethicon settled the Washington case. The California case started trial in July 2019 and concluded in September

2019. In January 2020, the court found in favor of the state and awarded the state civil penalties of approximately $344 million. The Company intends to appeal when further proceedings are concluded in the trial court. Similar complaints were filed against the companies by Kentucky in August 2016, by Mississippi in October 2017, by West Virginia in September 2019 and by Oregon in December 2019. The trial date for the Kentucky case was scheduled for September 2019 but has been adjourned and no new trial date has been scheduled. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD’s portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney’s Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants violated the Mississippi Consumer Protection Act by
failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The matter is stayed pending interlocutory appeal of a December 2018 denial of Johnson & Johnson and JJCI's motion for summary judgment. The Mississippi Supreme Court granted J&J and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019 and it will soon establish a briefing schedule. The Company has also received inquiries from several other State Attorneys General.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney’s Office for the Southern District of New York related to JPI’s contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In July 2016, Johnson & Johnson and Janssen Products LP were served with a *qui tam* complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA® and INTELENCE®, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. The United States District Court for the Central District of California dismissed the claim in April 2018. In May 2018, the relator filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. In January 2020, the U.S. Court of Appeals for the Ninth Circuit dismissed the relator's appeal.

In November 2018, a second whistleblower lawsuit was unsealed in the United States District Court for the Central District of California. The lawsuit was substantially similar to the lawsuit under appeal but was brought in the name of the original relator. The federal and state governments declined to intervene in the second suit, and the relator moved to dismiss the lawsuit without prejudice. In April 2019, the court granted the relator's motion and dismissed the complaint without prejudice.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®. In August 2019,

the Unites States Department of Justice notified Janssen Biotech, Inc. that it was closing the investigation. In January 2020, Janssen Biotech, Inc. was served with a newly-unsealed qui tam suit filed in the U.S. District Court for the District of Massachusetts.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The United States Department of Justice and the United States Securities and Exchange Commission have made additional inquiries, and Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. is cooperating with those requests.

In January 2020, the New Mexico Attorney General's Office filed a suit against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. in the First Judicial District Court, New Mexico. The suit relates to the safety and marketing of the Company's talc products. The State included claims for violations of the New Mexico Unfair Practices Act, Medicaid Fraud Act, Fraud Against Taxpayers Act, Fraud and Negligent Misrepresentation, Negligence and Unjust Enrichment. Other state Attorneys General have informed the Company that they are conducting an inquiry into this matter.

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

GENERAL LITIGATION

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed the complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015. In May 2019, US CBP issued its Mitigation Decision and determined that Janssen Ortho had negligently misrepresented that darunavir ethanolate is entitled to duty free treatment. In June 2019, Janssen Ortho filed a Supplemental Petition for Relief. The Penalties Proceeding will be impacted by the related Classification Litigation pending in the United States Court of International Trade. The Classification Litigation will determine whether darunavir ethanolate was properly classified as exempt from duties upon importation into the United States. The trial in the Classification Litigation was held in July 2019. In February 2020, the Court ruled that darunavir ethanolate is eligible for duty free treatment.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints

allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In December 2018, the district court granted the plaintiffs' motion for class certification. Defendants filed two motions for interlocutory appeal of class certification to the United States Court of Appeals for the Eleventh Circuit. Both motions were denied. Defendants' motions for summary judgment were denied in November 2019. Trial is scheduled for June 2020.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. Discovery is ongoing.

Beginning in September 2017, multiple purported class actions of direct and indirect purchasers were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation. Motions to dismiss were denied in both the direct and indirect purchaser cases. A motion to compel arbitration of the direct purchaser case was denied by the district court. The United States Court of Appeals for the Third Circuit reversed the district court's ruling.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In March 2019, summary judgment was granted in favor of Janssen. This ruling is on appeal to the United States Court of Appeals for the Third Circuit.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In January 2019, plaintiffs' motion to file a Second Amended Complaint adding plaintiffs to the lawsuit was granted. In April 2019, the Company moved to dismiss the Second Amended Complaint.

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

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District

Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug

reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. Janssen has moved to dismiss the complaint.

In April 2019, Blue Cross & Blue Shield of Louisiana and HMO Louisiana, Inc. filed a class action complaint against Janssen Biotech, Inc, Janssen Oncology, Inc, Janssen Research & Development, LLC and BTG International Limited in the United States District Court for the Eastern District of Virginia. Several additional complaints were filed thereafter. The complaints generally allege that the defendants violated the antitrust and consumer protections laws of several states and the Sherman Act
by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry. The case has been transferred to the United States District Court for the District of New Jersey and consolidated for pretrial purposes.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers-Squibb and Japan Tobacco. The case is pending in the United States District Court for the District of Northern California. The defendants have filed motions to dismiss the complaint.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. BWI filed a motion to dismiss the complaint.

The Company received notices from Pfizer, Inc. and Sanofi Consumer Health, Inc. in November 2019 and Boehringer Ingelheim Pharmaceuticals, Inc. in January 2020 tendering for defense and indemnification of legal claims related to personal injury matters and putative class actions in the U.S. and Canada related to Zantac (ranitidine) products. The notices were based on certain indemnification provisions regarding assumed liabilities in connection with the Stock and Asset Purchase Agreement between Pfizer, Inc. and the Company in 2006. Plaintiffs in the underlying suits allege generally that Zantac and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, for which plaintiffs are seeking injunctive and monetary relief.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 20 to the Consolidated Financial Statements. In 2019, the Company recorded a pre-tax charge of $0.6 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.2 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $0.8 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2019:

(Dollars in Millions)	Severance	Asset Write-offs	Other[2]	Total
Reserve balance, December 31, 2017	229	—	38	267
2018 activity	(35)	—	10	(25)
Reserve balance, December 30, 2018	194	—	48	242
Current year activity:				
Charges	—	151	460	611
Cash payments	(30)	—	(424)	(454)
Settled non cash	—	(151)	(68) [3]	(219)
Reserve balance, December 29, 2019[1]	$ 164	—	16	180

[1] Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Relates to pension related actuarial losses associated with the transfer of employees to Jabil Inc. as part of the strategic collaboration.

The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 29, 2019 and December 30, 2018, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three fiscal years in the period ended December 29, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 29, 2019 based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 29, 2019 and December 30, 2018, and the results of its operations and its cash flows for each of the three fiscal years in the period ended December 29, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 29, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control Over Financial Reporting, management has excluded Ci:z Holdings Co., Ltd., ("DR. CI:LABO") from its assessment of internal control over financial reporting as of December 29, 2019, because it was acquired by the Company in a business combination during 2019. We have also excluded DR. CI:LABO from our audit of internal control over financial reporting. DR. CI:LABO is wholly-owned subsidiary whose total assets, excluding intangible assets and goodwill, and total sales excluded from management's assessment and our audit of internal control over financial reporting represent less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended December 29, 2019.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and

dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. Pharmaceutical Rebate Reserves - Managed Care, Medicare and Medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.0 billion as of December 29, 2019. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the use of significant judgment by management due to the significant measurement uncertainty involved in developing these reserves. This in turn led to a high degree of auditor judgment and subjectivity and audit effort in applying procedures for the assumptions related to contractual terms with customers, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S., the terms of the specific rebate programs, and the historical trend of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimate to management's estimates.

Litigation Contingencies - Talc

As described in Notes 1 and 21 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the reasonably possible loss or range of loss. The

ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. There have been verdicts against the Company for this matter, including a verdict in July 2018 of $4.7 billion. As described by management, the Company believes

that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual primarily for defense costs in connection with product liability litigation associated with body powders containing talc.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the use of significant judgment by management when assessing the likelihood of a loss being incurred and management's determination of whether a reasonable estimate of the loss or range of loss for each claim can be made. This in turn led to a high degree of auditor judgment and effort in evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

Litigation - Opioids

As described in Notes 18 and 21 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including opioids, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the reasonably possible loss or range of loss. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. The Company has been named in numerous lawsuits brought by certain state and local governments related to opioids matters. The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against the Company in the amount of $572 million which was subsequently reduced to $465 million. The Company has appealed the judgment and, as described by management, believes that it has strong grounds to overturn this judgment. Separately in October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these lawsuits, subject to various conditions and an agreement being finalized. The Company cannot predict if or when the agreement will be finalized. The Company has recorded a pre-tax charge of $4 billion during the fiscal year ended December 29, 2019 for this matter.

The principal considerations for our determination that performing procedures relating to the opioids litigation is a critical audit matter are the use of significant judgment by management when assessing the likelihood of a loss being incurred for the judgment against the Company in Oklahoma and management's determination of whether a reasonable estimate of the range of loss for the proposed agreement in principle to settle opioids litigation can be made. This in turn led to a high degree of auditor judgment and effort in evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the opioid litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the opioids litigation; (ii) discussing the status of significant known actual and potential litigation and ongoing settlement negotiations with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and

external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP Florham Park, New Jersey February 18, 2020

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 29, 2019. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Ci:z Holdings Co., Ltd., (DR. CI:LABO), in a business combination during January 2019. DR. CI:LABO's total assets, excluding intangible assets and goodwill, and total sales represented less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended December 29, 2019. As the acquisition occurred in the fiscal year 2019, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2019 excluded the above mentioned acquisition. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 29, 2019, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 29, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2019, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2014 and December 31, 2009 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

jnj5yearshareholder2019.jpg

	2014	2015	2016	2017	2018	2019
Johnson & Johnson	$100.00	$101.16	$116.66	$145.13	$137.67	$159.99
S&P 500 Index	$100.00	$101.37	$113.49	$138.26	$132.19	$173.80
S&P Pharmaceutical Index	$100.00	$105.79	$104.13	$117.22	$126.71	$145.83
S&P Healthcare Equipment Index	$100.00	$105.97	$112.85	$147.71	$171.70	$222.04

10 Year Shareholder Return Performance J&J vs. Indices

jnj10yearshareholder2019.jpg

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Johnson & Johnson	$100.00	$99.42	$109.25	$121.08	$162.99	$191.25	$193.46	$223.10	$277.55	$263.30	$305.98
S&P 500 Index	$100.00	$115.06	$117.48	$136.27	$180.39	$205.06	$207.88	$232.73	$283.51	$271.06	$356.39
S&P Pharmaceutical Index	$100.00	$100.77	$118.67	$135.79	$183.63	$224.43	$237.41	$233.70	$263.08	$284.37	$327.28
S&P Healthcare Equipment Index	$100.00	$97.29	$96.51	$113.18	$144.52	$182.49	$193.40	$205.94	$269.56	$313.34	$405.21

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 29, 2019, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Delinquent Section 16(a) Reports" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 29, 2019 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	130,579,915	$90.31	314,776,315
Equity Compensation Plans Not Approved by Security Holders		-	-
Total	130,579,915	$90.31	314,776,315

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2019 and 2018

   Consolidated Statements of Earnings for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Comprehensive Income for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Equity for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Cash Flows for Fiscal Years 2019, 2018 and 2017

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 18, 2020

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 18, 2020
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 18, 2020
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 18, 2020
/s/ M. C. Beckerle M. C. Beckerle	Director	February 18, 2020
/s/ D. S. Davis D. S. Davis	Director	February 18, 2020
/s/ I. E. L. Davis I. E. L. Davis	Director	February 18, 2020
/s/ J. A. Doudna J. A. Doudna	Director	February 18, 2020

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 18, 2020
/s/ H. Joly H. Joly	Director	February 18, 2020
/s/ M. B. McClellan M. B. McClellan	Director	February 18, 2020
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 18, 2020
/s/ W. D. Perez W. D. Perez	Director	February 18, 2020
/s/ C. Prince C. Prince	Director	February 18, 2020
/s/ A. E. Washington A. E. Washington	Director	February 18, 2020
/s/ M. A. Weinberger M. A. Weinberger	Director	February 18, 2020
/s/ R. A. Williams R. A. Williams	Director	February 18, 2020

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report filed May 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for filed May 1, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated Effective January 1, 2010) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(p)	

	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(q)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(t)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(u)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(v)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

10-K 1 form10-k20181230.htm 10-K 2018

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 30, 2018 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: **(732) 524-0400**

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

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
0.250% Notes Due January 2022	New York Stock Exchange
0.650% Notes Due May 2024	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange
1.150% Notes Due November 2028	New York Stock Exchange
1.650% Notes Due May 2035	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $325 billion.

On February 15, 2019, there were 2,663,138,579 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;

- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;

- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;

- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;

- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;

- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;

- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and

- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;

-

Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;

- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;

- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and

- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;

- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;

- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;

- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and

- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Market conditions and the possibility that the Company's share repurchase program may be delayed, suspended or discontinued;

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;

- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;

- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of

goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;

- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;

- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company’s products; and

- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

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

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 260 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

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

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; NEUTROGENA® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases and Vaccines (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), INTELENCE® (etravirine), PREZISTA® (darunavir) and PREZCOBIX®/ REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/ tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV ; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/ XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults;

INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-

resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/ EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; and vision products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 260 operating companies located in more than 60 countries, including the U.S., which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

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

Raw Materials

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

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's 2nd largest product, STELARA® (ustekinumab), accounted for approximately 6.3% of the Company's total revenues for fiscal 2018. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA®. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the

United States. In the U.S., the latest projected expiration date for patents in this set is 2023 due to a patent term extension. In Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplemental Patent Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021.

In addition to competing in the immunology market with STELARA®, the Company is currently marketing SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to six years. The Company also markets REMICADE® (infliximab) in the immunology market which is the Company's largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

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

Seasonality

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

Competition

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

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

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

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com.* All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

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

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

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

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

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

Changes in tax laws or regulations around the world could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

On December 22, 2017, the U.S. enacted The Tax Cuts and Jobs Act (the TCJA), which introduced significant changes to U.S. corporate income tax law that will have a meaningful impact on the Company's provision for income taxes. Accounting for the income tax effects of the TCJA requires significant judgments to be made in interpreting its provisions. Anticipated guidance from the U.S. Treasury about implementing the TCJA, which should be final by June 22, 2019 (18 months after enactment),

may result in adjustments that could materially affect the Company's financial position and results of operations as well as the effective tax rate in the period in which the adjustments are made.

On September 28, 2018, the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform). However, a referendum has been called and, as a result, a public vote on the Swiss Tax Reform will take place on May 19th, 2019. If the Swiss Tax Reform passes, then the measures are expected to come into force in either January 2020 or January 2021. Prior to approval in the referendum and its subsequent cantonal implementation, the proposed Swiss Tax Reform is not enacted and therefore the Company has not reflected any of the potential impacts in its fiscal results. The Company is currently assessing the impact of the proposed Swiss Tax Reform, and when enacted, the law may have a material impact on the Company's operating results.

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

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

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

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

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

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product

candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or

less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

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

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2018 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

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

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

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company’s extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2018, approximately 49% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 8% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

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

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

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

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

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 111 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in

product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 111 manufacturing facilities occupying approximately 20.5 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,503
Pharmaceutical	6,819
Medical Devices	7,183
Worldwide Total	20,505

Within the U.S., five facilities are used by the Consumer segment, five by the Pharmaceutical segment and 27 by the Medical Devices segment. Outside of the U.S., 25 facilities are used by the Consumer segment, 14 by the Pharmaceutical segment and 35 by the Medical Devices segment.

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

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	37	5,855
Europe	34	7,587
Western Hemisphere, excluding U.S.	12	2,800
Africa, Asia and Pacific	28	4,263
Worldwide Total	111	20,505

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report.

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

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

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 “Legal Proceedings” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned “Item 1. Election of Directors” in the Proxy Statement.

Name	Age	Position
Joaquin Duato	56	Vice Chairman, Executive Committee[a]
Peter M. Fasolo	56	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	58	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	48	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Jorge Mesquita	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer[d]
Thibaut Mongon	49	Appointee, Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer[e]
Michael E. Sneed	59	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[f]
Paulus Stoffels	56	Vice Chairman, Executive Committee; Chief Scientific Officer[g]
Jennifer L. Taubert	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[h]
Michael H. Ullmann	60	Member, Executive Committee; Executive Vice President, General Counsel[i]
Kathryn E. Wengel	53	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[j]
Joseph J. Wolk	52	Member, Executive Committee; Executive Vice President, Chief Financial Officer[k]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman,

Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Mr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1997 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. She has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. J. Mesquita joined the Company in 2014 as Worldwide Chairman, Consumer. Prior to joining the Company, he served in various marketing and leadership capacities across Latin America, including roles in Oral Care and Beauty at The Procter & Gamble Company from 1984 to 2013. In April 2016, Mr. Mesquita became a member of the Executive Committee and was promoted to Executive Vice President, Worldwide Chairman, Consumer. Mr. Mesquita plans to retire from the Company in March 2019.

(e) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the consumer sector as Company Group Chairman Asia-Pacific. The Company has announced that Mr. Mongon will be named Executive Vice President and Worldwide Chairman, Consumer, and a member of the Executive Committee, upon the retirement of his predecessor, Mr. Mesquita, effective March 1, 2019. In addition to leading the Consumer business, Mr. Mongon will have responsibility for Johnson & Johnson Southeast Asia.

(f) Mr. M. E. Sneed joined the Company in 1986 as Product Director for Personal Products, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the corporation's global marketing, communication, design and philanthropy functions.

(g) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company’s innovation agenda across the Pharmaceutical, Medical Devices and Consumer sectors, product safety strategy, and the Company’s global public health strategy.

(h) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America

Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee.

(i) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

(j) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(k) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk is responsible for leading the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 15, 2019, there were 142,029 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases take place from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2018. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
October 1, 2018 through October 28, 2018	2,192,500	$ 138.74	-	-
October 29, 2018 through November 25, 2018	6,849,298	143.27	-	-
November 26, 2018 through December 30, 2018	18,130,189	139.10	7,073,136	32,131,870
Total	27,171,987			

[1] During the fiscal fourth quarter of 2018, the Company repurchased an aggregate of 27,171,987 shares of Johnson & Johnson Common Stock in open-market transactions, of which 7,073,136 shares were purchased pursuant to the repurchase program that was publicly announced on December 17, 2018, and of which 20,098,851 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

[2] As of December 30, 2018, an aggregate of 7,073,136 shares were purchased for a total of $0.9 billion since the inception of the repurchase program announced on December 17, 2018.

[3] As of December 30, 2018, the maximum number of shares that may yet be purchased under the plan is 32,131,870 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 28, 2018 of $127.27 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2008-2018*

(Dollars in Millions Except Per Share Amounts)	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008
Sales to customers — U.S.	$41,884	39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309
Sales to customers — International	39,697	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438
Total sales	81,581	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747
Cost of products sold	27,091	25,439	21,789	21,426	22,684	22,181	21,515	20,219	18,688	18,380	18,463
Selling, marketing and administrative expenses	22,540	21,520	20,067	21,079	21,887	21,650	20,697	20,800	19,296	19,712	21,431
Research and development expense	10,775	10,594	9,143	8,999	8,471	8,119	7,602	7,486	6,796	6,949	7,554
In-process research and development	1,126	408	29	224	178	580	1,163	—	—	—	181
Interest income	(611)	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)
Interest expense, net of portion capitalized	1,005	934	726	552	533	482	532	571	455	451	435
Other (income) expense, net	1,405	(42)	210	(1,783)	82	2,903	2,004	3,115	(488)	(333)	(885)
Restructuring	251	309	491	509	—	—	—	569	—	1,073	—
	63,582	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818
Earnings before provision for taxes on income	$17,999	17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929
Provision for taxes on income	2,702	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980
Net earnings	15,297	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	—	339	—	—	—	—
Net earnings attributable to Johnson & Johnson	15,297	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949
Percent of sales to customers	18.8%	1.7	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3
Diluted net earnings per share of common stock [(1)]	$5.61	0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57
Percent return on average shareholders' equity	25.5%	2.0	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4	30.2
Percent increase (decrease) over previous year:											
Sales to customers	6.7%	6.3	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3

Diluted net earnings per share	N/M	(92.1)%	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9
Supplementary balance sheet data:											
Property, plant and equipment, net	17,035	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365
Additions to property, plant and equipment	3,670	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066
Total assets	152,954	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912
Long-term debt	27,684	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120
Operating cash flow	22,201	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571	14,972
Common stock information											
Dividends paid per share	$3.54	3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795
Shareholders' equity per share	22.44	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35
Market price per share (year-end close)	$127.27	139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56
Average shares outstanding (millions)											
— basic	2,681.5	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5
— diluted	2,728.7	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6
Employees (thousands)	135.1	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7

(1) Attributable to Johnson & Johnson

* Per the adoption of ASU 2017-07 prior year amounts on the Consolidated Statement of Earnings have been reclassified to retroactively apply classification of the service cost component and the other components of net periodic benefit cost

N/M = Not Meaningful

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and vision fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

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

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2018 sales. In 2018, $10.8 billion was invested in research and development and $0.9 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success, is the 135,100 diverse employees that work across more than 260 operating companies, which are located in more than 60 countries. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

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Results of Operations

Analysis of Consolidated Sales

In 2018, worldwide sales increased 6.7% to $81.6 billion, compared to an increases of 6.3% and 2.6% in 2017 and 2016, respectively. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2018	2017	2016
Volume	8.5 %	8.0 %	3.2 %
Price	(2.2)	(2.0)	0.7
Currency	0.4	0.3	(1.3)
Total	**6.7 %**	**6.3 %**	**2.6 %**

In 2018, the net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 0.8%. In 2017, acquisitions and divestitures had a positive impact of 3.6% on the worldwide sales growth. In 2016, acquisitions and divestitures had a negative impact of 1.1% on the worldwide sales growth and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 0.8% on the worldwide sales growth. Operations in Venezuela negatively impacted the worldwide sales growth 0.3%.

Sales by U.S. companies were $41.9 billion in 2018, $39.9 billion in 2017 and $37.8 billion in 2016. This represents increases of 5.1% in 2018, 5.4% in 2017 and 6.0% in 2016. Sales by international companies were $39.7 billion in 2018, $36.6 billion in 2017 and $34.1 billion in 2016. This represents an increase of 8.5% in 2018, 7.4% in 2017, and a decrease of 0.9% in 2016.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.7%, 5.6% and 0.1%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.5%, 2.6% and 2.4%, respectively.

In 2018, sales by companies in Europe achieved growth of 9.5% as compared to the prior year, including operational growth of 6.2% and a positive currency impact of 3.3%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 1.2% as compared to the prior year, including operational growth of 8.2% and a negative currency impact of 7.0%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 10.5% as compared to the prior year, including operational growth of 9.4% and a positive currency impact of 1.1%.

In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues.

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Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2018 were $13.9 billion, an increase of 1.8% from 2017, which included 2.2% operational growth and a negative currency impact of 0.4%. U.S. Consumer segment sales were $5.8 billion, an increase of 3.5%. International sales were $8.1 billion, an increase of 0.7%, which included 1.4% operational growth and a negative currency impact of 0.7%. In 2018, acquisitions and divestitures had a net negative impact of 1.0% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	**2018**	**2017**	**2016**	**'18 vs. '17**	**'17 vs. '16**
Beauty	$ 4,382	4,200	3,897	4.3 %	7.8
OTC	4,334	4,126	3,977	5.0	3.7
Baby Care	1,858	1,916	2,001	(3.0)	(4.2)
Oral Care	1,555	1,531	1,568	1.6	(2.4)
Women's Health	1,049	1,050	1,067	(0.1)	(1.6)
Wound Care/Other	675	779	797	(13.4)	(2.3)
Total Consumer Sales	**$ 13,853**	**13,602**	**13,307**	**1.8 %**	**2.2**

The Beauty franchise sales of $4.4 billion increased 4.3% as compared to the prior year. Growth was primarily driven by NEUTROGENA®, OGX® and AVEENO® products as well as strength of DR. CI: LABO and DABAO® products outside the U.S. Growth was partially offset by the divestiture of NIZORAL®.

The Over-the-Counter (OTC) franchise sales of $4.3 billion increased 5.0% as compared to the prior year. Growth was primarily driven by share, consumption and market growth across multiple brands including ZYRTEC®, TYLENOL® and Children's MOTRIN®, as well as digestive health products and anti-smoking aids. Additionally, sales from the recent U.S. acquisition of Zarbee's Inc. contributed approximately 0.9% to growth.

The Baby Care franchise sales were $1.9 billion in 2018, a decrease of 3.0% compared to the prior year, primarily due to JOHNSON's® share decline and increased trade promotions due to the JOHNSON's® baby relaunch and the negative impact of currency. This was partially offset by strong growth of AVEENO® baby driven by geographic expansion.

The Oral Care franchise sales of $1.6 billion increased 1.6% as compared to the prior year, primarily driven by strong marketing campaigns and new product launches.

The Women's Health franchise sales were $1.0 billion in 2018, a decrease of 0.1% as compared to the prior year. Growth in Latin America was offset by the negative impact of currency.

The Wound Care/Other franchise sales were $0.7 billion in 2018, a decrease of 13.4% as compared to the prior year, primarily due to the divestiture of COMPEED®.

Consumer segment sales in 2017 were $13.6 billion, an increase of 2.2% from 2016, which included 1.3% operational growth and a positive currency impact of 0.9%. U.S. Consumer segment sales were $5.6 billion, an increase of 2.7%. International sales were $8.0 billion, an increase of 1.9%, which included 0.4% operational growth and a positive currency impact of 1.5%. In 2017, acquisitions and divestitures had a net positive impact of 1.8% on the operational sales growth of the worldwide Consumer segment.

Pharmaceutical Segment

Pharmaceutical segment sales in 2018 were $40.7 billion, an increase of 12.4% from 2017, which included operational growth of 11.8% and a positive currency impact of 0.6%. U.S. sales were $23.3 billion, an increase of 8.4%. International sales were $17.4 billion, an increase of 18.0%, which included 16.5% operational growth and a positive currency impact of 1.5%. In 2018, acquisitions and divestitures had a net positive impact of 3.4% on the operational sales growth of the worldwide Pharmaceutical segment.

Major Pharmaceutical Therapeutic Area Sales:*

				% Change	
(Dollars in Millions)	2018	2017	2016	'18 vs. '17	'17 vs. '16
Total Immunology	**$ 13,120**	**12,244**	**11,968**	**7.2 %**	**2.3**
REMICADE®	5,326	6,315	6,966	(15.7)	(9.3)
SIMPONI®/SIMPONI ARIA®	2,084	1,833	1,745	13.7	5.0
STELARA®	5,156	4,011	3,232	28.5	24.1
TREMFYA®	544	63	—	**	**
Other Immunology	10	22	25	(54.5)	(12.0)
Total Infectious Diseases	**3,304**	**3,154**	**3,208**	**4.8**	**(1.7)**
EDURANT®/rilpivirine	816	714	573	14.3	24.6
PREZISTA®/ PREZCOBIX®/REZOLSTA®/ SYMTUZA®	1,955	1,821	1,851	7.4	(1.6)
Other Infectious Diseases	533	619	784	(13.9)	(21.0)
Total Neuroscience	**6,077**	**5,986**	**6,085**	**1.5**	**(1.6)**
CONCERTA®/methylphenidate	663	791	863	(16.2)	(8.3)
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/ TREVICTA®	2,928	2,569	2,214	14.0	16.0
RISPERDAL CONSTA®	737	805	893	(8.4)	(9.9)
Other Neuroscience	1,749	1,821	2,115	(4.0)	(13.9)
Total Oncology	**9,844**	**7,258**	**5,807**	**35.6**	**25.0**
DARZALEX®	2,025	1,242	572	63.0	**
IMBRUVICA®	2,615	1,893	1,251	38.1	51.3
VELCADE®	1,116	1,114	1,224	0.2	(9.0)
ZYTIGA® /abiraterone acetate	3,498	2,505	2,260	39.6	10.8
Other Oncology	590	504	500	17.1	0.8
Pulmonary Hypertension	**2,573**	**1,327**	**—**	**93.9**	***
OPSUMIT®	1,215	573	—	**	***
TRACLEER®	546	403	—	35.5	***
UPTRAVI®	663	263	—	**	***
Other	149	88	—	69.3	***
Cardiovascular / Metabolism / Other	**5,816**	**6,287**	**6,396**	**(7.5)**	**(1.7)**
XARELTO®	2,477	2,500	2,288	(0.9)	9.3
INVOKANA®/ INVOKAMET®	881	1,111	1,407	(20.7)	(21.0)
PROCRIT®/EPREX®	988	972	1,105	1.6	(12.0)
Other	1,470	1,704	1,596	(13.7)	6.8
Total Pharmaceutical Sales	**$ 40,734**	**36,256**	**33,464**	**12.4 %**	**8.3**

* Prior year amounts have been reclassified to conform to current year presentation

** Percentage greater than 100% or not meaningful

***Products acquired from Actelion on June 16, 2017

Immunology products sales were $13.1 billion in 2018, representing an increase of 7.2% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease, strong launch uptake of TREMFYA® (guselkumab), expanded indications of SIMPONI®/SIMPONI ARIA® (golimumab), and the U.S. immunology market growth. Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the U.S., resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the U.S., a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.3 billion in 2018, representing an increase of 4.8% as compared to the prior year. Sales growth of PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), EDURANT®/rilpivirine, and the launch of SYMTUZA® and JULUCA® (dolutegravir/rilpivirine) was partially offset by lower sales of PREZISTA®(darunavir).

Neuroscience products sales were $6.1 billion, representing an increase of 1.5% as compared to the prior year. Strong sales of long-acting injectables INVEGA TRINZA®/TREVICTA®(paliperidone palmitate) and INVEGA SUSTENNA®/XEPLION® were partially offset by cannibalization of RISPERDAL CONSTA® (risperidone) and generic competition for CONCERTA®/methylphenidate.

Oncology products achieved sales of $9.8 billion in 2018, representing an increase of 35.6% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) with continued market growth and share gain, IMBRUVICA® (ibrutinib) due to increased patient uptake globally and sales of ZYTIGA® (abiraterone acetate) driven by LATITUDE data and market growth. Additionally, sales from the launch of ERLEADA™ (apalutamide) contributed to the growth. A number of companies marketing generic pharmaceuticals have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the U.S., seeking to market generic forms of ZYTIGA® prior to expiration of its applicable patents. These ANDAs include allegations of non-infringement and invalidity of the applicable patents. In October 2018, the Court issued a ruling invalidating all asserted claims of the applicable patent. Janssen has appealed the Court’s decision. In November 2018, the U.S. Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market, resulting in a decline in sales of ZYTIGA® in the United States. In 2018, the Company reported U.S. sales of $1.8 billion for ZYTIGA®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding ZYTIGA®.

The Pulmonary Hypertension therapeutic area was established with the acquisition of Actelion Ltd on June 16, 2017. Sales in 2018 represented a full year as compared to half a year in 2017. Sales of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were positively impacted by market growth and share gains while sales of TRACLEER® (bosetan) were negatively impacted by increased use of OPSUMIT® and generics.

Cardiovascular/Metabolism/Other products sales were $5.8 billion, a decline of 7.5% as compared to the prior year. Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. was primarily due to an increase in price discounts, higher rebates and market share decline driven by competitive pressure. Lower sales of XARELTO® (rivaroxaban) were driven by an increase in discounts and rebates, partially offset by an increase in market share.

During 2018, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
DARZALEX® (daratumumab)	Frontline multiple myeloma transplant ineligible patients in combination with bortezomib, melphalan, and prednisone	Ÿ	Ÿ		
erdafitinib	Treatment of locally advanced or metastatic urothelial cancer			Ÿ	
ERLEADA™ (apalutamide)	Treatment of non-metastatic castration-resistant prostate cancer	Ÿ			Ÿ
esketamine	Antidepressant for treatment-resistant depression in adults			Ÿ	Ÿ
IMBRUVICA® (ibrutinib)	Treatment of Waldenstrom's macroglobulinemia used in combination with rituximab	Ÿ			Ÿ
	Treatment for previously untreated Chronic Lymphocytic Leukemia in combination with obinutuzumab			Ÿ	Ÿ
INVOKANA® (canagliflozin)	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease. (CANVAS/CANVAS-R)	Ÿ	Ÿ		
JULUCA® (rilpivirine and dolutegravir)	Single-tablet, once-daily, two-drug regimen for the treatment of HIV-1 infection		Ÿ		
OPSUMIT® (macitentan)	Treatment of adults with inoperable chronic thromboembolic pulmonary hypertension to improve exercise capacity and pulmonary vascular resistance			Ÿ	Ÿ
STELARA® (ustekinumab)	Treatment of adults with moderately to severely active ulcerative colitis			Ÿ	Ÿ
SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide)	A complete darunavir-based single-tablet regimen for the treatment of HIV-1 infection	Ÿ			
TREMFYA® (guselkumab)	Patient controlled injector for the treatment of adults living with moderate to severe plaque psoriasis		Ÿ	Ÿ	
XARELTO® (rivaroxaban)	Treatment to reduce the risk of major cardiovascular events in people with chronic coronary or peripheral artery disease	Ÿ			
	For the prevention of venous thromboembolism for medically ill patients			Ÿ	
ZYTIGA® (abiraterone acetate)	Treatment of Hormone Naïve Metastatic Prostate Cancer	Ÿ			

Pharmaceutical segment sales in 2017 were $36.3 billion, an increase of 8.3% from 2016, which included operational growth of 8.0% and a positive currency impact of 0.3%. U.S. sales were $21.5 billion, an increase of 6.7%. International sales were $14.8 billion, an increase of 10.8%, which included 10.1% operational growth and a positive currency impact of 0.7%. In 2017, acquisitions and divestitures had a net positive impact of 3.8% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the reported Pharmaceutical segment operational growth by approximately 1.8%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Medical Devices Segment

The Medical Devices segment sales in 2018 were $27.0 billion, an increase of 1.5% from 2017, which included an operational increase of 1.1% and a positive currency impact of 0.4%. U.S. sales were $12.8 billion, an increase of 0.1% as compared to the prior year. International sales were $14.2 billion, an increase of 2.8% as compared to the prior year, with an operational increase of 1.9% and a positive currency impact of 0.9%. In 2018, acquisitions and divestitures had a net negative impact of 1.5% on the worldwide operational sales growth of the Medical Devices segment as compared to 2017.

Major Medical Devices Franchise Sales:*

				% Change	
(Dollars in Millions)	**2018**	**2017**	**2016**	**'18 vs. '17**	**'17 vs. '16**
Surgery	**$ 9,901**	**9,559**	**9,296**	**3.6 %**	**2.8**
Advanced	4,002	3,756	3,517	6.5	6.8
General	4,557	4,463	4,362	2.1	2.3
Specialty	1,342	1,340	1,417	0.1	(5.4)
Orthopaedics	**8,885**	**9,058**	**9,128**	**(1.9)**	**(0.8)**
Hips	1,418	1,394	1,361	1.7	2.4
Knees	1,502	1,523	1,524	(1.4)	(0.1)
Trauma	2,699	2,616	2,569	3.2	1.8
Spine & Other	3,266	3,525	3,674	(7.3)	(4.1)
Vision	**4,553**	**4,063**	**2,785**	**12.1**	**45.9**
Contact Lenses/Other	3,302	3,036	2,785	8.8	9.0
Surgical	1,251	1,027	—	21.8	**
Interventional Solutions [1]	**2,646**	**2,296**	**2,055**	**15.2**	**11.7**
Diabetes Care	**1,009**	**1,615**	**1,789**	**(37.5)**	**(9.7)**
Diagnostics [2]	**—**	**1**	**66**	***	***
Total Medical Devices Sales	**$ 26,994**	**26,592**	**25,119**	**1.5 %**	**5.9**

[1]Previously referred to as Cardiovascular

[2]On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) and amounts represent transitional service agreement that concluded in 2017.

* Prior year amounts have been reclassified to conform to current year presentation

**Products acquired from Abbott Medical Optics (AMO) on February 27, 2017

*** Percentage greater than 100% or not meaningful

The Surgery franchise sales were $9.9 billion in 2018, an increase of 3.6% from 2017. Growth in Advanced Surgery was primarily driven by endocutter, biosurgery and energy products. Growth in General Surgery was primarily driven by wound care products. Growth in Specialty Surgery was primarily driven by Advanced Sterilization Products.

The Orthopaedics franchise sales were $8.9 billion in 2018, a decrease of 1.9% from 2017. The decline in Spine & Other was primarily due to the Codman Neurosurgery divestiture and share loss in Spine partially offset by new product launches. The decline in knees was primarily due to competitive pressure in the U.S. partially offset by growth in Asia Pacific. Growth in hips and trauma was due to continued uptake of new products.

The Vision franchise achieved sales of $4.6 billion in 2018, an increase of 12.1% from 2017. Growth was primarily driven by strength of the astigmatism and daily disposable lenses in the OASYS® contact lenses category. Surgical growth was driven by cataract performance primarily outside the U.S.

The Interventional Solutions franchise (includes the Cerenovus business previously included in Spine and Other in Orthopaedics) sales were $2.6 billion, an increase of 15.2% from 2017. Strong growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

The Diabetes Care franchise sales were $1.0 billion, a decrease of 37.5% from 2017. The decline was primarily due to divestiture of its LifeScan business in the fiscal fourth quarter of 2018 and the Company's decision to exit the Animas insulin pump business in the fiscal fourth quarter of 2017.

The Medical Devices segment sales in 2017 were $26.6 billion, an increase of 5.9% from 2016, which included an operational increase of 5.7% and a positive currency impact of 0.2%. U.S. sales were $12.8 billion, an increase of 4.5% as compared to the prior year. International sales were $13.8 billion, an increase of 7.1% as compared to the prior year, with an

operational increase of 6.7% and a positive currency impact of 0.4%. In 2017, acquisitions and divestitures had a net positive impact of 4.2% on the worldwide operational sales growth of the Medical Devices segment as compared to 2016.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income was $18.0 billion, $17.7 billion and $19.8 billion for the fiscal years ended 2018, 2017 and 2016, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 22.1%, 23.1%, and 27.5% in 2018, 2017 and 2016, respectively.

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Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:*

% of Sales	2018	2017	2016
Cost of products sold*	33.2%	33.3	30.3
Percent point increase/(decrease) over the prior year	(0.1)	3.0	(0.3)
Selling, marketing and administrative expenses*	27.6%	28.1	27.9
Percent point increase/(decrease) over the prior year	(0.5)	0.2	(2.2)

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)

In 2018, cost of products sold as a percent to sales decreased to 33.2% from 33.3% as compared to the same period a year ago primarily due to lower inventory step-up costs related to the Actelion acquisition and favorable product and segment mix driven by a higher percentage of sales from the Pharmaceutical segment. This was mostly offset by higher amortization expense primarily related to the Actelion acquisition on June 16, 2017. Intangible asset amortization expense of $4.4 billion was included in cost of products sold for 2018 as compared to $3.0 billion in 2017. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2018 as compared to the prior year, primarily due to lower costs relative to sales growth in the Pharmaceutical business and favorable segment mix.

In 2017, cost of products sold as a percent to sales increased to 33.3% from 30.3% as compared to the same period a year ago. The unfavorable increase was primarily driven by $2.3 billion of higher amortization expense and charges for inventory step-up related to the recent acquisitions, primarily Actelion. Intangible asset amortization expense of $3.0 billion was included in cost of products sold for 2017 as compared to $1.2 billion in 2016. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2017 as compared to the prior year, primarily due to investments in new product launches partially offset by favorable mix.

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

(Dollars in Millions)	2018 Amount	2018 % of Sales**	2017 Amount	2017 % of Sales**	2016 Amount	2016 % of Sales**
Consumer	$ 565	4.1%	586	4.3	585	4.4
Pharmaceutical	8,446	20.7	8,392	23.1	7,001	20.9
Medical Devices	1,764	6.5	1,616	6.1	1,557	6.2
Total research and development expense	$ 10,775	13.2%	10,594	13.9	9,143	12.7
Percent increase/(decrease) over the prior year	1.7%		15.9		1.6	

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)
**As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2018, worldwide costs of research and development activities increased by 1.7% compared to 2017 but decreased as a percent of sales. The decrease as a percent of sales in the Pharmaceutical segment was attributable to lower costs relative to sales growth. The increased dollar spend in the Medical Devices and Pharmaceutical segments was for investment spending to advance the pipeline. In 2017, worldwide costs of research and development activities increased by 15.9% compared to 2016. The increase as a percent of sales was primarily in the Pharmaceutical segment due to general portfolio progression as well as collaborative agreements entered into with Idorsia Ltd. and Legend Biotech. Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In 2018, the Company recorded an IPR&D charge of $1.1 billion. Of the $1.1 billion, a partial impairment charge of $0.8 billion related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was calculated based on updated cash flow projections discounted for the inherent risk in the asset development and reflects the impact of the phase 2b clinical trial suspension, a decrease in the probability of success factors and the ongoing analysis of asset development activities. The Company continues to evaluate information with respect to the development program and will monitor the remaining $0.9 billion intangible asset for further impairment. In addition, an impairment charge of $0.3 billion was recorded for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1 Limited.

In 2017, the Company recorded an IPR&D charge of $0.4 billion primarily for the discontinuation of certain development projects related to Novira which was acquired in 2015. The product development was canceled due to safety concerns. In 2016, the Company recorded an IPR&D charge of $29 million for the discontinuation of a development program related to Crucell.

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

The change in other (income) expense, net for the fiscal year 2018 was an unfavorable change of $1.4 billion primarily due to litigation expense of $2.0 billion in 2018 as compared to $1.3 billion in 2017. Additionally, 2018 included unrealized losses on securities of $0.2 billion and lower realized gains of $0.4 billion related to investments in equity securities as compared to the prior year. This was partially offset by a reversal of a contingent liability of $0.2 billion and lower costs of $0.1 billion related to the Actelion and AMO acquisitions in 2018 as compared to 2017. The fiscal year of 2017 included a gain of $0.2 billion related to monetization of future royalty receivables offset by an asset impairment charge of $0.2 billion primarily related to the insulin pump business. Divestiture gains

were approximately $1.2 billion in 2018 and included the LifeScan business, NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. Divestiture gains were approximately $1.3 billion in 2017 and primarily included the Codman Neurosurgery and COMPEED® divestitures. Additionally, restructuring related expense in 2018 was $0.3 billion as compared to $0.4 billion 2017.

The change in other (income) expense, net for the fiscal year 2017 was a favorable change of $0.3 billion due to higher gains of $0.7 billion on the sale of assets/businesses, primarily the Codman Neurosurgery and COMPEED® divestitures, a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities as compared to the prior year. This was partially offset by higher litigation expense of $0.4 billion, $0.3 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of $0.2 billion primarily

related to the insulin pump business and a higher restructuring related charge of $0.2 billion as compared to the fiscal year 2016.

Interest (Income) Expense: Interest income was higher in 2018 as compared to 2017 due to a higher average interest rate and a benefit from net investment hedging partially offset by a lower average cash, cash equivalents and marketable securities balance during the period. Cash, cash equivalents and marketable securities totaled $19.7 billion at the end of 2018, and averaged $19.0 billion as compared to the cash, cash equivalents and marketable securities total of $18.3 billion and $30.1 billion average cash balance in 2017. The decrease in the average balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes, primarily the Actelion acquisition for $29.6 billion, net of cash acquired late in the fiscal second quarter of 2017.

Interest expense in 2018 was higher as compared to 2017 due to a higher average debt balance. The average debt balance was $32.5 billion in 2018 versus $30.9 billion in 2017. The total debt balance at the end of 2018 was $30.5 billion as compared to $34.6 billion at the end of 2017.

Interest income in 2017 increased slightly as compared to 2016 due to higher average interest rates partially offset by lower cash, cash equivalents and marketable securities balances during the period. Cash, cash equivalents and marketable securities totaled $18.3 billion at the end of 2017, and averaged $30.1 billion as compared to the $40.1 billion average cash balance in 2016. The decrease in the balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes including acquisitions, primarily the Actelion acquisition for $29.6 billion, net of cash acquired.

Interest expense in 2017 was higher as compared to 2016. The average debt balance was $30.9 billion in 2017 versus $23.5 billion in 2016. The total debt balance at the end of 2017 was $34.6 billion as compared to $27.1 billion at the end of 2016. The higher debt balance of approximately $7.5 billion was primarily due to increased borrowings. The Company increased borrowings in February and November of 2017, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, including the completion of the stock repurchase program.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**
Consumer	$ 2,320	2,524	13,853	13,602	16.7%	18.6
Pharmaceutical	12,568	11,083	40,734	36,256	30.9	30.6
Medical Devices	4,397	5,392	26,994	26,592	16.3	20.3
Total [1]	19,285	18,999	81,581	76,450	23.6	24.9
Less: Expenses not allocated to segments [2]	1,286	1,326				
Earnings before provision for taxes on income	$ 17,999	17,673	81,581	76,450	22.1%	23.1

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Segment: In 2018, the Consumer segment income before tax as a percent to sales was 16.7%, versus 18.6% in 2017. The decrease in the income before tax as a percent of sales in 2018 as compared to 2017 was primarily attributable to higher litigation expense of $0.3 billion in 2018 partially offset by slower increases in expenses relative to the increase in sales. Divestiture gains for the fiscal year of 2018, which included the divestitures of NIZORAL® and RoC® were comparable to fiscal year of 2017. A gain of $0.3 billion was recognized from the divestiture of NIZORAL®.

In 2017, the Consumer segment income before tax as a percent to sales was 18.6%, versus 18.3% in 2016. The increase in the income before tax as a percent of sales in 2017 as compared to 2016 was attributable to higher gains on divestitures, primarily the divestiture of COMPEED® in 2017. This was partially offset by higher selling, marketing and administrative expenses as compared to the prior year due to increased advertising and promotional spending and slightly higher amortization expense in 2017 related to acquisitions. Additionally, the fiscal year 2016 was negatively impacted by operations in Venezuela.

Pharmaceutical Segment: In 2018, the Pharmaceutical segment income before tax as a percent to sales was 30.9% versus 30.6% in 2017. The increase in the income before tax as a percent of sales was primarily due to lower inventory step-up costs related to Actelion of $0.6 billion, favorable product mix and slower increases in expenses relative to the increase in sales, a contingent liability reversal of $0.2 billion and higher divestiture gains of $0.2 billion from divestitures of certain non-strategic Pharmaceutical products. This was partially offset by higher amortization expense of $1.3 billion primarily related to the Actelion acquisition, a higher IPR&D charge of $0.7 billion and an unrealized loss on securities of $0.2 billion as compared to

the prior year. Additionally, 2017 included a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities.

In 2017, the Pharmaceutical segment income before tax as a percent to sales was 30.6% versus 38.3% in 2016. The decrease in the income before tax as a percent of sales was primarily due to $2.3 billion of higher amortization expense and other costs related to the Actelion acquisition, higher research and development expense, a higher IPR&D charge of $0.4 billion related to Novira and lower gains on divestitures as compared to the prior year. Additionally, the fiscal year 2016 included a positive adjustment of $0.5 billion to previous reserve estimates. This was partially offset by a gain of $0.2 billion related to monetization of future royalty receivables, a higher gain of $0.2 billion related to the sale of certain investments in equity securities and favorable product mix in 2017.

Medical Devices Segment: In 2018, the Medical Devices segment income before tax as a percent to sales was 16.3% versus 20.3% in 2017. The decrease in the income before tax as a percent to sales was primarily due higher litigation expense of $1.7 billion in 2018 as compared to $1.1 billion in 2017 and higher investments in the business in 2018. Additionally, 2018 had lower divestiture gains of approximately $0.3 billion as compared to divestiture gains in 2017. In 2018 the Company recorded a gain of $0.5 billion related to the LifeScan divestiture. This was partially offset by lower restructuring expense of $0.2 billion in 2018 as compared to 2017. Additionally, 2017 included an asset impairment charge of $0.2 billion primarily related to the insulin pump business.

In 2017, the Medical Devices segment income before tax as a percent to sales was 20.3% versus 22.2% in 2016. The decrease in the income before tax as a percent to sales was primarily due to $0.3 billion of higher amortization expense and other acquisition costs related to AMO, $0.3 billion of higher litigation, an asset impairment charge of $0.2 billion primarily related to the insulin pump business, $0.1 billion of higher restructuring and investments in new product launches as compared to the fiscal year 2016. This was partially offset by $0.8 billion higher gains in 2017 related to divestitures, primarily the divestiture of Codman Neurosurgery.

Restructuring: In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment. The Company has achieved approximately $0.7 billion of annualized pre-tax cost saving in 2018 and is on track to achieve the annualized pre-tax cost savings of $0.8 billion to $1.0 billion as outlined in the restructuring actions. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. In 2018, the Company recorded a pre-tax charge of $462 million, of which $46 million is included in cost of products sold and $227 million is included in other (income) expense. Total project costs of approximately $2.5 billion have been recorded since the restructuring was announced. This restructuring program was completed in the fiscal fourth quarter of 2018.

In the second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2018, the Company recorded a pre-tax charge of $238 million, of which $59 million is included in cost of products sold and $117 million is included in other (income) expense.

See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 15.0% in 2018, 92.6% in 2017 and 16.5% in 2016. The 2018 effective tax rate decreased by 77.6% as compared to 2017. The 2017 effective tax rate was primarily driven by a provisional tax charge of approximately $13.0 billion as a result of the Tax Cuts and Jobs Act (TCJA) recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. The Company also received a benefit in 2018 from a lower U.S. statutory tax rate vs. 2017 as well as favorable adjustments to the 2017 provisional TCJA tax charge partially offset by unfavorable income tax mix and the U.S. tax on global intangible low-taxed income (GILTI).

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the Tax Cuts and Jobs Act (TCJA) in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage

point increase to the effective tax rate. See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate, enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA and income taxes.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $18.1 billion at the end of 2018 as compared to $17.8 billion at the end of 2017. The primary sources and uses of cash that contributed to the $0.3 billion increase were approximately $22.2 billion of cash generated from operating activities. This was partially offset by $3.2 billion net cash used by investing activities, $18.5 billion net cash used by financing activities and $0.2 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $1.6 billion in marketable securities at the end of 2018 and $0.5 billion at the end of 2017. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $22.2 billion was the result of $15.3 billion of net earnings and $9.2 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, offset by $2.3 billion from net gains on sale of assets/businesses, deferred tax provision and accounts receivable allowances, $3.9 billion related to an increase in accounts receivable, inventories and other current and non-current assets and a decrease in other current and non-current liabilities. Additional sources of operating cash flow of $4.0 billion resulted from an increase in accounts payable and accrued liabilities. The decrease in current and non-current liabilities is primarily due to the 2018 tax payment related to TCJA.

Investing activities use of $3.2 billion was for additions to property, plant and equipment of $3.7 billion, the net purchase of investments primarily marketable securities of $1.3 billion, acquisitions, net of cash acquired of $0.9 billion (primarily the acquisitions of Zarbee's) and other uses of $0.5 billion. This was partially offset by $3.2 billion of proceeds from the disposal of assets/businesses (primarily the divestiture of LifeScan).

Financing activities use of $18.5 billion was primarily for dividends to shareholders of $9.5 billion, $5.9 billion for the repurchase of common stock, $3.9 billion for the net retirement of short and long-term debt and $0.2 billion of other financing. Financing activities also included sources of $1.0 billion of proceeds from stock options exercised/ employee withholding tax on stock awards, net.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash. As of December 30, 2018, $0.9 billion has been repurchased under the program.

As of December 30, 2018, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 30, 2018, the net debt position was $10.8 billion as compared to the prior year of $16.3 billion. There was a decrease in the net debt position due to retirement of debt. The debt balance at the end of 2018 was $30.5 billion as compared to $34.6 billion in 2017. Additionally there was a higher cash, cash equivalents and marketable securities balance at the end of 2018. In 2018, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs for the next twelve months. The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a new shelf registration on February 27, 2017 which will enable it to issue debt securities on a timely basis. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 30, 2018 market rates would increase the unrealized value of the Company's forward contracts by $57 million. Conversely, a 10% depreciation of the U.S. Dollar from the December 30, 2018

market rates would decrease the unrealized value of the Company's forward contracts by $69 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $226 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $8 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2018, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 12, 2019. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2018 and 2017 were $30.5 billion and $34.6 billion, respectively. The decrease in borrowings was due to the retirement of debt in 2018. In 2018, net debt (cash and current marketable securities, net of debt) was $10.8 billion compared to net debt of $16.3 billion in 2017. Total debt represented 33.8% of total capital (shareholders' equity and total debt) in 2018 and 36.5% of total capital in 2017. Shareholders' equity per share at the end of 2018 was $22.44 compared to $22.43 at year-end 2017.

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

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 30, 2018 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2019	$ —	2,636	949	92	223	3,900
2020	531	1,098	886	95	188	2,798
2021	812	1,796	841	101	154	3,704
2022	812	2,134	796	108	116	3,966
2023	1,522	1,553	764	115	76	4,030
After 2023	4,565	21,103	8,850	697	139	35,354
Total	**$ 8,242**	**30,320**	**13,086**	**1,208**	**896**	**53,752**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends

The Company increased its dividend in 2018 for the 56th consecutive year. Cash dividends paid were $3.54 per share in 2018 compared with dividends of $3.32 per share in 2017, and $3.15 per share in 2016.

Other Information

Critical Accounting Policies and Estimates

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

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which was adopted in 2018.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately
1.0% of annual net trade sales during the fiscal reporting years 2018, 2017 and 2016.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 2.0% of the total revenues and are included in sales to customers.

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

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

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 30, 2018 and December 31, 2017.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2018				
Accrued rebates [1]	$ 186	836	(751)	271
Accrued returns	68	98	(109)	57
Accrued promotions	481	2,233	(2,217)	497
Subtotal	$ 735	3,167	(3,077)	825
Reserve for doubtful accounts	31	10	(9)	32
Reserve for cash discounts	23	204	(204)	23
Total	$ 789	3,381	(3,290)	880
2017				
Accrued rebates[1]	$ 136	638	(588)	186
Accrued returns	65	128	(125)	68
Accrued promotions	358	2,148	(2,025)	481
Subtotal	$ 559	2,914	(2,738)	735
Reserve for doubtful accounts	24	10	(3)	31
Reserve for cash discounts	25	205	(207)	23
Total	$ 608	3,129	(2,948)	789

(1) Includes reserve for customer rebates of $57 million at December 30, 2018 and $48 million at December 31, 2017, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2018				
Accrued rebates [1]	$ 4,862	22,644	(19,996)	7,510
Accrued returns	362	385	(311)	436
Accrued promotions	35	46	(68)	13
Subtotal	$ 5,259	23,075	(20,375)	7,959
Reserve for doubtful accounts	77	37	(67)	47
Reserve for cash discounts	55	860	(862)	53
Total	$ 5,391	23,972	(21,304)	8,059
2017				
Accrued rebates [1]	$ 3,420	16,447	(15,005)	4,862
Accrued returns	334	256	(228)	362
Accrued promotions	—	69	(34)	35
Subtotal	$ 3,754	16,772	(15,267)	5,259
Reserve for doubtful accounts	38	40	(1)	77
Reserve for cash discounts	58	714	(717)	55

Total	$ 3,850	17,526	(15,985)	5,391

(1) Includes reserve for customer rebates of $89 million at December 30, 2018 and $90 million at December 31, 2017, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2018				
Accrued rebates[(1)]	$ 1,620	6,344	(6,746)	1,218
Accrued returns	152	362	(400)	114
Accrued promotions	83	116	(157)	42
Subtotal	$ 1,855	6,822	(7,303)	1,374
Reserve for doubtful accounts	183	29	(43)	169
Reserve for cash discounts	15	372	(387)	—
Total	$ 2,053	7,223	(7,733)	1,543
2017				
Accrued rebates[(1)]	$ 1,500	6,407	(6,287)	1,620
Accrued returns	127	729	(704)	152
Accrued promotions	32	135	(84)	83
Subtotal	$ 1,659	7,271	(7,075)	1,855
Reserve for doubtful accounts	190	27	(34)	183
Reserve for cash discounts	16	389	(390)	15
Total	$ 1,865	7,687	(7,499)	2,053

(1) Includes reserve for customer rebates of $632 million at December 30, 2018 and $501 million at December 31, 2017, recorded as a contra asset.

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

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

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

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

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

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

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 30, 2018.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2008 - 2018, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and in March 2017 the U.K. formally started the process for the U.K. to leave the E.U. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 30, 2018, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2018 would have increased or decreased the translation of foreign sales by approximately $390 million and net income by approximately $100 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in

which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted. On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform). However, a referendum has been called and, as a result, a public vote on the Swiss Tax Reform

will take place on May 19th, 2019. If the Swiss Tax Reform passes, then the measures are expected to come into force in either January 2020 or January 2021. Prior to approval in the referendum and its subsequent cantonal implementation, the proposed Swiss Tax Reform is not enacted and therefore the Company has not reflected any of the potential impacts in its fiscal results. The Company is currently assessing the impact of the proposed Swiss Tax Reform, and when enacted, the law may have a material impact on the Company's operating results.

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

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 15, 2019, there were 142,029 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 30, 2018 and December 31, 2017
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2018	2017
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	18,107	17,824
Marketable securities (Notes 1 and 2)		1,580	472
Accounts receivable trade, less allowances for doubtful accounts $248 (2017, $291)		14,098	13,490
Inventories (Notes 1 and 3)		8,599	8,765
Prepaid expenses and other receivables		2,699	2,537
Assets held for sale (Note 20)		950	—
Total current assets		**46,033**	**43,088**
Property, plant and equipment, net (Notes 1 and 4)		17,035	17,005
Intangible assets, net (Notes 1 and 5)		47,611	53,228
Goodwill (Notes 1 and 5)		30,453	31,906
Deferred taxes on income (Note 8)		7,640	7,105
Other assets		4,182	4,971
Total assets	**$**	**152,954**	**157,303**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	2,796	3,906
Accounts payable		7,537	7,310
Accrued liabilities		7,601	7,304
Accrued rebates, returns and promotions		9,380	7,210
Accrued compensation and employee related obligations		3,098	2,953
Accrued taxes on income (Note 8)		818	1,854
Total current liabilities		**31,230**	**30,537**
Long-term debt (Note 7)		27,684	30,675
Deferred taxes on income (Note 8)		7,506	8,368
Employee related obligations (Notes 9 and 10)		9,951	10,074
Long-term taxes payable (Note 8)		8,242	8,472
Other liabilities		8,589	9,017
Total liabilities		**93,202**	**97,143**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,222)	(13,199)
Retained earnings		106,216	101,793
		94,114	91,714
Less: common stock held in treasury, at cost (Note 12) (457,519,000 shares and 437,318,000 shares)		34,362	31,554
Total shareholders' equity		**59,752**	**60,160**
Total liabilities and shareholders' equity	**$**	**152,954**	**157,303**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)*

	2018	2017	2016
Sales to customers	$ 81,581	76,450	71,890
Cost of products sold	27,091	25,439	21,789
Gross profit	54,490	51,011	50,101
Selling, marketing and administrative expenses	22,540	21,520	20,067
Research and development expense	10,775	10,594	9,143
In-process research and development	1,126	408	29
Interest income	(611)	(385)	(368)
Interest expense, net of portion capitalized (Note 4)	1,005	934	726
Other (income) expense, net	1,405	(42)	210
Restructuring (Note 22)	251	309	491
Earnings before provision for taxes on income	17,999	17,673	19,803
Provision for taxes on income (Note 8)	2,702	16,373	3,263
Net earnings	**$ 15,297**	**1,300**	**16,540**
Net earnings per share (Notes 1 and 15)			
Basic	**$ 5.70**	**0.48**	**6.04**
Diluted	**$ 5.61**	**0.47**	**5.93**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,681.5**	**2,692.0**	**2,737.3**
Diluted	**2,728.7**	**2,745.3**	**2,788.9**

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2018	2017	2016
Net earnings	$ 15,297	1,300	16,540
Other comprehensive income (loss), net of tax			
Foreign currency translation	(1,518)	1,696	(612)
Securities: [1]			
Unrealized holding gain (loss) arising during period	(1)	159	(52)
Reclassifications to earnings	1	(338)	(141)
Net change	—	(179)	(193)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(44)	2	21
Gain (loss), net of amortization	(56)	29	(862)
Effect of exchange rates	92	(201)	159
Net change	(8)	(170)	(682)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(73)	(4)	(359)
Reclassifications to earnings	(192)	359	110
Net change	(265)	355	(249)
Other comprehensive income (loss)	(1,791)	1,702	(1,736)
Comprehensive income	$ 13,506	3,002	14,804

[1] 2018 includes the impact from adoption of ASU 2016-01. For further details see Note 1 to the Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal years ended 2018, 2017 and 2016 respectively: Foreign Currency Translation $236 million in 2018 due to the enactment of the U.S. Tax Cuts and Jobs Act; Securities: $0 million, $96 million and $104 million, Employee Benefit Plans: $4 million, $83 million and $346 million, Derivatives & Hedges: $70 million, $191 million and $134 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2016	**$ 71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**
Net earnings	16,540	16,540			
Cash dividends paid ($3.15 per share)	(8,621)	(8,621)			
Employee compensation and stock option plans	2,130	(1,181)			3,311
Repurchase of common stock	(8,979)				(8,979)
Other	(66)	(66)			
Other comprehensive income (loss), net of tax	(1,736)		(1,736)		
Balance, January 1, 2017	**70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid ($3.32 per share)	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment	(486)	(254) [1]	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**$ 59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**

(1) See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2018	2017	2016
Cash flows from operating activities				
Net earnings	$	15,297	1,300	16,540
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		6,929	5,642	3,754
Stock based compensation		978	962	878
Asset write-downs		1,258	795	283
Gain on sale of assets/businesses		(1,217)	(1,307)	(563)
Deferred tax provision		(1,016)	2,406	(341)
Accounts receivable allowances		(31)	17	(11)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(1,185)	(633)	(1,065)
(Increase)/Decrease in inventories		(644)	581	(249)
Increase in accounts payable and accrued liabilities		3,951	2,725	656
Increase in other current and non-current assets		(275)	(411)	(529)
(Decrease)/Increase in other current and non-current liabilities		(1,844)	8,979	(586)
Net cash flows from operating activities		**22,201**	**21,056**	**18,767**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,670)	(3,279)	(3,226)
Proceeds from the disposal of assets/businesses, net		3,203	1,832	1,267
Acquisitions, net of cash acquired (Note 20)		(899)	(35,151)	(4,509)
Purchases of investments		(5,626)	(6,153)	(33,950)
Sales of investments		4,289	28,117	35,780
Other (primarily intangibles)		(464)	(234)	(123)
Net cash used by investing activities		**(3,167)**	**(14,868)**	**(4,761)**
Cash flows from financing activities				
Dividends to shareholders		(9,494)	(8,943)	(8,621)
Repurchase of common stock		(5,868)	(6,358)	(8,979)
Proceeds from short-term debt		80	869	111
Retirement of short-term debt		(2,479)	(1,330)	(2,017)
Proceeds from long-term debt, net of issuance costs		5	8,992	12,004
Retirement of long-term debt		(1,555)	(1,777)	(2,223)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		949	1,062	1,189
Other		(148)	(188)	(15)
Net cash used by financing activities		**(18,510)**	**(7,673)**	**(8,551)**
Effect of exchange rate changes on cash and cash equivalents		(241)	337	(215)
Increase/(Decrease) in cash and cash equivalents		283	(1,148)	5,240
Cash and cash equivalents, beginning of year (Note 1)		17,824	18,972	13,732
Cash and cash equivalents, end of year (Note 1)	**$**	**18,107**	**17,824**	**18,972**
Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	1,049	960	730
Interest, net of amount capitalized		963	866	628

Income taxes	4,570	3,312	2,843

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	2,095	2,062	2,043
Conversion of debt		6	16	35
Acquisitions				
Fair value of assets acquired	$	1,047	36,937	4,586
Fair value of liabilities assumed and noncontrolling interests		(148)	(1,786)	(77)
Net cash paid for acquisitions	**$**	**899**	**35,151**	**4,509**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and vision fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2014-09: Revenue from Contracts with Customers

On January 1, 2018, the Company adopted the new accounting standard, ASC 606, Revenue from Contracts with Customers and all the related amendments (new revenue standard) to all contracts using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was recognized as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. The adoption of the new revenue standard has not had a material impact to either reported Sales to customers or Net earnings. Additionally, the Company will continue to recognize revenue from product sales as goods are shipped or delivered to the customer, as control of goods transfers at the same time.

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on the Company's Consolidated Statement of Earnings and Balance Sheet was as follows:

Statement of Earnings - For the fiscal year ended December 30, 2018

(Dollars in millions)	As Reported	Effect of change	Balance without adoption of ASC 606
Sales to customers	$ 81,581	(35)	81,546
Net earnings	15,297	(28)	15,269

Balance Sheet - As of December 30, 2018

	As Reported	Effect of change	Balance without adoption of ASC 606
Assets	152,954	23	152,977
Liabilities	93,202	4	93,206
Equity	$ 59,752	19	59,771

The Company made a cumulative effect adjustment to the 2018 opening balance of retained earnings upon adoption of ASU 2014-09, which decreased beginning retained earnings by $47 million.

As part of the adoption of ASC 606 see Note 18 to the Consolidated Financial Statements for further disaggregation of revenue.

ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities
The Company adopted this standard as of the beginning of the fiscal year 2018 on a modified retrospective basis. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net earnings. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income.

The Company made a cumulative effect adjustment to the opening balance of retained earnings upon adoption of ASU 2016-01 that increased retained earnings by $232 million net of tax and decreased accumulated other comprehensive income for previously unrealized gains from equity investments. For additional details see Note 6 to the Consolidated Financial Statements.

ASU 2016-16: Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory
The Company adopted this standard as of the beginning of the fiscal year 2018. This update removes the current exception in U.S. GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. As discussed further in Note 8 to the Consolidated Financial Statements, in the fourth fiscal quarter of 2018 the Company elected an accounting policy to treat the tax on global intangible low-taxed income (GILTI) under the deferred tax accounting model. As a result, the Company is required to record an additional deferred tax liability related to the basis difference of these intra-entity asset transfers. The Company recorded net adjustments including an increase to deferred tax assets of approximately $2.0 billion, an increase to deferred tax liabilities of approximately $1.7 billion, related to the GILTI accounting policy election in the fourth fiscal quarter of 2018, a decrease to Other Assets of approximately $0.7 billion and a decrease to retained earnings of approximately $0.4 billion. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2017-01: Clarifying the Definition of a Business
The Company adopted this standard as of the beginning of the fiscal year 2018. This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update was applied prospectively. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2017-07: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost
The Company adopted this standard as of the beginning of the fiscal year 2018. This update requires that an employer disaggregate the service cost component from the other components of net periodic benefit cost (NPBC). In addition, only the service cost component will be eligible for capitalization. The amendments in this update are required to be applied retrospectively for the presentation of the service cost component and the other components of NPBC in the Consolidated Statement of Earnings and prospectively, on and after the adoption date, for the capitalization of the service cost component of NPBC in assets. As required by the transition provisions of this update, the following table shows the impact of the adoption on the respective line items in the Consolidated Statement of Earnings for 2018 and the reclassifications to the 2017 and 2016 fiscal year Consolidated Statement of Earnings to retroactively apply classification of the service cost component and the other components of NPBC:

(Dollars In millions)	Increase (Decrease) to Net Expense		
	2018	2017	2016
Cost of products sold	$ 51	85	104
Selling, marketing and administrative expenses	55	100	122
Research and development expense	21	40	48
Other (income) expense, net	(127)	(225)	(274)
Earnings before provision for taxes on income	$ —	—	—

The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of the new accounting standards mentioned above:

(Dollars in Millions)	Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$ (47)
ASU 2016-01 - Financial Instruments	232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers	(439)
Total	$ (254)

ASU 2017-12: Targeted Improvements to Accounting for Hedging Activities
The Company elected to early adopt this standard as of the beginning of the fiscal second quarter of 2018. This update makes more financial and nonfinancial hedging strategies eligible for hedge accounting. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. For additional required disclosures see Note 6 to the Consolidated Financial Statements.

Recently Issued Accounting Standards
Not Adopted as of December 30, 2018
ASU 2018-18: Collaborative Arrangements
This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2018-16: Derivatives and Hedging (Topic ASC 815)
This update adds the Overnight Index Swap (OIS) rate based on the Secured Overnight Financing Rate (SOFR) as an eligible benchmark interest rate permitted in the application of hedge accounting. This update will be effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted if an entity has adopted ASU 2017-12. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income
This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017. This update will be effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses
This update introduces the current expected credit loss (CECL) model, which will require an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity will be required to recognize an allowance that reflects the entity’s current estimate of credit losses expected to be incurred over the life of the financial instrument. This update will be effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2016-02: Leases
This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and

lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company will apply the new standard at its adoption date rather than at the earliest comparative period

presented in the financial statements. The Company's operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

Cash Equivalents

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

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

Investments

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

Property, Plant and Equipment and Depreciation

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

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

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

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

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

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to

customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2018, 2017 and 2016.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 2.0% of the total revenues and are included in sales to customers.

Shipping and Handling

Shipping and handling costs incurred were $1,090 million, $1,042 million and $974 million in 2018, 2017 and 2016, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

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

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2018 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

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

Financial Instruments

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

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

Product Liability

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

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

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

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

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

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

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

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

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

Advertising
Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.6 billion, $2.5 billion and $2.4 billion in 2018, 2017 and 2016, respectively.

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

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

In the fourth fiscal quarter of 2018, the Company has elected to account for the GILTI tax under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to

repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 for further information regarding income taxes.

Net Earnings Per Share

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

Use of Estimates

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

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

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2018 and 2017, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2018			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,619	2,619	2,619	—
U.S. Reverse repurchase agreements	3,009	3,009	3,009	—
Other Reverse repurchase agreements	443	443	443	—
Money market funds	3,397	3,397	3,397	—
Time deposits[1]	485	485	485	—
Subtotal	$ 9,953	9,953	9,953	—
Gov't Securities	$ 9,474	9,474	8,144	1,330
Corporate debt securities	260	260	10	250
Subtotal available for sale[2]	$ 9,734	9,734	8,154	1,580
Total cash, cash equivalents and current marketable securities			**$ 18,107**	**1,580**

In 2018, the carrying amount was the same as the estimated fair value.
In 2017, the carrying amount was the same as the estimated fair value.

(Dollars in Millions)	2017			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,929	2,929	2,929	—
Other Sovereign Securities[1]	279	279	219	60
U.S. Reverse repurchase agreements	4,025	4,025	4,025	—
Corporate debt securities[1]	289	289	244	45
Money market funds	4,288	4,288	4,288	—
Time deposits[1]	1,176	1,176	1,175	1
Subtotal	$ 12,986	12,986	12,880	106
Gov't Securities	$ 4,864	4,864	4,833	31
Other Sovereign Securities	186	186	80	106
Corporate debt securities	260	260	31	229
Subtotal available for sale[2]	$ 5,310	5,310	4,944	366
Total cash, cash equivalents and current marketable securities			**$ 17,824**	**472**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

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

The contractual maturities of the available for sale debt securities at December 30, 2018 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 9,670	9,670
Due after one year through five years	64	64
Due after five years through ten years	—	—
Total debt securities	$ 9,734	9,734

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

3. Inventories

At the end of 2018 and 2017, inventories were comprised of:

(Dollars in Millions)	2018		2017
Raw materials and supplies	$ 1,114		1,140
Goods in process	2,109		2,317
Finished goods	5,376		5,308
Total inventories	**$ 8,599**	(1)	**8,765**

[1] Net of assets held for sale on the Consolidated Balance Sheet for approximately $0.2 billion related to the divestiture of the Advanced Sterilization Products business and $0.3 billion related to the strategic collaboration with Jabil Inc., both of which were pending as of December 30, 2018.

4. Property, Plant and Equipment

At the end of 2018 and 2017, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2018		2017
Land and land improvements	$ 807		829
Buildings and building equipment	11,176		11,240
Machinery and equipment	25,992		25,949
Construction in progress	3,876		3,448
Total property, plant and equipment, gross	$ 41,851		41,466
Less accumulated depreciation	24,816		24,461
Total property, plant and equipment, net	**$ 17,035**	(1)	**17,005**

(1) Net of assets held for sale on the Consolidated Balance Sheet for approximately $0.1 billion related to the divestiture of the Advanced Sterilization Products business and $0.1 billion related to the strategic collaboration with Jabil Inc., both of which were pending as of December 30, 2018.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2018, 2017 and 2016 was $86 million, $94 million and $102 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2018, 2017 and 2016 was $2.6 billion, $2.6 billion and $2.5 billion, respectively.

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

5. Intangible Assets and Goodwill

At the end of 2018 and 2017, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2018	2017
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 35,194	36,427
Less accumulated amortization	9,784	7,223
Patents and trademarks — net	**$ 25,410**	**29,204**
Customer relationships and other intangibles — gross	$ 21,334	20,204
Less accumulated amortization	8,323	7,463
Customer relationships and other intangibles — net	**$ 13,011**	**12,741**
Intangible assets with indefinite lives:		
Trademarks	$ 6,937	7,082
Purchased in-process research and development(1)	2,253	4,201
Total intangible assets with indefinite lives	**$ 9,190**	**11,283**
Total intangible assets — net	**$ 47,611**	**53,228**

(1) The decrease was primarily attributable to the write-down of $1.1 billion related to the assets acquired in the acquisitions of Alios Biopharma Inc. (Alios) and XO1 Limited (XO1). Of the $1.1 billion, the Company recorded a partial impairment charge of $0.8 billion related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios. The impairment charge was calculated based on updated cash flow projections discounted for the inherent risk in the asset development and reflects the impact of the phase 2b clinical trial suspension, a decrease in the probability of success factors and the ongoing analysis of asset development activities. In addition, an impairment charge of $0.3 billion was recorded for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1. Additionally, $0.8 billion of IPR&D related to ERLEADA™ was reclassified to definite lived intangible assets upon commercialization.

Goodwill as of December 30, 2018 and December 31, 2017, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at January 1, 2017	$ 8,263	2,840	11,702	22,805
Goodwill, related to acquisitions [1]	102	6,161	2,200	8,463
Goodwill, related to divestitures	(74)	(1)	(102)	(177)
Currency translation/other	584	109	122	815
Goodwill at December 31, 2017	$ 8,875	9,109	13,922	31,906
Goodwill, related to acquisitions	168	51	184	403
Goodwill, related to divestitures	—	—	(1,348) [2]	(1,348)
Currency translation/other	(373)	(97)	(38)	(508)
Goodwill at December 30, 2018	**$ 8,670**	**9,063**	**12,720**	**30,453**

[1] Goodwill of $6.2 billion related to the Actelion acquisition acquired in the fiscal second quarter of 2017, within the Pharmaceutical segment and $1.7 billion related to the AMO acquisition acquired in the fiscal first quarter of 2017, within the Medical Devices segment.
[2] Goodwill of $1.0 billion is related to the divestiture of the LifeScan business. Goodwill of $0.3 billion is related to the divestiture of the Advanced Sterilization Products business, which was pending and classified as assets held for sale on the Consolidated Balance Sheet as of December 30, 2018.

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 11 years and 22 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $4.4 billion, $3.0 billion and $1.2 billion before tax, for the fiscal years ended December 30, 2018, December 31, 2017 and January 1, 2017, respectively. The estimated amortization expense for the five succeeding years approximates $4.3 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

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

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

The Company early adopted ASU 2017-12: Targeted Improvements to Accounting for Hedge Activities effective as of the beginning of fiscal second quarter of 2018.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 30, 2018, the total amount of collateral paid under the credit support agreements (CSA) amounted to $182 million net. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 30, 2018, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.1 billion, $7.3 billion, and $0.5 billion respectively. As of December 31, 2017, the Company had

notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $34.5 billion, $2.3 billion, and $1.1 billion respectively.

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

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

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

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

As of December 30, 2018, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $195 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 30, 2018 and December 31, 2017:

	December 30, 2018					December 31, 2017				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$ —	—	—	5	—	—	—	—	5	—
Derivatives designated as hedging instruments	—	—	—	(5)	—	—	—	—	(5)	—
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	56	—	—	—	—	—	—
Amount of gain or (loss) recognized in AOCI	—	—	—	56	—	—	—	—	—	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income [1]	47	200	(220)	—	(24)	(31)	(159)	(165)	—	(87)
Amount of gain or (loss) recognized in AOCI [1]	(32)	(17)	(193)	—	(4)	49	96	(199)	—	(60)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	133	—	—	—	—	83	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	117	—	—	—	—	110	—

[1] Includes equity collar contracts. The equity collar contracts expired in December of 2017.

For the fiscal years ended December 30, 2018 and December 31, 2017, the following amounts were recorded on the Consolidated Balance Sheet

Line item in the Consolidated Balance Sheet in which the hedged item is included	**Carrying Amount of the Hedged Liability**		**Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability**	
(Dollars in Millions)	December 30, 2018	December 31, 2017	December 30, 2018	December 31, 2017
Current Portion of Long-term Debt	$ 494	597	5	2

Long-term Debt	—	496	—	3

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 30, 2018 and December 31, 2017:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 30, 2018	December 31, 2017
Foreign Exchange Contracts	Other (income) expense	(68)	(5)

The following table is the effect of net investment hedges for the fiscal years ended December 30, 2018 and December 31, 2017:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
	Fiscal Nine Months Ended				
	December 30, 2018	December 31, 2017		December 30, 2018	December 31, 2017
Debt	$ 218	(597)	Other (income) expense	—	—
Cross Currency interest rate swaps	$ 150	—	Other (income) expense	—	—

The Company adopted ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities as of the beginning of the fiscal year 2018. This ASU amends prior guidance to classify equity investments with readily determinable market values into different categories (that is, trading or available-for-sale) and require equity investments to be measured at fair value with changes in fair value recognized through net earnings. The Company made a cumulative effect adjustment to the opening balance of retained earnings upon adoption of ASU 2016-01 which increased retained earnings by $232 million, net of tax, and decreased accumulated other comprehensive income for previously net unrealized gains from equity investments.

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

The following table is a summary of the activity related to equity investments as of December 30, 2018:

(Dollars in Millions)	December 31, 2017			December 30, 2018	
	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/ Other [2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 751	(247)	7	511	511
Equity Investments without readily determinable value	$ 510	13	158	681	681

[1] Recorded in Other Income/Expense

[2] Other includes impact of currency

For equity investments without readily determinable market values, $54 million of the changes in fair value reflected in net income were the result of impairments. There were $67 million of changes in fair value reflected in net income due to changes in observable prices.

For the fiscal years ended December 31, 2017, changes in fair value reflected within other comprehensive income due to previously unrealized gains on equity investments with readily determinable fair values net of tax was a net gain of $232 million.

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

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of December 30, 2018 and December 31, 2017 were as follows:

	2018				2017
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	501	—	501	418
Interest rate contracts [2][4]	—	161	—	161	7
Total	—	**662**	—	**662**	**425**
Liabilities:					
Forward foreign exchange contracts	—	548	—	548	402
Interest rate contracts [3][4]	—	292	—	292	165
Total	—	**840**	—	**840**	**567**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	32	—	32	38
Liabilities:					
Forward foreign exchange contracts	—	32	—	32	38
Available For Sale Other Investments:					
Equity investments[5]	511	—	—	511	751
Debt securities[6]	$ —	9,734	—	9,734	5,310

Gross to Net Derivative Reconciliation		2018	2017
(Dollars in Millions)			
Total Gross Assets	$	694	463
Credit Support Agreement (CSA)		(423)	(76)
Total Net Asset		271	387
Total Gross Liabilities		872	605
Credit Support Agreement (CSA)		(605)	(238)
Total Net Liabilities	$	267	367

(1) 2017 assets and liabilities are all classified as Level 2 with the exception of equity investments of $751 million, which are classified as Level 1.

(2) Includes $6 million and $7 million of non-current assets for the fiscal years ending December 30, 2018 and December 31, 2017, respectively.

(3) Includes $3 million and $9 million of non-current liabilities for the fiscal years ending December 30, 2018 and December 31, 2017, respectively.

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

(5) Classified as non-current other assets. The carrying amount of the equity investments were $511 million and $751 million as of December 30, 2018 and December 31, 2017, respectively.

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

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

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2018	Effective Rate %	2017	Effective Rate %
5.15% Debentures due 2018	$ —		900	5.18
1.65% Notes due 2018	—		597	1.70
4.75% Notes due 2019 (1B Euro 1.14)[2]/(1B Euro 1.1947)[3]	1,139 [2]	5.83	1,192 [3]	5.83
1.875% Notes due 2019	494	1.93	496	1.93
0.89% Notes due 2019	300	1.32	300	1.75
1.125% Notes due 2019	699	1.13	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	51	3.00	60	3.00
2.95% Debentures due 2020	548	3.15	547	3.15
1.950% Notes due 2020	499	1.99	499	1.99
3.55% Notes due 2021	449	3.67	448	3.67
2.45% Notes due 2021	349	2.48	349	2.48
1.65% Notes due 2021	998	1.65	998	1.65
0.250% Notes due 2022 (1B Euro 1.14)[2]/(1B Euro 1.1947)[3]	1,137 [2]	0.26	1,191 [3]	0.26
2.25% Notes due 2022	996	2.31	995	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	805	3.17	806	3.17
2.05% Notes due 2023	498	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.14) [2]/(750MM Euro 1.1947)[3]	851 [2]	0.68	891 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.2636) [2]/(500MM GBP 1.3444)[3]	627 [2]	6.75	666 [3]	6.75
2.625% Notes due 2025	748	2.63	747	2.63
2.45% Notes due 2026	1,992	2.47	1,990	2.47
2.95% Notes due 2027	996	2.96	995	2.96
1.150% Notes due 2028 (750MM Euro 1.14) [2]/(750MM Euro 1.1947)[3]	847 [2]	1.21	887 [3]	1.21
2.900% Notes due 2028	1,493	2.91	1,492	2.91
6.95% Notes due 2029	297	7.14	296	7.14
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	856	4.24	856	4.24
1.650% Notes due 2035 (1.5B Euro 1.14)[2]/ (1.5B Euro 1.1947)[3]	1,693 [2]	1.68	1,774 [3]	1.68
3.55% Notes due 2036	988	3.59	987	3.59
5.95% Notes due 2037	991	5.99	991	5.99
3.625% Notes due 2037	1,486	3.64	1,486	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	990	3.42	990	3.42
4.50% Debentures due 2040	538	4.63	538	4.63
4.85% Notes due 2041	297	4.89	296	4.89
4.50% Notes due 2043	495	4.52	495	4.52
3.70% Notes due 2046	1,972	3.74	1,971	3.74
3.75% Notes due 2047	991	3.76	990	3.76

3.500% Notes due 2048	742	3.52	742	3.52
Other	24	—	75	—
Subtotal	**30,320** (4)	**3.19 %** (1)	**32,174** (4)	**3.19** (1)
Less current portion	2,636		1,499	
Total long-term debt	**$ 27,684**		**30,675**	

(1) Weighted average effective rate.

(2) Translation rate at December 30, 2018.

(3) Translation rate at December 31, 2017.

(4) The excess of the fair value over the carrying value of debt was $0.3 billion in 2018 and $2.0 billion in 2017.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.(Level 2)

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2018, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 12, 2019. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2018, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.8 billion at the end of 2018, of which $2.6 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2017, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.9 billion at the end of 2017, of which $2.3 billion was borrowed under the Commercial Paper Program, $1.5 billion is the current portion of the long-term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2019 are:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023
$2,636	1,098	1,796	2,134	1,553	21,103

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2018	2017	2016
Currently payable:			
U.S. taxes	$ 1,081	11,969	1,896
U.S. taxes on international operations	203	126	49
International taxes	2,434	1,872	1,659
Total currently payable	3,718	13,967	3,604
Deferred:			
U.S. taxes	(148)	(1,956)	294
U.S. taxes on international operations	1,358		
International taxes	(2,226)	4,362	(635)
Total deferred	(1,016)	2,406	(341)
Provision for taxes on income	**$ 2,702**	**16,373**	**3,263**

A comparison of income tax expense at the U.S. statutory rate of 21% in 2018 and 35% in 2017 and 2016, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2018	2017	2016
U.S.	$ 5,575	4,865	7,457
International	12,424	12,808	12,346
Earnings before taxes on income:	$ 17,999	17,673	19,803
Tax rates:			
U.S. statutory rate	21.0 %	35.0	35.0
International operations [1]	(3.7)	(12.8)	(17.2)
Research and orphan drug tax credits	(1.0)	(0.4)	(0.4)
U.S. state and local	0.8	0.6	(0.1)
U.S. manufacturing deduction	—	(0.8)	(0.6)
U.S. tax on international income [2]	1.4	0.7	1.3
Tax benefits on share-based compensation	(1.5)	(2.1)	(1.8)
U.S. tax benefit on asset/business disposals	0.5	(0.8)	—
All other	(0.6)	(0.1)	0.3
TCJA and related impacts [3]	(1.9) [3]	73.3 [4]	—
Effective Rate	15.0 %	92.6	16.5

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to the 2017 TCJA provisional tax charge. This also includes a net tax benefit from the reduction of a deferred tax liability related to foreign withholding taxes originally accrued as part of the provisional charge. This benefit reduced the Company's effective tax rate by approximately 11%. Further description is included below.
(4) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate.

On December 22, 2017, the United States enacted into law new U.S. tax legislation, the Tax Cuts and Jobs Act (TCJA).
This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest and these payments began in 2018 and will continue through 2025. The remaining balance at the end of the fiscal year 2018 was approximately $8.2 billion.

In December 2017, the SEC provided regulatory guidance for accounting of the impacts of the TCJA, referred to as SAB 118. Under the guidance in SAB 118, the income tax effects, which the accounting under ASC 740 is incomplete, are reported as a provisional amount based on a reasonable estimate. The reasonable estimate is subject to adjustment during a "measurement period", not to exceed one year, until the accounting is complete. The estimate is also subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provision of the TCJA, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries and the filing of tax returns.

In the fourth quarter of 2017, the Company recorded a provisional tax cost of approximately $13.0 billion which consisted primarily of the following components:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings
- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on unrecognized tax benefits

- a $0.1
  billion charge for U.S. state and local taxes on the repatriation of these foreign earnings

During the fourth quarter of 2018, the Company completed its full assessment and finalized the accounting for the impact of TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying

interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This 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 provisional charge in the fourth quarter of 2017.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). Through the third fiscal quarter of 2018, the Company had provisionally elected to treat GILTI as a period expense. Upon further analysis of this new tax provision, the Company has elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred. As a result of this election, the Company recorded a deferred tax cost related to GILTI of approximately $1.4 billion in the fourth fiscal quarter of 2018 related to facts and circumstances that existed on the date of TCJA enactment.

As a result of the GILTI deferred tax charge and the other adjustments to the provisional amount, the Company recorded a total of $1.6 billion of adjustments to the 2017 provisional charge increasing the Company's annual effective tax rate by approximately 9%.

During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring in the fourth quarter 2018, and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. As this restructuring occurred after the TCJA enactment date, the benefit is not considered an adjustment to the provisional amount recorded in 2017 under SAB118. This benefit with the SAB 118 adjustments has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.

As described in Note 1 to the Consolidated Financial Statements, in 2018 the Company adopted ASU 2016-16: *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory.* This standard requires entities to recognize deferred tax assets and liabilities related to transfer of assets, other than inventory, within the consolidated entity. At the beginning of fiscal 2018, the Company recorded a net adjustment to deferred tax assets of approximately $2.0 billion. In the fourth quarter of 2018, as a result of the election to record GILTI on the deferred method, the Company recorded a GILTI deferred tax liability of $1.7 billion related to the adoption provisions of ASU 2016-16 as an adjustment to retained earnings.

The 2018 effective tax rate decreased by 77.6% compared to 2017. The 2017 effective tax rate was primarily driven by the approximately $13 billion provisional tax charge recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. Additional drivers of the 2018 annual effective tax were:

- the reduction of the U.S. statutory corporate tax rate including the effects of tax elections which resulted in the acceleration of certain deductions into the 2017 tax return. The impact of these accelerated deductions decreased the annual effective tax rate by approximately 1.7%
- the impact of the adjustments to the 2017 provisional TCJA charge, including both SAB 118 adjustments and the internal restructuring, decreased the effective tax rate by approximately 1.9%
- GILTI tax which increased the annual effective tax rate by approximately 1.6%, which excludes the impact of the SAB 118 adjustment for the adoption of the deferred method for GILTI
- tax benefits received from stock-based compensation during fiscal 2018 and 2017, reduced the effective tax rate by 1.5% and 2.0%, respectively
- in the fourth quarter of 2018, the Company completed the divestiture of its LifeScan business (Note 20), which increased the Company annual effective tax rate by approximately 0.8%
- more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2017

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the TCJA in the U.S. in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

Temporary differences and carryforwards for 2018 and 2017 were as follows:

	2018 Deferred Tax		2017 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,398		2,259	
Stock based compensation	639		507	
Depreciation & amortization	1,784			(9)
Non-deductible intangibles		(5,967)		(6,506)
International R&D capitalized for tax	1,282		1,307	
Reserves & liabilities	1,647		1,718	
Income reported for tax purposes	1,104		1,316	
Net operating loss carryforward international	786		762	
Undistributed foreign earnings	693	(2,240)	1,101	(4,457)
Global intangible low-taxed income		(2,971)		
Miscellaneous international	603	(93)	755	(194)
Miscellaneous U.S.	469		177	
Total deferred income taxes	**$ 11,405**	**(11,271)**	**9,902**	**(11,166)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

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

(Dollars in Millions)	**2018**	**2017**	**2016**
Beginning of year	$ 3,151	3,041	3,080
Increases related to current year tax positions	242	332	348
Increases related to prior period tax positions	145	232	11
Decreases related to prior period tax positions	(137)	(416) [1]	(338)
Settlements	(40)	(2)	(37)
Lapse of statute of limitations	(35)	(36)	(23)
End of year	**$ 3,326**	**3,151**	**3,041**

[1] In 2017, $347 million of this decrease is related to the TCJA

The unrecognized tax benefits of $3.3 billion at December 30, 2018, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit during 2019. Final conclusion of the tax audit may result in an outcome that is different than the Company's estimates and may result in a material impact on the Company's current and future operating results or cash flows in the period that the audit is concluded. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $53 million, $60 million and $7 million in 2018, 2017 and 2016, respectively. The total amount of accrued interest was $503 million and $436 million in 2018 and 2017, respectively.

9. Employee Related Obligations

At the end of 2018 and 2017, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2018	2017
Pension benefits	$ 5,327	5,343
Postretirement benefits	2,283	2,331
Postemployment benefits	2,330	2,250
Deferred compensation	410	475
Total employee obligations	10,350	10,399
Less current benefits payable	399	325
Employee related obligations — non-current	**$ 9,951**	**10,074**

Prepaid employee related obligations of $475 million and $526 million for 2018 and 2017, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit Plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

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

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2018 and 2017 the Company used December 31, 2018 and December 31, 2017, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2018, 2017 and 2016 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2018	2017	2016	2018	2017	2016
Service cost	$ 1,283	1,080	949	269	247	224
Interest cost	996	927	927	148	159	158
Expected return on plan assets	(2,212)	(2,041)	(1,962)	(7)	(6)	(6)
Amortization of prior service cost (credit)	3	2	1	(31)	(30)	(34)
Recognized actuarial losses	852	609	496	123	138	135
Curtailments and settlements	1	17	11	—	—	—
Net periodic benefit cost	**$ 923**	**594**	**422**	**502**	**508**	**477**

In 2018, as per the adoption of ASU 2017-07, the service cost component of net periodic benefit cost was presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings.

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	656
Amortization of prior service credit	27

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2018**	**2017**	**2016**	**2018**	**2017**	**2016**
Net Periodic Benefit Cost						
Service cost discount rate	3.20%	3.59	3.98	3.85	4.63	4.77
Interest cost discount rate	3.60%	3.98	4.24	3.62	3.94	4.10
Rate of increase in compensation levels	3.98%	4.01	4.02	4.29	4.31	4.32
Expected long-term rate of return on plan assets	8.46%	8.43	8.55			
Benefit Obligation						
Discount rate	3.76%	3.30	3.78	4.40	3.78	4.42
Rate of increase in compensation levels	3.97%	3.99	4.02	4.29	4.30	4.29

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. In the fiscal year 2016, the Company changed its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change does not impact the benefit obligation and did not have a material impact to the 2016 full year results.

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

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

Health Care Plans	2018	2017
Health care cost trend rate assumed for next year	6.12%	6.33%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.55%	4.55%
Year the rate reaches the ultimate trend rate	2038	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 28	(22)
Post-retirement benefit obligation	$ 340	(280)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2018 and 2017 for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	Retirement Plans 2018	Retirement Plans 2017	Other Benefit Plans 2018	Other Benefit Plans 2017
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 33,221	28,116	4,582	4,605
Service cost	1,283	1,080	269	247
Interest cost	996	927	148	159
Plan participant contributions	66	60	—	—
Amendments	26	(7)	—	(17)
Actuarial (gains) losses	(2,326)	2,996	(119)	(166)
Divestitures & acquisitions	(29)	201	—	88
Curtailments, settlements & restructuring	(21)	(35)	—	2
Benefits paid from plan	(1,018)	(1,050)	(383)	(351)
Effect of exchange rates	(528)	933	(17)	15
Projected benefit obligation — end of year	**$ 31,670**	**33,221**	**4,480**	**4,582**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 28,404	23,633	281	75
Actual return on plan assets	(1,269)	4,274	—	12
Company contributions	1,140	664	282	545
Plan participant contributions	66	60	—	—
Settlements	(13)	(32)	—	—
Divestitures & acquisitions	(17)	173	—	—
Benefits paid from plan assets	(1,018)	(1,050)	(383)	(351)
Effect of exchange rates	(475)	682	—	—
Plan assets at fair value — end of year	**$ 26,818**	**28,404**	**180**	**281**
Funded status — end of year	**$ (4,852)**	**(4,817)**	**(4,300)**	**(4,301)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 475	526	—	—
Current liabilities	(98)	(92)	(281)	(228)
Non-current liabilities	(5,229)	(5,251)	(4,019)	(4,073)
Total recognized in the consolidated balance sheet — end of year	**$ (4,852)**	**(4,817)**	**(4,300)**	**(4,301)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,323	8,140	1,263	1,500
Prior service cost (credit)	2	(25)	(106)	(137)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,325**	**8,115**	**1,157**	**1,363**
Accumulated Benefit Obligations — end of year	**$ 28,533**	**29,793**		

(Dollars in Millions)	Retirement Plans 2018	Retirement Plans 2017	Other Benefit Plans 2018	Other Benefit Plans 2017
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 923**	**594**	**502**	**508**
Net actuarial (gain) loss	1,153	740	(111)	(169)
Amortization of net actuarial loss	(852)	(609)	(123)	(138)
Prior service cost (credit)	26	(7)	—	(17)
Amortization of prior service (cost) credit	(3)	(2)	31	30
Effect of exchange rates	(114)	256	(3)	3
Total loss/(income) recognized in other comprehensive income, before tax	**$ 210**	**378**	**(206)**	**(291)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,133**	**972**	**296**	**217**

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

In 2018, the Company contributed $679 million and $461 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2018 and December 31, 2017, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2018	2017	2018	2017	2018	2017	2018	2017
Plan Assets	$ 17,725	18,681	—	—	9,093	9,723	—	—
Projected Benefit Obligation	18,609	19,652	2,176	2,257	10,467	10,863	418	449
Accumulated Benefit Obligation	16,851	17,654	1,793	1,849	9,510	9,893	379	397
Over (Under) Funded Status								
Projected Benefit Obligation	$ (884)	(971)	(2,176)	(2,257)	(1,374)	(1,140)	(418)	(449)
Accumulated Benefit Obligation	874	1,027	(1,793)	(1,849)	(417)	(170)	(379)	(397)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $7.5 billion, $8.8 billion and $4.3 billion, respectively, at the end of 2018, and $3.8 billion, $4.6 billion and $0.7 billion, respectively, at the end of 2017.

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

(Dollars in Millions)	2019	2020	2021	2022	2023	2024-2028
Projected future benefit payments						
Retirement plans	$ 1,062	1,104	1,182	1,257	1,332	7,679
Other benefit plans	$ 375	397	411	428	413	2,273

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

(Dollars in Millions)	2019	2020	2021	2022	2023	2024-2028
Projected future contributions	$ 92	95	101	108	115	697

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

The Company's retirement plan asset allocation at the end of 2018 and 2017 and target allocations for 2019 are as follows:

	Percent of Plan Assets		Target Allocation
	2018	2017	2019
Worldwide Retirement Plans			
Equity securities	71 %	76 %	70 %
Debt securities	29	24	30
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of Fair Value of Plan Assets

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

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

Valuation Hierarchy

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

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

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

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.

- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.

- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

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Equity securities — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.

- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.

- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2018 and December 31, 2017:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**
Short-term investment funds	$ 122	429	529	427	—	—	—	—	651	856
Government and agency securities	—	—	3,595	3,094	—	—	—	—	3,595	3,094
Debt instruments	—	—	3,105	2,013	—	—	—	—	3,105	2,013
Equity securities	11,298	13,848	4	—	—	—	—	—	11,302	13,848
Commingled funds	—	—	2,304	1,780	133	57	5,201	6,158	7,638	7,995
Insurance contracts	—	—	—	—	193	199	—	—	193	199
Other assets	—	—	33	121	—	—	301	278	334	399
Investments at fair value	**$ 11,420**	**14,277**	**9,570**	**7,435**	**326**	**256**	**5,502**	**6,436**	**26,818**	**28,404**

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

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $72 million and $81 million and U.S. short-term investment funds (Level 2) of $108 million and $200 million at December 31, 2018 and December 31, 2017, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $876 million (3.3% of total plan assets) at December 31, 2018 and $938 million (3.3% of total plan assets) at December 31, 2017.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee’s contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $242 million, $214 million and $191 million in 2018, 2017 and 2016, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock	
	Shares	Amount
Balance at January 3, 2016	364,681	$ 22,684
Employee compensation and stock option plans	(30,839)	(3,311)
Repurchase of common stock	79,490	8,979
Balance at January 1, 2017	413,332	28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	$ 34,362

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2018, 2017 and 2016.

Cash dividends paid were $3.54 per share in 2018, compared with dividends of $3.32 per share in 2017, and $3.15 per share in 2016.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash. As of December 30, 2018, $0.9 billion has been repurchased under the program.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

13. Accumulated Other Comprehensive Income (Loss)

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

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 3, 2016	$ (8,435)	604	(5,298)	(36)	(13,165)
Net 2016 changes	(612)	(193)	(682)	(249)	(1,736)
January 1, 2017	(9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	(7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings		(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	$ (8,869)	—	(6,158)	(195)	(15,222)

[1] See Note 1 to Consolidated Financial Statements for additional details on the adoption of ASU 2016-01

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

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

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

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

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. Beginning in the fiscal third quarter of 2018, the Company accounted for operations in Argentina as highly inflationary. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2018, 2017 and 2016 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $265 million, $216 million and $289 million in 2018, 2017 and 2016, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 30, 2018, December 31, 2017 and January 1, 2017:

(In Millions Except Per Share Amounts)	2018	2017	2016
Basic net earnings per share	$ 5.70	0.48	6.04
Average shares outstanding — basic	2,681.5	2,692.0	2,737.3
Potential shares exercisable under stock option plans	139.0	139.7	142.4
Less: shares repurchased under treasury stock method	(92.5)	(87.3)	(92.1)
Convertible debt shares	0.7	0.9	1.3
Adjusted average shares outstanding — diluted	2,728.7	2,745.3	2,788.9
Diluted net earnings per share	$ 5.61	0.47	5.93

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for 2018 and 2017, and $2 million for 2016.

The diluted net earnings per share calculation for 2018, 2017 and 2016 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $332 million, $372 million and $330 million in 2018, 2017 and 2016, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 30, 2018 are:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023	Total
$223	188	154	116	76	139	896

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 30, 2018, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 351 million at the end of 2018.

The compensation cost that has been charged against income for these plans was $978 million, $962 million and $878 million for 2018, 2017 and 2016, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $192 million, $275 million and $256 million for 2018, 2017 and 2016, respectively. An additional tax benefit of $353 million was recognized in 2016 due to the adoption of a new accounting standard for the reporting of additional tax benefits on share-based compensation. The total unrecognized compensation cost was $827 million, $798 million and $749 million for 2018, 2017 and 2016, respectively. The weighted average period for this cost to be recognized was 1.73 years, 1.76 years and 1.09 years for 2018, 2017, and 2016, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

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

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company’s Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2018, 2017 and 2016 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $17.98, $13.38 and $10.01, in 2018, 2017 and 2016, respectively. The fair value was estimated based on the weighted average assumptions of:

	2018	2017	2016
Risk-free rate	2.77%	2.25%	1.51%
Expected volatility	15.77%	15.30%	15.76%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.70%	2.90%	3.10%

A summary of option activity under the Plan as of December 30, 2018, December 31, 2017 and January 1, 2017, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 3, 2016	116,517	$ 76.41	$ 3,065
Options granted	22,491	101.87	
Options exercised	(22,547)	65.66	
Options canceled/forfeited	(3,006)	92.83	
Shares at January 1, 2017	113,455	83.16	3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	111,306	90.48	5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	**109,652**	**$ 98.29**	**$ 3,214**

The total intrinsic value of options exercised was $1,028 million, $1,060 million and $980 million in 2018, 2017 and 2016, respectively.

The following table summarizes stock options outstanding and exercisable at December 30, 2018:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$65.62	13,466	1.8	$62.67	13,466	$62.67
$66.07-$72.54	12,710	4.0	$72.53	12,710	$72.53
$90.44-$100.48	29,162	5.6	$95.34	28,537	$95.23
$101.87-$115.67	37,877	7.6	$108.33	111	$108.04
$115.68-$129.51	16,437	9.1	$129.51	38	$129.51
	109,652	**6.2**	**$98.29**	**54,862**	**$82.03**

[1] Average contractual life remaining in years.

Stock options outstanding at December 31, 2017 and January 1, 2017 were 111,306 and an average life of 6.3 years and 113,455 and an average life of 6.2 years, respectively. Stock options exercisable at December 31, 2017 and January 1, 2017 were 52,421 at an average price of $73.61 and 50,414 at an average price of $65.77, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that are scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 30, 2018 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 31, 2017	20,161	2,625
Granted	6,074	1,142
Issued	(6,684)	(1,151)
Canceled/forfeited/adjusted	(1,091)	(122)
Shares at December 30, 2018	18,460	2,494

The average fair value of the restricted share units granted was $119.67, $107.69 and $92.45 in 2018, 2017 and 2016, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $613.7 million, $596.5 million and $587.7 million in 2018, 2017 and 2016, respectively.

The weighted average fair value of the performance share units granted was $120.64, $114.13 and $105.30 in 2018, 2017 and 2016, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $128.8 million, $132.5 million and $127.7 million in 2018, 2017 and 2016, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers 2018	2017	2016	% Change '18 vs. '17	'17 vs. '16
CONSUMER					
Baby Care					
U.S.	$ 422	449	488	(6.0)%	(8.0)
International	1,436	1,467	1,513	(2.1)	(3.0)
Worldwide	1,858	1,916	2,001	(3.0)	(4.2)
Beauty					
U.S.	2,403	2,335	2,135	2.9	9.4
International	1,979	1,865	1,762	6.1	5.8
Worldwide	4,382	4,200	3,897	4.3	7.8
Oral Care					
U.S.	637	616	648	3.4	(4.9)
International	918	915	920	0.3	(0.5)
Worldwide	1,555	1,531	1,568	1.6	(2.4)
OTC					
U.S.	1,850	1,716	1,675	7.8	2.4
International	2,484	2,410	2,302	3.1	4.7
Worldwide	4,334	4,126	3,977	5.0	3.7
Women's Health					
U.S.	13	12	19	8.3	(36.8)
International	1,036	1,038	1,048	(0.2)	(1.0)
Worldwide	1,049	1,050	1,067	(0.1)	(1.6)
Wound Care/Other					
U.S.	436	437	455	(0.2)	(4.0)
International	239	342	342	(30.1)	0.0
Worldwide	675	779	797	(13.4)	(2.3)
TOTAL CONSUMER					
U.S.	5,761	5,565	5,420	3.5	2.7
International	8,092	8,037	7,887	0.7	1.9
Worldwide	13,853	13,602	13,307	1.8	2.2
PHARMACEUTICAL					
Immunology					
U.S.	9,073	8,871	8,846	2.3	0.3
International	4,047	3,373	3,122	20.0	8.0
Worldwide	13,120	12,244	11,968	7.2	2.3
REMICADE®					
U.S.	3,664	4,525	4,842	(19.0)	(6.5)
U.S. Exports	436	563	782	(22.6)	(28.0)
International	1,226	1,227	1,342	(0.1)	(8.6)
Worldwide	5,326	6,315	6,966	(15.7)	(9.3)

SIMPONI / SIMPONI ARIA®					
U.S.	1,051	954	959	10.2	(0.5)
International	1,033	879	786	17.5	11.8
Worldwide	2,084	1,833	1,745	13.7	5.0
STELARA®					
U.S.	3,469	2,767	2,263	25.4	22.3
International	1,687	1,244	969	35.6	28.4
Worldwide	5,156	4,011	3,232	28.5	24.1
TREMFAYA®					
U.S.	453	62	—	*	*
International	91	1	—	*	*
Worldwide	544	63	—	*	*
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	10	22	25	(54.5)	(12.0)
Worldwide	10	22	25	(54.5)	(12.0)
Infectious Diseases					
U.S.	1,378	1,358	1,461	1.5	(7.0)
International	1,926	1,796	1,747	7.2	2.8
Worldwide	3,304	3,154	3,208	4.8	(1.7)
EDURANT® / rilpivirine					
U.S.	58	58	52	0.0	11.5
International	758	656	521	15.5	25.9
Worldwide	816	714	573	14.3	24.6
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®					
U.S.	1,169	1,109	1,143	5.4	(3.0)
International	786	712	708	10.4	0.6
Worldwide	1,955	1,821	1,851	7.4	(1.6)
OTHER INFECTIOUS DISEASES					
U.S.	151	191	266	(20.9)	(28.2)
International	382	428	518	(10.7)	(17.4)
Worldwide	533	619	784	(13.9)	(21.0)
Neuroscience					
U.S.	2,574	2,630	2,628	(2.1)	0.1
International	3,503	3,356	3,457	4.4	(2.9)
Worldwide	6,077	5,986	6,085	1.5	(1.6)
CONCERTA® / Methylphenidate					
U.S.	229	384	468	(40.4)	(17.9)
International	434	407	395	6.6	3.0
Worldwide	663	791	863	(16.2)	(8.3)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	1,791	1,590	1,343	12.6	18.4
International	1,137	979	871	16.1	12.4
Worldwide	2,928	2,569	2,214	14.0	16.0

RISPERDAL CONSTA®					
U.S.	315	360	381	(12.5)	(5.5)
International	422	445	512	(5.2)	(13.1)
Worldwide	737	805	893	(8.4)	(9.9)
OTHER NEUROSCIENCE					
U.S.	239	296	436	(19.3)	(32.1)
International	1,510	1,525	1,679	(1.0)	(9.2)
Worldwide	1,749	1,821	2,115	(4.0)	(13.9)
Oncology					
U.S.	4,331	3,098	2,335	39.8	32.7
International	5,513	4,160	3,472	32.5	19.8
Worldwide	9,844	7,258	5,807	35.6	25.0
DARZALEX®					
U.S.	1,203	884	471	36.1	87.7
International	822	358	101	*	*
Worldwide	2,025	1,242	572	63.0	*
IMBRUVICA®					
U.S.	1,129	841	613	34.2	37.2
International	1,486	1,052	638	41.3	64.9
Worldwide	2,615	1,893	1,251	38.1	51.3
VELCADE®					
U.S.	—	—	—	—	—
International	1,116	1,114	1,224	0.2	(9.0)
Worldwide	1,116	1,114	1,224	0.2	(9.0)
ZYTIGA® /abiraterone acetate					
U.S.	1,771	1,228	1,089	44.2	12.8
International	1,727	1,277	1,171	35.2	9.1
Worldwide	3,498	2,505	2,260	39.6	10.8
OTHER ONCOLOGY					
U.S.	228	145	162	57.2	(10.5)
International	362	359	338	0.8	6.2
Worldwide	590	504	500	17.1	0.8
Pulmonary Hypertension					
U.S.	1,651	773	—	*	*
International	922	554	—	66.4	*
Worldwide	2,573	1,327	—	93.9	*
OPSUMIT®					
U.S.	700	320	—	*	*
International	515	253	—	*	*
Worldwide	1,215	573	—	*	*
TRACLEER®					
U.S.	268	161	—	66.5	*
International	278	242	—	14.9	*
Worldwide	546	403	—	35.5	*

UPTRAVI®					
U.S.	598	238	—	*	*
International	65	25	—	*	*
Worldwide	663	263	—	*	*
OTHER					
U.S.	85	54	—	57.4	*
International	64	34	—	88.2	*
Worldwide	149	88	—	69.3	*
Cardiovascular / Metabolism / Other					
U.S.	4,279	4,744	4,855	(9.8)	(2.3)
International	1,537	1,543	1,541	(0.4)	0.1
Worldwide	5,816	6,287	6,396	(7.5)	(1.7)
XARELTO®					
U.S.	2,477	2,500	2,288	(0.9)	9.3
International	—	—	—	—	—
Worldwide	2,477	2,500	2,288	(0.9)	9.3
INVOKANA® / INVOKAMET®					
U.S.	711	944	1,273	(24.7)	(25.8)
International	170	167	134	1.8	24.6
Worldwide	881	1,111	1,407	(20.7)	(21.0)
PROCRIT® / EPREX®					
U.S.	674	675	767	(0.1)	(12.0)
International	314	297	338	5.7	(12.1)
Worldwide	988	972	1,105	1.6	(12.0)
OTHER					
U.S.	417	625	527	(33.3)	18.6
International	1,053	1,079	1,069	(2.4)	0.9
Worldwide	1,470	1,704	1,596	(13.7)	6.8
TOTAL PHARMACEUTICAL					
U.S.	23,286	21,474	20,125	8.4	6.7
International	17,448	14,782	13,339	18.0	10.8
Worldwide	40,734	36,256	33,464	12.4	8.3
MEDICAL DEVICES					
Diabetes Care					
U.S.	371	612	739	(39.4)	(17.2)
International	638	1,003	1,050	(36.4)	(4.5)
Worldwide	1,009	1,615	1,789	(37.5)	(9.7)
Diagnostics					
U.S.	—	—	—	—	—
International	—	1	66	*	*
Worldwide	—	1	66	*	*
Interventional Solutions					
U.S.	1,283	1,148	1,031	11.8	11.3
International	1,363	1,148	1,024	18.7	12.1
Worldwide	2,646	2,296	2,055	15.2	11.7

Orthopaedics					
U.S.	5,281	5,404	5,438	(2.3)	(0.6)
International	3,604	3,654	3,690	(1.4)	(1.0)
Worldwide	8,885	9,058	9,128	(1.9)	(0.8)
HIPS					
U.S.	841	827	798	1.7	3.6
International	577	567	563	1.8	0.7
Worldwide	1,418	1,394	1,361	1.7	2.4
KNEES					
U.S.	911	948	943	(3.9)	0.5
International	591	575	581	2.8	(1.0)
Worldwide	1,502	1,523	1,524	(1.4)	(0.1)
TRAUMA					
U.S.	1,599	1,576	1,545	1.5	2.0
International	1,100	1,040	1,024	5.8	1.6
Worldwide	2,699	2,616	2,569	3.2	1.8
SPINE & OTHER					
U.S.	1,930	2,053	2,152	(6.0)	(4.6)
International	1,336	1,472	1,522	(9.2)	(3.3)
Worldwide	3,266	3,525	3,674	(7.3)	(4.1)
Surgery					
U.S.	4,125	4,085	4,026	1.0	1.5
International	5,776	5,474	5,270	5.5	3.9
Worldwide	9,901	9,559	9,296	3.6	2.8
ADVANCED					
U.S.	1,657	1,620	1,524	2.3	6.3
International	2,345	2,136	1,993	9.8	7.2
Worldwide	4,002	3,756	3,517	6.5	6.8
GENERAL					
U.S.	1,751	1,728	1,669	1.3	3.5
International	2,806	2,735	2,693	2.6	1.6
Worldwide	4,557	4,463	4,362	2.1	2.3
SPECIALTY					
U.S.	717	737	833	(2.7)	(11.5)
International	625	603	584	3.6	3.3
Worldwide	1,342	1,340	1,417	0.1	(5.4)
Vision					
U.S.	1,777	1,575	1,032	12.8	52.6
International	2,776	2,488	1,753	11.6	41.9
Worldwide	4,553	4,063	2,785	12.1	45.9
CONTACT LENSES / OTHER					
U.S.	1,237	1,122	1,032	10.2	8.7
International	2,065	1,914	1,753	7.9	9.2
Worldwide	3,302	3,036	2,785	8.8	9.0

SURGICAL					
U.S.	540	453	—	19.2	*
International	711	574	—	23.9	*
Worldwide	1,251	1,027	—	21.8	*
TOTAL MEDICAL DEVICES					
U.S.	12,837	12,824	12,266	0.1	4.5
International	14,157	13,768	12,853	2.8	7.1
Worldwide	26,994	26,592	25,119	1.5	5.9
WORLDWIDE					
U.S.	41,884	39,863	37,811	5.1	5.4
International	39,697	36,587	34,079	8.5	7.4
Worldwide	$ 81,581	76,450	71,890	6.7 %	6.3

*Percentage greater than 100% or not meaningful

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	**2018 [3]**	**2017 [4]**	**2016 [5]**	**2018**	**2017**
Consumer	$ 2,320	2,524	2,441	$ 25,877	25,030
Pharmaceutical	12,568	11,083	12,827	56,636	59,450
Medical Devices	4,397	5,392	5,578	46,254	45,413
Total	19,285	18,999	20,846	128,767	129,893
Less: Expense not allocated to segments [1]	1,286	1,326	1,043		
General corporate [2]				24,187	27,410
Worldwide total	**$ 17,999**	**17,673**	**19,803**	**$ 152,954**	**157,303**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2018**	**2017**	**2016**	**2018**	**2017**	**2016**
Consumer	$ 438	485	486	$ 688	674	608
Pharmaceutical	1,012	936	927	3,802	2,416	886
Medical Devices	1,843	1,566	1,472	2,103	2,216	1,928
Segments total	3,293	2,987	2,885	6,593	5,306	3,422
General corporate	377	292	341	336	336	332
Worldwide total	**$ 3,670**	**3,279**	**3,226**	**$ 6,929**	**5,642**	**3,754**

	Sales to Customers			Long-Lived Assets [6]	
(Dollars in Millions)	**2018**	**2017**	**2016**	**2018**	**2017**
United States	$ 41,884	39,863	37,811	$ 37,117	38,556
Europe	18,753	17,126	15,770	51,433	56,677
Western Hemisphere excluding U.S.	6,113	6,041	5,734	2,752	2,990
Asia-Pacific, Africa	14,831	13,420	12,575	2,733	2,773
Segments total	81,581	76,450	71,890	94,035	100,996
General corporate				1,064	1,143
Other non long-lived assets				57,855	55,164
Worldwide total	**$ 81,581**	**76,450**	**71,890**	**$ 152,954**	**157,303**

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

Export sales are not significant. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

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

(3) The Consumer segment includes a gain of $0.3 billion from the divestiture of NIZORAL® and litigation expense of $0.3 billion. The Pharmaceutical segment includes an in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion, Actelion acquisition related costs of $0.2 billion, unrealized loss on securities of $0.2 billion and a gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products. The Medical Devices segment includes net litigation expense of $1.7 billion, a restructuring related charge of $0.6 billion, AMO acquisition related costs of $0.1 billion and a gain of $0.5 billion from the divestiture of the LifeScan business in the fiscal fourth quarter.

(4) The Pharmaceutical segment includes $0.8 billion for Actelion acquisition related costs, an in-process research and development expense of $0.4 billion and litigation expense of $0.1 billion. The Medical Devices segment includes litigation expense of $1.1 billion, a restructuring related charge of $0.8 billion, an asset impairment of $0.2 billion primarily related to the insulin pump business and $0.1 billion for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(5) Includes net litigation expense of $0.8 billion and a restructuring related charge of $0.7 billion in the Medical Devices segment. The Pharmaceutical segment includes a positive adjustment of $0.5 billion to previous reserve estimates and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.

(6) Long-lived assets include property, plant and equipment, net for 2018, and 2017 of $17,035 and $17,005, respectively, and intangible assets and goodwill, net for 2018 and 2017 of $78,064 and $85,134, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2018 and 2017 are summarized below:

(Dollars in Millions Except Per Share Data)	2018				2017			
	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,398	3,504	3,415	3,536	3,228	3,478	3,356	3,540
Pharmaceutical	9,844	10,354	10,346	10,190	8,245	8,635	9,695	9,681
Medical Devices	6,767	6,972	6,587	6,668	6,293	6,726	6,599	6,974
Total sales	20,009	20,830	20,348	20,394	17,766	18,839	19,650	20,195
Gross profit	13,395	13,903	13,759	13,433	12,357	12,993	12,725	12,936
Earnings before provision for taxes on income	5,481	4,973	4,423	3,122	5,575	4,748	4,790	2,560
Net earnings (loss)	4,367	3,954	3,934	3,042	4,422	3,827	3,764	(10,713)
Basic net earnings (loss) per share	$ 1.63	1.47	1.47	1.14	1.63	1.42	1.40	(3.99)
Diluted net earnings (loss) per share	$ 1.60	1.45	1.44	1.12	1.61	1.40	1.37	(3.99)

(1) The first quarter of 2018 includes an Actelion acquisition related cost of $92 million after-tax ($96 million before-tax) and a restructuring related charge of $81 million after-tax ($107 million before-tax).

(2) The second quarter of 2018 includes a litigation expense of $609 million after-tax ($703 million before-tax) and a restructuring related charge of $152 million after-tax ($176 million before-tax).

(3) The third quarter of 2018 includes an in-process research and development expense of $859 million after-tax ($1,126 million before-tax) related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $184 million after and before tax, a restructuring related charge of $162 million after-tax ($190 million before-tax) and a $265 million benefit after-tax from the impact of tax legislation.

(4) The fourth quarter of 2018 includes a litigation expense of $1,113 million after-tax ($1,288 million before-tax), a restructuring related charge of $190 million after-tax ($227 million before-tax) and a $137 million benefit after-tax from the impact of tax legislation.

(5) The first quarter of 2017 includes a restructuring charge of $121 million after-tax ($161 million before-tax) and an AMO acquisition related cost of $251 million after-tax ($38 million before-tax).

(6) The second quarter of 2017 includes a litigation expense of $352 million after-tax ($493 million before-tax), Actelion acquisition related costs of $199 million after-tax ($213 million before-tax) a restructuring charge of $101 million after-tax ($128 million before-tax) and an asset impairment charge of $125 million after-tax ($182 million before-tax).

(7) The third quarter of 2017 includes a litigation expense of $97 million after-tax ($118 million before-tax), Actelion acquisition related costs of $255 million after-tax ($367 million before-tax) and a restructuring charge of $136 million after-tax ($187 million before-tax).

(8) The fourth quarter of 2017 includes a litigation expense of $506 million after-tax ($645 million before-tax), Actelion acquisition related costs of $313 million after-tax ($217 million before-tax), a restructuring charge of $237 million after-tax ($284 million before-tax), an in-process research and development expense of $266 million after-tax ($408 million before-tax) and an after-tax benefit of $116 million related to the insulin pump business. Additionally, the fourth quarter of 2017 includes a provisional charge of $13.6 billion for recently enacted tax legislation.

20. Business Combinations and Divestitures

Certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed during 2018. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2018 acquisitions primarily included: Zarbee's, Inc., a privately held company that is a leader in naturally-based consumer healthcare products; Medical Enterprises Distribution LLC, a privately held healthcare technology firm focused on surgical procedure innovation; BeneVir Biopharm, Inc. (BeneVir), a privately-held, biopharmaceutical company specializing in the development of oncolytic immunotherapies and Orthotaxy, a privately-held developer of software-enabled surgery technologies, including a differentiated robotic-assisted surgery solution.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

On October 23, 2018, the Company entered into an agreement to acquire Ci:z Holdings Co., Ltd., a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. The acquisition was completed on January 17, 2019, through a series of transactions that included an all-cash tender offer to acquire the publicly held shares not already held by the Company for ¥5,900 per share. Upon completion of the tender offer and the related transactions, the Company acquired 89% of the outstanding shares. The Company plans to acquire the remaining shares that were not tendered in the tender offer through a share consolidation under Japanese law during the first half of 2019 and take appropriate actions to delist from the Tokyo Stock Exchange. The acquisition will include the range of brands comprising DR.CI:LABO, LABO LABO and GENOMER line of skincare products. The Company expects to treat this transaction as a business combination and will include it in the Consumer segment.

On February 13, 2019, the Company entered into a definitive agreement to acquire Auris Health, Inc. for approximately $3.4 billion in cash. Additional contingent payments of up to$2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health is a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The closing is subject to antitrust clearance and other customary closing conditions. The transaction is expected to close by the end of the second quarter of 2019. The Company expects to treat this transaction as a business combination and will include it in the Medical Devices segment.

During 2017 certain businesses were acquired for $35.2 billion in cash and $1.8 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd, an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34.4 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1.1 billion has been identified as the value of IPR&D, primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). In 2017 the Company held 9.9% of the shares of Idorsia and had rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. As a result of Idorsia raising additional capital in July 2018, the Company currently holds 9.0% of the shares of Idorsia and has rights to an additional 20.8% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more

than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia

with a Swiss franc denominated credit facility of approximately $250 million. As of December 30, 2018, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion's specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

During the fiscal second quarter of 2018, the Company finalized the purchase price allocation to the individual assets acquired and liabilities assumed using the acquisition method. The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through the second quarter of 2018:

(Dollars in Millions)	
Cash & Cash equivalents	469
Inventory[(1)]	759
Accounts Receivable	485
Other current assets	93
Property, plant and equipment	104
Goodwill	6,161
Intangible assets	25,010
Deferred Taxes	99
Other non-current assets	19
Total Assets Acquired	33,199
Current liabilities	956
Deferred Taxes	1,776
Other non-current liabilities	413
Total Liabilities Assumed	3,145
Net Assets Acquired	30,054

(1) Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

The adjustments made since the date of acquisition were $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill. The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks*	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

*Includes $0.4 billion related to VALCHLOR®, one of the acquired products, which was divested in the fiscal second quarter of 2018.

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017, total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017 and January 1, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

	Unaudited Pro forma Consolidated Results	
(Dollars in Millions Except Per Share Data)	**2017**	**2016**
Net Sales	77,681	74,339
Net Earnings	1,509	13,916
Diluted Net Earnings per Common Share	0.55	4.99

The Company recorded Actelion acquisition related costs before tax of approximately $0.2 billion and $0.8 billion in 2018 and 2017, respectively, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

Certain businesses were acquired for $4.5 billion in cash and $0.1 billion of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics; and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $4.1 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of $3.3 billion was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.1 billion. The weighted average life for the $2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2018, 2017 and 2016 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company’s results of operations, cash flows or financial position.

During 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion. Additionally, in 2018, the Company accepted the binding

offer from Fortive Corporation to acquire its Advanced Sterilization Products (ASP) business for approximately $2.7 billion, subject to customary adjustments. The transaction is expected to close in 2019. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.2 billion of inventory, $0.1 billion of property, plant and equipment and $0.3 billion of goodwill. The Company will retain certain net receivables of approximately $0.1 billion associated with the ASP business.

In 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.3 billion of inventory and $0.1 billion of property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 22 to the Consolidated Financial Statements.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately $0.6 billion.

21. Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 30, 2018, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of December 30, 2018, in the United States there were approximately 1,800 plaintiffs with direct claims in pending lawsuits

regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 10,500 with respect to the PINNACLE® Acetabular Cup System; 34,800 with respect to pelvic meshes; 13,400 with respect to RISPERDAL®; 25,600 with respect to XARELTO®; 13,000 with respect to body powders containing talc; 1,050 with respect to INVOKANA®; and 2,100 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The British Columbia order is currently the subject of an appeal. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial, the second remains under appeal and the third is pending decision on post-trial motions in the district court. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System. The Company is negotiating settlements of these cases and the related costs are reflected in the Company’s accruals.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. The Company has settled or otherwise resolved a majority of the United States cases and the costs associated with these settlements are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In Australia, a trial of class action issues has been completed and the parties are awaiting a decision. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established

accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I

disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs only in connection with product liability litigation associated with XARELTO®.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in July 2018 of $4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily
JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In October 2018, a shareholder derivative lawsuit was filed against Johnson & Johnson as the nominal defendant and its current directors as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. Plaintiff is seeking damages and an order for the Company to reform its internal policies and procedures. In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. Each of these matters will be adjudicated in conjunction with the multi-district litigation referenced in the prior paragraph. In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice and the Securities and Exchange Commission. The Company is cooperating with these government inquiries and will be producing documents in response.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or

otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

INTELLECTUAL PROPERTY

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

Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt's United States Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the district court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the district court for a new trial. A new trial was held in August 2017, and the jury returned a verdict of non-infringement in favor of JJVCI. Rembrandt has appealed the verdict to the United States Court of Appeals for the Federal Circuit (CAFC). In February 2019, the CAFC affirmed the judgment in favor of JJVCI.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial, and briefing in the district court was completed in June 2018.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants. MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In January 2019, the district court stayed the case pending a decision in the Inter Partes Review proceeding on the '426 patent (see below). In December 2017, DePuy Synthes Products, Inc. filed a Petition for Inter Partes Review with the United States Patent and Trademark Office (USPTO), seeking to invalidate the two claims of the '426 patent asserted in the district court litigation, and in June 2018, the USPTO instituted review of those claims. A hearing trial is scheduled for March 2019, and a decision in the proceeding is due by June 2019.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the

allegations, asserting willful infringement of the ’735 patent, the ’284 patent and United States Patent Nos. 8,323,310 (the ’310 patent); 9,084,608; 9,241,759 (the ’759 patent) and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in

October 2017. The parties have entered joint stipulations such that only the ’735 patent, the ’310 patent and the ’759 patent remain in dispute. Trial is scheduled to begin in September 2019.

In November 2017, Board of Regents, The University of Texas System and Tissuegen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® POS® Antibacterial Sutures and STRATAFIX® MONOCRYL®Plus Antibacterial Sutures infringe plaintiffs’ United States Patent Nos. 6,596,296 and 7,033,603 directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the USPTO, seeking Inter Partes Review (IPR) of both asserted patents. Those petitions have been stayed by the USPTO pending a decision by the U.S. Court of Appeals for the Federal Circuit in an unrelated case.

Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleged that JBI’s manufacture and sale of DARZALEX® (daratumumab) willfully infringed MorphoSys’ United States Patent Nos. 8,263,746, 9,200,061 and 9,785,590. MorphoSys sought money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. In January 2019, the district court granted summary judgment in JBI and Genmab’s favor, invalidating the asserted claims of the patents-in-suit, and the parties filed a joint stipulation of dismissal of the action.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC, a Pfizer company (Searle) and Janssen Sciences Ireland UC (JSI) alleging that Searle’s supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the court’s decision and the injunction is stayed pending the appeal. In January 2018, the court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU’s ruling on the issue.

In April 2018, Acerta Pharma B.V., AstraZeneca UK Ltd and AstraZeneca Pharmaceuticals LP filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Pharmacylics LLC and Abbvie Inc. (collectively, Abbvie), alleging that the manufacture and sale of IMBRUVICA® infringes U.S. Patent No. 7,459,554. Janssen Biotech, Inc., which commercializes IMBRUVICA® jointly with Abbvie, intervened in the action in November 2018. A trial is scheduled to begin in January 2021.

REMICADE® Related Cases

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, Janssen Biotech, Inc. (JBI) filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion’s infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the ’471 patent) and United States Patent No. 7,598,083 (the ’083 patent) directed to the cell culture media used to make Celltrion’s biosimilar. In August 2016, the district court granted both Celltrion’s and Hospira’s motions for summary judgment of invalidity of the ’471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of a decision by the USPTO’s Patent Trial and Appeal Board affirming invalidity of the ’471 patent.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the ’083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone

Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. On July 30, 2018 the district court granted Celltrion's motion for summary judgment of non-infringement and entered an order dismissing the '083 lawsuit against Celltrion and Hospira. JBI appealed to the United States Court of

Appeals for the Federal Circuit. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved the first infliximab biosimilar for sale in the United States in 2016, and a number of such products have been launched.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the ’438 patent). The generic companies include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy’s); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma).

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. (Glenmark) in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the ’438 patent. These lawsuits have been consolidated with the lawsuit filed in July 2015.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the ’438 patent. This lawsuit has been consolidated with the lawsuit filed in July 2015.

In February 2018, Janssen and BTG filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively, MSN) in United States District Court for the District of New Jersey based on its ANDA seeking approval for a generic version of ZYTIGA® prior to the expiration of the ’438 patent.

In November 2018, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, Qilu), who filed an ANDA seeking approval to market a generic version of ZYTIGA® before the expiration of the ’438 patent.

In December 2017, Janssen and BTG entered into a settlement agreement with Glenmark. In January 2018, Janssen dismissed its lawsuit against Sun after it withdrew its ANDA. In April 2018, Janssen and BTG entered into a settlement agreement with Apotex.

In October 2018, the United States District Court for the District of New Jersey issued a ruling invalidating all asserted claims of the ’438 patent. The court held that the patent claims would be infringed if the patent were valid. Janssen appealed the court’s decision.

In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market. Janssen has appealed the decision of the United States District Court for the District of New Jersey, and the oral argument on the appeal is scheduled for March 2019.

The lawsuits against MSN and Qilu remain pending in the district courts. In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the ’438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions finding the ’438 patent claims unpatentable, and Janssen requested rehearing. In December 2018, the USPTO denied Janssen’s request for rehearing of the IPR decisions. Janssen filed an appeal, which was consolidated with the above-mentioned appeal of the decision of the United States District Court for the District of New Jersey.

In October 2017, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated two Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in Canada in response to Teva's filing Abbreviated New Drug Submissions (ANDS) and seeking approval to market generic versions of ZYTIGA® 250mg and ZYTIGA® 500mg before the expiration of Canadian Patent No. 2,661,422. In June 2018, the parties entered into a settlement agreement.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. The federal court of Canada scheduled the Final Hearing for April 2019. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex’s ANDS before the expiration of Janssen’s patent.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex’s ANDS before the expiration of Janssen’s patent.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer’s United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). Trial concluded in April 2018. In July 2018 the district court entered judgment against Mylan and Sigmapharm, holding that the asserted compound patent is valid and infringed. In September 2018, the district court entered judgment against the remaining defendants. None of the defendants appealed the judgment.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (Alembic); Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc.

(collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin counterclaimed for declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent, Micro, Breckenridge, InvaGen, Sigmapharm, Lupin and Alembic have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The ’218 cases have been consolidated for discovery and trial, and are currently set for trial in April 2019.

In December 2018, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of Bayer AG’s ’218 patent.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

In May 2018, Mylan filed a Petition for Inter Partes Review with the USPTO, seeking to invalidate the ’218 patent. In December 2018, the USPTO issued a decision denying institution of Mylan’s Petition for Inter Partes Review.

PREZISTA®

In May 2018, Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddys Laboratories, Inc., Dr. Reddys Laboratories, Ltd., Laurus Labs, Ltd. and Pharmaq, Inc. (collectively, DRL) who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. Trial is scheduled to begin in May 2020.

In December 2018, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt Ltd., and Raks Pharma Pvt. Ltd. (collectively, Amneal), who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408.

In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing its generic versions of PREZISTA® before the expiration of the relevant patents.

INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC’s United States Patent Nos. 7,943,582 and/or 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC’s United States Patent No. 7,943,788 (the ’788 patent) relating to INVOKANA® and

INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the ’788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC’s United States Patent No. 8,785,403 relating to INVOKAMET®, and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the ’788 patent and the ’219 patent relating to INVOKANA®.

Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In April 2018, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Prinston, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent relating to INVOKANA®.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA® and/or INVOKAMET® before the expiration of the relevant patents.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), each of whom filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781. In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent. In December 2018, the district court entered an order wherein one of the defendants, Amneal, stipulated to infringement. Trial is scheduled to commence in October 2020.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. In the lawsuit, Janssen is seeking an order enjoining Teva from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 and 2,655,335. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's ANDS before the expiration of these patents. The Final Hearing is scheduled to begin in September 2019.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). Trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting newly issued United States Patent No. 10,004,746.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

In January 2019, Pharmacyclics and JBI amended their complaints against Fresenius Kabi, Zydus, Teva and Sandoz to further allege infringement of U.S. Patent Nos. 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the

expiration of U.S. Patent Nos. 514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,540,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, trial has been scheduled for March 2019. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 1,600 lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed in state court by the state Attorneys General in Arkansas, Florida, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma and South Dakota. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama; Arkansas; California; Connecticut; Florida; Georgia; Illinois; Kentucky; Louisiana; Maine; Maryland; Massachusetts; Mississippi; Missouri; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; Ohio; Oklahoma; Oregon; Pennsylvania; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Utah; Virginia; Washington; West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. In addition, the Province of British Columbia filed suit in Canada. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. These cases are in early stages of litigation. In October 2017, Johnson & Johnson and JPI were both served with a motion to consolidate 66 pending matters into a federal Multi District Litigation in the Southern District of Ohio. In December 2017, the MDL was approved in the Northern District of Ohio and there are over 1,400 cases that have been transferred to the MDL.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. The multi-state coalition served Johnson & Johnson and

JPI with subpoenas as part of the investigation. Johnson & Johnson and JPI have also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court, and fact discovery is currently scheduled to close in September 2019. Additionally, DePuy filed a petition for certiorari with the United States Supreme Court, seeking review of the First Circuit's decision. The Supreme Court denied the petition in April 2018.

Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation with the State of Oregon. In December 2018, the Company, the remaining states and the District of Columbia agreed to settle all of the investigations, and on January 22, 2019, the states and the Company filed consent judgments resolving the matter.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by Kentucky in August 2016 and by Mississippi in October 2017. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 43 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. Trial is stayed pending interlocutory appeal of a denial of JJCI's motion for summary judgment.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including

NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. The United States

District Court for the Central District of California dismissed the claim in April 2018. In May 2018, the relator filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit.

In November 2018, a second whistleblower lawsuit was unsealed in the United States District Court for the Central District of California. The lawsuit is substantially similar to the lawsuit under appeal but is brought in the name of the original relator. The federal and state governments have declined to intervene in the second suit at this time.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below. The government has represented that it will not be pursuing action against the company in this matter.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests for documents from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients. In December 2018, the Company and the United States Department of Justice agreed to a settlement in this matter.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018, Advanced Sterilization Products (ASP) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning the pricing, quality, marketing and promotion of EvoTech ECR, Tyvek Peel Pouches, or Sterrad Cyclesure 24 biological indicators.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The United States Department of Justice and the United States Securities and Exchange Commission have made additional preliminary inquiries about the inspection in Brazil, and Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. is cooperating with those requests.

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

GENERAL LITIGATION

In April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. (now known as Johnson & Johnson Consumer, Inc.) in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in

May 2017, the court denied a motion to dismiss the amended complaint. In December 2018, a settlement was reached and the matter has been dismissed.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed their complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the district court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification. The district court held a hearing on the motion for class certification in August 2018. In December 2018, the district court granted the plaintiffs motion for class certification.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC (Janssen R&D). Lonza alleges that Janssen R&D breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages. The arbitration hearing was held in September 2018. Post hearing briefing is complete, and the parties are awaiting a decision.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against LifeScan Inc., Johnson & Johnson, other diabetes test strip manufacturers and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages. In November 2017, the case was ordered transferred to United States District Court for the District of New Jersey. The LifeScan business was divested in October 2018 and Johnson & Johnson retained liability that may result from these claims prior to the closing of the divestiture.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

Beginning in September 2017, multiple purported class actions were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and

state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health.

Andover Healthcare, Inc. (Andover) filed a Lanham act case against Johnson & Johnson Consumer Inc. in April 2017 in the United States District Court for the District of Massachusetts. Andover asserts that the claim "not made with natural rubber latex" on COACH® Sports Wrap, BAND-AID® Brand SECURE-FLEX® Wrap and BAND-AID® Brand HURT-FREE® Wrap is false. Andover seeks actual damages and pre-judgment interest thereon, disgorgement of profits, treble damages, attorney's fees and injunctive relief. In December 2018, the parties entered into a settlement agreement.

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

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company has undertaken actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

In 2018, the Company recorded a pre-tax charge of $462 million, of which $46 million was included in cost of products sold and $227 million was included in other (income) expense. Total project costs of $2.5 billion have been recorded since the restructuring has been announced. This restructuring program was completed in the fiscal fourth quarter of 2018.

On April 17, 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 20 to the Consolidated Financial Statements. In 2018, the Company recorded a pre-tax charge of $238 million, of which $59 million was included in cost of products sold and $117 million was included in other (income) expense. See the following table for additional details on the restructuring programs.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2018:

(Dollars in Millions)	Severance	Asset Write-offs	Other**	Total
Reserve balance, January 3, 2016	$ 484	—	17	501
2016 activity	(104)	—	(16)	(120)
Reserve balance, January 1, 2017	380	—	1	381
2017 activity	(151)	—	37	(114)
Reserve balance, December 31, 2017	229	—	38	267
Current year activity:				
Charges	—	132	568	700
Cash payments	(35)	—	(558)	(593)
Settled non cash	—	(132)	—	(132)
Reserve balance, December 30, 2018*	$ 194	—	48	242

*Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
**Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Although the Medical Devices restructuring program was completed in 2018, the Company expects that severance charges will continue beyond that date. The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments has extended due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable. Approximately 2,375 individuals received separation payments since these restructuring announcements.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 30, 2018 and December 31, 2017, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three years in the period ended December 30, 2018 including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 30, 2018 and December 31, 2017**,** and the results of its operations and its cash flows for each of the three years in the period ended December 30, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance

with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 20, 2019

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 30, 2018. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 30, 2018, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 30, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2018, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2013 and December 31, 2008 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices jnj5yearshareholder2018.jpg

	2013	2014	2015	2016	2017	2018
Johnson & Johnson	$100.00	$117.34	$118.69	$136.88	$170.29	$161.54
S&P 500 Index	$100.00	$113.68	$115.24	$129.02	$157.17	$150.27
S&P Pharmaceutical Index	$100.00	$122.22	$129.29	$127.27	$143.27	$154.86
S&P Healthcare Equipment Index	$100.00	$126.28	$133.82	$142.50	$186.53	$216.82

10 Year Shareholder Return Performance J&J vs. Indices jnj10yearshareholder2018.jpg

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Johnson & Johnson	$100.00	$111.28	$110.63	$121.57	$134.73	$181.37	$212.81	$215.28	$248.26	$308.85	$292.99
S&P 500 Index	$100.00	$126.45	$145.49	$148.55	$172.31	$228.09	$259.29	$262.86	$294.28	$358.50	$342.75
S&P Pharmaceutical Index	$100.00	$118.62	$119.54	$140.77	$161.07	$217.82	$266.21	$281.62	$277.21	$312.06	$337.32
S&P Healthcare Equipment Index	$100.00	$128.79	$125.30	$124.30	$145.76	$186.12	$235.04	$249.08	$265.23	$347.17	$403.55

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 30, 2018, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 30, 2018 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	130,605,768	$82.52	351,079,202
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	130,605,768	$82.52	351,079,202

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2018 and 2017

   Consolidated Statements of Earnings for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Comprehensive Income for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Equity for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Cash Flows for Fiscal Years 2018, 2017 and 2016

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 20, 2019

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 20, 2019
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 20, 2019
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 20, 2019
/s/ M. C. Beckerle M. C. Beckerle	Director	February 20, 2019
/s/ D. S. Davis D. S. Davis	Director	February 20, 2019
/s/ I. E. L. Davis I. E. L. Davis	Director	February 20, 2019
/s/ J. A. Doudna J. A. Doudna	Director	February 20, 2019

Signature	Title	Date
/s/ M. B. McClellan M. B. McClellan	Director	February 20, 2019
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 20, 2019
/s/ W. D. Perez W. D. Perez	Director	February 20, 2019
/s/ C. Prince C. Prince	Director	February 20, 2019
/s/ A. E. Washington A. E. Washington	Director	February 20, 2019
/s/ R. A. Williams R. A. Williams	Director	February 20, 2019

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report filed May 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 31, 2000.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated Effective January 1, 2010) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(p)	

	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(q)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(t)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(u)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(v)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(w)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended December 30, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

10-K 1 form10-k20171231.htm 10-K 2017

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

FORM 10-K

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

For the fiscal year ended December 31, 2017 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: **(732) 524-0400**

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

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
0.250% Notes Due January 2022	New York Stock Exchange
0.650% Notes Due May 2024	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange
1.150% Notes Due November 2028	New York Stock Exchange
1.650% Notes Due May 2035	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	(Do not check if a smaller reporting company)
Smaller reporting company ☐	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $355 billion.

On February 16, 2018, there were 2,682,901,553 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2018 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;

- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the U.S. and other important markets;

- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;

- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products, and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product;

- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;

- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;

- Competition on the basis of cost-effectiveness, product performance, technological advances and patents attained by competitors; and

- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage;

- Impact of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or the Corporate Integrity Agreements of the Johnson & Johnson Pharmaceutical Affiliates, or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

- Potential changes to applicable laws and regulations affecting U.S. and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;

- Changes in tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of reserves; and

- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Health Care Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, and significant new entrants to the health care markets seeking to reduce costs;

- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;

- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;

- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company, including the integration of Actelion Ltd., may not be realized or may take longer to realize than expected; and

- The potential that the expected benefits and opportunities related to past and future restructuring actions may not be realized or may take longer to realize than expected, including due to any required consultation procedures relating to restructuring of workforce.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;

- Potential changes in export/import and trade laws, regulations and policies of the U.S., U.K. and other countries, including any increased trade restrictions and potential drug reimportation legislation;

- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

- The impact of armed conflicts and terrorist attacks in the U.S. and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally or within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;

- Interruptions and breaches of the Company's information technology systems, and those of the Company's vendors, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action; and

- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company’s products.

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

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 260 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

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

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; NEUTROGENA®; RoC® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases and Vaccines (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension), a new therapeutic area, which was established with the acquisition of Actelion in June 2017. Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; EDURANT® (rilpivirine) and PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia

and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma; ZYTIGA® (abiraterone

acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), for the treatment of relapsed/refractory multiple myeloma; PROCRIT®/ EPREX®, to stimulate red blood cell production; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/ VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; diabetes care products, such as blood glucose monitoring; and vision care products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 260 operating companies located in more than 60 countries, including the U.S., which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

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

Raw Materials

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

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 8.3% of the Company's total net trade sales for fiscal 2017.

There are two sets of patents related specifically to REMICADE®. The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU).

Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. These patents have expired in all countries outside the United States. In the United States, the one remaining patent, which expires in September 2018, stands rejected following

reexamination proceedings instituted by a third party in the United States Patent and Trademark Office (USPTO). The patent has also been held invalid by the Federal District Court in the District of Massachusetts. In January 2018, the U.S. Court of Appeals for the Federal Circuit affirmed the invalidity of the remaining patent.

The second set of patents specifically related to REMICADE® was granted to The Kennedy Institute of Rheumatology in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents, which expired in 2017 outside of the United States and will expire in August 2018 in the United States. Certain of these patents have been successfully challenged and invalidated, and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any extensions will be available for the above described patents specifically related to REMICADE®. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 “Legal Proceedings – Intellectual Property – Pharmaceutical – REMICADE® Related Cases” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab), SIMPONI ARIA® (golimumab) and TREMFYA® (guselkumab), next generation immunology products with remaining patent lives of up to six years.

Trademarks

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

Seasonality

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

Competition

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

Research and Development

Research activities represent a significant part of the Company’s businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $10.6 billion, $9.1 billion and $9.0 billion for fiscal years 2017, 2016 and 2015, respectively. Research facilities are located in the United States, Belgium, Brazil, Canada, China, France, Germany, Israel, Japan, the Netherlands, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company’s compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

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

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com.* Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the SEC), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

The Company's largest product, REMICADE® (infliximab), is experiencing biosimilar competition, which will result in a reduction in U.S. sales of REMICADE®.

The Company has experienced significant challenges to patents covering its largest product, REMICADE® (infliximab) (accounting for approximately 8.3% of the Company's total net trade sales for fiscal 2017), and continues to assert certain patents related to the product. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Sales of infliximab biosimilars in the U.S. market will result in a continued reduction in U.S. sales of REMICADE®.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the United States, increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the United States, numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

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

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

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

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

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

Changes in tax laws or regulations could negatively impact the Company's effective tax rate and results of operations. On December 22, 2017, the U.S. enacted The Tax Cuts and Jobs Act (the TCJA), which resulted in the revaluation of the Company's U.S. related deferred tax assets and liabilities and had an impact on the Company's Consolidated Statement of Earnings. The TCJA introduces significant changes to U.S. corporate income tax law that will have a meaningful impact on the

Company's provision for income taxes. Accounting for the income tax effects of the TCJA requires significant judgments to be made in interpreting its provisions. Due to the timing of the enactment and the complexity involved in applying the provisions of the TCJA, the Company made reasonable estimates of the effects and recorded provisional amounts in the financial statements for fiscal year 2017. These provisional amounts are based on the Company's initial analysis of the TCJA as of January 18, 2018. Anticipated guidance from the U.S. Treasury about implementing the TCJA, and the potential for additional guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the TCJA, may result in adjustments to these estimates which could materially affect the Company's financial position and results of operations as well as the effective tax rate in the period in which the adjustments are made.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

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

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

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

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the United States, manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries. For example, the key patent for ZYTIGA® is currently subject to patent litigation, and the USPTO has issued a decision invalidating that patent in a related IPR action.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

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

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological

innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing

agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

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

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 22% of 2017 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

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

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

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the United States and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant

current investigations and litigation brought by government agencies are described in Note 21, “Legal Proceedings-Government Proceedings” under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2017, approximately 48% of the Company's sales occurred outside of the U.S., with approximately 22% in Europe, 8% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

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

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

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

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

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 125 manufacturing facilities as well as sourcing from

hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such

delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

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

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 125 manufacturing facilities occupying approximately 21.9 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,787
Pharmaceutical	7,304
Medical Devices	7,782
Worldwide Total	21,873

Within the United States, seven facilities are used by the Consumer segment, six by the Pharmaceutical segment and 27 by the Medical Devices segment. Outside of the United States, 30 facilities are used by the Consumer segment, 16 by the Pharmaceutical segment and 39 by the Medical Devices segment.

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

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	40	6,300
Europe	37	7,939
Western Hemisphere, excluding U.S.	14	2,800
Africa, Asia and Pacific	34	4,834
Worldwide Total	125	21,873

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 of this Report under "Business – Research and Development."

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

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

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 “Legal Proceedings” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned “Item 1. Election of Directors” in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	60	Member, Executive Committee; Executive Vice President; Chief Financial Officer [(a)]
Joaquin Duato	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[(b)]
Peter M. Fasolo	55	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[(c)]
Alex Gorsky	57	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Jorge Mesquita	56	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer[(d)]
Sandra E. Peterson	59	Member, Executive Committee; Executive Vice President, Group Worldwide Chairman[(e)]
Paulus Stoffels	56	Member, Executive Committee; Executive Vice President, Chief Scientific Officer[(f)]
Michael H. Ullmann	59	Member, Executive Committee; Executive Vice President, General Counsel[(g)]

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc., where he was Senior Vice President, Finance. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001, and Vice President, Group Finance of the Company’s Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company’s Group Finance organization. Mr. Caruso became a member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007. In April 2016, he was named Executive Vice President, Chief Financial Officer. Mr. Caruso has responsibility for financial and investor relations activities, as well as the Company’s procurement organization.

(b) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain) and in 1997 became Managing Director of Janssen-Cilag S.p.A. (Italy). In 2000, he led Ortho Biotech Europe before relocating to the United States in 2002 to serve as Vice President, and, in 2005, President of Ortho Biotech Inc. In 2008, he was named Company Group Chairman, Ortho-Clinical Diagnostics, and in 2009, Company Group Chairman, Pharmaceuticals, where he oversaw pharmaceutical product launches and the major

therapeutic franchises in Canada, the United States and Latin America. In 2011, he was named Worldwide Chairman, Pharmaceuticals, responsible for the global commercial businesses of the Janssen Pharmaceutical Companies, including functional support for the research & development organizations. In April 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals.

(c) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Mr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of human resources for the Company.

(d) Mr. J. Mesquita joined the Company in 2014 as Worldwide Chairman, Consumer. Prior to joining the Company, he served in various marketing and leadership capacities across Latin America, including roles in Oral Care and Beauty at The Procter & Gamble Company from 1984 to 2013. In April 2016, Mr. Mesquita became a member of the Executive Committee and was named as Executive Vice President, Worldwide Chairman, Consumer.

(e) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a member of the Executive Committee. Prior to joining the Company, Ms. Peterson was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). In April 2016, Ms. Peterson was named Executive Vice President, Group Worldwide Chairman of Johnson & Johnson. Ms. Peterson is responsible for the Company’s consumer-facing businesses, including the consumer family of companies and the consumer medical device businesses; the Company’s medical device businesses; and for supply chain, quality, information technology, and design across the enterprise.

(f) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and became a member of the Executive Committee. In April 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. He is responsible for the Company’s innovation pipeline across the pharmaceutical, medical devices and consumer segments and steers the Company’s global public health strategy.

(g) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 16, 2018, there were 147,484 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition – Liquidity and Capital Resources – Dividends" and "— Other Information — Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's Common Stock. Share repurchases take place on the open market from time to time based on market conditions. As of July 2, 2017, $10.0 billion was repurchased under the program and the program was completed.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2017. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 2, 2017 through October 29, 2017	335,583	$ 141.89	-	-
October 30, 2017 through November 26, 2017	2,139,701	139.98	-	-
November 27, 2017 through December 31, 2017	3,318,630	141.06	-	-
Total	5,793,914			

(1) During the fiscal fourth quarter of 2017, the Company repurchased an aggregate of 5,793,914 shares of Johnson & Johnson Common Stock in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of July 2, 2017, the share repurchase program was completed with an aggregate of 86,592,946 shares purchased for a total of $10.0 billion since the inception of the repurchase program announced on October 13, 2015.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2007-2017

(Dollars in Millions Except Per Share Amounts)	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007
Sales to customers — U.S.	$39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309	32,444
Sales to customers — International	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438	28,651
Total sales	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747	61,095
Cost of products sold	25,354	21,685	21,536	22,746	22,342	21,658	20,360	18,792	18,447	18,511	17,751
Selling, marketing and administrative expenses	21,420	19,945	21,203	21,954	21,830	20,869	20,969	19,424	19,801	21,490	20,451
Research and development expense	10,554	9,095	9,046	8,494	8,183	7,665	7,548	6,844	6,986	7,577	7,680
In-process research and development	408	29	224	178	580	1,163	—	—	—	181	807
Interest income	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)	(452)
Interest expense, net of portion capitalized	934	726	552	533	482	532	571	455	451	435	296
Other (income) expense, net	183	484	(2,064)	(70)	2,498	1,626	2,743	(768)	(526)	(1,015)	534
Restructuring	309	491	509	—	—	—	569	—	1,073	—	745
	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818	47,812
Earnings before provision for taxes on income	$17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929	13,283
Provision for taxes on income	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980	2,707
Net earnings	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949	10,576
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	339	—	—	—	—	—
Net earnings attributable to Johnson & Johnson	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949	10,576
Percent of sales to customers	1.7%	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3	17.3
Diluted net earnings per share of common stock [1]	$0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57	3.63
Percent return on average shareholders' equity	2.0%	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4	30.2	25.6
Percent increase (decrease) over previous year:											
Sales to customers	6.3%	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3	14.6

Diluted net earnings per share	(92.1)%	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9	(2.7)
Supplementary balance sheet data:											
Property, plant and equipment, net	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365	14,185
Additions to property, plant and equipment	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066	2,942
Total assets	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912	80,954
Long-term debt	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120	7,074
Operating cash flow	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571	14,972	15,022
Common stock information											
Dividends paid per share	$3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795	1.62
Shareholders' equity per share	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35	15.25
Market price per share (year-end close)	$139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56	67.38
Average shares outstanding (millions)											
— basic	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9
— diluted	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7
Employees (thousands)	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7	119.2

(1) Attributable to Johnson & Johnson

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

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

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 22% of 2017 sales. In 2017, $10.6 billion was invested in research and development and $35.2 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success, is the 134,000 diverse employees that work across more than 260 operating companies, which are located in more than 60 countries. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

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Results of Operations

Analysis of Consolidated Sales

In 2017, worldwide sales increased 6.3% to $76.5 billion, compared to an increase of 2.6% in 2016 and a decrease of 5.7% in 2015. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2017	2016	2015
Volume	8.0 %	3.2 %	1.2 %
Price	(2.0)	0.7	0.6
Currency	0.3	(1.3)	(7.5)
Total	**6.3 %**	**2.6 %**	**(5.7 %)**

In 2017, the net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 3.6%. In 2016, acquisitions and divestitures had a negative impact of 1.1% on the worldwide sales growth and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 0.8% on the worldwide sales growth. Operations in Venezuela negatively impacted the worldwide sales growth 0.3%. In 2015, the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.7% on the worldwide sales growth. In 2015, the impact of acquisitions and divestitures on the worldwide sales growth was negative 2.0%.

Sales by U.S. companies were $39.9 billion in 2017, $37.8 billion in 2016 and $35.7 billion in 2015. This represents increases of 5.4% in 2017, 6.0% in 2016 and 2.6% in 2015. Sales by international companies were $36.6 billion in 2017, $34.1 billion in 2016 and $34.4 billion in 2015. This represents an increase of 7.4% in 2017, and decreases of 0.9% in 2016, and 13.1% in 2015.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.6%, 6.0% and (0.4)%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.3%, 2.1% and 2.5%, respectively.

In 2017, sales by companies in Europe achieved growth of 8.6% as compared to the prior year, including operational growth of 7.2% and a positive currency impact of 1.4%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 5.4% as compared to the prior year, including operational growth of 2.8% and a positive currency impact of 2.6%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 6.7% as compared to the prior year, including operational growth of 7.5% partially offset by a negative currency impact of 0.8%.

The 2016 sales growth percentage as compared to the prior year was negatively impacted by approximately 1.3% from additional shipping days in 2015. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). While the additional week in 2015 added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% of the total consolidated revenues.

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Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2017 were $13.6 billion, an increase of 2.2% from 2016, which included 1.3% operational growth and a positive currency impact of 0.9%. U.S. Consumer segment sales were $5.6 billion, an increase of 2.7%. International sales were $8.0 billion, an increase of 1.9%, which included 0.4% operational growth and a positive currency impact of 1.5%. In 2017, acquisitions and divestitures had a net positive impact of 1.8% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Beauty	$ 4,200	3,897	3,633	7.8 %	7.3
OTC	4,126	3,977	3,895	3.7	2.1
Baby Care	1,916	2,001	2,157	(4.2)	(7.2)
Oral Care	1,531	1,568	1,580	(2.4)	(0.8)
Women's Health	1,050	1,067	1,200	(1.6)	(11.1)
Wound Care/Other	779	797	1,042	(2.3)	(23.5)
Total Consumer Sales	**$ 13,602**	**13,307**	**13,507**	**2.2 %**	**(1.5)**

The Beauty franchise sales of $4.2 billion increased 7.8% as compared to the prior year. Growth was primarily driven by the inclusion of sales from the recent acquisitions, Vogue International LLC and Dr. Ci: Labo, as well as sales growth of NEUTROGENA® products.

The Over-the-Counter (OTC) franchise sales of $4.1 billion increased 3.7% as compared to the prior year. Growth was primarily driven by analgesic products in the U.S., upper respiratory products outside the U.S., sales from the recent acquisition of Rhinocort and anti-smoking aids.

The Baby Care franchise sales were $1.9 billion in 2017, a decrease of 4.2% compared to the prior year, primarily due to competitive pressure.

The Oral Care franchise sales were $1.5 billion in 2017, a decrease of 2.4% as compared to the prior year, primarily driven by category declines and competitive pressure partially offset by new product launches outside the U.S.

The Women's Health franchise sales were $1.1 billion in 2017, a decrease of 1.6% as compared to the prior year, primarily due to category declines in EMEA and share loss in Brazil.

The Wound Care/Other franchise sales were $0.8 billion in 2017, a decrease of 2.3% as compared to the prior year, primarily due to private label competitive pressure in the U.S. partially offset by BAND-AID® new product launches outside the U.S.

Consumer segment sales in 2016 were $13.3 billion, a decrease of 1.5% from 2015, which included 1.5% operational growth offset by a negative currency impact of 3.0%. U.S. Consumer segment sales were $5.4 billion, an increase of 3.8%. International sales were $7.9 billion, a decrease of 4.8%, which included 0.1% operational growth offset by a negative currency impact of 4.9%. In 2016, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was negative 0.5%. In 2016, the Consumer segment operational sales growth was negatively impacted 1.2% by operations in Venezuela and negatively impacted by 1.1% due to additional shipping days in 2015.

Pharmaceutical Segment

Pharmaceutical segment sales in 2017 were $36.3 billion, an increase of 8.3% from 2016, which included operational growth of 8.0% and a positive currency impact of 0.3%. U.S. sales were $21.5 billion, an increase of 6.7%. International sales were $14.8 billion, an increase of 10.8%, which included 10.1% operational growth and a positive currency impact of 0.7%. In 2017, acquisitions and divestitures had a net positive impact of 3.8% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the reported Pharmaceutical segment operational growth by approximately 1.8%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales:*

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Total Immunology	**$ 12,244**	**11,968**	**10,402**	**2.3 %**	**15.1**
REMICADE®	6,315	6,966	6,561	(9.3)	6.2
SIMPONI®/SIMPONI ARIA®	1,833	1,745	1,328	5.0	31.4
STELARA®	4,011	3,232	2,474	24.1	30.6
Other Immunology	85	25	39	**	(35.9)
Total Infectious Diseases	**3,154**	**3,208**	**3,656**	**(1.7)**	**(12.3)**
EDURANT®/rilpivirine	714	573	410	24.6	39.8
PREZISTA®/ PREZCOBIX®/REZOLSTA®/ SYMTUZA®	1,821	1,851	1,810	(1.6)	2.3
Other Infectious Diseases	619	784	1,436	(21.0)	(45.4)
Total Neuroscience	**5,986**	**6,085**	**6,259**	**(1.6)**	**(2.8)**
CONCERTA®/methylphenidate	791	863	821	(8.3)	5.1
INVEGA SUSTENNA®/XEPLION®/TRINZA®/ TREVICTA®	2,569	2,214	1,830	16.0	21.0
RISPERDAL CONSTA®	805	893	970	(9.9)	(7.9)
Other Neuroscience	1,821	2,115	2,638	(13.9)	(19.8)
Total Oncology	**7,258**	**5,807**	**4,695**	**25.0**	**23.7**
DARZALEX®	1,242	572	20	**	**
IMBRUVICA®	1,893	1,251	689	51.3	81.6
VELCADE®	1,114	1,224	1,333	(9.0)	(8.2)
ZYTIGA®	2,505	2,260	2,231	10.8	1.3
Other Oncology	504	500	422	0.8	18.5
Pulmonary Hypertension	**1,327**	**—**	**—**	***	***
OPSUMIT®	573	—	—	***	***
TRACLEER®	403	—	—	***	***
UPTRAVI®	263	—	—	***	***
Other	88	—	—	***	***
Cardiovascular / Metabolism / Other	**6,287**	**6,396**	**6,418**	**(1.7)**	**(0.3)**
XARELTO®	2,500	2,288	1,868	9.3	22.5
INVOKANA®/ INVOKAMET®	1,111	1,407	1,308	(21.0)	**7.6**
PROCRIT®/EPREX®	972	1,105	1,068	(12.0)	3.5
Other	1,704	1,596	2,174	6.8	(26.6)
Total Pharmaceutical Sales	**$ 36,256**	**33,464**	**31,430**	**8.3 %**	**6.5**

* Prior year amounts have been reclassified to conform to current year presentation.

** Percentage greater than 100% or not meaningful

***Products acquired from Actelion on June 16, 2017

Immunology products achieved sales of $12.2 billion in 2017, representing an increase of 2.3% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab), the launch of TREMFYA® (guselkumab) and sales growth of SIMPONI®/SIMPONI ARIA® (golimumab) outside the U.S. Lower sales of REMICADE® (infliximab) were due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. The Company continues to assert REMICADE® related patent rights. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.2 billion, a decline of 1.7% from 2016. Lower sales of OLYSIO® (simeprevir), vaccines and PREZISTA® (darunavir/cobicistat) were partially offset by sales growth of EDURANT®/ rilpivirine, PREZCOBIX®/REZOLSTA® and the launch of SYMTUZA®.

Neuroscience products sales were $6.0 billion, a decrease of 1.6% from 2016. Lower sales of RISPERDAL CONSTA® (risperidone) and CONCERTA®/methylphenidate as well as the impact of divestitures were partially offset by strong sales of INVEGA SUSTENNA®/XEPLION®/ TRINZA®/TREVICTA®(paliperidone palmitate) long-acting injectables.

Oncology products achieved sales of $7.3 billion in 2017, representing an increase of 25.0% as compared to the prior year. Contributors to the growth of Oncology products were strong sales of DARZALEX® (daratumumab) and IMBRUVICA® (ibrutinib) driven by market share and market growth and sales of ZYTIGA® (abiraterone acetate) driven by market growth. Several generic companies are challenging the remaining patent for ZYTIGA® in the USPTO and in the United States District Court for the District of New Jersey. The Company is appealing a decision by the USPTO invalidating this patent, and the parties are awaiting a decision on a motion for summary judgment of non-infringement filed by the generic companies. In the event that the rulings are unfavorable to the Company, a generic launch is expected to follow. If there is a launch of a generic version of ZYTIGA® following FDA approval, it will result in a reduction in U.S. sales, and such reduction could occur in a short period of time. In 2017, the Company reported U.S. sales of $1.2 billion for ZYTIGA®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding ZYTIGA®.

Pulmonary Hypertension is a new therapeutic area which was established with the acquisition of Actelion Ltd on June 16, 2017. See Note 20 to the Consolidated Financial Statements for additional details regarding the acquisition.

Cardiovascular/Metabolism/Other products sales were $6.3 billion, a decline of 1.7% as compared to the prior year attributable to lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. primarily due to an increase in price discounts and market share decline driven by competitive pressure. This was partially offset by sales growth of XARELTO®(rivaroxaban) due to increased market growth and market share, as well as sales of non-PAH (pulmonary arterial hypertension) products from the Actelion acquisition.

During 2017, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approv	EU Approv	US Filing	EU Filing
apalutamide	An oral androgen receptor inhibitor for men with non-metastatic castration-resistant prostate cancer			✓	
DARZALEX® (daratumumab)	In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy		✓		
	In combination with pomalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least two prior therapies	✓			
	Frontline multiple myeloma transplant ineligible patients in combination with bortezomib, melphalan, and prednisone			✓	✓
IMBRUVICA® (ibrutinib)	Treatment for adult patients with chronic graft-versus-host-disease after failure of one or more lines of systemic therapy	✓			
	Marginal zone lymphoma	✓			
INVOKANA® (canagliflozin)	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease. (CANVAS/CANVAS-R)			✓	✓
JULUCA® (rilpivirine and dolutegravir)	Single-tablet, two-drug regimen of dolutegravir and rilpivirine for the maintenance treatment of HIV-1 infection	✓			✓
SIMPONI ARIA® (golimumab)	Treatment of adults living with active psoriatic arthritis and the treatment of adults living with active ankylosing spondylitis	✓			
STELARA® (ustekinumab)	Treatment of adolescents (12 to 17 years of age) with moderate to severe plaque psoriasis	✓			
SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide)	Single tablet regimen for HIV in treatment naïve patients and treatment experienced patients		✓	✓	
TREMFYA® (guselkumab)	Treatment of adults living with moderate to severe plaque psoriasis	✓	✓		
XARELTO® (rivaroxaban)	A 10 mg once-daily dose for reducing the continued risk for recurrent venous thromboembolism after completing at least six months of initial anticoagulation therapy	✓			
	For two new vascular indications: reducing the risk of major cardiovascular events and reducing the risk of acute limb ischemia in patients with PAD			✓	
ZYTIGA® (abiraterone acetate)	Prostate Cancer Newly Diagnosed Hormone Naïve Metastatic		✓	✓	

Pharmaceutical segment sales in 2016 were $33.5 billion, an increase of 6.5% from 2015, which included operational growth of 7.4% partially offset by a negative currency impact of 0.9%. U.S. sales were $20.1 billion, an increase of 9.8%. International sales were $13.3 billion, an increase of 1.8%, which included 4.0% operational growth partially offset by a negative currency impact of 2.2%. In 2016, acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.5% on the operational growth of the Pharmaceutical segment. In 2016, the Pharmaceutical segment operational growth was negatively impacted by 1.5% due to additional shipping days in 2015. The

Pharmaceutical segment operational growth for 2016, as compared to the prior year, was not impacted by adjustments to previous reserve estimates as both periods included approximately $0.5 billion of adjustments.

Medical Devices Segment

The Medical Devices segment sales in 2017 were $26.6 billion, an increase of 5.9% from 2016, which included an operational increase of 5.7% and a positive currency impact of 0.2%. U.S. sales were $12.8 billion, an increase of 4.5% as compared to the prior year. International sales were $13.8 billion, an increase of 7.1% as compared to the prior year, with an operational increase of 6.7% and a positive currency impact of 0.4%. In 2017, acquisitions and divestitures had a net positive impact of 4.2% on the worldwide operational sales growth of the Medical Devices segment as compared to 2016.

Major Medical Devices Franchise Sales:

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Surgery	**$ 9,559**	**9,296**	**9,217**	2.8 %	0.9
Advanced	3,756	3,517	3,275	6.8	7.4
General	4,463	4,362	4,482	2.3	(2.7)
Specialty	1,340	1,417	1,460	(5.4)	(2.9)
Orthopaedics	**9,258**	**9,334**	**9,262**	(0.8)	0.8
Hips	1,394	1,361	1,332	2.4	2.2
Knees	1,523	1,524	1,496	(0.1)	1.9
Trauma	2,616	2,569	2,528	1.8	1.6
Spine & Other	3,725	3,880	3,906	(4.0)	(0.7)
Vision Care	**4,063**	**2,785**	**2,608**	45.9	6.8
Contact Lenses/Other	3,036	2,785	2,608	9.0	6.8
Surgical	1,027	—	—	*	*
Cardiovascular	**2,096**	**1,849**	**2,036**	13.4	(9.2)
Diabetes Care	**1,615**	**1,789**	**1,928**	(9.7)	(7.2)
Diagnostics	**1**	**66**	**86**	**	**
Total Medical Devices Sales	**$ 26,592**	**$ 25,119**	**25,137**	**5.9 %**	**(0.1)**

*Products acquired from Abbott Medical Optics (AMO) on February 27, 2017

** On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise)

The Surgery franchise sales were $9.6 billion in 2017, an increase of 2.8% from 2016. Growth in Advanced Surgery was primarily driven by endocutter, energy, including the acquisition of Megadyne Medical Products, Inc., and biosurgery products. Growth in General Surgery was primarily driven by sutures and sales from the acquisition of Torax Medical, Inc. The sales decline in Specialty Surgery was primarily due to lower sales of aesthetic, Advanced Sterilization and Sterilmed products.

The Orthopaedics franchise sales were $9.3 billion in 2017, a decrease of 0.8% from 2016. The decline in Spine & Other was primarily due to the Codman Neurosurgery divestiture, share loss in U.S. Spine, pricing and competitive pressures. This was partially offset by sales growth of trauma, sports medicine products and U.S. hips.

The Vision Care franchise achieved sales of $4.1 billion in 2017, an increase of 45.9% from 2016. Growth was driven by sales from the acquisition of AMO, with the majority of AMO sales in the surgical category, and new product launches in the contact lenses category.

The Cardiovascular franchise sales were $2.1 billion, an increase of 13.4% from 2016. Strong growth in the electrophysiology business was driven by market growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

The Diabetes Care franchise sales were $1.6 billion, a decrease of 9.7% from 2016. The decline was primarily due to price declines and competitive pressures. Additionally, in the fourth quarter of 2017, the Company announced its decision to exit the Animas insulin pump business. Animas has selected Medtronic plc to facilitate a seamless transition for patients, caregivers and healthcare providers. The Company is continuing to evaluate potential strategic options for LifeScan, Inc. and determine the best opportunity to drive future growth and maximize shareholder value.

The Medical Devices segment sales in 2016 were $25.1 billion, a decrease of 0.1% from 2015, which included an operational increase of 0.9% and a negative currency impact of 1.0%. U.S. sales were $12.3 billion, an increase of 1.1% as compared to the prior year. International sales were $12.9 billion, a decrease of 1.2% as compared to the

prior year, with an operational increase of 0.7% and a negative currency impact of 1.9%. In 2016, acquisitions and divestitures had a negative

impact of 1.8% on the worldwide operational growth of the Medical Devices segment as compared to 2015. In 2016, the Medical Devices segment operational growth was negatively impacted by 0.9% due to additional shipping days in 2015.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income decreased to $17.7 billion in 2017, as compared to $19.8 billion in 2016, a decrease of 10.8%. The decrease was primarily attributable to higher amortization expense and other charges related to recent acquisitions, higher selling, marketing and administrative costs due to investments in new product launches and higher research and development costs due to general portfolio progression and collaborations.

Consolidated earnings before provision for taxes on income increased to $19.8 billion in 2016, as compared to $19.2 billion in 2015, an increase of 3.2%. The increase was primarily attributable to higher sales volume, favorable mix in the business and lower selling, marketing and administrative costs. This was partially offset by higher net litigation expense of $0.7 billion and a higher restructuring charge of $0.1 billion as compared to 2015. Additionally, the fiscal year 2015 included higher gains on the sale of assets/businesses as compared to 2016.

As a percent to sales, consolidated earnings before provision for taxes on income in 2017 was 23.1% versus 27.5% in 2016.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2017	2016	2015
Cost of products sold	33.2%	30.2%	30.7
Percent point increase/(decrease) over the prior year	3.0	(0.5)	0.1
Selling, marketing and administrative expenses	28.0%	27.7%	30.3
Percent point increase/(decrease) over the prior year	0.3	(2.6)	0.8

In 2017, cost of products sold as a percent to sales increased to 33.2% from 30.2% as compared to the same period a year ago. The unfavorable increase was primarily driven by $2.3 billion of higher amortization expense and charges for inventory step-up related to the recent acquisitions, primarily Actelion. Intangible asset amortization expense of $3.0 billion was included in cost of products sold for 2017 as compared to $1.2 billion in 2016. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2017 as compared to the prior year, primarily due to investments in new product launches partially offset by favorable mix.

In 2016, cost of products sold as a percent to sales decreased to 30.2% from 30.7% as compared to the same period a year ago. Favorable mix in the business and cost improvement programs was partially offset by the unfavorable impact of transactional currency. Intangible asset amortization expense of $1.2 billion was included in cost of products sold for 2016 and 2015. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2016 compared to the prior year, primarily due to cost management in all the segments and favorable mix.

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

	2017		2016		2015	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 584	4.3%	$ 580	4.4%	625	4.6
Pharmaceutical	8,360	23.1	6,967	20.8	6,821	21.7
Medical Devices	1,610	6.1	1,548	6.2	1,600	6.4
Total research and development expense	$ 10,554	13.8%	$ 9,095	12.7%	9,046	12.9
Percent increase/(decrease) over the prior year	16.0%		0.5%		6.5	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones,

improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2017, worldwide costs of research and development activities increased by 16.0% compared to 2016. The increase as a percent of sales was primarily in the pharmaceutical segment due to general portfolio progression as well as collaborative agreements entered into with Idorsia Ltd. and Legend Biotech. In 2016, worldwide costs of research and development activities increased by 0.5% compared to

2015 but decreased as a percent of sales. The decrease as a percent of sales was attributable to higher overall sales in the Pharmaceutical segment. The increased dollar spend in the Pharmaceutical segment was for investment spending to advance the pipeline.

In-Process Research and Development (IPR&D): In 2017, the Company recorded an IPR&D charge of $0.4 billion primarily for the discontinuation of certain development projects related to Novira which was acquired in 2015. The product development was canceled due to safety concerns. In 2016, the Company recorded an IPR&D charge of $29 million for the discontinuation of a development program related to Crucell. In 2015, the Company recorded an IPR&D charge of $0.2 billion primarily for the discontinuation of certain development projects related to Covagen.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal year 2017 was a favorable change of $0.3 billion due to higher gains of $0.7 billion on the sale of assets/businesses, primarily the Codman Neurosurgery and COMPEED® divestitures, a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities as compared to the prior year. This was partially offset by higher litigation expense of $0.4 billion, $0.3 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of $0.2 billion primarily related to the insulin pump business and a higher restructuring related charge of $0.2 billion as compared to the fiscal year 2016.

The change in other (income) expense, net for the fiscal year 2016 was an unfavorable change of $2.5 billion as compared to the prior year primarily due to higher gains on the sale of assets/businesses in the fiscal year 2015 as compared to 2016. The fiscal year of 2016 included gains of $0.6 billion from the divestitures of the controlled substance raw material and API business, certain anesthetic products in Europe and certain non-strategic Consumer brands versus gains of $2.6 billion recorded in 2015 primarily from the divestiture of the Cordis business, the U.S. divestiture of NUCYNTA® and the SPLENDA® brand. Additionally, the fiscal year of 2016 included higher litigation expense of $0.7 billion as compared to 2015. This was partially offset by a $0.3 billion intangible asset write-down related to Acclarent included in the fiscal year 2015.

Interest (Income) Expense: Interest income in 2017 increased slightly as compared to 2016 due to higher average interest rates partially offset by lower cash, cash equivalents and marketable securities balances during the period. Cash, cash equivalents and marketable securities totaled $18.3 billion at the end of 2017, and averaged $30.1 billion as compared to the $40.1 billion average cash balance in 2016. The decrease in the balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes including acquisitions, primarily the Actelion acquisition for $29.6 billion, net of cash acquired.

Interest expense in 2017 was higher as compared to 2016. The average debt balance was $30.9 billion in 2017 versus $23.5 billion in 2016. The total debt balance at the end of 2017 was $34.6 billion as compared to $27.1 billion at the end of 2016. The higher debt balance of approximately $7.5 billion was primarily due to increased borrowings. The Company increased borrowings in February and November of 2017, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, including the completion of the stock repurchase program.

Interest income in 2016 increased by $0.2 billion as compared to 2015 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled $41.9 billion at the end of 2016, and averaged $40.1 billion as compared to the $35.7 billion average cash balance in 2015.

Interest expense in 2016 was higher as compared to 2015. The average debt balance was $23.5 billion in 2016 versus $19.3 billion in 2015. The total debt balance at the end of 2016 was $27.1 billion as compared to $19.9 billion at the end of 2015. The higher debt balance of approximately $7.2 billion was primarily due to increased borrowings in February and May of 2016. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, primarily the stock repurchase program.

Income Before Tax by Segment
Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	2017	2016	2017	2016	2017	2016
Consumer	$ 2,524	2,441	$ 13,602	13,307	18.6%	18.3
Pharmaceutical	11,083	12,827	36,256	33,464	30.6	38.3
Medical Devices	5,392	5,578	26,592	25,119	20.3	22.2
Total [1]	18,999	20,846	76,450	71,890	24.9	29.0
Less: Expenses not allocated to segments [2]	1,326	1,043				
Earnings before provision for taxes on income	$ 17,673	19,803	$ 76,450	71,890	23.1%	27.5

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Increase in 2017 was primarily due to higher interest expense of $0.2 billion on higher debt balance.

Consumer Segment: In 2017, the Consumer segment income before tax as a percent to sales was 18.6%, versus 18.3% in 2016. The increase in the income before tax as a percent of sales in 2017 as compared to 2016 was attributable to higher gains on divestitures, primarily the divestiture of COMPEED® in 2017. This was partially offset by higher selling, marketing and administrative expenses as compared to the prior year due to increased advertising and promotional spending and slightly higher amortization expense in 2017 related to acquisitions. Additionally, the fiscal year 2016 was negatively impacted by operations in Venezuela.

In 2016, the Consumer segment income before tax as a percent to sales was 18.3%, versus 13.2% in 2015, primarily driven by favorable selling, marketing and administrative expenses due to cost management and higher gross profit margins from cost improvement projects and favorable mix. This was partially offset by higher gains in 2015 related to divestitures, primarily the divestiture of the SPLENDA® brand. Additionally, operations in Venezuela negatively impacted the Consumer segment income before tax in 2016 as compared to 2015.

Pharmaceutical Segment: In 2017, the Pharmaceutical segment income before tax as a percent to sales was 30.6% versus 38.3% in 2016. The decrease in the income before tax as a percent of sales was primarily due to $2.3 billion of higher amortization expense and other costs related to the Actelion acquisition, higher research and development expense, a higher IPR&D charge of $0.4 billion related to Novira and lower gains on divestitures as compared to the prior year. Additionally, the fiscal year 2016 included a positive adjustment of $0.5 billion to previous reserve estimates. This was partially offset by a gain of $0.2 billion related to monetization of future royalty receivables, a higher gain of $0.2 billion related to the sale of certain investments in equity securities and favorable product mix in 2017.

In 2016, the Pharmaceutical segment income before tax as a percent to sales was 38.3% versus 37.3% in 2015. The increase in income before tax was primarily due to strong sales volume growth and favorable selling, marketing and administrative expenses due to cost management. Additionally, the fiscal year 2015, had higher gains of $0.7 billion related to divestitures partially offset by a higher IPR&D charge of $0.2 billion as compared to 2016. The fiscal year of 2016 included the gains from the divestitures of the controlled substance raw material and API business and certain anesthetic products in Europe versus the gains recorded in 2015 from the U.S. divestiture of NUCYNTA®.

Medical Devices Segment: In 2017, the Medical Devices segment income before tax as a percent to sales was 20.3% versus 22.2% in 2016. The decrease in the income before tax as a percent to sales was primarily due to $0.3 billion of higher amortization expense and other acquisition costs related to AMO, $0.3 billion of higher litigation, an asset impairment charge of $0.2 billion primarily related to the insulin pump business, $0.1 billion of higher restructuring and investments in new product launches as compared to the fiscal year 2016. This was partially offset by $0.8 billion higher gains in 2017 related to divestitures, primarily the divestiture of Codman Neurosurgery.

In 2016, the Medical Devices segment income before tax as a percent to sales was 22.2% versus 27.2% in 2015. The decrease in the income before tax as a percent to sales was primarily due to lower gains of $1.4 billion related to divestitures, higher litigation expense of $0.8 billion and a higher restructuring charge of $0.1 billion as compared to 2015. This was partially offset by an intangible asset write-down of $0.3 billion related to Acclarent in 2015 and favorable selling, marketing and administrative expenses in 2016.

Restructuring: In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment. The restructuring actions are expected to result in annualized pre-tax cost savings of $800 million to $1.0 billion, the majority of which is expected to be realized by the end of 2018. Approximately $500 million in savings were realized in 2017. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion. In 2017, the Company recorded a pre-tax charge of $760 million, of which $88 million is included in cost of products sold and $363 million is included in other (income) expense. In 2016, the Company recorded a pre-tax charge of $685 million, of which $45 million is included in cost of products sold and $149 million is included in other (income) expense. In 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million was included in cost of products sold. Restructuring related charges of $2.0 billion have been recorded since the restructuring was announced. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income: The worldwide effective income tax rate was 92.6% in 2017, 16.5% in 2016 and 19.7% in 2015. The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the Tax Cuts and Jobs Act (TCJA) in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate. See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate, enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

The decrease in the 2016 effective tax rate, as compared to 2015 was primarily attributable to the Company adopting a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $17.8 billion at the end of 2017 as compared to $19.0 billion at the end of 2016. The primary sources and uses of cash that contributed to the $1.2 billion decrease were approximately $21.1 billion of cash generated from operating activities and $0.3 billion due to the effect on exchange rate changes on cash and cash equivalents offset by $14.9 billion net cash used by investing activities and $7.7 billion net cash used by financing activities. In addition, the Company had $0.5 billion in marketable securities at the end of 2017 and $22.9 billion at the end of 2016. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $21.1 billion was the result of $1.3 billion of net earnings and $9.8 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation, assets write-downs and deferred tax provision, reduced by $1.3 billion from net gains on sale of assets/businesses and $1.0 billion related to an increase in accounts receivable and an increase in other current and non-current assets. Additional sources of operating cash flow of $12.3 billion resulted from an increase in accounts payable and accrued liabilities, a decrease in inventories and an increase in other current and non-current liabilities. The increase in accrued liabilities and non-current liabilities is primarily due to the 2017 U.S. tax legislation (TCJA). The U.S. tax of $10.1 billion is payable over 8 years. Additionally, foreign taxes of $3.4 billion, net were recorded in the deferred tax provision.

Investing activities use of $14.9 billion was for acquisitions, net of cash acquired of $35.2 billion (primarily the acquisitions of Actelion and AMO for approximately $29.6 billion and $4.3 billion, respectively) and additions to property, plant and equipment of $3.3 billion. This was partially offset by proceeds from the net sale of investments primarily marketable securities of $22.0 billion and $1.8 billion of proceeds from the disposal of assets/businesses (primarily the divestitures of Codman Neurosurgery and COMPEED®).

Financing activities use of $7.7 billion was primarily for dividends to shareholders of $8.9 billion, $6.4 billion for the repurchase of common stock and $0.2 billion of other financing. Financing activities also included sources of $6.8 billion from net proceeds of short and long-term debt and $1.1 billion of proceeds from stock options exercised/ employee withholding tax on stock awards, net.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. As of July 2, 2017, $10.0 billion was repurchased under the program and the program was completed. Shares acquired are available for general corporate purposes.

As of December 31, 2017, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. In 2017, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs for the next twelve months. The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a new shelf registration on February 27, 2017 which will enable it to issue debt securities on a timely basis. In the fiscal first and fourth quarters of 2017, the Company issued bonds for a total of $9.0 billion for general corporate purposes, including the completion of the stock repurchase program. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 31, 2017 market rates would increase the unrealized value of the Company’s forward contracts by $167 million. Conversely, a 10% depreciation of the U.S. Dollar from the December 31, 2017 market rates would decrease the unrealized value of the Company’s forward contracts by $197 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $69 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company’s interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $8 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2017, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 13, 2018. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2017 and 2016 were $34.6 billion and $27.1 billion, respectively. The increase in borrowings between 2017 and 2016 was a result of financing for the Company's share repurchase program and general corporate purposes. In 2017, net debt (cash and current marketable securities, net of debt) was $16.3 billion compared to net cash of $14.8 billion in 2016. Total debt represented 36.5% of total capital (shareholders’ equity and total debt) in 2017 and 27.8% of total capital in 2016. Shareholders’ equity per share at the end of 2017 was $22.43 compared to $26.02 at year-end 2016, a decrease of 13.8%.

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

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 31, 2017 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2018	$ 1,614	1,499	1,002	88	227	4,430
2019	807	2,752	949	89	184	4,781
2020	807	1,105	883	94	143	3,032
2021	807	1,797	840	100	106	3,650
2022	1,513	2,189	796	108	76	4,682
After 2022	4,538	22,832	9,659	651	103	37,783
Total	**$ 10,086**	**32,174**	**14,129**	**1,130**	**839**	**58,358**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends

The Company increased its dividend in 2017 for the 55th consecutive year. Cash dividends paid were $3.32 per share in 2017 compared with dividends of $3.15 per share in 2016, and $2.95 per share in 2015. The dividends were distributed as follows:

	2017	2016	2015
First quarter	$ 0.80	0.75	0.70
Second quarter	0.84	0.80	0.75
Third quarter	0.84	0.80	0.75
Fourth quarter	0.84	0.80	0.75
Total	**$ 3.32**	**3.15**	**2.95**

On January 2, 2018, the Board of Directors declared a regular quarterly cash dividend of $0.84 per share, payable on March 13, 2018, to shareholders of record as of February 27, 2018. The Company expects to continue the practice of paying regular cash dividends.

Other Information

Critical Accounting Policies and Estimates

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

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which will be adopted in 2018.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2017, 2016 and 2015.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were approximately 1% or less of the total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

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

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

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 31, 2017 and January 1, 2017.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2017				
Accrued rebates [1]	$ 136	638	(588)	186
Accrued returns	65	128	(125)	68
Accrued promotions	358	2,148	(2,025)	481
Subtotal	$ 559	2,914	(2,738)	735
Reserve for doubtful accounts	24	10	(3)	31
Reserve for cash discounts	25	205	(207)	23
Total	$ 608	3,129	(2,948)	789
2016				
Accrued rebates[1]	$ 139	615	(618)	136
Accrued returns	54	111	(100)	65
Accrued promotions	412	1,908	(1,962)	358
Subtotal	$ 605	2,634	(2,680)	559
Reserve for doubtful accounts	18	12	(6)	24
Reserve for cash discounts	17	209	(201)	25
Total	$ 640	2,855	(2,887)	608

(1) Includes reserve for customer rebates of $48 million at December 31, 2017 and $37 million at January 1, 2017, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2017				
Accrued rebates [1]	$ 3,420	16,447	(15,005)	4,862
Accrued returns	334	256	(228)	362
Accrued promotions	—	69	(34)	35
Subtotal	$ 3,754	16,772	(15,267)	5,259
Reserve for doubtful accounts	38	40	(1)	77
Reserve for cash discounts	58	714	(717)	55
Total	$ 3,850	17,526	(15,985)	5,391
2016				
Accrued rebates [1]	$ 3,451	12,306	(12,337)	3,420
Accrued returns	404	140	(210)	334
Accrued promotions	11	10	(21)	—
Subtotal	$ 3,866	12,456	(12,568)	3,754
Reserve for doubtful accounts	46	2	(10)	38
Reserve for cash discounts	63	613	(618)	58

Total	$ 3,975	13,071	(13,196)	3,850

(1) Includes reserve for customer rebates of $90 million at December 31, 2017 and $102 million at January 1, 2017, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2017				
Accrued rebates[(1)]	$ 1,500	6,407	(6,287)	1,620
Accrued returns	127	729	(704)	152
Accrued promotions	32	135	(84)	83
Subtotal	$ 1,659	7,271	(7,075)	1,855
Reserve for doubtful accounts	190	27	(34)	183
Reserve for cash discounts	16	389	(390)	15
Total	$ 1,865	7,687	(7,499)	2,053
2016				
Accrued rebates[(1)]	$ 1,189	5,700	(5,389)	1,500
Accrued returns	239	518	(630)	127
Accrued promotions	47	78	(93)	32
Subtotal	$ 1,475	6,296	(6,112)	1,659
Reserve for doubtful accounts	204	21	(35)	190
Reserve for cash discounts	20	430	(434)	16
Total	$ 1,699	6,747	(6,581)	1,865

(1) Includes reserve for customer rebates of $501 million at December 31, 2017 and $430 million at January 1, 2017, recorded as a contra asset.

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

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

In the fourth quarter of 2017, the United States enacted the TCJA, which includes provisions for a tax on all previously undistributed earnings in foreign jurisdictions. The Company has provisionally booked a $10.1 billion charge on these undistributed earnings in 2017. Additionally, the Company has provisionally recorded a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all undistributed foreign earnings. The Company is currently evaluating the remaining undistributed foreign earnings for which it has not provided deferred taxes for foreign local and withholding tax, as these earnings are considered to be indefinitely reinvested. The amount of these unrecorded deferred taxes is not expected to be material.

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

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

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

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2017.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2007 - 2017, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and in March 2017 the U.K. formally started the process for the U.K. to leave the E.U. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 31, 2017, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2017 would have increased or decreased the translation of foreign sales by approximately $360 million and income by $105 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries

where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

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

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 16, 2018, there were 147,484 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2017 and 2016 were:

	2017		2016	
	High	Low	High	Low
First quarter	$ 129.00	110.76	$ 109.56	94.28
Second quarter	137.00	120.95	121.54	107.88
Third quarter	137.08	129.05	126.07	117.04
Fourth quarter	144.35	130.02	122.50	109.32
Year-end close	$139.72		$115.21	

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to “Item 7. Management’s Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk” of this Report; and Note 1 “Summary of Significant Accounting Policies - Financial Instruments” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 31, 2017 and January 1, 2017
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2017	2016
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	17,824	18,972
Marketable securities (Notes 1 and 2)		472	22,935
Accounts receivable trade, less allowances for doubtful accounts $291 (2016, $252)		13,490	11,699
Inventories (Notes 1 and 3)		8,765	8,144
Prepaid expenses and other receivables		2,537	3,282
Total current assets		**43,088**	**65,032**
Property, plant and equipment, net (Notes 1 and 4)		17,005	15,912
Intangible assets, net (Notes 1 and 5)		53,228	26,876
Goodwill (Notes 1 and 5)		31,906	22,805
Deferred taxes on income (Note 8)		7,105	6,148
Other assets		4,971	4,435
Total assets	**$**	**157,303**	**141,208**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	3,906	4,684
Accounts payable		7,310	6,918
Accrued liabilities		7,304	5,635
Accrued rebates, returns and promotions		7,210	5,403
Accrued compensation and employee related obligations		2,953	2,676
Accrued taxes on income (Note 8)		1,854	971
Total current liabilities		**30,537**	**26,287**
Long-term debt (Note 7)		30,675	22,442
Deferred taxes on income (Note 8)		8,368	2,910
Employee related obligations (Notes 9 and 10)		10,074	9,615
Long-term taxes payable (Note 8)		8,472	—
Other liabilities		9,017	9,536
Total liabilities		**97,143**	**70,790**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(13,199)	(14,901)
Retained earnings		101,793	110,551
		91,714	98,770
Less: common stock held in treasury, at cost (Note 12) (437,318,000 shares and 413,332,000 shares)		31,554	28,352
Total shareholders' equity		**60,160**	**70,418**
Total liabilities and shareholders' equity	**$**	**157,303**	**141,208**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2017	2016	2015
Sales to customers	$ 76,450	71,890	70,074
Cost of products sold	25,354	21,685	21,536
Gross profit	51,096	50,205	48,538
Selling, marketing and administrative expenses	21,420	19,945	21,203
Research and development expense	10,554	9,095	9,046
In-process research and development	408	29	224
Interest income	(385)	(368)	(128)
Interest expense, net of portion capitalized (Note 4)	934	726	552
Other (income) expense, net	183	484	(2,064)
Restructuring (Note 22)	309	491	509
Earnings before provision for taxes on income	17,673	19,803	19,196
Provision for taxes on income (Note 8)	16,373	3,263	3,787
Net earnings	**$ 1,300**	**16,540**	**15,409**
Net earnings per share (Notes 1 and 15)			
Basic	**$ 0.48**	**6.04**	**5.56**
Diluted	**$ 0.47**	**5.93**	**5.48**
Cash dividends per share	**$ 3.32**	**3.15**	**2.95**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,692.0**	**2,737.3**	**2,771.8**
Diluted	**2,745.3**	**2,788.9**	**2,812.9**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2017	2016	2015
Net earnings	$ 1,300	16,540	15,409
Other comprehensive income (loss), net of tax			
Foreign currency translation	1,696	(612)	(3,632)
Securities:			
Unrealized holding gain (loss) arising during period	159	(52)	471
Reclassifications to earnings	(338)	(141)	(124)
Net change	(179)	(193)	347
Employee benefit plans:			
Prior service credit (cost), net of amortization	2	21	(60)
Gain (loss), net of amortization	29	(862)	931
Effect of exchange rates	(201)	159	148
Net change	(170)	(682)	1,019
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(4)	(359)	(115)
Reclassifications to earnings	359	110	(62)
Net change	355	(249)	(177)
Other comprehensive income (loss)	1,702	(1,736)	(2,443)
Comprehensive income	$ 3,002	14,804	12,966

The tax effects in other comprehensive income for the fiscal years ended 2017, 2016 and 2015 respectively: Securities; $96 million, $104 million and $187 million, Employee Benefit Plans; $83 million, $346 million and $519 million, Derivatives & Hedges; $191 million, $134 million and $95 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 28, 2014	**$ 69,752**	**97,245**	**(10,722)**	**3,120**	**(19,891)**
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	**71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**
Net earnings	16,540	16,540			
Cash dividends paid	(8,621)	(8,621)			
Employee compensation and stock option plans	2,130	(1,181)			3,311
Repurchase of common stock	(8,979)				(8,979)
Other	(66)	(66)			
Other comprehensive income (loss), net of tax	(1,736)		(1,736)		
Balance, January 1, 2017	**70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**$ 60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2017	2016	2015
Cash flows from operating activities				
Net earnings	$	1,300	16,540	15,409
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		5,642	3,754	3,746
Stock based compensation		962	878	874
Venezuela adjustments		—	—	122
Asset write-downs		795	283	624
Net gain on sale of assets/businesses		(1,307)	(563)	(2,583)
Deferred tax provision		2,406	(341)	(270)
Accounts receivable allowances		17	(11)	18
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(633)	(1,065)	(433)
Decrease/(Increase) in inventories		581	(249)	(449)
Increase in accounts payable and accrued liabilities		2,725	656	287
Increase in other current and non-current assets		(411)	(529)	(103)
Increase/(Decrease) in other current and non-current liabilities		8,979	(586)	2,327
Net cash flows from operating activities		**21,056**	**18,767**	**19,569**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,279)	(3,226)	(3,463)
Proceeds from the disposal of assets/businesses, net		1,832	1,267	3,464
Acquisitions, net of cash acquired (Note 20)		(35,151)	(4,509)	(954)
Purchases of investments		(6,153)	(33,950)	(40,828)
Sales of investments		28,117	35,780	34,149
Other (primarily intangibles)		(234)	(123)	(103)
Net cash used by investing activities		**(14,868)**	**(4,761)**	**(7,735)**
Cash flows from financing activities				
Dividends to shareholders		(8,943)	(8,621)	(8,173)
Repurchase of common stock		(6,358)	(8,979)	(5,290)
Proceeds from short-term debt		869	111	2,416
Retirement of short-term debt		(1,330)	(2,017)	(1,044)
Proceeds from long-term debt, net of issuance costs		8,992	12,004	75
Retirement of long-term debt		(1,777)	(2,223)	(68)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		1,062	1,189	1,005
Other		(188)	(15)	(57)
Net cash used by financing activities		**(7,673)**	**(8,551)**	**(11,136)**
Effect of exchange rate changes on cash and cash equivalents		337	(215)	(1,489)
(Decrease)/Increase in cash and cash equivalents		(1,148)	5,240	(791)
Cash and cash equivalents, beginning of year (Note 1)		18,972	13,732	14,523
Cash and cash equivalents, end of year (Note 1)	**$**	**17,824**	**18,972**	**13,732**

Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	960	730	617

Interest, net of amount capitalized	866	628	515
Income taxes	3,312	2,843	2,865

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	2,062	2,043	1,486
Conversion of debt		16	35	16

Acquisitions				
Fair value of assets acquired	$	36,937	4,586	1,174
Fair value of liabilities assumed and noncontrolling interests		(1,786)	(77)	(220)
Net cash paid for acquisitions	**$**	**35,151**	**4,509**	**954**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Accounting Standard adopted in 2016

During the fiscal second quarter of 2016, the Company adopted Accounting Standards Update (ASU) 2016-09 Compensation - Stock Compensation: Improvements to Employee Share Based Payment Accounting for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The update requires all excess tax benefits and deficiencies to be recognized as a reduction or an increase to the provision for taxes on income. Previously, the Company recorded these benefits directly to Retained Earnings. The tax benefit for the Company was $353 million for the fiscal year 2016. The standard does not permit retroactive presentation of this benefit to prior fiscal years on the Consolidated Statement of Earnings.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2016-07: Simplifying the Transition to the Equity Method of Accounting

The amendments in the update eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step by step basis as if the equity method had been in effect during all previous periods that the investment had been held. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The amendments should be applied prospectively upon their effective date to increases in the level of ownership interest or degree of influence that result in the application of the equity method. The adoption of this standard did not have a material impact on the presentation of the Company's consolidated financial statements.

ASU 2015-11: Simplifying the Measurement of Inventory

This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update is effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively. This update did not have any material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

Not Adopted as of December 31, 2017

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017. This update will be effective for the

Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2017-12: Targeted Improvements to Accounting for Hedging Activities
This update makes more financial and nonfinancial hedging strategies eligible for hedge accounting. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. This update will be effective for the Company for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted upon its issuance. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

ASU 2017-07: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost
This update requires that an employer disaggregate the service cost component from the other components of net periodic benefit cost ("NPBC"). In addition, only the service cost component will be eligible for capitalization. This update is effective for the Company for all annual and interim periods beginning after December 15, 2017. Early adoption is permitted as of the beginning of an annual period for which financial statements (interim or annual) have not been issued or made available for issuance. The amendments in this Update should be applied retrospectively for the presentation of the service cost component and the other components of NPBC in the income statement and prospectively, on and after the effective date, for the capitalization of the service cost component of NPBC in assets. The Company is assessing the retroactive restatement methodology and impact to the individual line items on Consolidated Statement of Earnings. The Company does not expect there to be a material impact to net earnings.

ASU 2017-01: Clarifying the Definition of a Business
This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted. This update should be applied prospectively. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2016-16: Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory
This update removes the current exception in US GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The amendments in this update are effective for public entities for annual reporting periods beginning after December 15, 2017. The results from a preliminary assessment indicate that the adoption of the standard will not have a significant impact on the Company's financial results. The Company expects to record net adjustments to deferred taxes of approximately $2.0 billion, a decrease to Other Assets of approximately $0.7 billion and an increase to retained earnings of approximately $1.3 billion.

ASU 2016-02: Leases
This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company anticipates that most of its operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets, however does not expect the standard to have a material impact on the financial position. The actual impact will depend on the Company's lease portfolio at the time of adoption. The Company continues to assess all implications of the standard and related financial disclosures.

ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities
The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

ASU 2014-09: Revenue from Contracts with Customers
The amendments replace substantially all current U.S. GAAP guidance on this topic and eliminate industry-specific guidance. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting

periods beginning after December 15, 2017. The Company will adopt the standard using the modified retrospective method. The adoption of this standard will not have a material impact on the Company's consolidated financial statements including the additional disclosure requirements.

Cash Equivalents

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

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

Investments

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

Property, Plant and Equipment and Depreciation

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

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

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

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset’s fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for

returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2017, 2016 and 2015.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling

Shipping and handling costs incurred were $1,042 million, $974 million and $996 million in 2017, 2016 and 2015, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

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

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2017 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

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

Financial Instruments

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

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

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval.

Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

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

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

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

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

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

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.5 billion, $2.4 billion and $2.5 billion in 2017, 2016 and 2015, respectively.

Income Taxes

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

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

In the fourth quarter of 2017, the United States enacted the TCJA, which includes provisions for a tax on all previously undistributed earnings in foreign jurisdictions. The Company has provisionally booked a $10.1 billion charge on these undistributed earnings in 2017. Additionally, the Company has provisionally recorded a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all undistributed foreign earnings. The Company is currently evaluating the remaining undistributed foreign earnings for which it has not provided deferred taxes for foreign local and withholding tax, as these earnings are considered to be indefinitely reinvested. The amount of these unrecorded deferred taxes is not expected to be material.

See Note 8 for further information regarding income taxes.

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

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

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

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2017 and 2016, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2017			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,929	2,929	$ 2,929	—
U.S. Gov't Securities[1]	—	—	—	—
Other Sovereign Securities[1]	279	279	219	60
U.S. Reverse repurchase agreements	4,025	4,025	4,025	—
Other Reverse repurchase agreements	—	—	—	—
Corporate debt securities[1]	289	289	244	45
Money market funds	4,288	4,288	4,288	—
Time deposits[1]	1,176	1,176	1,175	1
Subtotal	$ 12,986	12,986	12,880	106
Gov't Securities	$ 4,864	4,864	4,833	31
Other Sovereign Securities	186	186	80	106
Corporate debt securities	260	260	31	229
Subtotal available for sale[2]	$ 5,310	5,310	4,944	366
Total cash, cash equivalents and current marketable securities			**$ 17,824**	**472**

In 2017, the carrying amount was the same as the estimated fair value.

(Dollars in Millions)	2016					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 1,979	—	—	1,979	1,979	—
U.S. Gov't Securities[1]	10,832	—	(1)	10,831	2,249	8,583
Other Sovereign Securities[1]	1,299	—	—	1,299	120	1,179
U.S. Reverse repurchase agreements	6,103	—	—	6,103	6,103	—
Other Reverse repurchase agreements	240	—	—	240	240	—
Corporate debt securities[1]	754	—	—	754	—	754
Money market funds	7,187	—	—	7,187	7,187	—
Time deposits[1]	1,094	—	—	1,094	1,094	—
Subtotal	$ 29,488	—	(1)	29,487	18,972	10,516
		Unrealized Gain	Unrealized Loss			
Gov't Securities	$ 10,277	5	(51)	10,231	—	10,231
Other Sovereign Securities	90	—	—	90		90
Corporate debt securities	1,777	1	(12)	1,766	—	1,766
Equity investments	34	298	—	332		332
Subtotal available for sale[2]	$ 12,178	304	(63)	12,419	—	12,419
Total cash, cash equivalents and current marketable securities					**$ 18,972**	**22,935**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

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

The contractual maturities of the available for sale debt securities at December 31, 2017 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 5,214	5,214
Due after one year through five years	96	96
Due after five years through ten years	—	—
Total debt securities	$ 5,310	5,310

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

3. Inventories

At the end of 2017 and 2016, inventories were comprised of:

(Dollars in Millions)	2017	2016
Raw materials and supplies	$ 1,140	952
Goods in process	2,317	2,185
Finished goods	5,308	5,007
Total inventories	**$ 8,765**	**8,144**

4. Property, Plant and Equipment

At the end of 2017 and 2016, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2017	2016
Land and land improvements	$ 829	753
Buildings and building equipment	11,240	10,112
Machinery and equipment	25,949	23,554
Construction in progress	3,448	3,354
Total property, plant and equipment, gross	$ 41,466	37,773
Less accumulated depreciation	24,461	21,861
Total property, plant and equipment, net	**$ 17,005**	**15,912**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2017, 2016 and 2015 was $94 million, $102 million and $102 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2017, 2016 and 2015 was $2.6 billion, $2.5 billion and $2.5 billion, respectively.

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

5. Intangible Assets and Goodwill

At the end of 2017 and 2016, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2017	2016
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 36,427	10,521
Less accumulated amortization	7,223	5,076
Patents and trademarks — net	**$ 29,204**	**5,445**
Customer relationships and other intangibles — gross	$ 20,204	17,615
Less accumulated amortization	7,463	6,515
Customer relationships and other intangibles — net	**$ 12,741**	**11,100**
Intangible assets with indefinite lives:		
Trademarks	$ 7,082	6,888
Purchased in-process research and development	4,201	3,443
Total intangible assets with indefinite lives	**$ 11,283**	**10,331**
Total intangible assets — net	**$ 53,228**	**26,876**

Goodwill as of December 31, 2017 and January 1, 2017, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at January 3, 2016	$ 7,240	2,889	11,500	21,629
Goodwill, related to acquisitions	1,362	—	210	1,572
Goodwill, related to divestitures	(63)	(12)	—	(75)
Currency translation/other	(276)	(37)	(8)	(321)
Goodwill at January 1, 2017	$ 8,263	2,840	11,702	22,805
Goodwill, related to acquisitions	102	6,161	2,200	8,463
Goodwill, related to divestitures	(74)	(1)	(102)	(177)
Currency translation/other	584	109	122	815
Goodwill at December 31, 2017	**$ 8,875**	**9,109**	**13,922**	**31,906**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 12 years and 23 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $3.0 billion, $1.2 billion and $1.2 billion before tax, for the fiscal years ended December 31, 2017, January 1, 2017 and January 3, 2016, respectively. The estimated amortization expense for the five succeeding years approximates $4.4 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

The primary driver of the increase to intangible assets and goodwill is related to the Actelion acquisition in the fiscal second quarter of 2017, which resulted in the recording of $25.0 billion to intangible assets and $6.2 billion to goodwill. The intangible assets and goodwill amounts related to the Actelion acquisition are based on the preliminary purchase price allocation. Additionally, the Abbott Medical Optics (AMO) acquisition in the fiscal first quarter of 2017, resulted in the recording of $2.3 billion to intangible assets and $1.7 billion to goodwill. The intangible assets and goodwill amounts related to the AMO acquisition are based on the final purchase price allocation.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

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

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

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 31, 2017, the total amount of collateral paid under the credit support agreements (CSA) amounted to $162 million net. For equity collar contracts, the Company pledged the underlying hedged marketable equity securities to the counter-party as collateral. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 31, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $34.5 billion, $2.3 billion, and $1.1 billion respectively. As of January 1, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate

swaps, interest rate swaps and equity collar contracts of $36.0 billion, $2.3 billion, $1.8 billion, and $0.3 billion respectively.

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

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts, cross currency interest rate swaps, net investment hedges and equity collar contracts. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

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

The change in the carrying value due to remeasurement of these Euro notes resulted in a $597 million unrealized pretax loss for the fiscal year ended December 31, 2017, reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income. The change in the carrying value due to remeasurement of these Euro notes resulted in a cumulative $222 million unrealized pretax loss from hedge inception through the fiscal year ended December 31, 2017, reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

As of December 31, 2017, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was $70 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended December 31, 2017 and January 1, 2017:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/ Expense[2]	
Cash Flow Hedges by Income Statement Caption	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**
Sales to customers [3]	$ 49	(65)	(31)	(47)	(1)	(1)
Cost of products sold [3]	96	(212)	(159)	(3)	(10)	(15)
Research and development expense [3]	(199)	(76)	(165)	(90)	5	—
Interest (income)/Interest expense, net [4]	110	66	83	37	—	—
Other (income) expense, net [3] [5]	(60)	(72)	(87)	(7)	—	2
Total	**$ (4)**	**(359)**	**(359)**	**(110)**	**(6)**	**(14)**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Forward foreign exchange contracts

(4) Cross currency interest rate swaps

(5) Includes equity collar contracts

For the fiscal years ended December 31, 2017 and January 1, 2017, a loss of $5 million and $56 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

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

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of December 31, 2017 and January 1, 2017 were as follows:

	2017				2016
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	$ —	342	—	342	747
Interest rate contracts [2][4] [7]	—	7	—	7	31
Total	—	**349**	—	**349**	**778**
Liabilities:					
Forward foreign exchange contracts [7]	—	314	—	314	723
Interest rate contracts [3][4] [7]	—	15	—	15	382
Equity collar contracts	—	—	—	—	57
Total	—	**329**	—	**329**	**1,162**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	—	38	—	38	34
Liabilities:					
Forward foreign exchange contracts [7]	—	38	—	38	57
Available For Sale Other Investments:					
Equity investments[5]	751	—	—	751	1,209
Debt securities[6]	$ —	5,310	—	5,310	12,087

(1) 2016 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,209 million, which are classified as Level 1.

(2)

Includes $7 million and $23 million of non-current assets for the fiscal years ending December 31, 2017 and January 1, 2017, respectively.

(3) Includes $9 million and $382 million of non-current liabilities for the fiscal years ending December 31, 2017 and January 1, 2017, respectively.

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

(5) Classified as non-current other assets. The carrying amount of the equity investments were $394 million and $520 million as of December 31, 2017 and January 1, 2017, respectively. The unrealized gains were $367 million and $757 million as of December 31, 2017 and January 1, 2017, respectively. The unrealized losses were $10 million and $68 million as of December 31, 2017 and January 1, 2017, respectively.

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

(7) Includes collateral exchanged on the credit support agreements on derivatives.

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

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2017	Effective Rate %	2016	Effective Rate %
5.55% Debentures due 2017	$ —	—	1,000	5.55
1.125% Notes due 2017	—	—	699	1.15
5.15% Debentures due 2018	900	5.18	899	5.18
1.65% Notes due 2018	597	1.70	600	1.70
4.75% Notes due 2019 (1B Euro 1.1947)[2]/ (1B Euro 1.0449)[3]	1,192 [2]	5.83	1,041 [3]	5.83
1.875% Notes due 2019	496	1.93	499	1.93
0.89% Notes due 2019	300	1.75	299	1.20
1.125% Notes due 2019	699	1.13	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	60	3.00	84	3.00
2.95% Debentures due 2020	547	3.15	546	3.15
1.950% Notes due 2020	499	1.99	—	—
3.55% Notes due 2021	448	3.67	447	3.67
2.45% Notes due 2021	349	2.48	348	2.48
1.65% Notes due 2021	998	1.65	997	1.65
0.250% Notes due 2022 (1B Euro 1.1947)[2]/ (1B Euro 1.0449)[3]	1,191 [2]	0.26	1,041 [3]	0.26
2.25% Notes due 2022	995	2.31	—	—
6.73% Debentures due 2023	250	6.73	249	6.73
3.375% Notes due 2023	806	3.17	807	3.17
2.05% Notes due 2023	498	2.09	497	2.09
0.650% Notes due 2024 (750MM Euro 1.1947)[2]/(750MM Euro 1.0449)[3]	891 [2]	0.68	779 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.3444)[2]/(500MM GBP 1.2237)[3]	666 [2]	6.75	605 [3]	6.75
2.625% Notes due 2025	747	2.63	—	—
2.45% Notes due 2026	1,990	2.47	1,989	2.47
2.95% Notes due 2027	995	2.96	—	—
1.150% Notes due 2028 (750MM Euro 1.1947)[2]/(750MM Euro 1.0449)[3]	887 [2]	1.21	775 [3]	1.21
2.900% Notes due 2028	1,492	2.91	—	—
6.95% Notes due 2029	296	7.14	296	7.14
4.95% Debentures due 2033	498	4.95	497	4.95
4.375% Notes due 2033	856	4.24	857	4.24
1.650% Notes due 2035 (1.5B Euro 1.1947) [2]/(1.5B Euro 1.0449)[3]	1,774 [2]	1.68	1,549 [3]	1.68
3.55% Notes due 2036	987	3.59	987	3.59
5.95% Notes due 2037	991	5.99	990	5.99
3.625% Notes due 2037	1,486	3.64	—	—
5.85% Debentures due 2038	696	5.85	695	5.85
3.400% Notes due 2038	990	3.42	—	—
4.50% Debentures due 2040	538	4.63	537	4.63
4.85% Notes due 2041	296	4.89	296	4.89
4.50% Notes due 2043	495	4.52	495	4.52

3.70% Notes due 2046	1,971	3.74	1,970	3.74
3.75% Notes due 2047	990	3.76	—	—
3.500% Notes due 2048	742	3.52	—	—
Other	75	—	77	—
Subtotal	**32,174** (4)	**3.19 %** (1)	**24,146** (4)	**3.33** (1)
Less current portion	1,499		1,704	
Total long-term debt	**$ 30,675**		**22,442**	

(1) Weighted average effective rate.

(2) Translation rate at December 31, 2017.

(3) Translation rate at January 1, 2017.

(4) The excess of the fair value over the carrying value of debt was $2.0 billion in 2017 and $1.6 billion in 2016.

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

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2017, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 13, 2018. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2017, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.9 billion at the end of 2017, of which $2.3 billion was borrowed under the Commercial Paper Program, $1.5 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2016, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $4.7 billion at the end of 2016, of which $2.7 billion was borrowed under the Commercial Paper Program, $1.7 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2018 are:

(Dollars in Millions)

2018	2019	2020	2021	2022	After 2022
$1,499	2,752	1,105	1,797	2,189	22,832

8. Income Taxes

Tax Cuts and Jobs Act (TCJA) and SEC Staff Accounting Bulletin 118 (SAB 118)

On December 22, 2017, the United States enacted into law new U.S. tax legislation, referred to as the TCJA. This law includes provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This new legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also includes a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents is taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest.

In December 2017, the SEC provided regulatory guidance for accounting of the impacts of the TCJA, referred to as SAB 118. Under the guidance in SAB 118, the income tax effects, which the accounting under ASC 740 is incomplete, are reported as a provisional amount based on a reasonable estimate. The reasonable estimate is subject to adjustment during a "measurement period", not to exceed one year, until the accounting is complete. The estimate is also subject to the finalization of management’s analysis related to certain matters, such as developing interpretations of the provision of the TCJA, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries and the filing of tax returns.

As a result of the enactment of the TCJA, the Company recorded a provisional tax cost of $13.0 billion in the fourth quarter of 2017. This provisional charge was assessed as of January 18, 2018 and consisted of:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings

- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on tax reserves, and
- a $0.1
billion charge for U.S. state and local taxes on the repatriation of these foreign earnings.

In determining this charge, the Company utilized the most recent information and guidance available related to the calculation of the tax liability and the impact to its deferred tax assets and liabilities, including those recorded for foreign local and withholding taxes that the Company assessed as of January 18, 2018. The provisional charge may require further adjustments and changes to the Company's estimates as new guidance is made available. Revisions to the provisional charge may be material to the Company's financial results.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, in response to inquiries by companies, the FASB issued guidance that allows companies to elect as an accounting policy whether to treat the GILTI tax as a period cost or to recognize deferred tax assets and liabilities when basis differences exist that are expected to affect the amount of GILTI inclusion upon reversal. The Company has provisionally elected to treat GILTI as a period expense pending further analysis of this new tax provision.

The provision for taxes on income consists of:

(Dollars in Millions)	2017	2016	2015
Currently payable:			
U.S. taxes	$ 11,969	1,896	2,748
International taxes	1,998	1,708	1,309
Total currently payable	13,967	3,604	4,057
Deferred:			
U.S. taxes	(1,956)	294	37
International taxes	4,362	(635)	(307)
Total deferred	2,406	(341)	(270)
Provision for taxes on income	**$ 16,373**	**3,263**	**3,787**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2017, 2016 and 2015, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2017	2016	2015
U.S.	$ 4,865	7,457	8,179
International	12,808	12,346	11,017
Earnings before taxes on income:	$ 17,673	19,803	19,196
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations [1]	(12.8)	(17.2)	(15.4)
Research and orphan drug tax credits	(0.4)	(0.4)	(0.2)
U.S. state and local	0.6	(0.1)	0.4
U.S. manufacturing deduction	(0.8)	(0.6)	(0.6)
U.S. tax on international income	0.7	1.3	0.2
Tax benefits on share based compensation	(2.1)	(1.8)	—
U.S. tax benefit on asset/business disposals	(0.8)	—	—
All other	(0.1)	0.3	0.3
TCJA impact	73.3 [2]	—	—
Effective Rate	92.6 %	16.5 %	19.7 %

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. In 2017, International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the United States, particularly Ireland, Switzerland and Puerto Rico, which is a

favorable impact on the effective tax rate as compared with the 35.0% U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the TCJA in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The decrease in the 2016 effective tax rate, as compared to 2015 was primarily attributable to the Company adopting a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2017 and 2016 were as follows:

	2017 Deferred Tax		2016 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,259		2,958	
Stock based compensation	507		749	
Depreciation		(9)		(219)
Non-deductible intangibles		(6,506)		(6,672)
International R&D capitalized for tax	1,307		1,264	
Reserves & liabilities	1,718		1,857	
Income reported for tax purposes	1,316		1,309	
Net operating loss carryforward international	762		717	
Undistributed foreign earnings	1,101	(4,457)		
Miscellaneous international	755	(194)	1,135	(15)
Miscellaneous U.S.	177		155	
Total deferred income taxes	**$ 9,902**	**(11,166)**	**10,144**	**(6,906)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

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

(Dollars in Millions)	**2017**	**2016**	**2015**
Beginning of year	$ 3,041	3,080	2,465
Increases related to current year tax positions	332	348	570
Increases related to prior period tax positions	232	11	182
Decreases related to prior period tax positions	(416) [1]	(338)	(79)
Settlements	(2)	(37)	(4)
Lapse of statute of limitations	(36)	(23)	(54)
End of year	**$ 3,151**	**3,041**	**3,080**

(1) $347 million of this decrease is related to the TCJA

The unrecognized tax benefits of $3.2 billion at December 31, 2017, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some

jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $60 million, $7 million and $44 million in 2017, 2016 and 2015, respectively. The total amount of accrued interest was $436 million and $344 million in 2017 and 2016, respectively.

9. Employee Related Obligations

At the end of 2017 and 2016, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2017	2016
Pension benefits	$ 5,343	4,710
Postretirement benefits	2,331	2,733
Postemployment benefits	2,250	2,050
Deferred compensation	475	534
Total employee obligations	10,399	10,027
Less current benefits payable	325	412
Employee related obligations — non-current	**$ 10,074**	**9,615**

Prepaid employee related obligations of $526 million and $227 million for 2017 and 2016, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

Retirement plan benefits for employees are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. Due to an amendment of the formula used to calculate benefits of the U.S. Defined Benefit Plan that occurred in 2014, benefits for employees hired on or after January 1, 2015, are primarily calculated using employee compensation over total years of service.

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

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2017 and 2016 the Company used December 31, 2017 and December 31, 2016, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2017, 2016 and 2015 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2017	2016	2015	2017	2016	2015
Service cost	$ 1,080	949	1,037	247	224	257
Interest cost	927	927	988	159	158	186
Expected return on plan assets	(2,041)	(1,962)	(1,809)	(6)	(6)	(7)
Amortization of prior service cost (credit)	2	1	2	(30)	(34)	(33)
Recognized actuarial losses	609	496	745	138	135	201
Curtailments and settlements	17	11	8	—	—	—
Net periodic benefit cost	**$ 594**	**422**	**971**	**508**	**477**	**604**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	931
Amortization of prior service credit	30

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2017**	**2016**	**2015**	**2017**	**2016**	**2015**
Net Periodic Benefit Cost						
Service cost discount rate	3.59%	3.98	3.78	4.63	4.77	4.31
Interest cost discount rate	3.98%	4.24	3.78	3.94	4.10	4.31
Rate of increase in compensation levels	4.01%	4.02	4.05	4.31	4.32	4.11
Expected long-term rate of return on plan assets	8.43%	8.55	8.53			
Benefit Obligation						
Discount rate	3.30%	3.78	4.11	3.78	4.42	4.63
Rate of increase in compensation levels	3.99%	4.02	4.01	4.30	4.29	4.28

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company changed its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change does not impact the benefit obligation and did not have a material impact to the 2016 full year results.

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

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

Health Care Plans	2017	2016
Health care cost trend rate assumed for next year	6.33%	6.32%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.55%	4.50%
Year the rate reaches the ultimate trend rate	2038	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 29	(23)
Post-retirement benefit obligation	$ 355	(291)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2017 and 2016 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2017**	**2016**	**2017**	**2016**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 28,116	25,855	4,605	4,669
Service cost	1,080	949	247	224
Interest cost	927	927	159	158
Plan participant contributions	60	54	—	—
Amendments	(7)	(48)	(17)	—
Actuarial (gains) losses	2,996	2,302	(166)	(73)
Divestitures & acquisitions	201	(24)	88	—
Curtailments, settlements & restructuring	(35)	(25)	2	—
Benefits paid from plan*	(1,050)	(1,210)	(351)	(378)
Effect of exchange rates	933	(664)	15	5
Projected benefit obligation — end of year	**$ 33,221**	**28,116**	**4,582**	**4,605**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 23,633	22,254	75	74
Actual return on plan assets	4,274	2,286	12	7
Company contributions	664	838	545	372
Plan participant contributions	60	54	—	—
Settlements	(32)	(25)	—	—
Divestitures & acquisitions	173	(24)	—	—
Benefits paid from plan assets*	(1,050)	(1,210)	(351)	(378)
Effect of exchange rates	682	(540)	—	—
Plan assets at fair value — end of year	**$ 28,404**	**23,633**	**281**	**75**
Funded status — end of year	**$ (4,817)**	**(4,483)**	**(4,301)**	**(4,530)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 526	227	—	—
Current liabilities	(92)	(86)	(228)	(315)
Non-current liabilities	(5,251)	(4,624)	(4,073)	(4,215)
Total recognized in the consolidated balance sheet — end of year	**$ (4,817)**	**(4,483)**	**(4,301)**	**(4,530)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,140	7,749	1,500	1,804
Prior service cost (credit)	(25)	(12)	(137)	(150)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,115**	**7,737**	**1,363**	**1,654**
Accumulated Benefit Obligations — end of year	**$ 29,793**	**25,319**		

*In 2016, the Company offered a voluntary lump-sum payment option below a pre-determined threshold for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2017. The amounts distributed in 2017 and 2016 were approximately $127 million and $420 million, respectively. These distributions from the plan did not have a material impact on the Company's financial position.

(Dollars in Millions)	Retirement Plans		Other Benefit Plans	
	2017	2016	2017	2016
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 594**	**422**	**508**	**477**
Net actuarial (gain) loss	740	1,965	(169)	(72)
Amortization of net actuarial loss	(609)	(496)	(138)	(135)
Prior service cost (credit)	(7)	(48)	(17)	—
Amortization of prior service (cost) credit	(2)	(1)	30	34
Effect of exchange rates	256	(218)	3	(1)
Total loss/(income) recognized in other comprehensive income, before tax	**$ 378**	**1,202**	**(291)**	**(174)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 972**	**1,624**	**217**	**303**

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

In 2017, the Company contributed $72 million and $592 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2017 and December 31, 2016, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2017	2016	2017	2016	2017	2016	2017	2016
Plan Assets	$ 18,681	16,057	—	—	9,723	7,576	—	—
Projected Benefit Obligation	19,652	16,336	2,257	1,905	10,863	9,502	449	373
Accumulated Benefit Obligation	17,654	14,759	1,849	1,568	9,893	8,663	397	329
Over (Under) Funded Status								
Projected Benefit Obligation	$ (971)	(279)	(2,257)	(1,905)	(1,140)	(1,926)	(449)	(373)
Accumulated Benefit Obligation	1,027	1,298	(1,849)	(1,568)	(170)	(1,087)	(397)	(329)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $3.8 billion, $4.6 billion and $0.7 billion, respectively, at the end of 2017, and $8.8 billion, $9.9 billion and $5.6 billion, respectively, at the end of 2016.

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

(Dollars in Millions)	2018	2019	2020	2021	2022	2023-2027
Projected future benefit payments						
Retirement plans	$ 970	1,007	1,057	1,131	1,190	7,062
Other benefit plans	$ 322	312	306	301	297	1,395

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

(Dollars in Millions)	2018	2019	2020	2021	2022	2023-2027
Projected future contributions	$ 88	89	94	100	108	651

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

The Company's retirement plan asset allocation at the end of 2017 and 2016 and target allocations for 2018 are as follows:

	Percent of Plan Assets		Target Allocation
	2017	2016	2018
Worldwide Retirement Plans			
Equity securities	76 %	75 %	73 %
Debt securities	24	25	27
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of Fair Value of Plan Assets

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

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

Valuation Hierarchy

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

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

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

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.

- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.

- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

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Equity securities — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.

- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.

- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2017 and December 31, 2016:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**
Short-term investment funds	$ 429	145	427	652	—	—	—	—	856	797
Government and agency securities	—	—	3,094	2,655	—	—	—	—	3,094	2,655
Debt instruments	—	—	2,013	1,237	—	—	—	—	2,013	1,237
Equity securities	13,848	11,433	—	12	—	—	—	—	13,848	11,445
Commingled funds	—	—	1,780	1,316	57	—	6,158	5,767	7,995	7,083
Insurance contracts	—	—	—	—	199	24	—	—	199	24
Other assets	—	—	121	—	—	—	278	392	399	392
Investments at fair value	**$ 14,277**	**11,578**	**7,435**	**5,872**	**256**	**24**	**6,436**	**6,159**	**28,404**	**23,633**

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

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $81 million and $75 million and U.S. short-term investment funds (Level 2) of $200 million and $0 at December 31, 2017 and December 31, 2016, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $938 million (3.3% of total plan assets) at December 31, 2017 and $847 million (3.6% of total plan assets) at December 31, 2016.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee’s contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $214 million, $191 million and $187 million in 2017, 2016 and 2015, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at December 28, 2014	336,620	$ 19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	22,684
Employee compensation and stock option plans	(30,839)	(3,311)
Repurchase of common stock	79,490	8,979
Balance at January 1, 2017	413,332	28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	$ 31,554

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2017, 2016 and 2015.

Cash dividends paid were $3.32 per share in 2017, compared with dividends of $3.15 per share in 2016, and $2.95 per share in 2015.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income (Loss)

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

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 28, 2014	$ (4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)
January 3, 2016	(8,435)	604	(5,298)	(36)	(13,165)
Net 2016 changes	(612)	(193)	(682)	(249)	(1,736)
January 1, 2017	(9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	$ (7,351)	232	(6,150)	70	(13,199)

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

Details on reclassifications out of Accumulated Other Comprehensive Income:

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

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

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

14. International Currency Translation

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

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2017, 2016 and 2015 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $216 million, $289 million and $104 million in 2017, 2016 and 2015, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 31, 2017, January 1, 2017 and January 3, 2016:

(In Millions Except Per Share Amounts)	2017	2016	2015
Basic net earnings per share	$ 0.48	6.04	5.56
Average shares outstanding — basic	2,692.0	2,737.3	2,771.8
Potential shares exercisable under stock option plans	139.7	142.4	141.5
Less: shares repurchased under treasury stock method	(87.3)	(92.1)	(102.6)
Convertible debt shares	0.9	1.3	2.2
Adjusted average shares outstanding — diluted	2,745.3	2,788.9	2,812.9
Diluted net earnings per share	$ 0.47	5.93	5.48

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for year 2017, $2 million for year 2016 and $3 million for year 2015.

The diluted net earnings per share calculation for 2017, 2016 and 2015 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $372 million, $330 million and $316 million in 2017, 2016 and 2015, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 31, 2017 are:

(Dollars in Millions)

2018	2019	2020	2021	2022	After 2022	Total
$227	184	143	106	76	103	839

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 31, 2017, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term

Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 389 million at the end of 2017.

The compensation cost that has been charged against income for these plans was $962 million, $878 million and $874 million for 2017, 2016 and 2015, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $275 million, $256 million and $253 million for 2017, 2016 and 2015, respectively. An additional tax

benefit of $353 million was recognized in 2016 due to the adoption of a new accounting standard for the reporting of additional tax benefits on share-based compensation. The total unrecognized compensation cost was $798 million, $749 million and $744 million for 2017, 2016 and 2015, respectively. The weighted average period for this cost to be recognized was 1.76 years, 1.09 years and 0.98 years for 2017, 2016, and 2015, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

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

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2017, 2016 and 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $13.38, $10.01 and $10.68, in 2017, 2016 and 2015, respectively. The fair value was estimated based on the weighted average assumptions of:

	2017	2016	2015
Risk-free rate	2.25%	1.51%	1.77%
Expected volatility	15.30%	15.76%	15.48%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.90%	3.10%	2.90%

A summary of option activity under the Plan as of December 31, 2017, January 1, 2017 and January 3, 2016, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 28, 2014	115,712	$ 70.37	$ 4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	116,517	76.41	3,065
Options granted	22,491	101.87	
Options exercised	(22,547)	65.66	
Options canceled/forfeited	(3,006)	92.83	
Shares at January 1, 2017	113,455	83.16	3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	**111,306**	**$ 90.48**	**$ 5,480**

The total intrinsic value of options exercised was $1,060 million, $980 million and $644 million in 2017, 2016 and 2015, respectively.

The following table summarizes stock options outstanding and exercisable at December 31, 2017:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$62.20	12,148	1.7	$60.37	12,148	$60.37
$62.62-$65.62	9,548	3.0	$63.91	9,547	$63.91
$66.07-$72.54	14,816	5.0	$72.53	14,816	$72.53
$90.44-$100.48	35,035	6.6	$95.48	15,843	$90.49
$101.87-$115.67	39,759	8.6	$108.35	67	$105.91
	111,306	**6.3**	**$90.48**	**52,421**	**$73.61**

[1] Average contractual life remaining in years.

Stock options outstanding at January 1, 2017 and January 3, 2016 were 113,455 and an average life of 6.2 years and 116,517 and an average life of 5.9 years, respectively. Stock options exercisable at January 1, 2017 and January 3, 2016 were 50,414 at an average price of $65.77 and 48,345 at an average price of $62.26, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that are scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 31, 2017 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 1, 2017	21,061	2,415
Granted	7,248	1,276
Issued	(7,205)	(1,361)
Canceled/forfeited/adjusted	(943)	295
Shares at December 31, 2017	20,161	2,625

The average fair value of the restricted share units granted was $107.69, $92.45 and $91.65 in 2017, 2016 and 2015, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $596.5 million, $587.7 million and $597.6 million in 2017, 2016 and 2015, respectively.

The weighted average fair value of the performance share units granted was $114.13, $105.30 and $93.54 in 2017, 2016 and 2015, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $132.5 million, $127.7 million and $16.7 million in 2017, 2016 and 2015, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers 2017	2016	2015
Consumer —			
United States	$ 5,565	5,420	5,222
International	8,037	7,887	8,285
Total	**13,602**	**13,307**	**13,507**
Pharmaceutical —			
United States	21,474	20,125	18,333
International	14,782	13,339	13,097
Total	**36,256**	**33,464**	**31,430**
Medical Devices —			
United States	12,824	12,266	12,132
International	13,768	12,853	13,005
Total	**26,592**	**25,119**	**25,137**
Worldwide total	**$ 76,450**	**71,890**	**70,074**

(Dollars in Millions)	Income Before Tax 2017 [3]	2016 [4]	2015 [5]	Identifiable Assets 2017	2016
Consumer	$ 2,524	2,441	1,787	$ 25,030	23,971
Pharmaceutical	11,083	12,827	11,734	59,450	27,477
Medical Devices	5,392	5,578	6,826	45,413	39,773
Total	18,999	20,846	20,347	129,893	91,221
Less: Expense not allocated to segments [1]	1,326	1,043	1,151		
General corporate [2]				27,410	49,987
Worldwide total	**$ 17,673**	**19,803**	**19,196**	**$ 157,303**	**141,208**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2017	2016	2015	Depreciation and Amortization 2017	2016	2015
Consumer	$ 485	486	544	$ 674	608	559
Pharmaceutical	936	927	1,063	2,416	886	929
Medical Devices	1,566	1,472	1,631	2,216	1,928	1,945
Segments total	2,987	2,885	3,238	5,306	3,422	3,433
General corporate	292	341	225	336	332	313
Worldwide total	**$ 3,279**	**3,226**	**3,463**	**$ 5,642**	**3,754**	**3,746**

(Dollars in Millions)	Sales to Customers 2017	2016	2015	Long-Lived Assets [6] 2017	2016
United States	$ 39,863	37,811	35,687	$ 38,556	36,934
Europe	17,126	15,770	15,995	56,677	21,996
Western Hemisphere excluding U.S.	6,041	5,734	6,045	2,990	2,961
Asia-Pacific, Africa	13,420	12,575	12,347	2,773	2,512
Segments total	76,450	71,890	70,074	100,996	64,403
General corporate				1,143	1,190
Other non long-lived assets				55,164	75,615

Worldwide total	**$ 76,450**	**71,890**	**70,074**	**$ 157,303**	**141,208**

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

Export sales are not significant. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

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

(3) The Pharmaceutical segment includes $797 million for Actelion acquisition related costs, an in-process research and development expense of $396 million and net litigation expense of $117 million. The Medical Devices segment includes net litigation expense of $1,139 million, a restructuring related charge of $760 million, an asset impairment of $215 million primarily related to the insulin pump business and $140 million for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(4) Includes net litigation expense of $806 million and a restructuring related charge of $685 million in the Medical Devices segment. The Pharmaceutical segment includes a positive adjustment of $0.5 billion to previous reserve estimates, an in-process research and development expense of $29 million, and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.

(5) The Medical Devices segment includes a restructuring related charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(6) Long-lived assets include property, plant and equipment, net for 2017, and 2016 of $17,005 and $15,912, respectively, and intangible assets and goodwill, net for 2017 and 2016 of $85,134 and $49,681, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2017 and 2016 are summarized below:

(Dollars in Millions Except Per Share Data)	2017				2016			
	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,228	3,478	3,356	3,540	3,195	3,419	3,261	3,432
Pharmaceutical	8,245	8,635	9,695	9,681	8,178	8,654	8,400	8,232
Medical Devices	6,293	6,726	6,599	6,974	6,109	6,409	6,159	6,442
Total sales	17,766	18,839	19,650	20,195	17,482	18,482	17,820	18,106
Gross profit	12,380	13,016	12,748	12,952	12,153	13,146	12,334	12,572
Earnings before provision for taxes on income	5,575	4,748	4,790	2,560	5,294	4,904	5,281	4,324
Net earnings (loss)	4,422	3,827	3,764	(10,713)	4,457	3,997	4,272	3,814
Basic net earnings (loss) per share	$ 1.63	1.42	1.40	(3.99)	1.62	1.46	1.56	1.41
Diluted net earnings (loss) per share	$ 1.61	1.40	1.37	(3.99)	1.59	1.43	1.53	1.38

(1) The first quarter of 2017 includes a restructuring charge of $121 million after-tax ($161 million before-tax) and an AMO acquisition related cost of $251 million after-tax ($38 million before-tax).

(2) The second quarter of 2017 includes a net litigation expense of $352 million after-tax ($493 million before-tax), Actelion acquisition related costs of $199 million after-tax ($213 million before-tax) a restructuring charge of $101 million after-tax ($128 million before-tax) and an asset impairment charge of $125 million after-tax ($182 million before-tax).

(3) The third quarter of 2017 includes a net litigation expense of $97 million after-tax ($118 million before-tax), Actelion acquisition related costs of $255 million after-tax ($367 million before-tax) and a restructuring charge of $136 million after-tax ($187 million before-tax).

(4) The fourth quarter of 2017 includes a net litigation expense of $506 million after-tax ($645 million before-tax), Actelion acquisition related costs of $313 million after-tax ($217 million before-tax), a restructuring charge of $237 million after-tax ($284 million before-tax), an in-process research and development expense of $266 million after-tax ($408 million before-tax) and an after-tax benefit of $116 million related to the insulin pump business. Additionally, the fourth quarter of 2017 includes a provisional charge of $13.6 billion for recently enacted tax legislation.

(5) The first quarter of 2016 includes a restructuring charge of $120 million after-tax ($137 million before-tax) and net litigation expense of $56 million after-tax ($66 million before-tax).

(6) The second quarter of 2016 includes a restructuring charge of $97 million after-tax ($141 million before-tax) and net litigation expense of $493 million after-tax ($600 million before-tax).

(7) The third quarter of 2016 includes a restructuring charge of $76 million after-tax ($109 million before-tax) and net litigation expense of $46 million after-tax ($55 million before-tax).

(8) The fourth quarter of 2016 includes a restructuring charge of $251 million after-tax ($298 million before-tax) and net litigation expense of $80 million after-tax ($96 million before-tax).

20. Business Combinations and Divestitures

Certain businesses were acquired for $35,151 million in cash and $1,786 million of liabilities assumed during 2017. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34,379 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,139 million has been identified as the value of IPR&D primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). The Company currently holds 9.9% of the shares of Idorsia and has rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia with a Swiss franc denominated credit facility of approximately $250 million. As of December 31, 2017, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion’s specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

The Company is still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. To assist management in the allocation, the Company engaged valuation specialists to prepare appraisals. The Company will finalize the amounts recognized as the information necessary to complete the analysis is obtained. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The following table presents the preliminary amounts recognized for assets acquired and liabilities assumed for Actelion as of the acquisition date as well as the adjustments made up to December 31, 2017:

(Dollars in Millions)		June 16, 2017	December 31, 2017
Cash & Cash equivalents	$	469	469
Inventory[1]		759	759
Accounts Receivable		485	485
Other current assets		93	93
Property, plant and equipment		104	104
Goodwill		5,986	6,161
Intangible assets		25,010	25,010
Deferred Taxes		3	99
Other non-current assets		19	19
Total Assets Acquired		32,928	33,199
Current liabilities		531	956
Deferred Taxes		1,960	1,776
Other non-current liabilities		383	413
Total Liabilities Assumed		2,874	3,145
Net Assets Acquired	$	30,054	30,054

[1] Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

Subsequent to the date of acquisition there was an adjustment of $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill.

The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017 total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017 and January 1, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on

the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned

integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

	Unaudited Pro forma Consolidated Results	
(Dollars in Millions Except Per Share Data)	**2017**	**2016**
Net Sales	77,681	74,339
Net Earnings	1,509	13,916
Diluted Net Earnings per Common Share	0.55	4.99

In 2017, the Company recorded Actelion acquisition related costs before tax of approximately $0.8 billion, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

Certain businesses were acquired for $4,509 million in cash and $77 million of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics, and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $4,077 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of $3.3 billion was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.1 billion. The weighted average life for the $2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to

reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%. During 2017, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Novira Therapeutics, Inc. The impairment was the result of the cancellation of product development due to safety concerns.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2017, 2016 and 2015 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2017, the Company announced it is engaging in a process to evaluate potential strategic options for the Johnson & Johnson Diabetes Care Companies, specifically LifeScan, Inc., Animas Corporation, and Calibra Medical, Inc. Strategic options may include the formation of operating partnerships, joint ventures or strategic alliances, a sale of the businesses, or other alternatives either separately or together. During the fiscal second quarter of 2017, the Company recorded an impairment charge of $0.2 billion, primarily related to the insulin pump business. During the fiscal fourth quarter of 2017, the Company announced its decision to exit the Animas insulin pump business. The Company is continuing to evaluate potential strategic options for LifeScan, Inc. and determine the best opportunity to drive future growth and maximize shareholder value. There were no assets held for sale as of December 31, 2017 related to the announcement.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately $0.6 billion.

During 2015, the Company divestitures included: the Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group; and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA®ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures were approximately $2.6 billion.

21. Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 31, 2017, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has

established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO® ; body powders containing talc, primarily JOHNSONS® Baby Powder; and INVOKANA®. As of December 31, 2017, in the U.S. there were approximately 2,000 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 10,000 with respect to the PINNACLE® Acetabular Cup System, 53,600 with respect to pelvic meshes, 13,700 with respect to RISPERDAL®, 22,900 with respect to XARELTO®, 6,610 with respect to body powders containing talc; and 1,100 with respect to INVOKANA®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, with more expected from the recent extension, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States, primarily in the United Kingdom. In the United Kingdom, a trial is ongoing regarding common issues of liability and a decision is expected in the first half of 2018. The Company has established an accrual for defense costs in connection with product liability litigation associated with the PINNACLE® Acetabular Cup System.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. The Company has settled or otherwise resolved a majority of the United States cases and the costs associated with these settlements are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In Australia,

a trial of class action issues is ongoing and a decision is expected in 2018. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product

liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with XARELTO®.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. The Company has established an accrual with respect to product liability litigation associated with INVOKANA®.

INTELLECTUAL PROPERTY

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

Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt’s United States Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the District Court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the District Court for a new trial. A new trial was held in August 2017, and the jury returned a verdict of non-infringement in favor of JJVCI. Rembrandt has appealed the verdict to the United States Court of Appeals for the Federal Circuit.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014,

the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit, then dismissed the appeal in order to file a petition for review with the United States Supreme Court. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases and remanded this case to the United States Court of Appeals for the Federal Circuit to consider Medinol's appeal of whether Medinol is entitled to seek a new trial. Cordis was divested in 2015, and the Company retained any liability that may result from this case.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. MedIdea alleges infringement of United States Patent Nos. 6,558,426 (’426); 8,273,132; 8,721,730 and 9,492,280 relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. In December 2017, DePuy Synthes Products, Inc. filed a Petition for Inter Partes Review with the United States Patent and Trademark Office, seeking to invalidate the ’426 patent.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the ’735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the ’284 patent), are either invalid or not infringed by Ethicon’s ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the ’735 patent, the ’284 patent and United States Patent Nos. 8,323,310; 9,084,608; 9,241,759 and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in October 2017. Trial is scheduled for September, 2019.

In November 2017, Board of Regents, The University of Texas System and Tissuegen, Inc. filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures and MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs’ United States Patent Nos. 6,596,296 and 7,033,603 directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent.

Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleges that JBI’s manufacture and sale of DARZALEX® (daratumumab) willfully infringes MorphoSys’ United States Patent Nos. 8,263,746, 9,200,061 and 9,785,590. MorphoSys is seeking money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. Trial in the case is scheduled to commence in February 2019.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC (a Pfizer company) and Janssen Sciences Ireland UC (JSI) alleging that Searle’s supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the Court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the Court’s decision and the injunction will be stayed pending the appeal. In January 2018, the Court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU’s ruling on the issue.

REMICADE® Related Cases

United States Proceedings
In September 2013, Janssen Biotech, Inc. (JBI) and NYU Langone Medical Center (NYU) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the ’471 patent) in a reexamination proceeding instituted by a third party. The ’471 patent expires in September 2018 and is co-owned by JBI and NYU, with NYU having granted JBI

an exclusive license to NYU's rights under the patent. Following several office actions by the patent examiner, including two further rejections, and responses by

JBI, the USPTO issued a further action maintaining its rejection of the ’471 patent. JBI filed a notice of appeal to the USPTO’s Patent Trial and Appeal Board (the Board), which issued a decision in November 2016 upholding the examiner's rejection. In January 2018, the United States Court of Appeals for the Federal Circuit affirmed the Board's decision.

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including the ’471 patent and United States Patent No. 7,598,083 (the ’083 patent). In August 2016, the District Court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the ’471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of the Board’s reexamination decision.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the ’083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. Although the ’083 patent is already asserted in the existing lawsuit against Celltrion, the additional lawsuit expands the claims to include the sale in the United States of Celltrion's biosimilar product manufactured with cell culture media made in the United States. This additional lawsuit against Celltrion has been consolidated with the existing lawsuit discussed above. Hospira has moved to dismiss all counts of the lawsuit related to the ’083 patent as to it. Celltrion's motion to dismiss all counts of the lawsuit related to the ’083 patent for failure to join all the co-owners of the '083 patent as plaintiffs was denied in October 2017. Trial is scheduled to begin in July 2018. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved Celltrion’s infliximab biosimilar for sale in the United States in April 2016. Hospira's parent company, Pfizer Inc., launched Celltrion's infliximab biosimilar in the United States in late 2016.

In April 2017, JBI received notice that the FDA approved a marketing application submitted by Samsung Bioepis Co. Ltd. (Samsung) for the sale of its infliximab biosimilar in the United States. In May 2017, JBI filed a patent infringement lawsuit against Samsung in the United States District Court for the District of New Jersey alleging that the sale of its biosimilar product may infringe three of JBI’s patents. In July 2017, Samsung launched its biosimilar product (commercialized by Merck) in the United States. In November 2017, JBI voluntarily dismissed this lawsuit.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The inter partes review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used by generic companies in conjunction with these ANDAs and lawsuits to challenge patents held by the Company’s subsidiaries.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers)

who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the ’438 patent). The generic companies currently include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy’s); Mylan Pharmaceuticals Inc. and Mylan Inc.

(collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma). In February 2018, the court heard oral arguments on a motion for summary judgment of non-infringement filed by certain defendants. The parties await a decision. If the decision is unfavorable, the stay could be lifted and a generic version of ZYTIGA® could enter the market.

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the ’438 patent.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the ’438 patent.

In January 2018, Janssen dismissed its lawsuit against Sun after it withdrew its ANDA.

In each of the above lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the ’438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions invalidating the '438 patent, and Janssen is appealing this decision. The IPR decisions are not binding on the district court in the pending litigation.

In October 2017, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated two Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in Canada in response to Teva's filing Abbreviated New Drug Submissions (ANDS) and seeking approval to market generic versions of ZYTIGA® 250mg and ZYTIGA® 500mg before the expiration of Canadian Patent No. 2,661,422.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422.

In each of these Notices of Application, Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's and Apotex's ANDS before the expiration of Janssen's patent.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) initiated patent infringement lawsuits in the United States District Courts for the District of Delaware and the District of West Virginia, respectively, against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan), who filed an ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310, 7,125,879 and 8,101,629. In July 2017, the West Virginia lawsuit was dismissed without prejudice by stipulation of the parties.

In the Delaware lawsuit, Janssen and Gilead amended their complaint to add claims for patent infringement with respect to United States Patent Nos. 8,080,551; 7,399,856; 7,563,922; 8,101,752 and 8,618,291. In November 2017, the parties entered into a settlement agreement.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration

of Bayer's United States Patent Nos. 7,157,456 , 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). All defendants except Mylan and Sigmapharm have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. Trial is scheduled for March 2018.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc.; Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin has counterclaimed for a declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent and Micro have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The '218 cases have been consolidated for discovery and trial, and are currently set for trial in April 2019.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

PREZISTA®

In September 2017, Janssen Sciences Ireland UC and Janssen Products, L.P. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo), who filed an ANDA seeking approval to market a generic version of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,700,645; 7,126,015; and 7,595,408. In January 2018, the parties entered into a settlement agreement.

In November 2017, Janssen Inc. initiated Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent Nos. 2,485,834 and 2,336,160, which is owned by the United States and the Board of Trustees of the University of Illinois. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex's ANDS before the expiration of the relevant patents.

RISPERDAL CONSTA®

In November 2016, the United States Patent and Trademark Office (USPTO) instituted an Inter Partes Review filed by Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Sandong Luye Pharmaceutical Co., Ltd. and Nanjing Luye Pharmaceutical Co., Ltd., seeking to invalidate United States Patent No. 6,667,061 relating to RISPERDAL CONSTA®. Janssen Pharmaceuticals, Inc. markets RISPERDAL CONSTA® pursuant to a license from Alkermes Pharma Ireland Ltd. In November 2017, the USPTO issued a decision upholding the validity of the patent.

INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent Nos. 7,943,582 and/or 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and MacLeods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent) relating to INVOKANA® and INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the '788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC's United States Patent No. 8,785,403 relating to INVOKAMET®, and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent and the '219 patent relating to INVOKANA®. Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA® and/or INVOKAMET® before the expiration of the relevant patents.

VELETRI®

In July 2017, Actelion Pharmaceuticals Ltd. (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Limited (collectively, Sun Pharmaceutical), who filed an ANDA seeking approval to market a generic version of VELETRI® before the expiration of United States Patent No. 8,598,227. Actelion is seeking an order enjoining Sun Pharmaceutical from marketing its generic version of VELETRI® before the expiration of the patent. Trial is scheduled to commence in June 2019.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), who filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781. In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. In the lawsuit, Janssen is seeking an order enjoining Teva from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (Janssen) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). In each of the lawsuits, Pharmacyclics and Janssen are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, the parties are awaiting assignment of a trial date. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in numerous lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed in state court by the state Attorneys General in Louisiana, Mississippi, Missouri, New Mexico, Ohio and Oklahoma. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Arkansas; California; Connecticut; Florida; Georgia; Illinois; Kentucky; Louisiana; Mississippi; Missouri; Nevada; New Hampshire; New Jersey; New Mexico; New York; Ohio; Oklahoma; Oregon; Pennsylvania; Tennessee; Texas; Washington and West Virginia. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief. These cases are in early stages of litigation. In October 2017, Johnson &

Johnson and JPI were both served with a motion to consolidate 66 pending matters into a federal Multi District Litigation in the Southern District of Ohio. In December 2017, the MDL was approved in the Northern District of Ohio and there are approximately 190 cases that have been transferred to the MDL.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, New Hampshire, New Jersey, Tennessee and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. The multi-state coalition served Johnson & Johnson and JPI with subpoenas as part of the investigation. Johnson & Johnson and JPI have also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the District Court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the District Court.

Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. The states are seeking monetary and injunctive relief, and DePuy Orthopaedics, Inc. has entered into a tolling agreement with the states. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation with the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon Inc. and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by Kentucky in August 2016 and by Mississippi in October 2017. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 43 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI) and seeks injunctive and monetary relief. The parties have agreed to adjourn the trial date and currently expect the trial to be re-scheduled to the fall of 2018.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the

period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. JPI filed a motion to dismiss in the United States District Court for the Central District of California in January 2018.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests in June and December 2016, from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of Company employees with physicians at these hospitals. Johnson & Johnson is producing documents in response to this subpoena.

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

GENERAL LITIGATION

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as In re Blood Reagent Antitrust Litigation. Following the appeal and reversal of its initial grant of a motion for class certification, on remand, the District Court in October 2015 again granted a motion by the plaintiffs for class certification. In July 2017, the Court issued an opinion granting in part and denying in part OCD's motion for summary judgment. The Court granted summary judgment concerning allegations of price fixing in 2005 and 2008, and denied summary judgment concerning allegations of price fixing in 2001. Trial has been set for June 2018. OCD was divested in 2014 and Johnson & Johnson retained any liability that may result from these cases.

In June 2011, DePuy Orthopaedics, Inc. (DePuy) filed suit against Orthopaedic Hospital (OH) in the United States District Court for the Northern District of Indiana seeking a declaratory judgment that DePuy did not owe OH royalties under a 1999 development agreement. In January 2012, OH filed a breach of contract case in California

federal court, which was later consolidated with the Indiana case. In February 2014, OH brought suit for patent infringement relating to the same technology, and that action was also consolidated with the Indiana case. In August 2017, the court denied DePuy's motions for summary judgment. A trial date has not been set.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington, Pennsylvania facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and the Court entered a Consent Order of Dismissal in November 2017 concluding this action. In addition, in April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. (now known as Johnson & Johnson Consumer, Inc.) in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in May 2017, the Court denied a motion to dismiss the amended complaint. Discovery is underway.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the Court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. The plaintiff has appealed. In September 2017, the plaintiff in the second case voluntarily dismissed their complaint.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the Court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against Lifescan Inc., Johnson & Johnson, other diabetes test strip manufacturers and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages. In November 2017, the case was ordered transferred to United States District Court for the District of New Jersey.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC (Janssen). Lonza alleges that Janssen breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages.

In September 2017, Strategic Products Group, Inc. (SPG) filed an antitrust complaint against Lifescan, Inc. and Lifescan Scotland, Ltd. (collectively, Lifescan) in the United States District Court for the Northern District of Florida (Pensacola Division). SPG, the exclusive distributor of Unistrip blood glucose meter test strips, alleges that Lifescan has monopolized or is attempting to monopolize the market for blood glucose meter test strips compatible with certain Lifescan meters. The complaint seeks damages.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In November 2017, Janssen moved to dismiss the complaint.

Beginning in September 2017, multiple purported class actions were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health.

Andover Healthcare, Inc. filed a Lanham act case against Johnson & Johnson Consumer Inc. in April 2017 in the United Stated District Court for the District of Massachusetts. Andover asserts that the claim "not made with natural rubber latex" on COACH® Sports Wrap, BAND-AID® Brand SECURE-FLEX® Wrap and BAND-AID® Brand HURT-FREE® Wrap is false. Andover seeks actual damages and pre-judgment interest thereon, disgorgement of profits, treble damages, attorney's fees and injunctive relief. The Court denied a motion to dismiss, an answer was filed and discovery is underway.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson in the United States District Court for the District of New Jersey alleging that Johnson & Johnson violated the federal Securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily JOHNSONS® Baby Powder. The lawsuit was assigned to the District Court Judge managing the personal injury multi-district litigation.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion. In 2017, the Company recorded a pre-tax charge of $760 million, of which $88 million was included in cost of products sold and $363 million was included in other (income) expense. See table below for additional details. Total project costs of $2.0 billion have been recorded since the restructuring has been announced.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next 15 months. Approximately 2,400 positions have been eliminated of which 1,700 received separation payments since the restructuring announcement.

The Company estimates that approximately one-half of the cumulative pre-tax costs will result in cash outlays, including approximately $400 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash, relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending under this initiative through the fiscal year ended 2017:

(Dollars in Millions)	Severance	Asset Write-offs	Other**	Total
2015 restructuring charge	$ 484	86	20	590
2015 activity		(86)	(3)	(89)
Reserve balance, January 3, 2016	484	—	17	501
2016 activity	(104)	—	(16)	(120)
Reserve balance, January 1, 2017	380	—	1	381
Current year activity:				
Charges		194	656	850
Cash payments	(61)		(619)	(680)
Settled non cash		(194)		(194)
Accrual adjustment	(90)			(90)
Reserve balance, December 31, 2017*	$ 229	—	38	267

*Cash outlays for severance are expected to be substantially paid out over the next 18 months in accordance with the Company's plans and local laws.

**Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries as of December 31, 2017 and January 1, 2017, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and January 1, 2017**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017 based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for and presents certain elements of share based payments in 2016.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control over Financial Reporting, management has excluded Abbott Medical Optics and Actelion Ltd. from its assessment of internal control over financial reporting as of December 31, 2017, because they were acquired by the Company in purchase business combinations during 2017. We have also excluded Abbott Medical Optics and Actelion Ltd. from our audit of internal control over financial reporting. Abbott Medical Optics and Actelion Ltd. are wholly-owned subsidiaries whose total assets and total

revenues excluded from management's assessment and our audit of internal control over financial reporting represent approximately 1% and 1% of total assets, respectively and approximately 1% and 2% of total revenues, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2017.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 21, 2018

We have served as the Company's auditor since at least 1920. We have not determined the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories and Actelion Ltd. and its consolidated subsidiaries (Actelion) in February and June 2017, respectively. Actelion's total assets, excluding intangible assets and goodwill, and total revenues represented approximately 1% and 2%, respectively, of the related consolidated financial statements as of and for the period ended December 31, 2017. AMO's total assets, excluding intangible assets and goodwill, and total revenues represented approximately 1% and 1%, respectively, of the related consolidated financial statements as of and for the period ended December 31, 2017. As the acquisitions occurred in the fiscal year 2017, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2017 excluded the above mentioned acquisitions. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 31, 2017, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2017 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Dominic J. Caruso
Dominic J. Caruso
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2017, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2012 and December 31, 2007 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

jnj5yearshareholder2017.jpg

	2012	2013	2014	2015	2016	2017
Johnson & Johnson	$100.00	$134.62	$157.95	$159.78	$184.26	$229.23
S&P 500 Index	$100.00	$132.37	$150.48	$152.55	$170.78	$208.05
S&P Pharmaceutical Index	$100.00	$135.23	$165.27	$174.84	$172.10	$193.74
S&P Healthcare Equipment Index	$100.00	$127.69	$161.24	$170.88	$181.96	$238.17

10 Year Shareholder Return Performance J&J vs. Indices

jnj10yearshareholder2017.jpg

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Johnson & Johnson	$100.00	$92.23	$102.63	$102.03	$112.13	$124.27	$167.28	$196.28	$198.55	$228.97	$284.85
S&P 500 Index	$100.00	$63.00	$79.66	$91.66	$93.59	$108.56	$143.70	$163.36	$165.60	$185.40	$225.85
S&P Pharmaceutical Index	$100.00	$81.80	$97.03	$97.78	$115.15	$131.76	$178.18	$217.77	$230.37	$226.77	$255.27
S&P Healthcare Equipment Index	$100.00	$72.36	$93.19	$90.66	$89.94	$105.47	$134.67	$170.06	$180.22	$191.91	$251.20

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 31, 2017, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2017 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	134,091,342	$75.11	389,083,761
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	134,091,342	$75.11	389,083,761

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2017 and 2016

   Consolidated Statements of Earnings for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Comprehensive Income for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Equity for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Cash Flows for Fiscal Years 2017, 2016 and 2015

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 21, 2018

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 21, 2018
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer (Principal Financial Officer)	February 21, 2018
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 21, 2018
/s/ M. C. Beckerle M. C. Beckerle	Director	February 21, 2018
/s/ D. S. Davis D. S. Davis	Director	February 21, 2018
/s/ I. E. L. Davis I. E. L. Davis	Director	February 21, 2018

Signature	Title	Date
/s/ M. B. McClellan M. B. McClellan	Director	February 21, 2018
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 21, 2018
/s/ W. D. Perez W. D. Perez	Director	February 21, 2018
/s/ C. Prince C. Prince	Director	February 21, 2018
/s/ A. E. Washington A. E. Washington	Director	February 21, 2018
/s/ R. A. Williams R. A. Williams	Director	February 21, 2018

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Johnson & Johnson Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 31, 2000.*
10(f)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(g)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(h)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(i)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(j)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(k)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(l)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(m)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(n)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(o)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(p)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*

10(q)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(r)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(s)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(t)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(u)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(v)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended December 31, 2017, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.