

JOHNSON & JOHNSON

Form 10-K

February 20, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 30, 2018

Commission file number
1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey

22-1024240

(State of incorporation)

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

One Johnson & Johnson Plaza

08933

New Brunswick, New Jersey

(Address of principal executive offices) (Zip Code)

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

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

Title of each class

Name of each exchange on which registered

Common Stock, Par Value \$1.00

New York Stock Exchange

4.75% Notes Due November 2019

New York Stock Exchange

0.250% Notes Due January 2022

New York Stock Exchange

0.650% Notes Due May 2024

New York Stock Exchange

5.50% Notes Due November 2024

New York Stock Exchange

1.150% Notes Due November 2028

New York Stock Exchange

1.650% Notes Due May 2035

New York Stock Exchange

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$325 billion.

On February 15, 2019, there were 2,663,138,579 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

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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.

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-

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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; PROCRT®/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^d largest product, STELARA[®] (ustekinumab), accounted for approximately 6.3% of the Company's total revenues for fiscal 2018. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA[®]. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the

United States. In the U.S., the latest projected expiration date for patents in this set is 2023 due to a patent term extension. In Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplemental Patent Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021. In addition to competing in the immunology market with STELARA[®], the Company is currently marketing SIMPONI[®] (golimumab) and SIMPONI ARIA[®] (golimumab), next generation immunology products with remaining patent lives of up to six years. The Company also markets REMICADE[®] (infliximab) in the immunology market which is the Company's largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE[®], see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE[®] Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

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

Seasonality

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

Competition

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

Environment

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

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation. The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

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

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

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

Available Information

The Company's main corporate website address is www.jnj.com. All of the Company's SEC filings are also available on the Company's website at www.investor.jnj.com/sec.cfm, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at www.sec.gov. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at www.investor.jnj.com/gov.cfm on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

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

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

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

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

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

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

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

On December 22, 2017, the U.S. enacted The Tax Cuts and Jobs Act (the TCJA), which introduced significant changes to U.S. corporate income tax law that will have a meaningful impact on the Company's provision for income taxes. Accounting for the income tax effects of the TCJA requires significant judgments to be made in interpreting its provisions. Anticipated guidance from the U.S. Treasury about implementing the TCJA, which should be final by June 22, 2019 (18 months after enactment),

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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.

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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.

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 111 manufacturing facilities occupying approximately 20.5 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,503
Pharmaceutical	6,819
Medical Devices	7,183
Worldwide Total	20,505

Within the U.S., five facilities are used by the Consumer segment, five by the Pharmaceutical segment and 27 by the Medical Devices segment. Outside of the U.S., 25 facilities are used by the Consumer segment, 14 by the Pharmaceutical segment and 35 by the Medical Devices segment.

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

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	37	5,855
Europe	34	7,587
Western Hemisphere, excluding U.S.	12	2,800
Africa, Asia and Pacific	28	4,263
Worldwide Total	111	20,505

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

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

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

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

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 “Legal Proceedings” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

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

Name	Age	Position
Joaquin Duato	56	Vice Chairman, Executive Committee ^(a)
Peter M. Fasolo	56	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer ^(b)
Alex Gorsky	58	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	48	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices ^(c)
Jorge Mesquita	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer ^(d)
Thibaut Mongon	49	Appointee, Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer ^(e)
Michael E. Sneed	59	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer ^(f)
Paulus Stoffels	56	Vice Chairman, Executive Committee; Chief Scientific Officer ^(g)
Jennifer L. Taubert	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals ^(h)
Michael H. Ullmann	60	Member, Executive Committee; Executive Vice President, General Counsel ⁽ⁱ⁾
Kathryn E. Wengel	53	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer ^(j)
Joseph J. Wolk	52	Member, Executive Committee; Executive Vice President, Chief Financial Officer ^(k)

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 (a) 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.

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 (b) 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.

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 (c) 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.

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 (d) 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.

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 (e) 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.

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 (f) 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.

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 (g) 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. 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 (i) 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.

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, (j) 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.

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

As of February 15, 2019, there were 142,029 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's Common Stock. Share repurchases take place from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2018. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased ⁽¹⁾	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs ⁽²⁾	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs ⁽³⁾
October 1, 2018 through October 28, 2018	2,192,500	\$ 138.74	-	-
October 29, 2018 through November 25, 2018	6,849,298	143.27	-	-
November 26, 2018 through December 30, 2018	18,130,189	139.10	7,073,136	32,131,870
Total	27,171,987			

During the fiscal fourth quarter of 2018, the Company repurchased an aggregate of 27,171,987 shares of Johnson & Johnson Common Stock in open-market transactions, of which 7,073,136 shares were purchased pursuant to the repurchase program that was publicly announced on December 17, 2018, and of which 20,098,851 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

⁽²⁾ As of December 30, 2018, an aggregate of 7,073,136 shares were purchased for a total of \$0.9 billion since the inception of the repurchase program announced on December 17, 2018.

⁽³⁾ As of December 30, 2018, the maximum number of shares that may yet be purchased under the plan is 32,131,870 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 28, 2018 of \$127.27 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2008-2018*

(Dollars in Millions

Except Per Share Amounts)	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008
Sales to customers — U.S.	\$41,884	39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309
Sales to customers — International	39,697	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438
Total sales	81,581	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747
Cost of products sold	27,091	25,439	21,789	21,426	22,684	22,181	21,515	20,219	18,688	18,380	18,463
Selling, marketing and administrative expenses	22,540	21,520	20,067	21,079	21,887	21,650	20,697	20,800	19,296	19,712	21,431
Research and development expense	10,775	10,594	9,143	8,999	8,471	8,119	7,602	7,486	6,796	6,949	7,554
In-process research and development	1,126	408	29	224	178	580	1,163	—	—	—	181
Interest income	(611)	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)
Interest expense, net of portion capitalized	1,005	934	726	552	533	482	532	571	455	451	435
Other (income) expense, net	1,405	(42)	210	(1,783)	82	2,903	2,004	3,115	(488)	(333)	(885)
Restructuring	251	309	491	509	—	—	—	569	—	1,073	—
Earnings before provision for taxes on income	63,582	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818
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
Net earnings	2,702	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980
Add: Net loss attributable to noncontrolling interest	15,297	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949
Net earnings attributable to Johnson & Johnson	—	—	—	—	—	—	339	—	—	—	—
Percent of sales to customers	18.8%	1.7	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3
Diluted net earnings per share of common stock ⁽¹⁾	\$5.61	0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78		