

**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**

(State of incorporation)

**22-1024240**

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

**One Johnson & Johnson Plaza**

**New Brunswick, New Jersey**

(Address of principal executive offices)

**08933**

(Zip Code)

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

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
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 Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the III: registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

#### ***Risks Related to Product Development, Market Success and Competition***

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

#### ***Risks Related to Product Liability, Litigation and Regulatory Activity***

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;
- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, 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.

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## 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 2<sup>nd</sup> 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](http://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](http://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](http://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](http://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 <sup>(a)</sup>
Peter M. Fasolo	56	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer <sup>(b)</sup>
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 <sup>(c)</sup>
Jorge Mesquita	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer <sup>(d)</sup>
Thibaut Mongon	49	Appointee, Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer <sup>(e)</sup>
Michael E. Sneed	59	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer <sup>(f)</sup>
Paulus Stoffels	56	Vice Chairman, Executive Committee; Chief Scientific Officer <sup>(g)</sup>
Jennifer L. Taubert	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals <sup>(h)</sup>
Michael H. Ullmann	60	Member, Executive Committee; Executive Vice President, General Counsel <sup>(i)</sup>
Kathryn E. Wengel	53	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer <sup>(j)</sup>
Joseph J. Wolk	52	Member, Executive Committee; Executive Vice President, Chief Financial Officer <sup>(k)</sup>

- (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.

<u>Period</u>	<u>Total Number of Shares Purchased<sup>(1)</sup></u>	<u>Avg. Price Paid Per Share</u>	<u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs<sup>(2)</sup></u>	<u>Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs<sup>(3)</sup></u>
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			

<sup>(1)</sup>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.

<sup>(2)</sup> 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.

<sup>(3)</sup> 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
<b>Total sales</b>	<b>81,581</b>	<b>76,450</b>	<b>71,890</b>	<b>70,074</b>	<b>74,331</b>	<b>71,312</b>	<b>67,224</b>	<b>65,030</b>	<b>61,587</b>	<b>61,897</b>	<b>63,747</b>
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	—
	<b>63,582</b>	<b>58,777</b>	<b>52,087</b>	<b>50,878</b>	<b>53,768</b>	<b>55,841</b>	<b>53,449</b>	<b>52,669</b>	<b>44,640</b>	<b>46,142</b>	<b>46,818</b>
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
<b>Net earnings</b>	<b>15,297</b>	<b>1,300</b>	<b>16,540</b>	<b>15,409</b>	<b>16,323</b>	<b>13,831</b>	<b>10,514</b>	<b>9,672</b>	<b>13,334</b>	<b>12,266</b>	<b>12,949</b>
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	—	339	—	—	—	—
<b>Net earnings attributable to Johnson &amp; Johnson</b>	<b>15,297</b>	<b>1,300</b>	<b>16,540</b>	<b>15,409</b>	<b>16,323</b>	<b>13,831</b>	<b>10,853</b>	<b>9,672</b>	<b>13,334</b>	<b>12,266</b>	<b>12,949</b>
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 <sup>(1)</sup>	\$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
<b>Percent increase (decrease) over previous year:</b>											
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
<b>Supplementary balance sheet data:</b>											
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
<b>Common stock information</b>											
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
<b>Employees (thousands)</b>	<b>135.1</b>	<b>134.0</b>	<b>126.4</b>	<b>127.1</b>	<b>126.5</b>	<b>128.1</b>	<b>127.6</b>	<b>117.9</b>	<b>114.0</b>	<b>115.5</b>	<b>118.7</b>

<sup>(1)</sup> Attributable to Johnson & Johnson

\* Per the adoption of ASU 2017-07 prior year amounts on the Consolidated Statement of Earnings have been reclassified to retroactively apply classification of the service cost component and the other components of net periodic benefit cost

N/M = Not Meaningful



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

### **Organization and Business Segments**

#### **Description of the Company and Business Segments**

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and vision fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

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

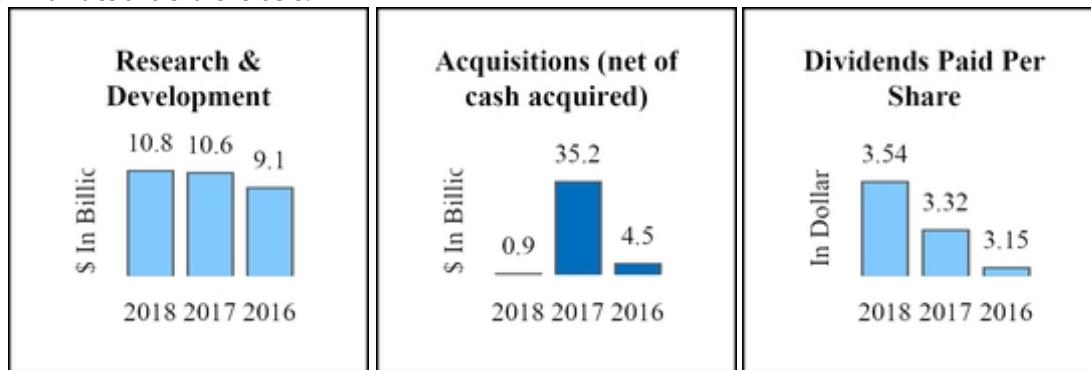
In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of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

### **Management's Objectives**

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

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2018 sales. In 2018, \$10.8 billion was invested in research and development and \$0.9 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success, is the 135,100 diverse employees that work across more than 260 operating companies, which are located in more than 60 countries. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.



## Results of Operations

### Analysis of Consolidated Sales

In 2018, worldwide sales increased 6.7% to \$81.6 billion, compared to an increases of 6.3% and 2.6% in 2017 and 2016, respectively. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2018	2017	2016
Volume	8.5 %	8.0%	3.2%
Price	(2.2)	(2.0)	0.7
Currency	0.4	0.3	(1.3)
<b>Total</b>	<b>6.7 %</b>	<b>6.3%</b>	<b>2.6%</b>

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.

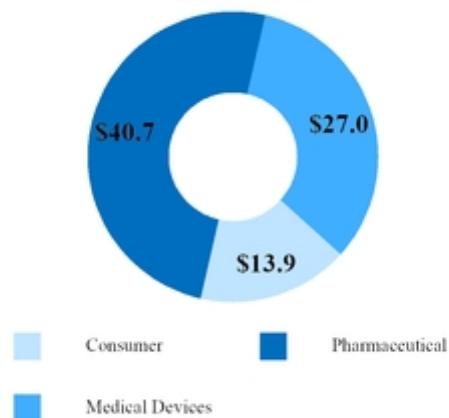
In 2018, sales by companies in Europe achieved growth of 9.5% as compared to the prior year, including operational growth of 6.2% and a positive currency impact of 3.3%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 1.2% as compared to the prior year, including 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.

**2018 Sales by Geographic Region (in billions)**



**2018 Sales by Segment (in billions)**



## 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:

(Dollars in Millions)	2018	2017	2016	% Change	
				'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)
<b>Total Consumer Sales</b>	<b>\$ 13,853</b>	<b>13,602</b>	<b>13,307</b>	<b>1.8 %</b>	<b>2.2</b>

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:<sup>\*</sup>

(Dollars in Millions)	2018	2017	2016	% Change	
				'18 vs. '17	'17 vs. '16
<b>Total Immunology</b>	<b>\$ 13,120</b>	<b>12,244</b>	<b>11,968</b>	<b>7.2 %</b>	<b>2.3</b>
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)
<b>Total Infectious Diseases</b>	<b>3,304</b>	<b>3,154</b>	<b>3,208</b>	<b>4.8</b>	<b>(1.7)</b>
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)
<b>Total Neuroscience</b>	<b>6,077</b>	<b>5,986</b>	<b>6,085</b>	<b>1.5</b>	<b>(1.6)</b>
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)
<b>Total Oncology</b>	<b>9,844</b>	<b>7,258</b>	<b>5,807</b>	<b>35.6</b>	<b>25.0</b>
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
<b>Pulmonary Hypertension</b>	<b>2,573</b>	<b>1,327</b>	<b>—</b>	<b>93.9</b>	<b>***</b>
OPSUMIT®	1,215	573	—	**	***
TRACLEER®	546	403	—	35.5	***
UPTRAVI®	663	263	—	**	***
Other	149	88	—	69.3	***
<b>Cardiovascular / Metabolism / Other</b>	<b>5,816</b>	<b>6,287</b>	<b>6,396</b>	<b>(7.5)</b>	<b>(1.7)</b>
XARELTO®	2,477	2,500	2,288	(0.9)	9.3
INVOKANA®/ INVOKAMET®	881	1,111	1,407	(20.7)	(21.0)
PROCIT®/EPREX®	988	972	1,105	1.6	(12.0)
Other	1,470	1,704	1,596	(13.7)	6.8
<b>Total Pharmaceutical Sales</b>	<b>\$ 40,734</b>	<b>36,256</b>	<b>33,464</b>	<b>12.4 %</b>	<b>8.3</b>

\* 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® (bosentan) 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	Y	Y		
erdafitinib	Treatment of locally advanced or metastatic urothelial cancer			Y	
ERLEADA™ (apalutamide)	Treatment of non-metastatic castration-resistant prostate cancer	Y			Y
esketamine	Antidepressant for treatment-resistant depression in adults			Y	Y
IMBRUVICA® (ibrutinib)	Treatment of Waldenstrom's macroglobulinemia used in combination with rituximab	Y			Y
	Treatment for previously untreated Chronic Lymphocytic Leukemia in combination with obinutuzumab			Y	Y
INVOKANA® (canagliflozin)	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease. (CANVAS/CANVAS-R )	Y	Y		
JULUCA® (rilpivirine and dolutegravir)	Single-tablet, once-daily, two-drug regimen for the treatment of HIV-1 infection			Y	
OPSUMIT®(macitentan)	Treatment of adults with inoperable chronic thromboembolic pulmonary hypertension to improve exercise capacity and pulmonary vascular resistance	Y		Y	
STELARA® (ustekinumab)	Treatment of adults with moderately to severely active ulcerative colitis			Y	Y
SYMTUZA® (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide)	A complete darunavir-based single-tablet regimen for the treatment of HIV-1 infection		Y		
TREMFYA® (guselkumab)	Patient controlled injector for the treatment of adults living with moderate to severe plaque psoriasis	Y		Y	
XARELTO® (rivaroxaban)	Treatment to reduce the risk of major cardiovascular events in people with chronic coronary or peripheral artery disease		Y		
	For the prevention of venous thromboembolism for medically ill patients			Y	
ZYTIGA® (abiraterone acetate)	Treatment of Hormone Naïve Metastatic Prostate Cancer		Y		

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:<sup>\*</sup>

(Dollars in Millions)	2018	2017	2016	% Change	
				'18 vs. '17	'17 vs. '16
<b>Surgery</b>	<b>\$ 9,901</b>	<b>9,559</b>	<b>9,296</b>	<b>3.6 %</b>	<b>2.8</b>
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)
<b>Orthopaedics</b>	<b>8,885</b>	<b>9,058</b>	<b>9,128</b>	<b>(1.9)</b>	<b>(0.8)</b>
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)
<b>Vision</b>	<b>4,553</b>	<b>4,063</b>	<b>2,785</b>	<b>12.1</b>	<b>45.9</b>
Contact Lenses/Other	3,302	3,036	2,785	8.8	9.0
Surgical	1,251	1,027	—	21.8	**
<b>Interventional Solutions<sup>(1)</sup></b>	<b>2,646</b>	<b>2,296</b>	<b>2,055</b>	<b>15.2</b>	<b>11.7</b>
<b>Diabetes Care</b>	<b>1,009</b>	<b>1,615</b>	<b>1,789</b>	<b>(37.5)</b>	<b>(9.7)</b>
<b>Diagnostics<sup>(2)</sup></b>	—	1	66	***	***
<b>Total Medical Devices Sales</b>	<b>\$ 26,994</b>	<b>26,592</b>	<b>25,119</b>	<b>1.5 %</b>	<b>5.9</b>

<sup>(1)</sup>Previously referred to as Cardiovascular

<sup>(2)</sup>On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) and amounts represent transitional service agreement that concluded in 2017.

\* Prior year amounts have been reclassified to conform to current year presentation

\*\*Products acquired from Abbott Medical Optics (AMO) on February 27, 2017

\*\*\* Percentage greater than 100% or not meaningful

The Surgery franchise sales were \$9.9 billion in 2018, an increase of 3.6% from 2017. Growth in Advanced Surgery was primarily driven by endocutter, biosurgery and energy products. Growth in General Surgery was primarily driven by wound care products. Growth in Specialty Surgery was primarily driven by Advanced Sterilization Products.

The Orthopaedics franchise sales were \$8.9 billion in 2018, a decrease of 1.9% from 2017. The decline in Spine & Other was primarily due to the Codman Neurosurgery divestiture and share loss in Spine partially offset by new product launches. The decline in knees was primarily due to competitive pressure in the U.S. partially offset by growth in Asia Pacific. Growth in hips and trauma was due to continued uptake of new products.

The Vision franchise achieved sales of \$4.6 billion in 2018, an increase of 12.1% from 2017. Growth was primarily driven by strength of the astigmatism and daily disposable lenses in the OASYS® contact lenses category. Surgical growth was driven by cataract performance primarily outside the U.S.

The Interventional Solutions franchise (includes the Cerenovus business previously included in Spine and Other in Orthopaedics) sales were \$2.6 billion, an increase of 15.2% from 2017. Strong growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

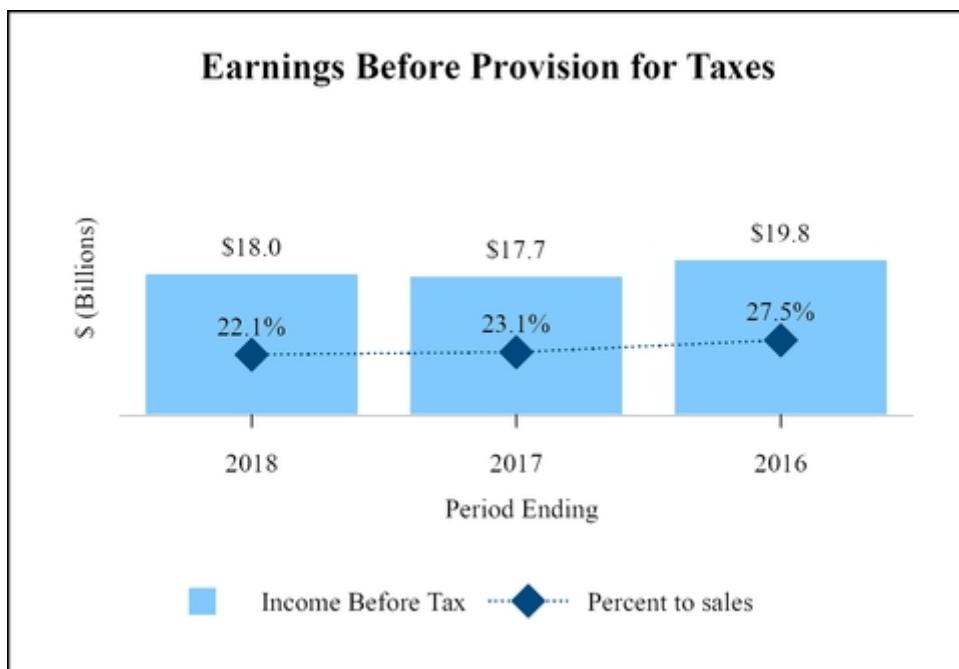
The Diabetes Care franchise sales were \$1.0 billion, a decrease of 37.5% from 2017. The decline was primarily due to divestiture of its LifeScan business in the fiscal fourth quarter of 2018 and the Company's decision to exit the Animas insulin pump business in the fiscal fourth quarter of 2017.

The Medical Devices segment sales in 2017 were \$26.6 billion, an increase of 5.9% from 2016, which included an operational increase of 5.7% and a positive currency impact of 0.2%. U.S. sales were \$12.8 billion, an increase of 4.5% as compared to the prior year. International sales were \$13.8 billion, an increase of 7.1% as compared to the prior year, with an

operational increase of 6.7% and a positive currency impact of 0.4%. In 2017, acquisitions and divestitures had a net positive impact of 4.2% on the worldwide operational sales growth of the Medical Devices segment as compared to 2016.

#### **Analysis of Consolidated Earnings Before Provision for Taxes on Income**

Consolidated earnings before provision for taxes on income was \$18.0 billion, \$17.7 billion and \$19.8 billion for the fiscal years ended 2018, 2017 and 2016, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 22.1%, 23.1%, and 27.5% in 2018, 2017 and 2016, respectively.



**Cost of Products Sold and Selling, Marketing and Administrative Expenses:** Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:\*

% of Sales	2018	2017	2016
Cost of products sold*	33.2%	33.3	30.3
Percent point increase/(decrease) over the prior year	(0.1)	3.0	(0.3)
Selling, marketing and administrative expenses*	27.6%	28.1	27.9
Percent point increase/(decrease) over the prior year	(0.5)	0.2	(2.2)

\*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)

In 2018, cost of products sold as a percent to sales decreased to 33.2% from 33.3% as compared to the same period a year ago primarily due to lower inventory step-up costs related to the Actelion acquisition and favorable product and segment mix driven by a higher percentage of sales from the Pharmaceutical segment. This was mostly offset by higher amortization expense primarily related to the Actelion acquisition on June 16, 2017. Intangible asset amortization expense of \$4.4 billion was included in cost of products sold for 2018 as compared to \$3.0 billion in 2017. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2018 as compared to the prior year, primarily due to lower costs relative to sales growth in the Pharmaceutical business and favorable segment mix.

In 2017, cost of products sold as a percent to sales increased to 33.3% from 30.3% as compared to the same period a year ago. The unfavorable increase was primarily driven by \$2.3 billion of higher amortization expense and charges for inventory step-up related to the recent acquisitions, primarily Actelion. Intangible asset amortization expense of \$3.0 billion was included in cost of products sold for 2017 as compared to \$1.2 billion in 2016. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2017 as compared to the prior year, primarily due to investments in new product launches partially offset by favorable mix.

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

(Dollars in Millions)	2018		2017		2016	
	Amount	% of Sales**	Amount	% of Sales**	Amount	% 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:

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	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 <sup>(1)</sup>	19,285	18,999	81,581	76,450	23.6	24.9
Less: Expenses not allocated to segments <sup>(2)</sup>	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 of 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
<b>Total</b>	<b>\$ 8,242</b>	<b>30,320</b>	<b>13,086</b>	<b>1,208</b>	<b>896</b>	<b>53,752</b>

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
<b>2018</b>				
Accrued rebates <sup>(1)</sup>	\$ 186	836	(751)	271
Accrued returns	68	98	(109)	57
Accrued promotions	481	2,233	(2,217)	497
<b>Subtotal</b>	<b>\$ 735</b>	<b>3,167</b>	<b>(3,077)</b>	<b>825</b>
Reserve for doubtful accounts	31	10	(9)	32
Reserve for cash discounts	23	204	(204)	23
<b>Total</b>	<b>\$ 789</b>	<b>3,381</b>	<b>(3,290)</b>	<b>880</b>
<b>2017</b>				
Accrued rebates <sup>(1)</sup>	\$ 136	638	(588)	186
Accrued returns	65	128	(125)	68
Accrued promotions	358	2,148	(2,025)	481
<b>Subtotal</b>	<b>\$ 559</b>	<b>2,914</b>	<b>(2,738)</b>	<b>735</b>
Reserve for doubtful accounts	24	10	(3)	31
Reserve for cash discounts	25	205	(207)	23
<b>Total</b>	<b>\$ 608</b>	<b>3,129</b>	<b>(2,948)</b>	<b>789</b>

<sup>(1)</sup> 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 <sup>(2)</sup>	Balance at End of Period
<b>2018</b>				
Accrued rebates <sup>(1)</sup>	\$ 4,862	22,644	(19,996)	7,510
Accrued returns	362	385	(311)	436
Accrued promotions	35	46	(68)	13
<b>Subtotal</b>	<b>\$ 5,259</b>	<b>23,075</b>	<b>(20,375)</b>	<b>7,959</b>
Reserve for doubtful accounts	77	37	(67)	47
Reserve for cash discounts	55	860	(862)	53
<b>Total</b>	<b>\$ 5,391</b>	<b>23,972</b>	<b>(21,304)</b>	<b>8,059</b>
<b>2017</b>				
Accrued rebates <sup>(1)</sup>	\$ 3,420	16,447	(15,005)	4,862
Accrued returns	334	256	(228)	362
Accrued promotions	—	69	(34)	35
<b>Subtotal</b>	<b>\$ 3,754</b>	<b>16,772</b>	<b>(15,267)</b>	<b>5,259</b>
Reserve for doubtful accounts	38	40	(1)	77
Reserve for cash discounts	58	714	(717)	55
<b>Total</b>	<b>\$ 3,850</b>	<b>17,526</b>	<b>(15,985)</b>	<b>5,391</b>

<sup>(1)</sup> Includes reserve for customer rebates of \$89 million at December 30, 2018 and \$90 million at December 31, 2017, recorded as a contra asset.

<sup>(2)</sup> Includes adjustments



## Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
<b>2018</b>				
Accrued rebates <sup>(1)</sup>	\$ 1,620	6,344	(6,746)	1,218
Accrued returns	152	362	(400)	114
Accrued promotions	83	116	(157)	42
<b>Subtotal</b>	<b>\$ 1,855</b>	<b>6,822</b>	<b>(7,303)</b>	<b>1,374</b>
Reserve for doubtful accounts	183	29	(43)	169
Reserve for cash discounts	15	372	(387)	—
<b>Total</b>	<b>\$ 2,053</b>	<b>7,223</b>	<b>(7,733)</b>	<b>1,543</b>
<b>2017</b>				
Accrued rebates <sup>(1)</sup>	\$ 1,500	6,407	(6,287)	1,620
Accrued returns	127	729	(704)	152
Accrued promotions	32	135	(84)	83
<b>Subtotal</b>	<b>\$ 1,659</b>	<b>7,271</b>	<b>(7,075)</b>	<b>1,855</b>
Reserve for doubtful accounts	190	27	(34)	183
Reserve for cash discounts	16	389	(390)	15
<b>Total</b>	<b>\$ 1,865</b>	<b>7,687</b>	<b>(7,499)</b>	<b>2,053</b>

<sup>(1)</sup> 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**

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**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)**

	<b>2018</b>	<b>2017</b>
<b>Assets</b>		
<b>Current assets</b>		
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	—
<b>Total current assets</b>	<b>46,033</b>	<b>43,088</b>
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
<b>Total assets</b>	<b>\$ 152,954</b>	<b>157,303</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities</b>		
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
<b>Total current liabilities</b>	<b>31,230</b>	<b>30,537</b>
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
<b>Total liabilities</b>	<b>93,202</b>	<b>97,143</b>
<b>Shareholders' equity</b>		
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
<b>Total shareholders' equity</b>	<b>59,752</b>	<b>60,160</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 152,954</b>	<b>157,303</b>

*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
<b>Sales to customers</b>	\$ 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
<b>Net earnings</b>	<b>\$ 15,297</b>	<b>1,300</b>	<b>16,540</b>
<b>Net earnings per share (Notes 1 and 15)</b>			
<b>Basic</b>	<b>\$ 5.70</b>	<b>0.48</b>	<b>6.04</b>
<b>Diluted</b>	<b>\$ 5.61</b>	<b>0.47</b>	<b>5.93</b>
<b>Average shares outstanding (Notes 1 and 15)</b>			
<b>Basic</b>	<b>2,681.5</b>	<b>2,692.0</b>	<b>2,737.3</b>
<b>Diluted</b>	<b>2,728.7</b>	<b>2,745.3</b>	<b>2,788.9</b>

\*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
<b>Other comprehensive income (loss), net of tax</b>			
Foreign currency translation	(1,518)	1,696	(612)
Securities: <sup>(1)</sup>			
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

<sup>(1)</sup> 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
<b>Balance, January 3, 2016</b>	<b>\$ 71,150</b>	<b>103,879</b>	<b>(13,165)</b>	<b>3,120</b>	<b>(22,684)</b>
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)		
<b>Balance, January 1, 2017</b>	<b>70,418</b>	<b>110,551</b>	<b>(14,901)</b>	<b>3,120</b>	<b>(28,352)</b>
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		
<b>Balance, December 31, 2017</b>	<b>60,160</b>	<b>101,793</b>	<b>(13,199)</b>	<b>3,120</b>	<b>(31,554)</b>
Cumulative adjustment	(486)	(254) <sup>(1)</sup>	(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)		
<b>Balance, December 30, 2018</b>	<b>\$ 59,752</b>	<b>106,216</b>	<b>(15,222)</b>	<b>3,120</b>	<b>(34,362)</b>

(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
<b>Cash flows from operating activities</b>			
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)
<b>Net cash flows from operating activities</b>	<b>22,201</b>	<b>21,056</b>	<b>18,767</b>
<b>Cash flows from investing activities</b>			
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)
<b>Net cash used by investing activities</b>	<b>(3,167)</b>	<b>(14,868)</b>	<b>(4,761)</b>
<b>Cash flows from financing activities</b>			
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)
<b>Net cash used by financing activities</b>	<b>(18,510)</b>	<b>(7,673)</b>	<b>(8,551)</b>
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
<b>Cash and cash equivalents, end of year (Note 1)</b>	<b>\$ 18,107</b>	<b>17,824</b>	<b>18,972</b>
<b>Supplemental cash flow data</b>			
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
<b>Acquisitions</b>			
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	<b>\$ 899</b>	<b>35,151</b>	<b>4,509</b>

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

#### 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)	<b>2018</b>			
	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 <sup>(1)</sup>	485	485	485	—
<b>Subtotal</b>	<b>\$ 9,953</b>	<b>9,953</b>	<b>9,953</b>	<b>—</b>
Gov't Securities	\$ 9,474	9,474	8,144	1,330
Corporate debt securities	260	260	10	250
<b>Subtotal available for sale<sup>(2)</sup></b>	<b>\$ 9,734</b>	<b>9,734</b>	<b>8,154</b>	<b>1,580</b>
<b>Total cash, cash equivalents and current marketable securities</b>			<b>\$ 18,107</b>	<b>1,580</b>

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 <sup>(1)</sup>	279	279	219	60
U.S. Reverse repurchase agreements	4,025	4,025	4,025	—
Corporate debt securities <sup>(1)</sup>	289	289	244	45
Money market funds	4,288	4,288	4,288	—
Time deposits <sup>(1)</sup>	1,176	1,176	1,175	1
<b>Subtotal</b>	<b>\$ 12,986</b>	<b>12,986</b>	<b>12,880</b>	<b>106</b>
Gov't Securities	\$ 4,864	4,864	4,833	31
Other Sovereign Securities	186	186	80	106
Corporate debt securities	260	260	31	229
<b>Subtotal available for sale<sup>(2)</sup></b>	<b>\$ 5,310</b>	<b>5,310</b>	<b>4,944</b>	<b>366</b>
<b>Total cash, cash equivalents and current marketable securities</b>			<b>\$ 17,824</b>	<b>472</b>

<sup>(1)</sup> Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.

<sup>(2)</sup> 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	—	—
<b>Total debt securities</b>	<b>\$ 9,734</b>	<b>9,734</b>

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
<b>Total inventories</b>	<b>\$ 8,599 <sup>(1)</sup></b>	<b>8,765</b>

<sup>(1)</sup> 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
<b>Total property, plant and equipment, net</b>	<b>\$ 17,035 <sup>(1)</sup></b>	<b>17,005</b>

<sup>(1)</sup> 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
<b>Intangible assets with definite lives:</b>		
Patents and trademarks — gross	\$ 35,194	36,427
Less accumulated amortization	9,784	7,223
Patents and trademarks — net	<b>\$ 25,410</b>	<b>29,204</b>
Customer relationships and other intangibles — gross	\$ 21,334	20,204
Less accumulated amortization	8,323	7,463
Customer relationships and other intangibles — net	<b>\$ 13,011</b>	<b>12,741</b>
<b>Intangible assets with indefinite lives:</b>		
Trademarks	\$ 6,937	7,082
Purchased in-process research and development <sup>(1)</sup>	2,253	4,201
Total intangible assets with indefinite lives	<b>\$ 9,190</b>	<b>11,283</b>
Total intangible assets — net	<b>\$ 47,611</b>	<b>53,228</b>

<sup>(1)</sup> 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 <sup>(1)</sup>	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) <sup>(2)</sup>	(1,348)
Currency translation/other	(373)	(97)	(38)	(508)
Goodwill at December 30, 2018	<b>\$ 8,670</b>	<b>9,063</b>	<b>12,720</b>	<b>30,453</b>

<sup>(1)</sup> 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.

<sup>(2)</sup> 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
<b>The effects of fair value, net investment and cash flow hedging:</b>										
<b>Gain (Loss) on fair value hedging relationship:</b>										
<b>Interest rate swaps contracts:</b>										
Hedged items	\$ —	—	—	5	—	—	—	—	5	—
Derivatives designated as hedging instruments	—	—	—	(5)	—	—	—	—	(5)	—
<b>Gain (Loss) on net investment hedging relationship:</b>										
<b>Cross currency interest rate swaps contracts:</b>										
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	—	—	—	—	—	—
<b>Gain (Loss) on cash flow hedging relationship:</b>										
<b>Forward foreign exchange contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income <sup>(1)</sup>	47	200	(220)	—	(24)	(31)	(159)	(165)	—	(87)
Amount of gain or (loss) recognized in AOCI <sup>(1)</sup>	(32)	(17)	(193)	—	(4)	49	96	(199)	—	(60)
<b>Cross currency interest rate swaps contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	133	—	—	—	—	83	—
Amount of gain or (loss) recognized in AOCI	\$ —	—	—	117	—	—	—	—	110	—

<sup>(1)</sup> 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
	December 30, 2018	December 31, 2017	Fiscal Nine Months Ended
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 <sup>(1)</sup>	Sales/ Purchases/Other <sup>(2)</sup>	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:

(Dollars in Millions)	2018			2017	
	Level 1	Level 2	Level 3	Total	Total <sup>(1)</sup>
<b>Derivatives designated as hedging instruments:</b>					
<b>Assets:</b>					
Forward foreign exchange contracts	\$ —	501	—	501	418
Interest rate contracts <sup>(2)(4)</sup>	—	161	—	161	7
<b>Total</b>	<b>—</b>	<b>662</b>	<b>—</b>	<b>662</b>	<b>425</b>
<b>Liabilities:</b>					
Forward foreign exchange contracts	—	548	—	548	402
Interest rate contracts <sup>(3)(4)</sup>	—	292	—	292	165
<b>Total</b>	<b>—</b>	<b>840</b>	<b>—</b>	<b>840</b>	<b>567</b>
<b>Derivatives not designated as hedging instruments:</b>					
<b>Assets:</b>					
Forward foreign exchange contracts	—	32	—	32	38
<b>Liabilities:</b>					
Forward foreign exchange contracts	—	32	—	32	38
<b>Available For Sale Other Investments:</b>					
Equity investments <sup>(5)</sup>	511	—	—	511	751
Debt securities <sup>(6)</sup>	\$ —	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) <sup>(2)</sup> /(1B Euro 1.1947) <sup>(3)</sup>	1,139 <sup>(2)</sup>	5.83	1,192 <sup>(3)</sup>	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) <sup>(2)</sup> /(1B Euro 1.1947) <sup>(3)</sup>	1,137 <sup>(2)</sup>	0.26	1,191 <sup>(3)</sup>	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) <sup>(2)</sup> /(750MM Euro 1.1947) <sup>(3)</sup>	851 <sup>(2)</sup>	0.68	891 <sup>(3)</sup>	0.68
5.50% Notes due 2024 (500MM GBP 1.2636) <sup>(2)</sup> /(500MM GBP 1.3444) <sup>(3)</sup>	627 <sup>(2)</sup>	6.75	666 <sup>(3)</sup>	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) <sup>(2)</sup> /(750MM Euro 1.1947) <sup>(3)</sup>	847 <sup>(2)</sup>	1.21	887 <sup>(3)</sup>	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) <sup>(2)</sup> /(1.5B Euro 1.1947) <sup>(3)</sup>	1,693 <sup>(2)</sup>	1.68	1,774 <sup>(3)</sup>	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	—
<b>Subtotal</b>	<b>30,320 <sup>(4)</sup></b>	<b>3.19% <sup>(1)</sup></b>	<b>32,174 <sup>(4)</sup></b>	<b>3.19 <sup>(1)</sup></b>
Less current portion	2,636		1,499	
<b>Total long-term debt</b>	<b>\$ 27,684</b>		<b>30,675</b>	

(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)					
<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>After 2023</u>
\$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
<b>Currently payable:</b>			
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
<b>Total currently payable</b>	<b>3,718</b>	<b>13,967</b>	<b>3,604</b>
<b>Deferred:</b>			
U.S. taxes	(148)	(1,956)	294
U.S. taxes on international operations	1,358		
International taxes	(2,226)	4,362	(635)
<b>Total deferred</b>	<b>(1,016)</b>	<b>2,406</b>	<b>(341)</b>
<b>Provision for taxes on income</b>	<b>\$ 2,702</b>	<b>16,373</b>	<b>3,263</b>

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:	<u>\$ 17,999</u>	<u>17,673</u>	<u>19,803</u>
Tax rates:			
U.S. statutory rate	21.0 %	35.0	35.0
International operations <sup>(1)</sup>	(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 <sup>(2)</sup>	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 <sup>(3)</sup>	(1.9) <sup>(3)</sup>	73.3 <sup>(4)</sup>	—
Effective Rate	<u>15.0 %</u>	<u>92.6</u>	<u>16.5</u>

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 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:

(Dollars in Millions)	2018 Deferred Tax		2017 Deferred Tax	
	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	<b>\$ 11,405</b>	<b>(11,271)</b>	<b>9,902</b>	<b>(11,166)</b>

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) <sup>(1)</sup>	(338)
Settlements	(40)	(2)	(37)
Lapse of statute of limitations	(35)	(36)	(23)
End of year	<b>\$ 3,326</b>	<b>3,151</b>	<b>3,041</b>

<sup>(1)</sup> 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	<b>\$ 9,951</b>	<b>10,074</b>

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:

(Dollars in Millions)	Retirement Plans			Other Benefit Plans		
	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	<b>\$ 923</b>	<b>594</b>	<b>422</b>	<b>502</b>	<b>508</b>	<b>477</b>

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:

Worldwide Benefit Plans	Retirement Plans			Other Benefit Plans		
	2018	2017	2016	2018	2017	2016
<b>Net Periodic Benefit Cost</b>						
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			
<b>Benefit Obligation</b>						
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:

<b>Health Care Plans</b>	<b>2018</b>	<b>2017</b>
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
<b>Health Care Plans</b>		
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		Other Benefit Plans	
	2018	2017	2018	2017
<b>Change in Benefit Obligation</b>				
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	<b>\$ 31,670</b>	<b>33,221</b>	<b>4,480</b>	<b>4,582</b>
<b>Change in Plan Assets</b>				
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	<b>\$ 26,818</b>	<b>28,404</b>	<b>180</b>	<b>281</b>
Funded status — end of year	<b>\$ (4,852)</b>	<b>(4,817)</b>	<b>(4,300)</b>	<b>(4,301)</b>
<b>Amounts Recognized in the Company's Balance Sheet consist of the following:</b>				
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	<b>\$ (4,852)</b>	<b>(4,817)</b>	<b>(4,300)</b>	<b>(4,301)</b>
<b>Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:</b>				
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	<b>\$ 8,325</b>	<b>8,115</b>	<b>1,157</b>	<b>1,363</b>
<b>Accumulated Benefit Obligations — end of year</b>	<b>\$ 28,533</b>	<b>29,793</b>		



(Dollars in Millions)	Retirement Plans		Other Benefit Plans	
	2018	2017	2018	2017
<b>Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income</b>				
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:

(Dollars in Millions)	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
	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
<b>Over (Under) Funded Status</b>								
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
<b>Projected future benefit payments</b>						
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
<b>Projected future contributions</b>						
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
<b>Worldwide Retirement Plans</b>			
Equity securities	71%	76%	70%
Debt securities	29	24	30
Total plan assets	<b>100%</b>	<b>100%</b>	<b>100%</b>

### Determination of Fair Value of Plan Assets

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

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

### Valuation Hierarchy

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

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

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

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

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2018 and December 31, 2017:

(Dollars in Millions)	Quoted Prices in Active Markets for Identical Assets		Significant Other Observable Inputs		Significant Unobservable Inputs <sup>(a)</sup>		Investments Measured at Net Asset Value		Total Assets	
	(Level 1)		(Level 2)		(Level 3)		2018	2017	2018	2017
	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
<b>Investments at fair value</b>	<b>\$ 11,420</b>	<b>14,277</b>	<b>9,570</b>	<b>7,435</b>	<b>326</b>	<b>256</b>	<b>5,502</b>	<b>6,436</b>	<b>26,818</b>	<b>28,404</b>

<sup>(a)</sup> 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)	<b>Treasury Stock</b>	
	<b>Shares</b>	<b>Amount</b>
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	<u>457,519</u>	<u>\$ 34,362</u>

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) <sup>(1)</sup>			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	\$ (8,869)	—	(6,158)	(195)	(15,222)

<sup>(1)</sup> 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	<u>\$ 5.61</u>	<u>0.47</u>	<u>5.93</u>

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)**

<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>After 2023</b>	<b>Total</b>
\$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:

	<b>2018</b>	<b>2017</b>	<b>2016</b>
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	<b>109,652</b>	<b>\$ 98.29</b>	<b>\$ 3,214</b>

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 <sup>(1)</sup>	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	
	<b>109,652</b>	<b>6.2</b>	<b>\$98.29</b>	<b>54,862</b>	<b>\$82.03</b>	

<sup>(1)</sup> 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)	<b>Outstanding Restricted Share Units</b>	<b>Outstanding Performance Share Units</b>
Shares at December 31, 2017	20,161	2,625
Granted	6,074	1,142
Issued	(6,684)	(1,151)
Canceled/forfeited/adjusted	<u>(1,091)</u>	<u>(122)</u>
Shares at December 30, 2018	<b>18,460</b>	<b>2,494</b>

The average fair value of the restricted share units granted was \$119.67, \$107.69 and \$92.45 in 2018, 2017 and 2016, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was \$613.7 million, \$596.5 million and \$587.7 million in 2018, 2017 and 2016, respectively.

The weighted average fair value of the performance share units granted was \$120.64, \$114.13 and \$105.30 in 2018, 2017 and 2016, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was \$128.8 million, \$132.5 million and \$127.7 million in 2018, 2017 and 2016, respectively.

## 18. Segments of Business and Geographic Areas

(Dollars in Millions)	Sales to Customers			% Change	
	2018	2017	2016	'18 vs. '17	'17 vs. '16
<b>CONSUMER</b>					
<b>Baby Care</b>					
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)
<b>Beauty</b>					
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
<b>Oral Care</b>					
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)
<b>OTC</b>					
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
<b>Women's Health</b>					
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)
<b>Wound Care/Other</b>					
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)
<b>TOTAL CONSUMER</b>					
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
<b>PHARMACEUTICAL</b>					
<b>Immunology</b>					
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
<b>REMICADE®</b>					
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	*

<b>UPTRAVI®</b>					
U.S.	598	238	—	*	*
International	65	25	—	*	*
Worldwide	663	263	—	*	*
<b>OTHER</b>					
U.S.	85	54	—	57.4	*
International	64	34	—	88.2	*
Worldwide	149	88	—	69.3	*
<b>Cardiovascular / Metabolism / Other</b>					
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)
<b>XARELTO®</b>					
U.S.	2,477	2,500	2,288	(0.9)	9.3
International	—	—	—	—	—
Worldwide	2,477	2,500	2,288	(0.9)	9.3
<b>INVOKANA® / INVOKAMET®</b>					
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)
<b>PROCRIT® / EPREX®</b>					
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)
<b>OTHER</b>					
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
<b>TOTAL PHARMACEUTICAL</b>					
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
<b>MEDICAL DEVICES</b>					
<b>Diabetes Care</b>					
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)
<b>Diagnostics</b>					
U.S.	—	—	—	—	—
International	—	1	66	*	*
Worldwide	—	1	66	*	*
<b>Interventional Solutions</b>					
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

<b>Orthopaedics</b>					
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)
<u>HIPS</u>					
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
<u>KNEES</u>					
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)
<u>TRAUMA</u>					
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
<u>SPINE &amp; OTHER</u>					
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)
<b>Surgery</b>					
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
<u>ADVANCED</u>					
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
<u>GENERAL</u>					
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
<u>SPECIALTY</u>					
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)
<b>Vision</b>					
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
<u>CONTACT LENSES / OTHER</u>					
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

(Dollars in Millions)	Income Before Tax			Identifiable Assets	
	2018 <sup>(3)</sup>	2017 <sup>(4)</sup>	2016 <sup>(5)</sup>	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 <sup>(1)</sup>	1,286	1,326	1,043		
General corporate <sup>(2)</sup>				24,187	27,410
Worldwide total	<u>\$ 17,999</u>	<u>17,673</u>	<u>19,803</u>	<u>\$ 152,954</u>	<u>157,303</u>

(Dollars in Millions)	Additions to Property, Plant & Equipment			Depreciation and Amortization		
	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	<u>\$ 3,670</u>	<u>3,279</u>	<u>3,226</u>	<u>\$ 6,929</u>	<u>5,642</u>	<u>3,754</u>

(Dollars in Millions)	Sales to Customers			Long-Lived Assets <sup>(6)</sup>	
	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	<u>\$ 81,581</u>	<u>76,450</u>	<u>71,890</u>	<u>\$ 152,954</u>	<u>157,303</u>

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 <sup>(1)</sup>	Second Quarter <sup>(2)</sup>	Third Quarter <sup>(3)</sup>	Fourth Quarter <sup>(4)</sup>	First Quarter <sup>(5)</sup>	Second Quarter <sup>(6)</sup>	Third Quarter <sup>(7)</sup>	Fourth Quarter <sup>(8)</sup>
<b>Segment sales to customers</b>								
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	<u>20,009</u>	<u>20,830</u>	<u>20,348</u>	<u>20,394</u>	<u>17,766</u>	<u>18,839</u>	<u>19,650</u>	<u>20,195</u>
Gross profit	13,395	13,903	13,759	13,433	12,357	12,993	12,725	12,936
<b>Earnings before provision for taxes on income</b>								
	5,481	4,973	4,423	3,122	5,575	4,748	4,790	2,560
Net earnings (loss)	<u>4,367</u>	<u>3,954</u>	<u>3,934</u>	<u>3,042</u>	<u>4,422</u>	<u>3,827</u>	<u>3,764</u>	<u>(10,713)</u>
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 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 <sup>(1)</sup>	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
<b>Total Assets Acquired</b>	<b>33,199</b>
Current liabilities	956
Deferred Taxes	1,776
Other non-current liabilities	413
<b>Total Liabilities Assumed</b>	<b>3,145</b>
<b>Net Assets Acquired</b>	<b>30,054</b>

<sup>(1)</sup> 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.

(Dollars in Millions Except Per Share Data)	<b>Unaudited Pro forma Consolidated Results</b>	
	<b>2017</b>	<b>2016</b>
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 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. 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 affirmation 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); Princeton 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.) (JJC). 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 JJC'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.) (JJC) 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 JJC). 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 JJC'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)		<b>Severance</b>	<b>Asset Write-offs</b>	<b>Other**</b>	<b>Total</b>
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
<b>Current year activity:</b>					
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

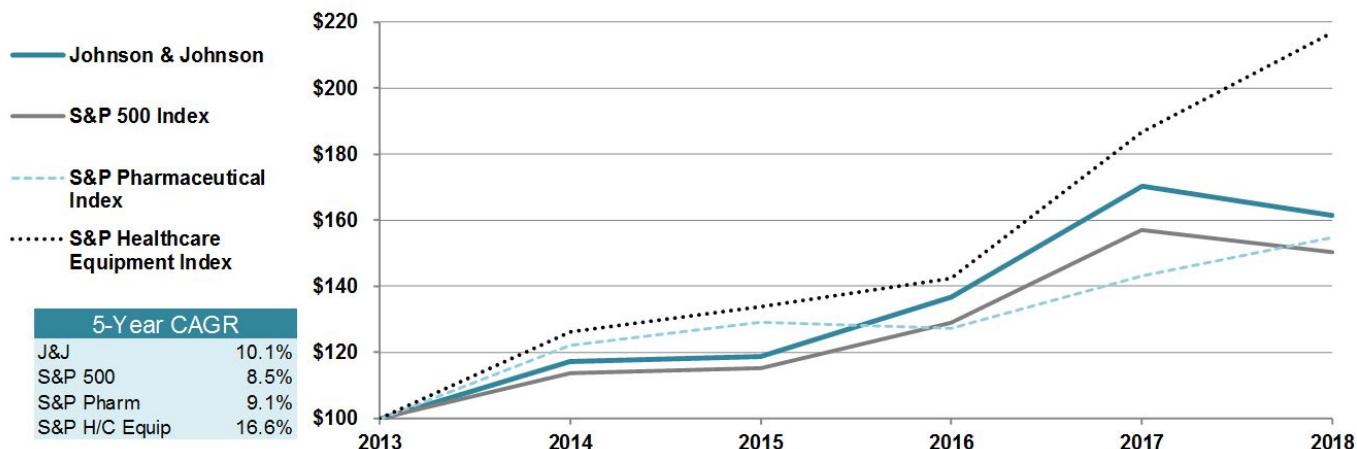
Joseph J. Wolk

Executive Vice President, Chief Financial Officer

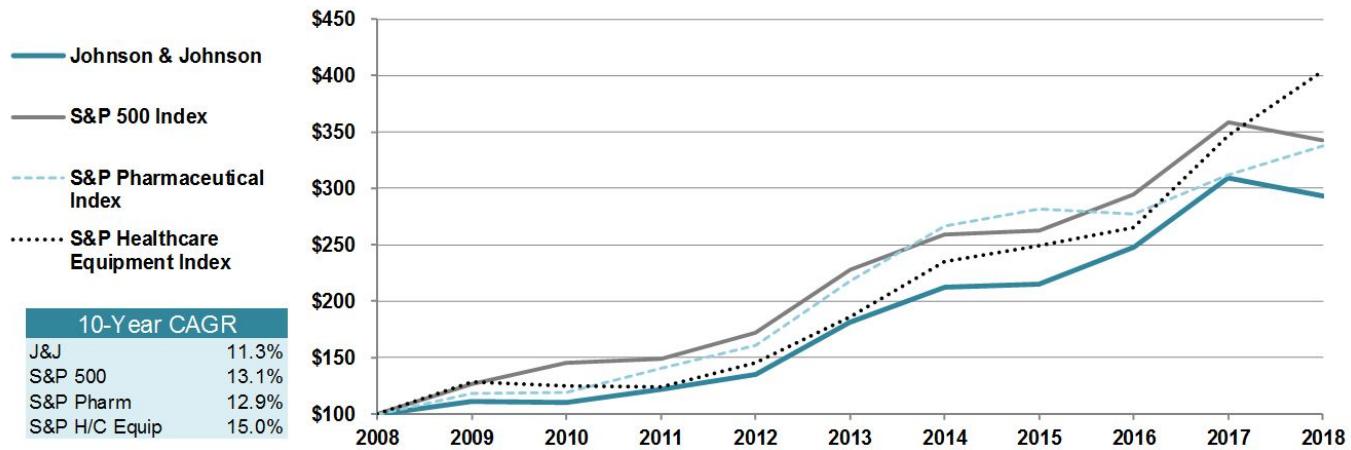
### Shareholder Return Performance Graphs

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



#### 10 Year Shareholder Return Performance J&J vs. Indices



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Johnson & Johnson	\$100.00	\$111.28	\$110.63	\$121.57	\$134.73	\$181.37	\$212.81	\$215.28	\$248.26	\$308.85	\$292.99
S&P 500 Index	\$100.00	\$126.45	\$145.49	\$148.55	\$172.31	\$228.09	\$259.29	\$262.86	\$294.28	\$358.50	\$342.75
S&P Pharmaceutical Index	\$100.00	\$118.62	\$119.54	\$140.77	\$161.07	\$217.82	\$266.21	\$281.62	\$277.21	\$312.06	\$337.32
S&P Healthcare Equipment Index	\$100.00	\$128.79	\$125.30	\$124.30	\$145.76	\$186.12	\$235.04	\$249.08	\$265.23	\$347.17	\$403.55

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

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](http://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](http://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](http://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](http://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 <sup>(2)(3)</sup>
Equity Compensation Plans Approved by Security Holders <sup>(1)</sup>	130,605,768	\$82.52	351,079,202
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	130,605,768	\$82.52	351,079,202

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

#### **Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

#### **Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

## PART IV

### Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

#### 1. *Financial Statements*

- Consolidated Balance Sheets at end of Fiscal Years 2018 and 2017
- Consolidated Statements of Earnings for Fiscal Years 2018, 2017 and 2016
- Consolidated Statements of Comprehensive Income for Fiscal Years 2018, 2017 and 2016
- Consolidated Statements of Equity for Fiscal Years 2018, 2017 and 2016
- Consolidated Statements of Cash Flows for Fiscal Years 2018, 2017 and 2016
- Notes to Consolidated Financial Statements
- Report of Independent Registered Public Accounting Firm

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

#### 2. *Exhibits Required to be Filed by Item 601 of Regulation S-K*

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

### Item 16. FORM 10-K SUMMARY

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

## SIGNATURES

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

Date: February 20, 2019

JOHNSON & JOHNSON

(Registrant)

By \_\_\_\_\_ /s/ A. Gorsky

A. Gorsky, Chairman, Board of Directors,  
and Chief Executive Officer

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

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 20, 2019
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 20, 2019
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 20, 2019
/s/ M. C. Beckerle M. C. Beckerle	Director	February 20, 2019
/s/ D. S. Davis D. S. Davis	Director	February 20, 2019
/s/ I. E. L. Davis I. E. L. Davis	Director	February 20, 2019
/s/ J. A. Doudna J. A. Doudna	Director	February 20, 2019

<b>Signature</b>		<b>Title</b>	<b>Date</b>
<hr/> <u>/s/ M. B. McClellan</u>	Director		February 20, 2019
M. B. McClellan			
<hr/> <u>/s/ A. M. Mulcahy</u>	Director		February 20, 2019
A. M. Mulcahy			
<hr/> <u>/s/ W. D. Perez</u>	Director		February 20, 2019
W. D. Perez			
<hr/> <u>/s/ C. Prince</u>	Director		February 20, 2019
C. Prince			
<hr/> <u>/s/ A. E. Washington</u>	Director		February 20, 2019
A. E. Washington			
<hr/> <u>/s/ R. A. Williams</u>	Director		February 20, 2019
R. A. Williams			

## EXHIBIT INDEX

**Reg. S-K**

**Exhibit Table**

<b>Item No.</b>	<b>Description of Exhibit</b>
<a href="#">3(i)</a>	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.
<a href="#">3(ii)</a>	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.
<a href="#">10(a)</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).*
<a href="#">10(b)</a>	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.*
<a href="#">10(c)</a>	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.*
<a href="#">10(d)</a>	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.*
<a href="#">10(e)</a>	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.*
<a href="#">10(f)</a>	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.*
<a href="#">10(g)</a>	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.*
<a href="#">10(h)</a>	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.*
<a href="#">10(i)</a>	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.*
<a href="#">10(j)</a>	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.*
<a href="#">10(k)</a>	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.*
<a href="#">10(l)</a>	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.*
<a href="#">10(m)</a>	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.*
<a href="#">10(o)</a>	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.*
<a href="#">10(p)</a>	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.*
<a href="#">10(r)</a>	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
<a href="#"><u>10(t)</u></a>	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.*
<a href="#"><u>10(u)</u></a>	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.*
<a href="#"><u>10(v)</u></a>	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.*
<a href="#"><u>10(w)</u></a>	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.*
<a href="#"><u>21</u></a>	Subsidiaries - Filed with this document.
<a href="#"><u>23</u></a>	Consent of Independent Registered Public Accounting Firm — Filed with this document.
<a href="#"><u>31.1</u></a>	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
<a href="#"><u>31.2</u></a>	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
<a href="#"><u>32.1</u></a>	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
<a href="#"><u>32.2</u></a>	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.