

JOHNSON & JOHNSON

Form 10-K

February 27, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 1, 2017 Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey 22-1024240

(State of incorporation) (I.R.S. Employer Identification No.)

One Johnson & Johnson Plaza 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

New York Stock Exchange

4.75% Notes Due November 2019 New York Stock Exchange

0.250% Notes Due January 2022 New York Stock Exchange

0.650% Notes Due May 2024 New York Stock Exchange

5.50% Notes Due November 2024 New York Stock Exchange

1.150% Notes Due November 2028 New York Stock Exchange

1.650% Notes Due May 2035 New York Stock Exchange

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

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

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

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

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

Edgar Filing: JOHNSON & JOHNSON - Form 10-K

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

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$332 billion.

On February 23, 2017, there were 2,713,346,602 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2017 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

Item	Page
<u>PART I</u>	
1 <u>Business</u>	<u>1</u>
<u>General</u>	<u>1</u>
<u>Segments of Business</u>	<u>1</u>
<u>Geographic Areas</u>	<u>2</u>
<u>Raw Materials</u>	<u>2</u>
<u>Patents</u>	<u>2</u>
<u>Trademarks</u>	<u>3</u>
<u>Seasonality</u>	<u>3</u>
<u>Competition</u>	<u>3</u>
<u>Research and Development</u>	<u>3</u>
<u>Environment</u>	<u>3</u>
<u>Regulation</u>	<u>4</u>
<u>Available Information</u>	<u>4</u>
1A. <u>Risk Factors</u>	<u>4</u>
1B. <u>Unresolved Staff Comments</u>	<u>9</u>
2 <u>Properties</u>	<u>9</u>
3 <u>Legal Proceedings</u>	<u>10</u>
4 <u>Mine Safety Disclosures</u>	<u>10</u>
<u>Executive Officers of the Registrant</u>	<u>10</u>
<u>PART II</u>	
5 <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>12</u>
6 <u>Selected Financial Data</u>	<u>13</u>
7 <u>Management’s Discussion and Analysis of Results of Operations and Financial Condition</u>	<u>14</u>
7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>33</u>
8 <u>Financial Statements and Supplementary Data</u>	<u>33</u>
9 <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>87</u>
9A. <u>Controls and Procedures</u>	<u>87</u>
9B. <u>Other Information</u>	<u>87</u>
<u>PART III</u>	
10 <u>Directors, Executive Officers and Corporate Governance</u>	<u>87</u>
11 <u>Executive Compensation</u>	<u>88</u>
12 <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>88</u>
13 <u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>88</u>
14 <u>Principal Accountant Fees and Services</u>	<u>88</u>
<u>PART IV</u>	
15 <u>Exhibits and Financial Statement Schedules</u>	<u>89</u>
16 <u>Form 10-K Summary</u>	<u>89</u>
<u>Signatures</u>	<u>90</u>
<u>Exhibit Index</u>	<u>92</u>

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Product Development, Market Success and Competition

Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;

Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the U.S. and other important markets;

The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;

Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product;

- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;

- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;

- Competition on the basis of cost-effectiveness, product performance, technological advances and patents attained by competitors; and

Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage;

- Impact of significant litigation or government action adverse to the Company, including product liability claims;

Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

-

Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or the Corporate Integrity Agreements of the Johnson & Johnson Pharmaceutical Affiliates, or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

Potential changes to applicable laws and regulations affecting U.S. and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;

• Changes in tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of reserves; and

• Issuance of new or revised accounting standards by the Financial Accounting Standards Board and the Securities and Exchange Commission.

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

Pricing pressures resulting from trends toward health care cost containment, including the continued

- consolidation among health care providers, trends toward managed care and the shift toward governments increasingly becoming the primary payers of health care expenses;

• Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;

Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;

The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company, including the planned acquisition of Actelion Ltd., may not be realized or may take longer to realize than expected;

The potential that the expected benefits and opportunities related to the planned restructuring actions in the Medical Device segment may not be realized or may take longer to realize than expected, including due to any required consultation procedures relating to restructuring of workforce; and

• Market conditions and the possibility that the Company's share repurchase program may be delayed, suspended or discontinued.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

• Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;

• Potential changes in export/import and trade laws, regulations and policies of the U.S., U.K. and other countries, including any increased trade restrictions and potential drug reimportation legislation;

The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;

• Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

• The impact of armed conflicts and terrorist attacks in the U.S. and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

• Difficulties and delays in manufacturing, internally or within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;

• Interruptions and breaches of the Company's information technology systems, and those of the Company's vendors, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action; and

• Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and

uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 126,400 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 230 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

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

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty (previously referred to as skin care), over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S Adult; LE PETITE MARSEILLAIS®; NEUTROGENA®; RoC® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on five therapeutic areas: immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), infectious diseases and vaccines (e.g., HIV, hepatitis, respiratory infections and tuberculosis), neuroscience (e.g., Alzheimer's disease, mood disorders and schizophrenia), oncology (e.g., prostate cancer, hematologic malignancies and lung cancer), and cardiovascular and metabolic diseases (e.g., thrombosis and diabetes). Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; PREZISTA® (darunavir), EDURANT® (rilpivirine), and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA® (paliperidone) extended-release tablets, for the treatment of schizophrenia and schizoaffective disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in

adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously

1

untreated mantle cell lymphoma; ZYTIGA[®] (abiraterone acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA[®] (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenström's Macroglobulinemia; DARZALEX[®] (daratumumab), for the treatment of relapsed/refractory multiple myeloma; PROCRT[®] (epoetin alfa, sold outside the U.S. as EPREX[®]), to stimulate red blood cell production; XARELTO[®] (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA[®] (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET[®]/VOKANAMET[®] (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET[®] XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; diabetes care products, such as blood glucose monitoring and insulin delivery products; and disposable contact lenses.

For details regarding acquisitions and divestitures see Note 20 to the Consolidated Financial Statements included in Item 8.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 230 operating companies located in 60 countries, including the U.S., in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under “– Segments of Business – Consumer,” “– Pharmaceutical” and “– Medical Devices.” However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

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

Raw Materials

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

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, “Legal Proceedings—Intellectual Property” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, REMICADE[®] (infliximab), accounted for approximately 9.7% of the Company's total revenues for fiscal 2016. Accordingly, the patents related to this product are believed to be material to the Company.

There are two sets of patents related specifically to REMICADE®. The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. These patents have expired in all countries outside the United States. In the United States, the one remaining patent, which expires in September 2018, stands rejected following

2

reexamination proceedings instituted by a third party in the United States Patent and Trademark Office (USPTO). The patent has also been held invalid by the Federal District Court in the District of Massachusetts. The decisions by the USPTO and the Federal District Court have been appealed to the U.S. Court of Appeals for the Federal Circuit. The appeals are pending.

The second set of patents specifically related to REMICADE[®] was granted to The Kennedy Institute of Rheumatology in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents, which expire in 2017 outside of the United States and 2018 in the United States. Certain of these patents have been successfully challenged and invalidated, and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any extensions will be available for the above described patents specifically related to REMICADE[®]. In 2016, a third party received approval from the Food and Drug Administration for sale of its infliximab biosimilar in the United States and introduced its biosimilar to the U.S. market in late 2016. For a more extensive description of legal matters regarding the patents related to REMICADE[®], see Note 21 “Legal Proceedings – Intellectual Property – Pharmaceutical – REMICADE[®] Related Cases” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition to competing in the immunology market with REMICADE[®], the Company is currently marketing STELARA[®] (ustekinumab), SIMPONI[®] (golimumab) and SIMPONI ARIA[®] (golimumab), next generation immunology products with remaining patent lives of up to seven years.

Trademarks

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

Seasonality

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

Competition

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

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to \$9.1 billion, \$9.0 billion and \$8.5 billion for fiscal years 2016, 2015 and 2014, respectively. Research facilities are located in the United States, Belgium, Brazil, Canada, China, France, Germany, India, Israel, Japan, the Netherlands, Singapore, Switzerland and the United Kingdom.

Environment

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

3

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the "FDA") continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

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

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

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

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

Available Information

The Company's main corporate website address is www.jnj.com. Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the "SEC"), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at www.investor.jnj.com/sec.cfm, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at www.sec.gov. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at www.investor.jnj.com/gov.cfm on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

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

