JOHNSON & JOHNSON
Form 10-K
February 24, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 3, 2016	Commission file number 1-3215

JOHNSON & JOHNSON
(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
5.50% Notes Due November 2024	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 þ No o
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 o No þ
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 þ No o
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 þ No o
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. þ
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 þ Accelerated filer o Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
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 $276 billion.
On February 19, 2016, there were 2,759,359,192 shares of Common Stock outstanding.
DOCUMENTS INCORPORATED BY REFERENCE
Parts I and III:

Portions of registrant’s proxy statement for its 2016 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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PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 127,100 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 250 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, 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 Skin Care include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; LUBRIDERM®; NEUTROGENA®; and RoC® 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 heartburn 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 adolescents with moderate to severe psoriasis; OLYSIO®/SOVRIAD®(simeprevir), for combination treatment of chronic hepatitis C in adult patients; 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; SIRTURO® (bedaquiline), a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (>18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB); 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® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of

schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma; ZYTIGA® (abiraterone acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenström's Macroglobulinemia; DARZALEX™ (daratumumab), for the treatment of double refractory multiple myeloma; YONDELIS® (trabectedin), for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen; PROCRIT® (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; and 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. 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.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 250 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 United States 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 number of patents relating to their products and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. Sales of the Company’s largest product, REMICADE® (infliximab), accounted for approximately 9.4% of the Company's total revenues for fiscal 2015. 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® (infliximab). 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 latest of these patents expires in September 2018 and this patent stands rejected and is subject to reexamination proceedings instituted by a third party in the United States

Patent and Trademark Office. Those proceedings are on going.

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 that expire in 2017 outside of the United

States and 2018 in the United States. The validity of these patents has been challenged. Certain claims have been 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 additional extensions will be available for the above described patents specifically related to REMICADE®. If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. 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 eight 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 United States 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 $9.0 billion, $8.5 billion and $8.2 billion for fiscal years 2015, 2014 and 2013, 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.

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 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/gov/sec-filings.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/materials.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 in Exhibit 99 to this Report. Investors should realize that if known or unknown risks or uncertainties materialize, the Company’s business, results of operations or financial condition could be adversely affected.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2.PROPERTIES

The Company's subsidiaries operate 121 manufacturing facilities occupying approximately 21.3 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	6,942
Pharmaceutical	7,435
Medical Devices	6,919
Worldwide Total	21,296

Within the United States, eight facilities are used by the Consumer segment, eight by the Pharmaceutical segment and 20 by the Medical Devices segment. Outside of the United States, 30 facilities are used by the Consumer segment, 18 by the Pharmaceutical segment and 37 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	36	5,808
Europe	38	7,917
Western Hemisphere, excluding U.S.	14	2,815
Africa, Asia and Pacific	33	4,756
Worldwide Total	121	21,296

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 of this Report under “Business – Research and Development.”

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

The Company is committed to maintaining all of its properties in good operating condition and repair, and the facilities are well utilized.

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"). The Fort Washington facility was voluntarily shut down in April 2010, and subsequently many products were transferred to other manufacturing sites and successfully reintroduced to the market. After McNEIL-PPC successfully completed all requirements contained in the Consent Decree Workplans for the Lancaster and Las Piedras manufacturing sites and completed the steps required for third-party certification of the Fort Washington plant, a third-party cGMP expert submitted written certifications to the FDA for all three manufacturing sites. 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. Commercial production in Fort Washington started as of September 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times for at least five years. A discussion of legal proceedings related to this matter can be found in Note 21 “Legal Proceedings – Government Proceedings – McNeil Consumer Healthcare” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

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.

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Item 3. LEGAL PROCEEDINGS

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

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company as of February 23, 2016. 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, is incorporated herein by reference to the material captioned "Item 1: Election of Directors" in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	58	Member, Executive Committee; Vice President, Finance; Chief Financial Officer(a)
Peter M. Fasolo	53	Member, Executive Committee; Vice President, Global Human Resources(b)
Alex Gorsky	55	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Sandra E. Peterson	57	Member, Executive Committee; Group Worldwide Chairman(c)
Paulus Stoffels	54	Member, Executive Committee; Chief Scientific Officer; Worldwide Chairman, Pharmaceuticals(d)
Michael H. Ullmann	57	Member, Executive Committee; Vice President, General Counsel(e)

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc. At the time of that acquisition, he had been Senior Vice President, Finance of Centocor. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001 and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a Member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company. He was then named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a Member of the Executive Committee.

(c) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a Member of the Executive Committee, with responsibility for the Consumer Group of Companies, consumer medical device businesses in the Vision Care and Diabetes Care franchises, and functions such as Johnson & Johnson Supply Chain, Information Technology, Wellness and Prevention and Global Strategic Design. Prior to joining Johnson & Johnson, Ms. Peterson had an extensive global career in healthcare, consumer goods and consulting. Most recently, she was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). Among her responsibilities was the application of information technology to

healthcare systems.

(d) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Virco and Tibotec, where he was Chief Executive Officer of Virco and Chairman of Tibotec. In 2005, he was appointed Company Group Chairman, Global Virology where he led the development of PREZISTA® and INTELENCE®, leading products for the treatment of HIV. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals, in 2009, and in 2011 became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was also appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and a Member of the Executive Committee.

(e) 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. Mr. Ullmann was appointed Vice President, General Counsel and a Member of the Executive Committee in 2012.

PART II

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

As of February 19, 2016, there were 158,749 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Item 7 "Management's Discussion and Analysis of Results of Operations and Financial Condition – Liquidity and Capital Resources – Dividends" and "— Other Information Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's Common Stock. Share repurchases take place on the open market from time to time based on market conditions. 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 2015. 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]
September 28, 2015 through October 25, 2015	1,134,367	$96.45	-	-
October 26, 2015 through November 22, 2015	6,298,421	100.21	5,408,965	-
November 23, 2015 through January 3, 2016	11,330,068	102.30	4,462,352	-
Total	18,762,856		9,871,317	87,618,945

[1] During the fiscal fourth quarter of 2015, the Company repurchased an aggregate of 18,762,856 shares of Johnson & Johnson Common Stock in open-market transactions, of which 9,871,317 shares were purchased pursuant to the repurchase program that was publicly announced on October 13, 2015, and of which 8,891,539 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 January 3, 2016, an aggregate of 9,871,317 shares were purchased for a total of $1.0 billion since the inception of the repurchase program announced on October 13, 2015.

(3) As of January 3, 2016, the maximum number of shares that may yet be purchased under the plan is 87,618,945 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 31, 2015 of $102.72 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2005-2015

(Dollars in Millions Except Per Share Amounts)	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
Sales to customers — U.S.	$35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309	32,444	29,775	28,377
Sales to customers — International	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438	28,651	23,549	22,137
Total sales	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747	61,095	53,324	50,514
Cost of products sold	21,536	22,746	22,342	21,658	20,360	18,792	18,447	18,511	17,751	15,057	14,010
Selling, marketing and administrative expenses	21,203	21,954	21,830	20,869	20,969	19,424	19,801	21,490	20,451	17,433	17,211
Research and development expense	9,046	8,494	8,183	7,665	7,548	6,844	6,986	7,577	7,680	7,125	6,462
In-process research and development	224	178	580	1,163	—	—	—	181	807	559	362
Interest income	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)	(452)	(829)	(487)
Interest expense, net of portion capitalized	552	533	482	532	571	455	451	435	296	63	54
Other (income) expense, net	(2,064)	(70)	2,498	1,626	2,743	(768)	(526)	(1,015)	534	(671)	(214)
Restructuring	509	—	—	—	569	—	1,073	—	745	—	—
	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818	47,812	38,737	37,398
Earnings before provision for taxes on income	$19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929	13,283	14,587	13,116
Provision for taxes on income	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980	2,707	3,534	3,056
Net earnings	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949	10,576	11,053	10,060
Add: Net loss attributable to noncontrolling interest	—	—	—	339	—	—	—	—	—	—	—
	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949	10,576	11,053	10,060

Net earnings attributable to Johnson & Johnson											
Percent of sales to customers	22.0%	22.0	19.4	16.1	14.9	21.7	19.8	20.3	17.3	20.7	19.9
Diluted net earnings per share of common stock [1]	$5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57	3.63	3.73	3.35
Percent return on average shareholders' equity	21.9%	22.7	19.9	17.8	17.0	24.9	26.4	30.2	25.6	28.3	28.2
Percent increase (decrease) over previous year:											
Sales to customers	(5.7)%	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3	14.6	5.6	6.7
Diluted net earnings per share	(3.9)%	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9	(2.7)	11.3	22.3
Supplementary balance sheet data:											
Property, plant and equipment, net	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365	14,185	13,044	10,830
Additions to property, plant and equipment	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066	2,942	2,666	2,632
Total assets[2]	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912	80,954	70,556	58,864
Long-term debt	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120	7,074	2,014	2,017
Operating cash flow	19,279	18,471	17,414	15,396	14,298	16,385	16,571	14,972	15,022	14,248	11,799
Common stock information											
Dividends paid per share	$2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795	1.62	1.455	1.275
Shareholders' equity per share	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35	15.25	13.59	13.01
Market price per share (year-end close)	$102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56	67.38	66.02	60.10

Average shares outstanding (millions)											
— basic	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9	2,936.4	2,973.9
— diluted	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7	2,961.0	3,002.8
Employees (thousands)	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7	119.2	122.2	115.6

(1) Attributable to Johnson & Johnson. (2) Amounts have been reclassified to conform to current year presentation.

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

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

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

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

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

Management's Objectives

The Company manages within a strategic framework with Our Credo as the foundation. The Company believes that our strategic operating principles: being broadly based in human health care, managing the business for the long term, having a decentralized management approach, and being committed to our people and values, are crucial to successfully meeting the demands of the rapidly evolving markets in which we compete. To this end, management is focused on our long-term strategic growth drivers: creating value through innovation, expanding our global reach with a local focus, excellence in execution and leading with purpose.

The Company is broadly based in human health care, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2015 sales. In 2015, $9.0 billion, or 12.9% of sales, was invested in research and development, reflecting management's commitment to delivering new and differentiated products and services to meet evolving health care needs and sustain the Company's long-term growth.

Our diverse businesses with more than 250 operating companies located in 60 countries are the key drivers of the Company's success. Maintaining the Company's decentralized management approach, while at the same time leveraging the extensive resources of the enterprise, positions the Company well to innovate, execute strategic plans and reach markets globally, as well as address the needs and challenges of the local markets.

In order to remain a leader in health care, the Company strives to maintain a purpose-driven organization and is committed to developing global business leaders who can achieve these growth objectives. Businesses are managed for the long-term in order to sustain market leadership positions and enable growth, which provides an enduring source of value to our shareholders.

Our Credo unifies all Johnson & Johnson employees in achieving these objectives, and provides a common set of values that serve as the foundation of the Company's responsibilities to patients, consumers and health care professionals, employees, communities and shareholders. The Company believes that these foundational values, its strategic framework and long-term growth drivers, along with its overall mission of improving the quality of life for people around the world, will enable Johnson & Johnson to continue to be a leader in the health care industry.

Results of Operations

Analysis of Consolidated Sales

In 2015, worldwide sales decreased 5.7% to $70.1 billion, compared to increases of 4.2% in 2014 and 6.1% in 2013. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2015	2014	2013
Volume	1.2%	6.3	7.6
Price	0.6	(0.2)	0.1
Currency	(7.5)	(1.9)	(1.6)
Total	(5.7)%	4.2	6.1

In 2015, the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.7% on the worldwide operational sales growth. In 2015, the impact of acquisitions and divestitures on the worldwide operational sales growth was negative 2.0%.

In 2014, sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 2.8%, and the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 1.4% on the worldwide operational growth. In 2013, the acquisition of Synthes, Inc., net of the related divestiture, increased worldwide operational growth by 2.5%.

Sales by U.S. companies were $35.7 billion in 2015, $34.8 billion in 2014 and $31.9 billion in 2013. This represents increases of 2.6% in 2015, 9.0% in 2014 and 7.0% in 2013. Sales by international companies were $34.4 billion in 2015, $39.5 billion in 2014 and $39.4 billion in 2013. This represents a decrease of 13.1% in 2015, and increases of 0.4% in 2014 and 5.4% in 2013.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.6%, 3.9% and 1.4%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.3%, 2.3% and 4.5%, respectively.

Sales by companies in Europe experienced a decline of 15.6% as compared to the prior year, including operational growth of 1.1%, offset by a negative currency impact of 16.7%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a decline of 15.6% as compared to the prior year, including operational growth of 2.6% offset by a negative currency impact of 18.2%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 8.1% as compared to the prior year, including operational growth of 0.3% and a negative currency impact of 8.4%.

2015 results benefited from the inclusion of a 53rd week. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). The Company estimated that the fiscal year 2015 growth rate was enhanced by approximately 1.0%. While the additional week added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues. In 2013, the Company did not have a customer that represented 10% or more of total consolidated revenues.

U.S. Health Care Reform

On July 28, 2014, the Internal Revenue Service issued final regulations for the Branded Prescription Drug Fee, an annual non-tax deductible fee imposed on entities engaged in the business of manufacturing or importing branded prescription drugs (covered entities), enacted by Section 9008 of the Patient Protection and Affordable Care Act. The final regulations accelerated the expense recognition criteria for the fee obligation by one year, from the year in which the fee is paid to the year in which the sales used to calculate the fee occur. This change impacted covered entities and resulted in the need for all entities to record an additional expense in 2014 for the fee that would have otherwise been expensed when paid in 2015. The Company accrued an additional $220 million in the fiscal third quarter of 2014 due to this change. The fee associated with this accelerated expense was paid, as scheduled, in 2015 and had no cash impact in 2014.

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Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2015 were $13.5 billion, a decrease of 6.8% from 2014, which included 2.7% operational growth offset by a negative currency impact of 9.5%. U.S. Consumer segment sales were $5.2 billion, an increase of 2.5%. International sales were $8.3 billion, a decrease of 11.9%, which included 2.7% operational growth offset by a negative currency impact of 14.6%. In 2015, divestitures had a negative impact of 1.4% on the worldwide Consumer segment operational growth.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	2015	2014	2013	’15 vs. ’14	’14 vs. ’13
OTC	$3,975	4,106	4,028	(3.2)%	1.9
Skin Care	3,531	3,758	3,704	(6.0)	1.5
Baby Care	2,044	2,239	2,295	(8.7)	(2.4)
Oral Care	1,580	1,647	1,622	(4.1)	1.5
Women’s Health	1,200	1,302	1,568	(7.8)	(17.0)
Wound Care/Other	1,177	1,444	1,480	(18.5)	(2.4)
Total Consumer Sales	$13,507	14,496	14,697	(6.8)%	(1.4)

The Over-the-Counter (OTC) franchise sales of $4.0 billion decreased 3.2% as compared to the prior year, which included 8.1% operational growth and a negative currency impact of 11.3%. Operational growth was primarily driven by analgesics, upper respiratory, including ZYRTEC®, and digestive health products.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the U.S. Food and Drug Administration (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). In February 2015, a third-party expert submitted written certification to the FDA for all three manufacturing sites. 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. 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 for at least five years.

The Skin Care franchise sales of $3.5 billion decreased 6.0% as compared to the prior year, which included 1.3% operational growth and a negative currency impact of 7.3%. Operational growth was primarily due to sales growth of NEUTROGENA® and AVEENO® products partially offset by lower sales in China.

The Baby Care franchise sales were $2.0 billion in 2015, a decrease of 8.7% compared to the prior year, which included 1.2% operational growth and a negative currency impact of 9.9%. Operational growth was primarily due to new product launches partially offset by competition in China.

The Oral Care franchise sales were $1.6 billion in 2015, a decrease of 4.1% as compared to the prior year, which included 5.2% operational growth and a negative currency impact of 9.3%. Operational growth was driven by increased sales of LISTERINE® products, attributable to geographical expansion of new products and successful marketing campaigns.

The Women’s Health franchise sales were $1.2 billion in 2015, a decrease of 7.8% as compared to the prior year, which included 7.6% operational growth and a negative currency impact of 15.4%. Operational growth outside the U.S. was driven by new product launches and successful marketing campaigns.

The Wound Care/Other franchise sales were $1.2 billion in 2015, a decrease of 18.5% from 2014, primarily due to the SPLENDA® and BENECOL® divestitures.

Consumer segment sales in 2014 were $14.5 billion, a decrease of 1.4% from 2013, which included 1.0% operational growth offset by a negative currency impact of 2.4%. U.S. Consumer segment sales were $5.1 billion, a decrease of 1.3%. International sales were $9.4 billion, a decrease of 1.4%, which included 2.3% operational growth offset by a

negative currency impact of 3.7%.

Pharmaceutical Segment

Pharmaceutical segment sales in 2015 were $31.4 billion, a decrease of 2.7% from 2014, which included operational growth of 4.2% offset by a negative currency impact of 6.9%. U.S. sales were $18.3 billion, an increase of 5.2%. International sales were $13.1 billion, a decrease of 12.0%, which included 3.0% operational growth offset by a negative currency impact of 15.0%. The Pharmaceutical segment operational growth was negatively impacted by 6.5% due to the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), and positively impacted by 1.4% due to an adjustment to previous reserve estimates, including Managed Medicaid rebates primarily in the Cardiovascular/Metabolism/Other therapeutic area. In 2015, divestitures had a negative impact of 0.3% on the worldwide Pharmaceutical segment operational growth.

Major Pharmaceutical Therapeutic Area Sales:*

				% Change	
(Dollars in Millions)	2015	2014	2013	'15 vs. '14	'14 vs. '13
Total Immunology	$10,402	10,193	9,190	2.1 %	10.9
REMICADE®	6,561	6,868	6,673	(4.5)	2.9
SIMPONI®/SIMPONI ARIA®	1,328	1,187	932	11.9	27.4
STELARA®	2,474	2,072	1,504	19.4	37.8
Other Immunology	39	66	81	(40.9)	(18.5)
Total Infectious Diseases	3,656	5,599	3,550	(34.7)	57.7
EDURANT®	410	365	236	12.3	54.7
OLYSIO®/SOVRIAD®	621	2,302	23	(73.0)	**
PREZISTA®/ PREZCOBIX®/REZOLSTA®	1,810	1,831	1,673	(1.1)	9.4
Other Infectious Diseases	815	1,101	1,618	(26.0)	(32.0)
Total Neuroscience	6,259	6,487	6,667	(3.5)	(2.7)
CONCERTA®/methylphenidate	821	599	782	37.1	(23.4)
INVEGA®/paliperidone	573	640	583	(10.5)	9.8
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®	1,830	1,588	1,248	15.2	27.2
RISPERDAL® CONSTA®	970	1,190	1,318	(18.5)	(9.7)
Other Neuroscience	2,065	2,470	2,736	(16.4)	(9.7)
Total Oncology	4,695	4,457	3,773	5.3	18.1
IMBRUVICA®	689	200	—	**	—
VELCADE®	1,333	1,618	1,660	(17.6)	(2.5)
ZYTIGA®	2,231	2,237	1,698	(0.3)	31.7
Other Oncology	442	402	415	10.0	(3.1)
Cardiovascular / Metabolism / Other***	6,418	5,577	4,945	15.1	12.8
XARELTO®	1,868	1,522	864	22.7	76.2
INVOKANA®/ INVOKAMET®	1,308	586	123	**	**
PROCRIT®/EPREX®	1,068	1,238	1,364	(13.7)	(9.2)
Other	2,174	2,231	2,594	(2.6)	(14.0)
Total Pharmaceutical Sales	$31,430	32,313	28,125	(2.7)%	14.9

* Prior year amounts have been reclassified to conform to current year presentation.
** Percentage greater than 100%
***Previously referred to as Other

Immunology products achieved sales of $10.4 billion in 2015, representing an increase of 2.1% as compared to the prior year. Immunology products growth of 2.1% included operational growth of 6.9% and a negative currency impact of 4.8%. The increased sales of STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab) were due to market growth and increased penetration of SIMPONI ARIA®. Growth was partially offset by lower REMICADE®

(infliximab) sales to the Company's distributor primarily due to the weakening of the euro and biosimilar competition in Europe. The patents for REMICADE® in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets.

Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the FDA and compliance with the 180-day notice provisions of the Biologics Price Competition and Innovation Act (the BPCIA). On February 9, 2016, the Arthritis Advisory Committee of the FDA recommended by a vote of 21-3 to approve the first investigational biosimilar infliximab across all eligible indications in the United States. There is a risk that a competitor could launch a biosimilar version of REMICADE® following FDA approval (subject to compliance with the 180-day notice provisions of the BPCIA), even though one or more valid patents are in place. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®. In 2015, U.S. sales of REMICADE® were $4.5 billion. The launch of a biosimilar version of REMICADE® in the U.S. is not expected to have a material adverse effect on the Company's results of operations and cash flows in 2016. See Note 21 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.7 billion, a decline of 34.7% from 2014, which included an operational decrease of 27.6% and a negative currency impact of 7.1%. Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on U.S. sales and will continue to have a negative impact on future sales. The decline of Hepatitis C sales was partially offset by sales growth of EDURANT®(rilpivirine) and sales of PREZISTA®/ PREZCOBIX®/REZOLSTA® (darunavir/cobicistat).

Neuroscience products sales were $6.3 billion, a decrease of 3.5% from 2014, which included an operational growth of 5.0% and a negative currency impact of 8.5%. The U.S. sales growth of CONCERTA®/methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors by the FDA in November 2014. Strong sales of INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA® (paliperidone palmitate) were primarily due to increased market share and the launch of INVEGA TRINZA®. Neuroscience products sales were negatively impacted by the U.S. divestiture of NUCYNTA® (tapentadol) and lower sales of RISPERDAL® CONSTA® (risperidone).

Oncology products achieved sales of $4.7 billion in 2015, representing an increase of 5.3% as compared to the prior year. Oncology products growth of 5.3% included operational growth of 17.7% and a negative currency impact of 12.4%. Contributors to the growth were strong sales of IMBRUVICA® (ibrutinib) due to the approval of new indications, additional country launches and strong patient uptake. Additionally, sales of ZYTIGA® (abiraterone acetate) grew in the U.S. due to market growth partially offset by share decline, and strong growth in Asia and Latin America was partially offset by lower sales in Europe due to competition.

Cardiovascular/Metabolism/Other products achieved sales of $6.4 billion in 2015, representing an increase of 15.1% as compared to the prior year due to strong sales of XARELTO®(rivaroxaban) and INVOKANA®/INVOKAMET® (canagliflozin). PROCRIT®/EPREX® (Epoetin alfa) sales were impacted by competition.

During 2015, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approv	EU Approv	US Filing	EU Filing
DARZALEX™ (daratumumab)	For the treatment of double refractory multiple myeloma	ü			ü
EDURANT® (rilpiravine)	For use in combination with other anti-retroviral agents, for the treatment-naïve adolescent patients aged 12 to 18 years with HIV-1 infection	ü	ü		
IMBRUVICA® (ibrutinib)	Treatment of Waldenström's Macroglobulinemia	ü	ü		
	Treatment for patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma in combination with bendamustine and rituximab			ü	ü
	For use in treatment-naïve patients with chronic lymphocytic leukemia			ü	ü
INVEGA TRINZA® (paliperidone palmitate)	An atypical antipsychotic injection administered four times a year for the treatment of schizophrenia	ü			ü
INVOKAMET® XR (canagliflozin)	A once-daily therapy combining fixed doses of canagliflozin and metformin hydrochloride extended release for the treatment of adults with type 2 diabetes			ü	
PREZCOBIX® (darunavir/cobicistat)	For use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1)	ü			
SIMPONI® (golimumab)	Treatment of non-radiographic axial spondyloarthritis		ü		
STELARA® (ustekinumab)	For the treatment of adolescents with moderate-to-severe psoriasis		ü		
	For the treatment of adult patients with moderately to severely active Crohn's disease			ü	ü
VELCADE ® (bortezomib)	For use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma		ü		
YONDELIS® (trabectedin)	For the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma	ü			

The Pharmaceutical segment achieved sales of $32.3 billion in 2014, representing an increase of 14.9% over the prior year, with strong operational growth of 16.5% and a negative currency impact of 1.6%. U.S. sales were $17.4 billion, an increase of 25.0%. International sales were $14.9 billion, an increase of 5.0%, which included 8.3% operational growth and a negative currency impact of 3.3%. In 2013, Pharmaceutical segment sales included a positive adjustment to previous estimates for Managed Medicaid rebates. This negatively impacted 2014 Pharmaceutical operational sales growth by 0.8% as compared to the prior year. In 2014, sales of the Company's Hepatitis C products,

OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 6.9% on the operational growth of the Pharmaceutical segment.

Medical Devices Segment

The Medical Devices segment sales in 2015 were $25.1 billion, a decrease of 8.7% from 2014, which included an operational decline of 1.4% and a negative currency impact of 7.3%. U.S. sales were $12.1 billion, a decrease of 1.0% as compared to the prior year. International sales were $13.0 billion, a decrease of 14.8% as compared to the prior year, with an operational decrease of 1.7% and a negative currency impact of 13.1%. The divestitures of the Ortho-Clinical Diagnostics and the Cordis Businesses had a negative impact of 3.2% and 0.6%, respectively, on the worldwide operational growth of the Medical Devices segment as compared to 2014.

Major Medical Devices Franchise Sales:*

				% Change	
(Dollars in Millions)	2015	2014	2013	'15 vs. '14	'14 vs. '13
Orthopaedics	$9,262	9,675	9,509	(4.3)%	1.7
Hips	1,332	1,368	1,333	(2.6)	2.6
Knees	1,496	1,533	1,496	(2.4)	2.5
Trauma	2,528	2,640	2,555	(4.2)	3.3
Spine & Other	3,906	4,134	4,125	(5.5)	0.2
Surgery	9,217	9,717	9,773	(5.1)	(0.6)
Advanced	3,275	3,237	3,088	1.2	4.8
General	4,482	4,970	5,136	(9.8)	(3.2)
Specialty	1,460	1,510	1,549	(3.3)	(2.5)
Vision Care	2,608	2,818	2,937	(7.5)	(4.1)
Cardiovascular	2,036	2,208	2,077	(7.8)	6.3
Diabetes Care	1,928	2,142	2,309	(10.0)	(7.2)
Diagnostics	86	962	1,885	(91.1)	(49.0)
Total Medical Devices Sales	$25,137	27,522	28,490	(8.7)%	(3.4)

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

The Orthopaedics franchise sales were $9.3 billion in 2015, a decrease of 4.3% from 2014, which included operational growth of 1.7% and a negative currency impact of 6.0%. Operational growth in the U.S. and Europe regions was primarily driven by sales of the hip primary stem platform, the ATTUNE® Knee System, trauma TFNA nailing system and sports medicine ORTHOVISC®/MONOVISC® products. Growth was negatively impacted by softer demand and a reduction in customer inventory levels primarily in China and continued pricing pressures.

The Surgery franchise sales were $9.2 billion in 2015, a decrease of 5.1% from 2014, which included operational growth of 2.7% and a negative currency impact of 7.8%. Operational growth in Advanced Surgery was driven by endocutter, biosurgical and energy products, primarily attributable to market growth, increased penetration in certain markets and new product launches. Operational growth in Specialty Surgery was primarily driven by Mentor products. Growth was partially offset by lower sales of women's health and urology products in General Surgery.

The Vision Care franchise sales were $2.6 billion in 2015, a decrease of 7.5% from 2014, which included operational growth of 1.7% and a negative currency impact of 9.2%. Operational growth in all the major regions was primarily driven by new product launches partially offset by lower price.

The Cardiovascular franchise sales were $2.0 billion, a decrease of 7.8% from 2014, which represented an operational decline of 0.1% and a negative currency impact of 7.7%. Strong operational growth in the electrophysiology business was driven by market growth and the success of the THERMOCOOL® SMARTTOUCH® Catheter and was offset by the impact of divesting the Cordis business. The Company completed the divestiture of the Cordis business to Cardinal Health on October 4, 2015. The Cordis business generated annual net revenues of approximately $535 million and $780 million in 2015 and 2014, respectively. For additional details see Note 20 to the Consolidated Financial Statements.

The Diabetes Care franchise sales were $1.9 billion, a decrease of 10.0% from 2014, which represented an operational decline of 0.7% and a negative currency impact of 9.3%. The operational decline was primarily due to lower price

partially offset by the success of the ANIMAS® VIBE® products.

On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) to The Carlyle Group. For additional details see Note 20 to the Consolidated Financial Statements.

The Medical Devices segment sales in 2014 were $27.5 billion, a decrease of 3.4% from 2013, which included an operational decline of 1.6% and a negative currency impact of 1.8%. U.S. sales were $12.3 billion, a decrease of 4.3% as compared to the prior year. International sales were $15.3 billion, a decline of 2.7% as compared to the prior year, with operational growth of 0.5% offset by a negative currency impact of 3.2%. In 2014, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 3.2% on the operational growth of the Medical Devices segment.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income decreased to $19.2 billion as compared to $20.6 billion in 2014, a decrease of 6.6%. The decrease was primarily attributable to significantly lower sales of OLYSIO®/SOVRIAD® (simeprevir), negative currency impacts, a restructuring charge of $0.6 billion and higher intangible asset write-downs of $0.1 billion in 2015 as compared to 2014. The decrease was partially offset by lower net litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion, a positive adjustment of $0.4 billion to previous reserve estimates including Managed Medicaid rebates, and higher gains of $0.3 billion from divestitures as compared to the prior year. The fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. Additionally, 2014 included an additional year of the Branded Prescription Drug Fee of $0.2 billion.

Consolidated earnings before provision for taxes on income increased to $20.6 billion in 2014 as compared to $15.5 billion in 2013, an increase of 32.9%. Earnings before provision for taxes on income were favorable due to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost reduction efforts across many of the businesses. Additionally, 2014 included higher net gains on divestitures of $2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of $1.0 billion, lower in-process research and development costs of $0.4 billion and lower expenses of $0.1 billion related to the DePuy ASR™ Hip program as compared to the fiscal year 2013. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of $0.2 billion and $0.1 billion of higher Synthes integration/transaction costs in 2014. The fiscal year 2013 included a net gain of $0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares.

As a percent to sales, consolidated earnings before provision for taxes on income in 2015 was 27.4% versus 27.7% in 2014.

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

% of Sales	2015		2014		2013	
Cost of products sold	30.7	%	30.6		31.3	
Percent point increase/(decrease) over the prior year	0.1		(0.7	)	(0.9	)
Selling, marketing and administrative expenses	30.3	%	29.5		30.6	
Percent point increase/(decrease) over the prior year	0.8		(1.1	)	(0.4	)

In 2015, cost of products sold as a percent to sales increased slightly as compared to the prior year. Favorable mix between the segments was offset by $81 million associated with the restructuring activity in the Medical Devices segment, negative transactional currency and lower sales of OLYSIO®/SOVRIAD® (simeprevir) in 2015. Intangible asset amortization expense included in cost of products sold for 2015 and 2014 was $1.2 billion and $1.4 billion, respectively. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2015 compared to the prior year, primarily due to incremental investment spending in all the segments and the impact from lower sales of OLYSIO®/SOVRIAD® (simeprevir), partially offset by favorable mix and the inclusion of an additional year of the Branded Prescription Drug Fee of $0.2 billion in 2014.

In 2014, cost of products sold as a percent to sales decreased compared to the prior year. This was primarily the result of positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost improvements across many of the businesses. This was partially offset by pricing and the impact of negative transactional currency. In addition, 2013 included an inventory step-up charge of $0.1 billion related to the Synthes acquisition. Intangible asset amortization expense included in cost of products sold for both 2014 and 2013 was $1.4 billion. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2014 compared to the prior year primarily due to leveraged costs resulting from growth in the Pharmaceutical business, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), and cost containment initiatives across many of the businesses. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of $220 million in the fiscal third quarter of 2014.

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

(Dollars in Millions)	2015 Amount	2015 % of Sales*	2014 Amount	2014 % of Sales*	2013 Amount	2013 % of Sales*
Consumer	$625	4.6 %	629	4.3	590	4.0
Pharmaceutical	6,821	21.7	6,213	19.2	5,810	20.7
Medical Devices	1,600	6.4	1,652	6.0	1,783	6.3
Total research and development expense	$9,046	12.9 %	8,494	11.4	8,183	11.5
Percent increase/(decrease) over the prior year	6.5 %		3.8		6.8	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2015, worldwide costs of research and development activities increased by 6.5% compared to 2014. The increase as a percent to sales was attributable to increased investment spending primarily in the Pharmaceutical segment, lower overall sales and business mix. In 2014, worldwide costs of research and development activities increased by 3.8% compared to 2013. The reduction as a percent to sales was primarily due to strong sales growth in the Pharmaceutical business. Research spending in the Pharmaceutical segment increased in absolute dollars to $6.2 billion as compared to $5.8 billion primarily due to higher levels of spending to advance the Company's Pharmaceutical pipeline.

In-Process Research and Development (IPR&D): In 2015, the Company recorded an IPR&D charge of $0.2 billion primarily for the discontinuation of certain development projects related to Covagen. In 2014, the Company recorded an IPR&D charge of $0.2 billion for the impairment of various IPR&D projects related to RespiVert, Crucell, Mentor and Synthes for the delay or discontinuation of certain development projects. In 2013, the Company recorded an IPR&D charge of $0.6 billion primarily for the impairment of various IPR&D projects related to Crucell, CorImmun and Acclarent for the delay or discontinuation of certain development projects.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (formerly Johnson & Johnson Development Corporation), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal year 2015 was a favorable change of $2.0 billion as compared to the prior year primarily due to lower litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion and higher JJDC portfolio gains of $0.2 billion as compared to the prior year. Additionally, the fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. This was partially offset by higher intangible asset write-downs of $0.1 billion in 2015.

The change in other (income) expense, net for the fiscal year 2014 was a favorable change of $2.6 billion as compared to the prior year. The fiscal year 2014 included higher net gains on divestitures of $2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of $1.0 billion and lower costs of $0.1 billion related to the DePuy ASR™ Hip program as compared to 2013. This was partially offset by higher Synthes integration/transaction costs of $0.2 billion and higher intangible asset write-downs of $0.1 billion primarily related to INCIVO® (telaprevir) in 2014. Additionally, the fiscal year 2013 included a higher net gain of $0.5 billion as compared to 2014 on equity investment transactions, primarily the sale of Elan American Depositary Shares.

Interest (Income) Expense: Interest income in 2015 increased by $61 million as compared to 2014 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled $38.4 billion at the end of 2015, and averaged $35.7 billion as compared to the $31.1 billion average cash balance in 2014. The increase in the year-end cash balance was primarily due to cash generated from operating activities.

Interest expense in 2015 increased slightly as compared to 2014. The average debt balance was $19.3 billion in 2015 versus $18.5 billion in 2014. The total debt balance at the end of 2015 was $19.9 billion as compared to $18.8 billion at the end of 2014. The higher debt balance of approximately $1.1 billion was an increase in commercial paper for general corporate purposes, primarily the stock repurchase program.

Interest income in 2014 was comparable to the prior year. A higher balance in cash, cash equivalents and marketable securities was offset by lower interest rates. Cash, cash equivalents and marketable securities totaled $33.1 billion at the end of

2014, and averaged $31.1 billion as compared to the $25.2 billion average cash balance in 2013. The increase in the year-end cash balance was primarily due to cash generated from operating activities.
Interest expense in 2014 increased by $51 million as compared to 2013 due to a higher average debt balance. The average debt balance was $18.5 billion in 2014 versus $17.2 billion in 2013. The total debt balance at the end of 2014 was $18.8 billion as compared to $18.2 billion at the end of 2013. The higher debt balance of approximately $0.6 billion was due to increased borrowings in November 2014. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes.

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

			Percent of Segment Sales	
(Dollars in Millions)	2015	2014	2015	2014
Consumer	$1,787	1,941	13.2 %	13.4
Pharmaceutical	11,734	11,696	37.3	36.2
Medical Devices	6,826	7,953	27.2	28.9
Total [1]	20,347	21,590	29.0	29.0
Less: Expenses not allocated to segments [2]	1,151	1,027		
Earnings before provision for taxes on income	$19,196	20,563	27.4 %	27.7

[1] See Note 18 to the Consolidated Financial Statements for more details.
[2] Amounts not allocated to segments include interest (income) expense, noncontrolling interests, and general corporate (income) expense.

Consumer Segment: In 2015, the Consumer segment income before tax as a percent to sales was 13.2%, versus 13.4% in 2014, primarily due to lower divestiture gains in 2015 versus 2014. In 2015, the Consumer segment tax included a gain of $0.3 billion from divestitures, primarily the divestiture of the SPLENDA® brand. In 2014, the Consumer segment included a gain of $0.5 billion from divestitures, primarily the divestiture of the K-Y® brand. In 2014, the Consumer segment income before tax as a percent to sales was 13.4%, flat to the prior year.

Pharmaceutical Segment: In 2015, the Pharmaceutical segment income before tax as a percent to sales was 37.3% versus 36.2% in 2014. The favorable income before tax was primarily due to higher gains recognized in 2015 partially offset by a sales decline of OLYSIO®/SOVRIAD®(simeprevir), increased investment spending and negative currency impacts as compared to 2014. Included in 2015 was a gain of $1.0 billion on the U.S. divestiture of NUCYNTA®, as well as receipt of a contingent payment and a positive adjustment to previous reserve estimates, including Managed Medicaid rebates. Additionally, the Pharmaceutical segment income before tax in 2014 was negatively impacted by $0.2 billion for an additional year of the Branded Prescription Drug Fee and higher intangible asset amortization expense of $0.3 billion primarily related to the write-down of INCIVO® (telaprevir).
In 2014, the Pharmaceutical segment income before tax as a percent to sales was 36.2% versus 32.6% in 2013. The favorable income before tax was attributable to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive sales mix of higher margin products and cost containment initiatives realized in selling, marketing and administrative expenses. This was partially offset by $0.2 billion for an additional year of the Branded Prescription Drug Fee and a $0.1 billion intangible asset write-down related to INCIVO® (telaprevir). Additionally, 2013 included a net gain of $0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares, and a positive adjustment of $0.2 billion to previous estimates for Managed Medicaid rebates, partially offset by higher write-downs of $0.4 billion for the impairment of IPR&D as compared to 2014.

Medical Devices Segment: In 2015, the Medical Devices segment income before tax as a percent to sales was 27.2% versus 28.9% in 2014 primarily due to a restructuring charge of $0.6 billion, an intangible asset write-down of $0.3 billion related to Acclarent, and lower gains of $0.5 billion on divestitures as compared to 2014. In 2015, the Medical

Devices segment included gains of $1.4 billion, primarily for the divestiture of the Cordis business versus a gain of $1.9 billion recorded in 2014 for the divestiture of the Ortho-Clinical Diagnostics business. The 2015 income before tax was favorably impacted by lower net litigation expense of $0.9 billion, which included a gain from the litigation settlement agreement of $0.6 billion with Guidant, and lower Synthes integration costs of $0.6 billion in 2015 as compared to 2014.

In 2014, Medical Devices segment income before tax as a percent to sales was 28.9% versus 18.5% in 2013. The favorable income before tax was attributable to the net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business in 2014 and lower litigation expense of $1.1 billion as compared to 2013.

Restructuring: The Company announced restructuring actions in its Medical Devices segment that are expected to result in annualized pre-tax cost savings of $800 million to $1.0 billion, the majority of which is expected to be realized by the end of 2018, including approximately $200 million savings in 2016. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by 2017. In the fiscal fourth quarter of 2015, the Company recorded a pre-tax charge of $0.6 billion, of which $81 million is included in cost of products sold. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income: The worldwide effective income tax rate was 19.7% in 2015, 20.6% in 2014 and 10.6% in 2013. The 2015 effective tax rate decrease of 0.9% as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 21 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009.

The 2013 effective tax rate was reduced by a tax benefit associated with the write-off of assets for tax purposes associated with Scios, Inc., and the inclusion of both the 2013 and 2012 benefit from the Research and Development tax credit and the Controlled Foreign Corporation look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $13.7 billion at the end of 2015 as compared to $14.5 billion at the end of 2014. The primary sources and uses of cash that contributed to the $0.8 billion decrease were approximately $19.3 billion of cash generated from operating activities offset by $7.7 billion net cash used by investing activities, and $10.8 billion net cash used by financing activities, and $1.5 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $24.6 billion in marketable securities at the end of 2015 and $18.6 billion at the end of 2014. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $19.3 billion was the result of $15.4 billion of net earnings and $5.4 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, primarily related to Acclarent and Venezuela write-downs, reduced by $2.6 billion from net gains on sale of assets/businesses, and $1.2 billion related to deferred taxes, accounts receivable and inventories. Additional sources of operating cash flow of $2.2 billion resulted from a decrease in other current and non-current assets and an increase in

other current and non-current liabilities.

Investing activities use of $7.7 billion was primarily for net purchases of investments in marketable securities of $6.7 billion, additions to property, plant and equipment of $3.5 billion, and acquisitions, net of cash acquired of $1.0 billion, partially offset by $3.5 billion of proceeds from the disposal of assets/businesses.

Financing activities use of $10.8 billion was primarily for dividends to shareholders of $8.2 billion and $5.3 billion for the repurchase of common stock. Financing activities also included a source of $1.4 billion from net proceeds of short and long-term debt and $1.3 billion of net proceeds from stock options exercised and associated tax benefits.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. As of January 3, 2016, $1.0 billion has been repurchased under the program. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. The previous share repurchase program approved on July 21, 2014, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock, was completed on April 28, 2015.

In 2015, the Company continued to have access to liquidity through the commercial paper market. The Company has a shelf registration with the U.S. Securities and Exchange Commission that enables the Company to issue debt securities and warrants to purchase debt securities on a timely basis. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

The Company anticipates that operating cash flows, existing credit facilities and access to the capital markets will provide sufficient resources to fund operating needs in 2016.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.3 billion as of January 3, 2016 and $1.8 billion as of December 28, 2014. Approximately $0.8 billion as of January 3, 2016 and approximately $1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.5 billion at January 3, 2016 and $0.7 billion at December 28, 2014. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 3, 2016 market rates would increase the unrealized value of the Company’s forward contracts by $15 million. Conversely, a 10% depreciation of the U.S. Dollar from the January 3, 2016 market rates would decrease the unrealized value of the Company’s forward contracts by $18 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $115 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while

floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company’s interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $314 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 15, 2016. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2015 and 2014 were $19.9 billion and $18.8 billion, respectively. The increase in borrowings between 2015 and 2014 was a result of financing for the Company's share repurchase program. In 2015, net cash

(cash and current marketable securities, net of debt) was $18.5 billion compared to net cash of $14.3 billion in 2014. Total debt represented 21.8% of total capital (shareholders' equity and total debt) in 2015 and 21.2% of total capital in 2014. Shareholders' equity per share at the end of 2015 was $25.82 compared to $25.06 at year-end 2014, an increase of 3.0%.
A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments
The Company's contractual obligations are primarily for leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of January 3, 2016 (see Notes 7, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2016	$2,104	586	76	224	2,990
2017	1,790	554	77	194	2,615
2018	1,501	490	82	136	2,209
2019	1,587	446	88	90	2,211
2020	683	373	93	74	1,223
After 2020	7,296	4,303	559	109	12,267
Total	$14,961	6,752	975	827	23,515

For tax matters, see Note 8 to the Consolidated Financial Statements.
Dividends
The Company increased its dividend in 2015 for the 53rd consecutive year. Cash dividends paid were $2.95 per share in 2015 compared with dividends of $2.76 per share in 2014, and $2.59 per share in 2013. The dividends were distributed as follows:

	2015	2014	2013
First quarter	$0.70	0.66	0.61
Second quarter	0.75	0.70	0.66
Third quarter	0.75	0.70	0.66
Fourth quarter	0.75	0.70	0.66
Total	$2.95	2.76	2.59

On January 4, 2016, the Board of Directors declared a regular quarterly cash dividend of $0.75 per share, payable on March 8, 2016, to shareholders of record as of February 23, 2016. The Company expects to continue the practice of paying regular cash dividends.

Other Information
Critical Accounting Policies and Estimates
Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

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

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2015, 2014 and 2013.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value.

Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were less than 1% of total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative fair value. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 3, 2016 and December 28, 2014.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates [1]	$122	581	(564)	139
Accrued returns	77	84	(107)	54
Accrued promotions	241	1,846	(1,675)	412
Subtotal	$440	2,511	(2,346)	605
Reserve for doubtful accounts	18	5	(5)	18
Reserve for cash discounts	22	206	(211)	17
Total	$480	2,722	(2,562)	640
2014				
Accrued rebates[1]	$137	619	(634)	122
Accrued returns	80	102	(105)	77
Accrued promotions	321	1,850	(1,930)	241
Subtotal	$538	2,571	(2,669)	440
Reserve for doubtful accounts	25	5	(12)	18
Reserve for cash discounts	24	215	(217)	22
Total	$587	2,791	(2,898)	480

[1] Includes reserve for customer rebates of $31 million at January 3, 2016 and $37 million at December 28, 2014, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates [1]	$2,717	10,449	(9,715)	3,451
Accrued returns	422	52	(70)	404
Accrued promotions	34	127	(150)	11
Subtotal	$3,173	10,628	(9,935)	3,866
Reserve for doubtful accounts	41	30	(25)	46
Reserve for cash discounts	51	625	(613)	63
Total	$3,265	11,283	(10,573)	3,975
2014				
Accrued rebates [1]	$1,985	7,652	(6,920)	2,717
Accrued returns	372	83	(33)	422
Accrued promotions	96	34	(96)	34
Subtotal	$2,453	7,769	(7,049)	3,173
Reserve for doubtful accounts	95	4	(58)	41
Reserve for cash discounts	61	576	(586)	51
Total	$2,609	8,349	(7,693)	3,265

[1]

Includes reserve for customer rebates of $64 million at January 3, 2016 and $70 million* at December 28, 2014, recorded as a contra asset. *Prior year amount has been reclassified to conform to current year presentation.

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates[1]	$844	5,216	(4,871)	1,189
Accrued returns	188	556	(505)	239
Accrued promotions	53	95	(101)	47
Subtotal	$1,085	5,867	(5,477)	1,475
Reserve for doubtful accounts	216	13	(25)	204
Reserve for cash discounts	16	877	(873)	20
Total	$1,317	6,757	(6,375)	1,699
2014				
Accrued rebates[1]	$801	4,663	(4,620)	844
Accrued returns	180	395	(387)	188
Accrued promotions	66	35	(48)	53
Subtotal	$1,047	5,093	(5,055)	1,085
Reserve for doubtful accounts	213	62	(59)	216
Reserve for cash discounts	18	815	(817)	16
Total	$1,278	5,970	(5,931)	1,317

(1) Includes reserve for customer rebates of $411 million at January 3, 2016 and $354 million at December 28, 2014, recorded as a contra asset.

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

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

At January 3, 2016 and December 28, 2014, the cumulative amounts of undistributed international earnings were approximately $58.0 billion and $53.4 billion, respectively. At January 3, 2016 and December 28, 2014, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $38.2 billion and $32.9 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

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

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

may not be collected from third-party insurers.

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

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

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

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

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 3, 2016.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2005 - 2015, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

The Venezuelan government has established alternative systems and offerings of various foreign currency exchanges. During 2015, the Company primarily utilized the official government rate of 6.3 Bolivares Fuertes to one U.S. Dollar in preparing its consolidated financial statements. During 2014, the Company applied to settle an outstanding dividend payable at one of the alternative foreign exchange rates. As a result, the Company has applied this alternative exchange rate to translate certain transactions, as appropriate. Through the fourth quarter of 2015, the number of the Company's transactions conducted at the official rate declined from prior quarters. As a result, the Company determined that it was no longer likely that all outstanding net monetary assets would be settled at the official government rate of 6.3 Bolivares Fuertes to one U.S. Dollar. Therefore, the Company recorded a charge of $161 million to revalue its net monetary assets in Venezuela at one of the government's alternative exchange rates (SIMADI) and impair its non-monetary assets. After the revaluation, as of January 3, 2016, the Company's Venezuelan subsidiaries represented less than 0.1% of the Company's consolidated assets and liabilities. Due to continuing

uncertain economic conditions in Venezuela, it is possible that additional charges may be recorded in the future. Any additional charges are not expected to have a material adverse effect on the Company's 2016 full year results.

While the Company continues to do business in Greece, the Company closely monitors the economic situation. As of January 3, 2016, the Company's Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2015 would have increased or decreased the translation of foreign sales by approximately $340 million and income by $90 million.

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

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

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company’s key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on “REMICADE® Related Cases” and “Litigation Against Filers of Abbreviated New Drug Applications” in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company’s Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 19, 2016, there were 158,749 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2015 and 2014 were:

	2015		2014	
	High	Low	High	Low
First quarter	$106.50	97.15	98.47	86.09
Second quarter	104.48	97.01	105.97	96.05

Third quarter	101.36	81.79	108.77	98.80
Fourth quarter	105.49	89.90	109.49	95.10
Year-end close	$102.72		105.06	

Cautionary Factors That May Affect Future Results

This Annual Report contains forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. 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, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures.

Forward-looking statements are based on current expectations of future events. The Company cannot guarantee that any forward-looking statement will be accurate, although the Company believes that it has been reasonable in its expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or that known or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Investors are therefore cautioned not to place undue reliance on any forward-looking statements. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.

Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success of new and existing products; challenges to patents; the impact of patent expirations; the ability of the company to successfully execute strategic plans, including restructuring plans; the potential that the expected benefits and opportunities related to the restructuring may not be realized or may take longer to realize than expected; significant adverse litigation or government action, including related to product liability claims; impact of business combinations and divestitures; market conditions and the possibility that the on-going share repurchase program may be suspended or discontinued; significant changes in customer relationships or changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; financial instability of international economies and legal systems and sovereign risk; manufacturing difficulties or delays, internally or within the supply chain; complex global supply chains with increasing regulatory requirements; product efficacy or safety concerns resulting in product recalls or regulatory action; disruptions due to natural disasters; and the potential failure to meet obligations in compliance agreements with government bodies.

A discussion of these and other factors that could cause actual results to differ materially from expectations can be found in this Report for the fiscal year ended January 3, 2016, including in Exhibit 99. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 3, 2016 and December 28, 2014
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

	2015	2014
Assets		
Current assets		
Cash and cash equivalents (Notes 1 and 2)	$13,732	14,523
Marketable securities (Notes 1 and 2)	24,644	18,566
Accounts receivable trade, less allowances for doubtful accounts $268 (2014, $275)	10,734	10,985
Inventories (Notes 1 and 3)	8,053	8,184
Prepaid expenses and other receivables	3,047	3,486
Total current assets	60,210	55,744
Property, plant and equipment, net (Notes 1 and 4)	15,905	16,126
Intangible assets, net (Notes 1 and 5)	25,764	27,222
Goodwill (Notes 1 and 5)	21,629	21,832
Deferred taxes on income (Note 1 and 8)	5,490	6,202
Other assets	4,413	3,232
Total assets	$133,411	130,358
Liabilities and Shareholders' Equity		
Current liabilities		
Loans and notes payable (Note 7)	$7,004	3,638
Accounts payable	6,668	7,633
Accrued liabilities	5,411	6,553
Accrued rebates, returns and promotions	5,440	4,010
Accrued compensation and employee related obligations	2,474	2,751
Accrued taxes on income (Note 8)	750	446
Total current liabilities	27,747	25,031
Long-term debt (Note 7)	12,857	15,122
Deferred taxes on income (Note 1 & 8)	2,562	2,447
Employee related obligations (Notes 9 and 10)	8,854	9,972
Other liabilities	10,241	8,034
Total liabilities	62,261	60,606
Shareholders' equity		
Preferred stock — without par value (authorized and unissued 2,000,000 shares)	—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	3,120	3,120
Accumulated other comprehensive income (Note 13)	(13,165)	(10,722)
Retained earnings	103,879	97,245
	93,834	89,643
Less: common stock held in treasury, at cost (Note 12) (364,681,000 shares and 336,620,000 shares)	22,684	19,891
Total shareholders' equity	71,150	69,752
Total liabilities and shareholders' equity	$133,411	130,358

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2015	2014	2013
Sales to customers	$70,074	74,331	71,312
Cost of products sold	21,536	22,746	22,342
Gross profit	48,538	51,585	48,970
Selling, marketing and administrative expenses	21,203	21,954	21,830
Research and development expense	9,046	8,494	8,183
In-process research and development	224	178	580
Interest income	(128)	(67)	(74)
Interest expense, net of portion capitalized (Note 4)	552	533	482
Other (income) expense, net	(2,064)	(70)	2,498
Restructuring (Note 22)	509	—	—
Earnings before provision for taxes on income	19,196	20,563	15,471
Provision for taxes on income (Note 8)	3,787	4,240	1,640
Net earnings	$15,409	16,323	13,831
Net earnings per share (Notes 1 and 15)			
Basic	$5.56	5.80	4.92
Diluted	$5.48	5.70	4.81
Cash dividends per share	$2.95	2.76	2.59
Average shares outstanding (Notes 1 and 15)			
Basic	2,771.8	2,815.2	2,809.2
Diluted	2,812.9	2,863.9	2,877.0

See Notes to Consolidated Financial Statements

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

	2015	2014	2013
Net earnings	$15,409	16,323	13,831
Other comprehensive income (loss), net of tax			
Foreign currency translation	(3,632)	(4,601)	94
Securities:			
Unrealized holding gain (loss) arising during period	471	156	225
Reclassifications to earnings	(124)	(5)	(314)
Net change	347	151	(89)
Employee benefit plans:			
Prior service cost amortization during period	(21)	(18)	9
Prior service credit (cost) - current year	(39)	211	(27)
Gain amortization during period	624	400	515
Gain (loss) - current year	307	(4,098)	2,203
Effect of exchange rates	148	197	8
Net change	1,019	(3,308)	2,708
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(115)	92	344
Reclassifications to earnings	(62)	(196)	(107)
Net change	(177)	(104)	237
Other comprehensive income (loss)	(2,443)	(7,862)	2,950
Comprehensive income	$12,966	8,461	16,781

The tax effects in other comprehensive income for the fiscal years ended 2015, 2014 and 2013 respectively: Securities; $187 million, $81 million and $48 million, Employee Benefit Plans; $519 million, $1,556 million and $1,421 million, Derivatives & Hedges; $95 million, $56 million and $128 million.

See Notes to Consolidated Financial Statements

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

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 30, 2012	$64,826	85,992	(5,810)	3,120	(18,476)
Net earnings	13,831	13,831			
Cash dividends paid	(7,286)	(7,286)			
Employee compensation and stock option plans	3,285	(82)			3,367
Repurchase of common stock	(3,538)	(2,947)			(591)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	2,950		2,950		
Balance, December 29, 2013	74,053	89,493	(2,860)	3,120	(15,700)
Net earnings	16,323	16,323			
Cash dividends paid	(7,768)	(7,768)			
Employee compensation and stock option plans	2,164	(769)			2,933
Repurchase of common stock	(7,124)				(7,124)
Other	(34)	(34)			
Other comprehensive income (loss), net of tax	(7,862)		(7,862)		
Balance, December 28, 2014	69,752	97,245	(10,722)	3,120	(19,891)
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	$71,150	103,879	(13,165)	3,120	(22,684)

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

	2015	2014	2013
Cash flows from operating activities			
Net earnings	$15,409	16,323	13,831
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	3,746	3,895	4,104
Stock based compensation	874	792	728
Venezuela adjustments	122	87	108
Asset write-downs	624	410	739
Net gain on sale of assets/businesses	(2,583)	(2,383)	(113)
Net gain on equity investment transactions	—	—	(417)
Deferred tax provision	(270)	441	(607)
Accounts receivable allowances	18	(28)	(131)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Increase in accounts receivable	(433)	(247)	(632)
Increase in inventories	(449)	(1,120)	(622)
(Decrease)/Increase in accounts payable and accrued liabilities	(3)	955	1,821
Decrease/(Increase) in other current and non-current assets	65	442	(1,693)
Increase/(Decrease) in other current and non-current liabilities	2,159	(1,096)	298
Net cash flows from operating activities	19,279	18,471	17,414
Cash flows from investing activities			
Additions to property, plant and equipment	(3,463)	(3,714)	(3,595)
Proceeds from the disposal of assets/businesses, net	3,464	4,631	458
Acquisitions, net of cash acquired (Note 20)	(954)	(2,129)	(835)
Purchases of investments	(40,828)	(34,913)	(18,923)
Sales of investments	34,149	24,119	18,058
Other (primarily intangibles)	(103)	(299)	(266)
Net cash used by investing activities	(7,735)	(12,305)	(5,103)
Cash flows from financing activities			
Dividends to shareholders	(8,173)	(7,768)	(7,286)
Repurchase of common stock	(5,290)	(7,124)	(3,538)
Proceeds from short-term debt	2,416	1,863	1,411
Retirement of short-term debt	(1,044)	(1,267)	(1,397)
Proceeds from long-term debt	75	2,098	3,607
Retirement of long-term debt	(68)	(1,844)	(1,593)
Proceeds from the exercise of stock options/excess tax benefits	1,295	1,782	2,649
Other	(57)	—	56
Net cash used by financing activities	(10,846)	(12,260)	(6,091)
Effect of exchange rate changes on cash and cash equivalents	(1,489)	(310)	(204)
(Decrease)/Increase in cash and cash equivalents	(791)	(6,404)	6,016
Cash and cash equivalents, beginning of year (Note 1)	14,523	20,927	14,911
Cash and cash equivalents, end of year (Note 1)	$13,732	14,523	20,927
Supplemental cash flow data			
Cash paid during the year for:			

Interest	$617	603	596
Interest, net of amount capitalized	515	488	491
Income taxes	2,865	3,536	3,155

Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds	1,196	1,170	743
Conversion of debt	16	17	22
Acquisitions			
Fair value of assets acquired	$1,174	2,167	1,028
Fair value of liabilities assumed and noncontrolling interests	(220)	(38)	(193)
Net cash paid for acquisitions	$954	2,129	835

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company And Business Segments

The Company has approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

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

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

During the fiscal second quarter of 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update 2015-04: Practical Expedient for the Measurement Date of an Employer's Defined Benefit Obligation and Plan Assets. This update provides a practical expedient option to entities that have defined benefit plans and have a fiscal year-end that does not coincide with a calendar month-end. This option allows an entity to elect to measure defined benefit plan assets and obligations using the calendar month-end that is closest to its fiscal year-end. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and if the practical expedient is elected by an entity, it is required to be adopted on a prospective basis. Early adoption is permitted. The Company has elected to adopt the practical expedient to measure its defined benefit plans. This election did not have a material impact on the Company's consolidated financial statements.

During the fiscal fourth quarter of 2015, the FASB issued Accounting Standard Update 2015-17 Income Taxes: Balance Sheet Classification of Deferred Taxes. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update is required to be effective for all public Companies for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted. The Company has elected to early adopt this standard on a retrospective basis. The 2014 Consolidated Balance Sheet reclassification reduced current assets by $3.6 billion, increased non-current assets by $2.8 billion and reduced liabilities by $0.8 billion.

Recently Issued Accounting Standards

Not Adopted as of January 3, 2016

During the fiscal first quarter of 2016, the FASB issued Accounting Standard Update 2016-01: Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update

will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be applied retroactively for all periods presented. This update will not have a material impact on the presentation of the Company’s financial position.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-11: Simplifying the Measurement of Inventory. This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal third quarter of 2015, the FASB issued Accounting Standard Update 2015-16 Business Combinations: Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015. The amendments in this update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. This update is not expected to have a material impact on the Company's consolidated financial statements.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2017. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2014, the FASB issued amended guidance Accounting Standards Update No. 2014-10: Development Stage Entities: Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entity Guidance in Topic 810, Consolidation. The change in the current guidance will require the Company to determine if it should consolidate one of these entities based on the change in the consolidation analysis. This update to the consolidation analysis will become effective for all annual periods and interim reporting periods beginning after December 15, 2015. The adoption of this standard is not expected to have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal third quarter of 2014, the FASB issued Accounting Standards Update No. 2014-15: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update will become effective for all annual periods and interim reporting periods ending after December 15, 2016. This standard is not expected to have any impact on current disclosures in the financial statements.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in reverse repurchase agreements (RRAs), government securities and obligations, corporate debt securities and money market funds.

RRAs are collateralized by deposits in the form of ‘Government Securities and Obligations’ for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

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

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

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded. Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include Medicaid, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

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

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2015, 2014 and 2013.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The

redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling

Shipping and handling costs incurred were $996 million, $1,068 million and $1,128 million in 2015, 2014 and 2013, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or market determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2015 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure’s impact on the Company’s financial performance; (2) protect the Company’s cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Based on the availability of prior coverage, receivables for insurance recoveries related to product liability claims are recorded on an undiscounted basis, when it is probable that a recovery will be realized. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.3 billion as of January 3, 2016

and approximately $1.8 billion as of December 28, 2014. Approximately $0.8 billion as of January 3, 2016 and approximately $1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers

were approximately $0.5 billion at January 3, 2016 and $0.7 billion at December 28, 2014. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company’s operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of goods sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.5 billion, $2.6 billion and $2.5 billion in 2015, 2014 and 2013, respectively.

Income Taxes

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

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

At January 3, 2016 and December 28, 2014, the cumulative amounts of undistributed international earnings were approximately $58.0 billion and $53.4 billion, respectively. At January 3, 2016 and December 28, 2014, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $38.2 billion and $32.9 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

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

Net Earnings Per Share

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

Use of Estimates

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

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

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, as was the case in 2015, and will be the case again in 2020.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2015 and 2014, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2015					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$1,832	—	—	1,832	1,832	—
U.S. Gov't Securities[1]	14,641	1	(2)	14,640	650	13,991
Other Sovereign Securities[1]	2,122	—	—	2,122	933	1,189
U.S. Reverse repurchase agreements[1]	1,579	—	—	1,579	1,579	—
Other Reverse repurchase agreements[1]	2,200	—	—	2,200	2,200	—
Corporate debt securities[1]	2,941	—	—	2,941	1,793	1,148
Money market funds	3,855	—	—	3,855	3,855	—
Time deposits[1]	890	—	—	890	890	—

	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value		
Gov't Securities	7,307	1	(34)	7,274	—	7,274
Corporate debt securities	1,046	1	(5)	1,042	—	1,042
Available for Sale[2]	$8,353	2	(39)	8,316	—	8,316
Total cash, cash equivalents and current marketable securities					$13,732	24,644

(Dollars in Millions)	2014					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$2,336	—	—	2,336	2,336	—
U.S. Gov't Securities[1]	16,345	1	(1)	16,345	1,950	14,395
Other Sovereign Securities[1]	4,265	—	—	4,265	978	3,287
U.S. Reverse repurchase agreements[1]	4,387	—	—	4,387	4,387	—
Other Reverse repurchase agreements[1]	2,348	—	—	2,348	2,348	—
Corporate debt securities[1]	1,343	—	—	1,343	459	884
Money market funds	1,352	—	—	1,352	1,352	—
Time deposits[1]	$713	—	—	713	713	—
Total cash, cash equivalents and current marketable securities					$14,523	18,566

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

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Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.
The contractual maturities of substantially all available for sale securities are from one to five years at January 3, 2016.
The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2015 and 2014, inventories were comprised of:

(Dollars in Millions)	2015	2014
Raw materials and supplies	$936	1,214
Goods in process	2,241	2,461
Finished goods	4,876	4,509
Total inventories	$8,053	8,184

4. Property, Plant and Equipment

At the end of 2015 and 2014, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2015	2014
Land and land improvements	$780	833
Buildings and building equipment	9,829	10,046
Machinery and equipment	22,511	22,206
Construction in progress	3,528	3,600
Total property, plant and equipment, gross	$36,648	36,685
Less accumulated depreciation	20,743	20,559
Total property, plant and equipment, net	$15,905	16,126

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2015, 2014 and 2013 was $102 million, $115 million and $105 million, respectively.
Depreciation expense, including the amortization of capitalized interest in 2015, 2014 and 2013, was $2.5 billion, $2.5 billion and $2.7 billion, respectively.
Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2015 and 2014, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2015	2014
Intangible assets with definite lives:		
Patents and trademarks — gross	$8,299	9,074
Less accumulated amortization	4,745	4,700
Patents and trademarks — net	$3,554	4,374
Customer relationships and other intangibles — gross	$17,583	17,970
Less accumulated amortization	5,816	5,227
Customer relationships and other intangibles — net	$11,767	12,743
Intangible assets with indefinite lives:		
Trademarks	$7,023	7,263
Purchased in-process research and development	3,420	2,842
Total intangible assets with indefinite lives	$10,443	10,105

Total intangible assets — net	$25,764	27,222

Goodwill as of January 3, 2016 and December 28, 2014, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Med Devices	Total
Goodwill at December 29, 2013	$8,531	2,068	12,199	22,798
Goodwill, related to acquisitions	13	665	—	678
Goodwill, related to divestitures	(138)	—	(603)	(741)
Currency translation/other	(731)	(107)	(65)	(903)
Goodwill at December 28, 2014	$7,675	2,626	11,531	21,832
Goodwill, related to acquisitions	110	366	34	510
Goodwill, related to divestitures	(119)	(17)	(57)	(193)
Currency translation/other	(426)	(86)	(8)	(520)
Goodwill at January 3, 2016	$7,240	2,889	11,500	21,629

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 18 years and 24 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $1.2 billion, $1.4 billion and $1.4 billion before tax, for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013, respectively. The estimated amortization expense for the five succeeding years approximates $1.2 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges. Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company may use forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral by either the Company or the counter-party. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 3, 2016, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $31.2 billion, $2.3 billion and $2.2 billion, respectively.

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

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in

interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts and cross currency interest rate swaps. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

As of January 3, 2016, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was $36 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended January 3, 2016 and December 28, 2014:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
Cash Flow Hedges by Income Statement Caption	2015	2014	2015	2014	2015	2014
Sales to customers [3]	$(83)	(106)	(126)	(3)	(5)	(5)
Cost of products sold [3]	(22)	58	122	204	14	2
Research and development expense [3]	(3)	39	6	7	1	—
Interest (income)/Interest expense, net [4]	(40)	21	—	(15)	—	—
Other (income) expense, net [3]	33	80	60	3	1	—
Total	$(115)	92	62	196	11	(3)

All amounts shown in the table above are net of tax.

[1] Effective portion

[2] Ineffective portion

[3] Forward foreign exchange contracts

[4] Cross currency interest rate swaps

For the fiscal years ended January 3, 2016 and December 28, 2014, a loss of $34 million and a gain of $5 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e. forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company’s results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.
The Company's significant financial assets and liabilities measured at fair value as of January 3, 2016 and December 28, 2014 were as follows:

(Dollars in Millions)	2015 Level 1	Level 2	Level 3	Total	2014 Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	$—	452	—	452	996
Interest rate contracts [2][4][7]	—	28	—	28	31
Total	—	480	—	480	1,027
Liabilities:					
Forward foreign exchange contracts [8]	—	358	—	358	751
Interest rate contracts [3][4][8]	—	241	—	241	8
Total	—	599	—	599	759
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	—	33	—	33	29
Liabilities:					
Forward foreign exchange contracts [8]	—	41	—	41	51
Available For Sale Other Investments:					
Equity investments[5]	1,494	—	—	1,494	679
Debt securities[6]	$—	8,316	—	8,316	—

(1) 2014 assets and liabilities are all classified as Level 2 with the exception of equity investments of $679 million, which are classified as Level 1.

(2) Includes $20 million and $29 million of non-current assets for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.

(3) Includes $239 million and $8 million of non-current liabilities for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.

(4) Includes cross currency interest rate swaps and interest rate swaps.

(5) Classified as non-current other assets. The carrying amount of the equity investments were $528 million and $284 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized gains were $979 million and $406 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized losses were $13 million and $11 million as of January 3, 2016 and December 28, 2014, respectively.

(6) Classified as current marketable securities.

(7) Classified as other current assets.

(8) Classified as accounts payable.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2015		Effective Rate %		2014		Effective Rate %	
2.15% Notes due 2016	$900		2.22	%	898		2.22	
3 month LIBOR+0.07% FRN due 2016	800		0.48		800		0.31	
0.70% Notes due 2016	398		0.74		398		0.74	
5.55% Debentures due 2017	1,000		5.55		1,000		5.55	
1.125% Notes due 2017	700		1.15		697		1.15	
5.15% Debentures due 2018	899		5.15		898		5.15	
1.65% Notes due 2018	602		1.70		597		1.70	
4.75% Notes due 2019 (1B Euro 1.0882)[2]/(1B Euro 1.2199)[3]	1,085	[2]	5.83		1,216	[3]	5.83	
1.875% Notes due 2019	502		1.93		497		1.93	
3% Zero Coupon Convertible Subordinated Debentures due 2020	137		3.00		158		3.00	
2.95% Debentures due 2020	545		3.15		543		3.15	
3.55% Notes due 2021	448		3.67		446		3.67	
2.45% Notes due 2021	349		2.48		349		2.48	
6.73% Debentures due 2023	250		6.73		250		6.73	
3.375% Notes due 2023	811		3.17		812		3.17	
5.50% Notes due 2024 (500MM GBP 1.4818)[2]/(500MM GBP 1.5542)[3]	737	[2]	6.75		772	[3]	6.75	
6.95% Notes due 2029	297		7.14		297		7.14	
4.95% Debentures due 2033	500		4.95		500		4.95	
4.375% Notes due 2033	864		4.24		865		4.23	
5.95% Notes due 2037	996		5.99		995		5.99	
5.85% Debentures due 2038	700		5.86		700		5.86	
4.50% Debentures due 2040	540		4.63		539		4.63	
4.85% Notes due 2041	298		4.89		298		4.89	
4.50% Notes due 2043	499		4.52		499		4.52	
Other	104		—		105		—	
Subtotal	14,961	[4]	4.06	%[1]	15,129	[4]	4.08	[1]
Less current portion	2,104				7			
Total long-term debt	$12,857				15,122			

[1] Weighted average effective rate.
[2] Translation rate at January 3, 2016.
[3] Translation rate at December 28, 2014.
[4] The excess of the fair value over the carrying value of debt was $1.7 billion in 2015 and $2.2 billion in 2014.

Fair value of the non-current debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 15, 2016. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2015, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $7.0 billion at the end of 2015, of which $4.6

billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2016 are:

(Dollars in Millions)

2016	2017	2018	2019	2020	After 2020
$2,104	1,790	1,501	1,587	683	7,296

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2015	2014	2013
Currently payable:			
U.S. taxes	$2,748	2,625	594
International taxes	1,309	1,174	1,653
Total currently payable	4,057	3,799	2,247
Deferred:			
U.S. taxes	37	(258)	(251)
International taxes	(307)	699	(356)
Total deferred	(270)	441	(607)
Provision for taxes on income	$3,787	4,240	1,640

A comparison of income tax expense at the U.S. statutory rate of 35% in 2015, 2014 and 2013, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2015	2014	2013
U.S.	$8,179	8,001	4,261
International	11,017	12,562	11,210
Earnings before taxes on income:	$19,196	20,563	15,471
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations excluding Ireland	(6.7)	(7.0)	(10.6)
Ireland and Puerto Rico operations[1]	(8.7)	(6.9)	(9.0)
Research and orphan drug tax credits	(0.2)	(0.3)	(0.8)
U.S. state and local	0.4	1.0	0.4
U.S. manufacturing deduction	(0.6)	(0.6)	(0.8)
U.S. tax on international income	0.2	1.4	1.7
U.S. tax benefit on asset/business disposals	—	(1.9)	(5.1)
All other	0.3	(0.1)	(0.2)
Effective tax rate	19.7 %	20.6	10.6

[1]The Company has subsidiaries operating in Puerto Rico under various tax incentives.

The 2015 effective tax rate decrease as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

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The 2013 effective tax rate was reduced by a tax benefit associated with the write-off of assets for tax purposes associated with Scios, Inc., and the inclusion of both the 2013 and 2012 benefit from the Research and Development tax credit and the Controlled Foreign Corporation look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 21 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009. The impact of the settlement is reflected in the U.S. tax on international income and the All other line items within the above reconciliation.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2015 and 2014 were as follows:

	2015 Deferred Tax		2014 Deferred Tax	
(Dollars in Millions)	Asset	Liability	Asset	Liability
Employee related obligations	$2,863		3,426	
Stock based compensation	790		799	
Depreciation		(247)		(564)
Non-deductible intangibles		(6,663)		(6,671)
International R&D capitalized for tax	1,318		1,433	
Reserves & liabilities	1,801		1,497	
Income reported for tax purposes	960		1,067	
Net operating loss carryforward international	997		949	
Miscellaneous international	922 [1]	(249)	1,128 [1]	(305)
Miscellaneous U.S.	436		996	
Total deferred income taxes	$10,087	(7,159)	11,295	(7,540)

[1] The $922 million in 2015 was net of a valuation allowance related to Belgium of $196 million. The $1,128 million in 2014 was net of a valuation allowance related to Belgium of $172 million.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

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

(Dollars in Millions)	2015	2014	2013
Beginning of year	$2,465	2,729	3,054
Increases related to current year tax positions	570	281	643
Increases related to prior period tax positions	182	295	80
Decreases related to prior period tax positions	(79)	(288)	(574)
Settlements	(4)	(477)	(418)
Lapse of statute of limitations	(54)	(75)	(56)
End of year	$3,080	2,465	2,729

The unrecognized tax benefits of $3.1 billion at January 3, 2016, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $44 million, $12 million and $40 million in 2015, 2014 and 2013, respectively. The total amount of accrued interest was $366 million and $298 million in 2015 and 2014, respectively.

9. Employee Related Obligations

At the end of 2015 and 2014, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2015	2014
Pension benefits	$3,857	4,547
Postretirement benefits	2,738	3,161
Postemployment benefits	2,092	2,062
Deferred compensation	584	599
Total employee obligations	9,271	10,369
Less current benefits payable	417	397
Employee related obligations — non-current	$8,854	9,972

Prepaid employee related obligations of $256 million and $233 million for 2015 and 2014, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

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

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

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

As described in Note 1 to the Consolidated Financial Statements, the Company has elected to early adopt a practical expedient beginning for the fiscal year end 2015 to measure its defined benefit plans using the calendar month end closest to its fiscal year end. In 2015 and 2014 the Company used December 31, 2015 and December 28, 2014, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2015, 2014 and 2013 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2015	2014	2013	2015	2014	2013
Service cost	$1,037	882	906	257	211	196
Interest cost	988	1,018	908	186	197	151
Expected return on plan assets	(1,809)	(1,607)	(1,447)	(7)	(7)	(6)
Amortization of prior service cost (credit)	2	6	6	(33)	(34)	(2)
Amortization of net transition obligation	—	1	1	—	—	—
Recognized actuarial losses	745	460	681	201	136	111
Curtailments and settlements	8	(17)	—	—	—	2
Net periodic benefit cost	$971	743	1,055	604	503	452

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$—
Amortization of net actuarial losses	638
Amortization of prior service credit	29

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

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

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	2015	2014	2013	2015	2014	2013
Net Periodic Benefit Cost						
Discount rate	3.78%	4.78	4.25	4.31	5.25	4.55
Rate of increase in compensation levels	4.05%	4.08	4.08	4.11	4.29	4.28
Expected long-term rate of return on plan assets	8.53%	8.46	8.45			
Benefit Obligation						
Discount rate	4.11%	3.78	4.78	4.63	4.31	5.25
Rate of increase in compensation levels	4.01%	4.05	4.08	4.28	4.11	4.29

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company will change its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change will not impact the benefit obligation and will not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

In 2014, for measurement of U.S. retirement benefit obligations, the mortality assumption was updated to a newly established 2014 mortality table resulting in an increase to the projected benefit obligation.

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The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2015		2014	
Health care cost trend rate assumed for next year	6.60	%	6.00	%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50	%	4.50	%
Year the rate reaches the ultimate trend rate	2038		2032	

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 36	(29)
Post-retirement benefit obligation	$ 417	(326)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2015 and 2014 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	2015	2014	2015	2014
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$26,889	21,488	5,081	4,407
Service cost	1,037	882	257	211
Interest cost	988	1,018	186	197
Plan participant contributions	48	59	—	—
Amendments	60	(60)	—	(254)
Actuarial (gains) losses	(1,578)	5,395	(400)	1,030
Divestitures & acquisitions	(5)	(121)	—	—
Curtailments, settlements & restructuring	(20)	(53)	(3)	—
Benefits paid from plan	(773)	(813)	(420)	(493)
Effect of exchange rates	(791)	(906)	(32)	(17)
Projected benefit obligation — end of year	$25,855	26,889	4,669	5,081
Change in Plan Assets				
Plan assets at fair value — beginning of year	$22,575	20,901	79	87
Actual return on plan assets	298	2,078	1	8
Company contributions	752	1,176	414	477
Plan participant contributions	48	59	—	—
Settlements	(20)	(40)	—	—
Divestitures & acquisitions	(5)	(109)	—	—
Benefits paid from plan assets	(773)	(813)	(420)	(493)
Effect of exchange rates	(621)	(677)	—	—
Plan assets at fair value — end of year	$22,254	22,575	74	79
Funded status — end of year	$(3,601)	(4,314)	(4,595)	(5,002)
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$256	233	—	—
Current liabilities	(77)	(74)	(324)	(309)
Non-current liabilities	(3,780)	(4,473)	(4,271)	(4,693)
Total recognized in the consolidated balance sheet — end of year	$(3,601)	(4,314)	(4,595)	(5,002)
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$6,501	7,547	2,013	2,611
Prior service cost (credit)	34	(33)	(185)	(225)
Unrecognized net transition obligation	—	1	—	—
Total before tax effects	$6,535	7,515	1,828	2,386
Accumulated Benefit Obligations — end of year	$23,262	23,816		

(Dollars in Millions)	Retirement Plans 2015	2014	Other Benefit Plans 2015	2014
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	$971	743	604	503
Net actuarial (gain) loss	(75)	4,942	(389)	1,015
Amortization of net actuarial loss	(745)	(460)	(201)	(136)
Prior service cost (credit)	60	(60)	—	(253)
Amortization of prior service (cost) credit	(2)	(6)	33	34
Effect of exchange rates	(218)	(273)	(1)	—
Total recognized in other comprehensive income, before tax	$(980)	4,143	(558)	660
Total recognized in net periodic benefit cost and other comprehensive income	$(9)	4,886	46	1,163

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2015, the Company contributed $435 million and $317 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2015 and December 28, 2014, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2015	2014	2015	2014	2015	2014	2015	2014
Plan Assets	$15,113	15,201	—	—	7,141	7,374	—	—
Projected Benefit Obligation	15,280	15,571	1,675	1,683	8,542	9,203	358	432
Accumulated Benefit Obligation	13,876	13,875	1,411	1,363	7,661	8,205	314	373
Over (Under) Funded Status								
Projected Benefit Obligation	$(167)	(370)	(1,675)	(1,683)	(1,401)	(1,829)	(358)	(432)
Accumulated Benefit Obligation	1,237	1,326	(1,411)	(1,363)	(520)	(831)	(314)	(373)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $4.5 billion, $5.3 billion and $1.9 billion, respectively, at the end of 2015, and $8.2 billion, $9.4 billion and $5.3 billion, respectively, at the end of 2014.

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

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future benefit payments						
Retirement plans	$839	872	911	967	1,031	6,098
Other benefit plans	$331	322	315	312	310	1,499

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future contributions	$76	77	82	88	93	559

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2015 and 2014 and target allocations for 2016 are as follows:

	Percent of Plan Assets		Target Allocation
	2015	2014	2016
Worldwide Retirement Plans			
Equity securities	79%	77%	74%
Debt securities	21	23	26
Total plan assets	100%	100%	100%

Determination of Fair Value of Plan Assets

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

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

Valuation Hierarchy

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

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

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

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

- Commingled funds — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price in a market that is not active.

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

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2015 and December 28, 2014:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Total Assets	
(Dollars in Millions)	2015	2014	2015	2014	2015	2014	2015	2014
Short-term investment funds	$184	168	312	551	—	—	496	719
Government and agency securities	—	—	1,767	1,934	—	—	1,767	1,934
Debt instruments	—	—	1,050	1,143	1	1	1,051	1,144
Equity securities	11,317	11,204	11	21	—	—	11,328	11,225
Commingled funds	—	—	7,189	7,205	33	46	7,222	7,251
Insurance contracts	—	—	—	—	23	24	23	24
Other assets	—	1	314	214	53	63	367	278
Investments at fair value	$11,501	11,373	10,643	11,068	110	134	22,254	22,575

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $74 million and $79 million at December 31, 2015 and December 28, 2014, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $751 million (3.4% of total plan assets) at December 31, 2015 and $778 million (3.4% of total plan assets) at December 28, 2014.

Level 3 Gains and Losses

The table below sets forth a summary of changes in the fair value of the Plan’s Level 3 assets for the years ended December 31, 2015 and December 28, 2014:

(Dollars in Millions)	Debt Instruments	Equity Securities	Commingled Funds	Insurance Contracts	Other Assets	Total Level 3
Balance December 29, 2013	$1	4	44	23	69	141
Realized gains (losses)	—	—	—	—	(5)	(5)
Unrealized gains (losses)	—	—	2	—	—	2
Purchases, sales, issuances and settlements, net	—	—	(2)	3	(1)	—
Transfers in/out and exchange rate changes	—	(4)	2	(2)	—	(4)
Balance December 28, 2014	1	—	46	24	63	134
Realized gains (losses)	—	—	1	—	(2)	(1)
Unrealized gains (losses)	—	—	(11)	—	(5)	(16)
Purchases, sales, issuances and settlements, net	—	—	(2)	1	(2)	(3)
Transfers in/out and exchange rate changes	—	—	(1)	(2)	(1)	(4)
Balance December 31, 2015	$1	—	33	23	53	110

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11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $187 million, $172 million and $164 million in 2015, 2014 and 2013, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Amount
Balance at December 30, 2012	341,354	$18,476
Employee compensation and stock option plans	(48,555)	(3,367)
Repurchase of common stock	6,416	591
Balance at December 29, 2013	299,215	15,700
Employee compensation and stock option plans	(32,302)	(2,933)
Repurchase of common stock	69,707	7,124
Balance at December 28, 2014	336,620	19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	$22,684

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2015, 2014 and 2013.

Cash dividends paid were $2.95 per share in 2015, compared with dividends of $2.76 per share in 2014, and $2.59 per share in 2013.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. As of January 3, 2016, $1.0 billion has been repurchased under the program.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 30, 2012	$(296)	195	(5,717)	8	(5,810)
Net 2013 changes	94	(89)	2,708	237	2,950
December 29, 2013	(202)	106	(3,009)	245	(2,860)
Net 2014 changes	(4,601)	151	(3,308)	(104)	(7,862)
December 28, 2014	(4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)

January 3, 2016	$(8,435)	604	(5,298)	(36)	(13,165)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.
Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2015, 2014 and 2013 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $104 million, $156 million and $186 million in 2015, 2014 and 2013, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013:

(In Millions Except Per Share Amounts)	2015	2014	2013
Basic net earnings per share	$5.56	5.80	4.92
Average shares outstanding — basic	2,771.8	2,815.2	2,809.2
Potential shares exercisable under stock option plans	141.5	142.6	148.5
Less: shares repurchased under treasury stock method	(102.6)	(96.5)	(103.3)
Convertible debt shares	2.2	2.6	3.0
Accelerated share repurchase program	—	—	19.6
Adjusted average shares outstanding — diluted	2,812.9	2,863.9	2,877.0
Diluted net earnings per share	$5.48	5.70	4.81

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $3 million after-tax for years 2015 and 2014 and $4 million for year 2013.

The diluted net earnings per share calculation for 2015, 2014 and 2013 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal year ended December 29, 2013 included the dilutive effect of 19.6 million shares, related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. in the fiscal year 2012.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $316 million, $341 million and $363 million in 2015, 2014 and 2013, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at January 3, 2016 are:

(Dollars in Millions)						
2016	2017	2018	2019	2020	After 2020	Total

$224	194	136	90	74	109	827

Commitments under capital leases are not significant.

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

At January 3, 2016, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 486 million at the end of 2015.

The compensation cost that has been charged against income for these plans was $874 million, $792 million and $728 million for 2015, 2014 and 2013, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $253 million, $259 million and $243 million for 2015, 2014 and 2013, respectively. The total unrecognized compensation cost was $744 million, $722 million and $636 million for 2015, 2014 and 2013, respectively. The weighted average period for this cost to be recognized was 0.98 years, 1.18 years and 1.26 years for 2015, 2014, and 2013, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company’s Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2014 and 2013 grants, expected volatility represents a blended rate of 4-year daily historical average volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $10.68, $8.42 and $4.88, in 2015, 2014 and 2013, respectively. The fair value was estimated based on the weighted average assumptions of:

	2015		2014		2013	
Risk-free rate	1.77	%	1.87	%	1.01	%
Expected volatility	15.48	%	14.60	%	14.04	%
Expected life (in years)	7.0		6.0		6.0	
Expected dividend yield	2.90	%	3.10	%	3.40	%

A summary of option activity under the Plan as of January 3, 2016, December 28, 2014 and December 29, 2013, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 30, 2012	134,351	$61.58	$1,061
Options granted	29,010	72.54	
Options exercised	(41,357)	59.99	
Options canceled/forfeited	(2,448)	65.89	
Shares at December 29, 2013	119,556	64.70	3,306
Options granted	24,356	90.44	
Options exercised	(25,319)	62.31	
Options canceled/forfeited	(2,881)	75.48	
Shares at December 28, 2014	115,712	70.37	4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	116,517	$76.41	$3,065

The total intrinsic value of options exercised was $644 million, $954 million and $941 million in 2015, 2014 and 2013, respectively.

The following table summarizes stock options outstanding and exercisable at January 3, 2016:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$58.33	8,694	3.1	$58.32	8,694	$58.32
$58.34-$62.20	17,644	2.6	$61.21	17,644	$61.21
$62.62-$65.62	22,139	3.4	$64.55	21,726	$64.54
$66.07-$72.54	25,617	7.0	$72.52	217	$69.77
$90.44-$100.48	42,423	8.6	$94.98	64	$90.47
	116,517	5.9	$76.41	48,345	$62.26

[1] Average contractual life remaining in years.

Stock options outstanding at December 28, 2014 and December 29, 2013 were 115,712 and an average life of 5.7 years and 119,556 and an average life of 5.1 years, respectively. Stock options exercisable at December 28, 2014 and December 29, 2013 were 57,846 at an average price of $61.94 and 75,210 at an average price of $62.01, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

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A summary of the restricted share units and performance share units activity under the Plans as of January 3, 2016 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 30, 2012	31,834	285
Granted	10,582	1,290
Issued	(10,078)	—
Canceled/forfeited	(1,721)	(40)
Shares at December 29, 2013	30,617	1,535
Granted	8,487	1,113
Issued	(9,685)	(19)
Canceled/forfeited	(1,726)	(98)
Shares at December 28, 2014	27,693	2,531
Granted	7,637	931
Issued	(10,164)	(285)
Canceled/forfeited	(1,281)	(99)
Shares at January 3, 2016	23,885	3,078

The average fair value of the restricted share units granted was $91.65, $83.01 and $65.90 in 2015, 2014 and 2013, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $597.6 million, $541.0 million and $569.2 million in 2015, 2014 and 2013, respectively.

The weighted average fair value of the performance share units granted was $93.54, $85.94 and $73.42 in 2015, 2014 and 2013, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $16.7 million and $1.4 million in 2015 and 2014, respectively. No performance share units vested in 2013.

18. Segments of Business and Geographic Areas

	Sales to Customers		
(Dollars in Millions)	2015	2014	2013
Consumer —			
United States	$5,222	5,096	5,162
International	8,285	9,400	9,535
Total	13,507	14,496	14,697
Pharmaceutical —			
United States	18,333	17,432	13,948
International	13,097	14,881	14,177
Total	31,430	32,313	28,125
Medical Devices —			
United States	12,132	12,254	12,800
International	13,005	15,268	15,690
Total	25,137	27,522	28,490
Worldwide total	$70,074	74,331	71,312

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	2015 [3]	2014 [4]	2013 [5]	2015	2014
Consumer	$1,787	1,941	1,973	20,772	21,813
Pharmaceutical	11,734	11,696	9,178	26,144	25,803
Medical Devices	6,826	7,953	5,261	40,979	41,445
Total	20,347	21,590	16,412	87,895	89,061
Less: Expense not allocated to segments [1]	1,151	1,027	941		
General corporate [2]				45,516	41,297
Worldwide total	$19,196	20,563	15,471	$133,411	130,358

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	2015	2014	2013	2015	2014	2013
Consumer	$544	581	533	$559	577	539
Pharmaceutical	1,063	977	856	929	1,053	1,075
Medical Devices	1,631	1,807	1,724	1,945	1,974	2,224
Segments total	3,238	3,365	3,113	3,433	3,604	3,838
General corporate	225	349	482	313	291	266
Worldwide total	$3,463	3,714	3,595	$3,746	3,895	4,104

	Sales to Customers			Long-Lived Assets [6]	
(Dollars in Millions)	2015	2014	2013	2015	2014
United States	$35,687	34,782	31,910	36,609	36,835
Europe	15,995	18,947	18,599	20,167	21,559
Western Hemisphere excluding U.S.	6,045	7,160	7,421	2,881	3,210
Asia-Pacific, Africa	12,347	13,442	13,382	2,493	2,438
Segments total	70,074	74,331	71,312	62,150	64,042
General corporate				1,148	1,138
Other non long-lived assets				70,113	65,178
Worldwide total	$70,074	74,331	71,312	133,411	130,358

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

Export sales are not significant. In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues. In 2013, the Company did not have a customer that represented 10.0% of total revenues.

(1) Amounts not allocated to segments include interest (income) expense, noncontrolling interests and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Medical Devices segment includes a restructuring charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(4) Includes net litigation expense of $1,253 million comprised of $907 million, $259 million and $87 million in the Medical Devices, Pharmaceutical and Consumer segments, respectively. Includes $178 million of in-process research and development expense, comprised of $147 million and $31 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment includes a net gain of $1,899 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration costs of $754 million and $126 million expense for the cost associated with the DePuy ASR™ Hip program. The Pharmaceutical segment includes an additional year of the Branded Prescription Drug Fee of $220 million and a positive adjustment of $0.1 billion to previous reserve estimates.

(5) Includes $2,276 million of net litigation expense comprised of $1,975 million and $301 million in the Medical Devices and Pharmaceutical segments, respectively. Includes $683 million of Synthes integration/transaction costs in the Medical Devices segment. Includes $580 million of in-process research and development expense, comprised of $514 million and $66 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment also includes $251 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $98 million of income related to other adjustments comprised of $55 million and $43 million in the Consumer and Pharmaceutical segments, respectively.

(6) Long-lived assets include property, plant and equipment, net for 2015, and 2014 of $15,905 and $16,126, respectively, and intangible assets and goodwill, net for 2015 and 2014 of $47,393 and $49,054, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2015 and 2014 are summarized below:

(Dollars in Millions Except Per Share Data)	2015 First Quarter (1)	Second Quarter (2)	Third Quarter (3)	Fourth Quarter (4)	2014 First Quarter (5)	Second Quarter (6)	Third Quarter (7)	Fourth Quarter (8)
Segment sales to customers								
Consumer	$3,390	3,483	3,314	3,320	3,557	3,744	3,589	3,606
Pharmaceutical	7,726	7,946	7,694	8,064	7,498	8,509	8,307	7,999
Medical Devices	6,258	6,358	6,094	6,427	7,060	7,242	6,571	6,649
Total sales	17,374	17,787	17,102	17,811	18,115	19,495	18,467	18,254
Gross profit	12,092	12,430	11,878	12,138	12,660	13,456	13,068	12,401
Earnings before provision for taxes on income	5,575	5,741	4,122	3,758	5,424	5,626	6,810	2,703
Net earnings	4,320	4,516	3,358	3,215	4,727	4,326	4,749	2,521
Basic net earnings per share	$1.55	1.63	1.21	1.16	1.67	1.53	1.69	0.90
Diluted net earnings per share	$1.53	1.61	1.20	1.15	1.64	1.51	1.66	0.89

(1) The first quarter of 2015 includes a net litigation gain of $253 million after-tax ($402 million before-tax) and $122 million after-tax ($139 million before-tax) for costs associated with the DePuy ASR™ Hip program.

(2) The second quarter of 2015 includes net litigation expense of $23 million after-tax ($134 million before-tax).

(3) The third quarter of 2015 includes net litigation expense of $348 million after-tax ($409 million before-tax).

(4) The fourth quarter of 2015 includes a restructuring charge of $415 million after-tax ($590 million before-tax), $156 million after-tax ($214 million before-tax) from impairment of in-process research and development and Synthes integration costs of $59 million after-tax ($83 million before-tax). Additionally, the fourth quarter of 2015 includes the gain on the Cordis divestiture.

(5) The first quarter of 2014 includes Synthes integration costs of $84 million after-tax ($118 million before-tax) and a $398 million tax benefit associated with Conor Medsystems.

(6) The second quarter of 2014 includes litigation expense of $342 million after-tax ($276 million before-tax) and Synthes integration costs of $104 million after-tax ($144 million before-tax).

(7) The third quarter of 2014 includes an additional year of the Branded Prescription Drug Fee of $220 million after and before tax, litigation expense of $231 million after-tax ($285 million before-tax), Synthes integration costs of $130 million after-tax ($167 million before-tax) and $111 million after-tax ($126 million before-tax) for costs associated with the DePuy ASR™ Hip program. Additionally, the fiscal third quarter of 2014 includes a net gain of $1.1 billion after-tax ($1.9 billion before-tax) for the divestiture of the Ortho-Clinical Diagnostics business.

(8) The fourth quarter of 2014 includes litigation expense, primarily related to product liability and patent litigation of $652 million after-tax ($692 million before-tax), Synthes integration costs of $237 million after-tax ($325 million before-tax) and $115 million after-tax ($156 million before-tax) from impairment of in-process research and development.

20. Business Combinations and Divestitures

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%.

Certain businesses were acquired for $2,129 million in cash and $38 million of liabilities assumed during 2014. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2014 acquisitions included: Covagen AG, a privately-held, biopharmaceutical company specializing in the development of multispecific protein therapeutics through the FynomAb® technology platform; Alios BioPharma, Inc., a privately-held, clinical stage biopharmaceutical company focused on developing therapies for viral diseases; and the ORSL™ electrolyte ready-to-drink brand from Jagdale Industries Ltd. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $2,069 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,913 million has been identified as the value of IPR&D associated with the acquisitions of Covagen AG and Alios BioPharma, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of Alios BioPharma, Inc. (Alios) of $1,688 million is associated with Alios' lead compound AL-8176, an orally administered antiviral therapy for treatment of infants with respiratory syncytial virus (RSV). A probability of success factor of 60.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.4%. The IPR&D related to the acquisition of Covagen AG of $225 million is associated with Covagen's lead compound COVA-322, currently in Phase 1b study for psoriasis and holding potential as a treatment for a broad range of inflammatory diseases including rheumatoid arthritis. A probability of success factor of 26.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 12.5%. During 2015, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Covagen AG.

Certain businesses were acquired for $835 million in cash and $193 million of liabilities assumed during 2013. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The assumed liabilities primarily represent the fair value of the contingent consideration which may be payable related to the acquisition of Aragon Pharmaceuticals, Inc., a privately-held, pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers. As per terms of the agreement, additional payments of up to $350 million may be paid in the future based on reaching predetermined milestones.

The 2013 acquisitions included: Flexible Stenting Solutions, Inc., a leading developer of innovative flexible peripheral arterial, venous and biliary stents; Shanghai Elsker Mother & Baby Co., Ltd, a baby care company in China and Aragon Pharmaceuticals, Inc.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $941 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $831 million has been identified as the value of IPR&D primarily associated with the acquisitions of Aragon Pharmaceuticals, Inc.

The IPR&D related to the acquisition of Aragon Pharmaceuticals, Inc. of $810 million is associated with Aragon's androgen receptor antagonist program for treatment of hormonally-driven cancers. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in such projects. Probability of success factors ranging from 37% - 52.0% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 15.5%.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the

Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

Supplemental pro forma information for 2015, 2014 and 2013 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2015, the Company divestitures included: The Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA ® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures of businesses were approximately $2.6 billion. As of January 3, 2016, assets held for sale were not material.

During 2014, the Company divestitures included: The Ortho-Clinical Diagnostics business to The Carlyle Group; the K-Y® brand to Reckitt Benckiser Group PLC in the U.S. and certain other markets; and the BENECOL® brand to Raisio plc. In 2014, the pre-tax gains on the divestitures of businesses were approximately $2.4 billion. The Company completed the divestiture of its Ortho-Clinical Diagnostics business to The Carlyle Group for approximately $4.0 billion and the Company recorded a pre-tax gain of approximately $1.9 billion. Ortho-Clinical Diagnostics' results are included in the Company's Medical Devices segment.
During 2013, the Company divestitures included: women's sanitary protection products in the U.S., Canada and the Caribbean to Energizer Holdings, Inc.; Rolaids® to Chattem, Inc.; DORIBAX® rights to Shionogi; and the sale of certain consumer brands and certain pharmaceutical products. In 2013, the pre-tax gains on the divestitures of businesses were $0.1 billion.

21. Legal Proceedings

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2016, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

PRODUCT LIABILITY

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While these subsidiaries believe they have substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damage and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, and XARELTO®. As of January 3, 2016, in the United States there were approximately 5,300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 8,700 with respect to the PINNACLE® Acetabular Cup System, 46,700 with respect to pelvic meshes, 10,700 with respect to RISPERDAL®, and 5,000 with respect to XARELTO®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a

multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement which would effectively extend the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,800 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the United States. However, many lawsuits in the United States will remain, and the settlement program does not address litigation outside of the United States. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom. The Company has established an accrual to cover only defense costs in connection with product liability litigation associated with DePuy's PINNACLE® Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, class actions and individual personal injury cases or claims have been commenced in Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland and Venezuela, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established an accrual with respect to product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of XARELTO®, an oral anticoagulant. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts

across the United States and many cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania. Class action lawsuits also have been filed in Canada. The Company has established an accrual with respect to product liability litigation associated with XARELTO®. Changes to this accrual may be required in the future as additional information becomes available.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company’s products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, and require the payment of past damages and future royalties, and which may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In January 2010, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that EES's HARMONIC® shears infringed three Tyco patents. The case was tried in July 2012, and in March 2013, the Court ruled that some of EES's HARMONIC® shears infringed Tyco's patents and ordered EES to pay damages of approximately $176 million, but declined to order injunctive relief. EES appealed and in December 2014, the United States Court of Appeals for the Federal Circuit reversed the District Court's ruling and found all the asserted claims invalid. In July 2015, Tyco filed a motion for review with the United States Supreme Court. In July 2014, Covidien filed another patent infringement lawsuit against EES in the United States District Court for the District of Connecticut seeking damages and a preliminary injunction, alleging that EES's newest version of its harmonic scalpels, the HARMONIC ACE®+ 7 Shears and the HARMONIC ACE®+ Shears, infringed the three Tyco patents asserted in the previous case. The claims asserted by Covidien in this case are the same claims that were declared invalid in December 2014 by the Court of Appeals in the Tyco case discussed above. In November 2015, the United States Supreme Court denied Tyco's petition for review; therefore, both cases have been dismissed.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, alleging LifeScan's OneTouch® Line of Blood Glucose Monitoring Systems infringe two patents related to the use of microelectrode sensors. Roche is seeking monetary damages and injunctive relief. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. Roche appealed and the Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. In December 2014, the District Court ruled in LifeScan's favor and reinstated the original claim construction. In February 2015, Roche appealed the ruling, and in February 2016, oral argument took place at the Court of Appeals. The parties are awaiting a decision.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE®ADVANCE® and ACUVUE® OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the '327 patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt asked the District Court to grant it a new trial based on alleged new evidence, and in July 2014, the District Court denied Rembrandt’s motion. Rembrandt has appealed the District Court's denial of its motion for a new trial.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claims that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he was a government employee. The State claims that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State is seeking damages plus royalties on QUIXIL™ and EVICEL® products, or alternatively, transfer of the patents to the State. The case remains active, but no trial date has been set.

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, LLC (Shasta), Instacare Corp (now Pharmatech Solutions, Inc. (Pharmatech)) and Conductive Technologies, Inc. (Conductive) in the United States District Court for the Northern District of California for patent infringement and false advertising for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. The defendants alleged that the three LifeScan patents-in-suit are invalid and challenged the validity of the asserted patents in the United States Patent and Trademark Office (USPTO). In April

2013, the defendants brought counterclaims for alleged antitrust violations and false advertising and those claims were stayed pending resolution of the patent infringement case. The validity of two of the patents was confirmed by the USPTO, but the USPTO determined that the third patent, U.S. Patent No. 7,250,105 (the '105 patent), is invalid. LifeScan lost an appeal of that decision, but is seeking a rehearing. LifeScan entered into a settlement agreement with Shasta and Conductive. A motion brought by Pharmatech for summary judgment of patent invalidity was argued in February 2016 and the parties are awaiting a decision. LifeScan's patent infringement and false advertising claims are scheduled to be tried in August 2016.

LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip) in the United States District Court for the District of North Carolina in May 2014, alleging that the making and marketing of Unistrip’s strips infringe the same patents asserted against Shasta above. That case has been stayed pending the outcome of the appeal of the USPTO's decision on the validity of the '105 patent. In July 2014, UniStrip brought a lawsuit against LifeScan in the United States District Court for the Eastern District of Pennsylvania, alleging antitrust violations relating to marketing practices for LifeScan strips.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that all of Cordis's sales of the CYPHER® and CYPHER SELECT™ Stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorney's fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims, and Medinol did not appeal the decision. In September 2014, the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol's appeal of this decision has been dismissed. Medinol has filed a petition for review with the United States Supreme Court. Following the divestiture of Cordis, the Company retains any liability that may result from this case.

In December 2014, Bonutti Skeletal Innovations LLC (Bonutti) sued DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. in the United States District Court for the District of Massachusetts, alleging that DePuy Synthes's product line of spine implants infringes six patents owned by Bonutti, generally covering wedge implants and their methods of implantation. Bonutti is seeking monetary damages and injunctive relief.

Pharmaceutical

In 2012 and 2013, Noramco, Inc. (Noramco) moved to intervene in several patent infringement lawsuits filed in the United States District Court for the Southern District of New York by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), Watson Laboratories, Inc.- Florida (Watson) and Andrx Labs, LLC (Andrx). The lawsuits are in response to the defendants' respective Abbreviated New Drug Applications seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco has agreed to defend the lawsuits on behalf of Impax, Teva, Amneal, Watson, and Andrx. In April 2013, Watson and Andrx entered into a settlement with Purdue. The trial against Impax and Teva (and others) took place in September 2013, and Noramco defended Teva and Impax. In November 2013, Impax entered into a settlement with Purdue, and in December 2014, Teva entered into a settlement with Purdue. The District Court issued a decision in January 2014 invalidating the relevant Purdue patents and, based on that decision, subsequently dismissed the lawsuit against Amneal (and other parties not defended by Noramco). Purdue appealed the Court's decision. In February 2016, the Federal Circuit affirmed the District Court decision invalidating the Purdue patents. If Purdue ultimately prevails in its appeal of the invalidity decision, it can reinstitute its action against Amneal. In December 2015, Purdue filed another patent infringement action against Amneal in the District of Delaware asserting, among others, the three above-referenced patents and a newly issued patent relating to oxycodone and processes for making oxycodone.

Johnson & Johnson acquired the prostate cancer business of Aragon Pharmaceuticals, Inc. (Aragon), including ARN-509, a compound being tested for treatment of prostate cancer, in September 2013. Prior to the acquisition, in May 2011, Medivation, Inc. (Medivation) had sued Aragon and the University of California seeking rights to ARN-509. In December 2012, the State Court granted summary judgment to Aragon on Medivation's claims, awarding the rights of the ARN-509 compound to Aragon, and in January 2013, the Court dismissed the case against Aragon. Medivation has appealed.

REMICADE® Related Cases

In September 2013, JBI and NYU Langone Medical Center (NYU Medical Center) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE® (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU Medical Center, and NYU Medical Center granted JBI an exclusive license to NYU Medical Center's rights under the patent. Currently, the '471 patent in the United States expires in September 2018. JBI responded to that rejection in December 2013 and in August 2014, JBI and NYU Medical Center received a further rejection. JBI responded to the rejection by filing a further amendment and in November 2014, JBI's petition to enter the amendment was granted. The application was returned to the examiner for issuance of a new Office Action, which occurred in February 2015, further rejecting the patent. JBI responded to that rejection and in April 2015, the USPTO issued a further action maintaining its rejection of the '471 patent. In May 2015, JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board, and the appeal is currently pending. The '471 patent remains a valid and enforceable patent as it undergoes reexamination at the USPTO. JBI will continue to defend the patent and, if necessary, will pursue all available appeals.

In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira seeking a declaratory judgment that their biosimilar product for which they are seeking FDA approval under the new Biologics Price Competition and Innovation Act (the BPCIA) infringes or potentially infringes six JBI patents. JBI is also seeking a declaratory judgment that defendants have failed to comply with certain procedural requirements of the BPCIA. In addition, JBI has moved for a preliminary and permanent injunction to prohibit Celltrion and Hospira from launching their biosimilar product until 180 days after they have given JBI a Notice of Commercial Marketing, such notice not to be given before FDA approval of Celltrion's product. Also in March 2015, JBI moved to stay all proceedings in the District Court with respect to the ‘471 patent, pending the USPTO re-examination proceeding. In August 2015, JBI also filed a motion seeking the District Court's permission to file a patent infringement lawsuit asserting U.S. Patent No. 7,598,083 (the '083 patent) against Celltrion and the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product. Although the '083 patent is already asserted in the existing lawsuit, this would expand the claims to include any use of the cell media made in the United States to manufacture Celltrion's biosimilar. In February 2016, Celltrion and Hospira agreed not to launch their biosimilar product before June 30, 2016 and the '471 and '083 patents will be the two remaining patents in the lawsuit. In light of this representation, and because the Federal Circuit Court of Appeals is expected to decide this issue in an unrelated but similar case before June 29th, the Court denied JBI's motion for preliminary injunction, but noted that JBI may renew its motion following the Court of Appeals decision, if necessary, or if the Court of Appeals fails to decide the issue by June 29th. In addition, in February 2016, Celltrion and Hospira filed a motion for summary judgment of invalidity of the ‘471 patent.

In March 2013, Hospira Healthcare Corporation (Hospira) filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE® (a Feldman patent), which is exclusively licensed to Janssen Biotech, Inc. (JBI). In October 2013, Kennedy, along with JBI, Janssen Inc. and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against Celltrion Healthcare Co., Ltd., Celltrion Inc. (together, Celltrion) and Hospira. The counterclaim alleges that the products described in Celltrion’s and Hospira’s marketing applications to Health Canada for their subsequent entry biologics (SEB) to REMICADE® would infringe the Feldman patents owned by Kennedy. Discovery in the patent action is ongoing. Trial has been scheduled for September 2016.

In January 2014, Health Canada approved Celltrion’s SEB to REMICADE®, allowing Celltrion to market its biosimilar version of REMICADE® in Canada, regardless of the pending patent action. In June 2014, Hospira received approval

for its SEB to REMICADE®. In July 2014, Janssen Inc. (Janssen) filed a lawsuit to compel the Canadian Minister of Health to withdraw the Notice of Compliance for Hospira's SEB because Hospira did not serve a Notice of Allegation on Janssen to address the patent listed by Janssen on the Patent Register. In March 2015, the parties entered into a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira's Notice of Compliance, subject to Health Canada's right to appeal, which appeal was filed in June 2015. Nevertheless, Hospira began marketing a biosimilar version of REMICADE® as a distributor under Celltrion's Notice of Compliance.

If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the FDA and compliance with the 180-day notice provisions of the BPCIA. In February 2016, the Arthritis Advisory Committee of the FDA recommended approval of Celltrion's investigational biosimilar version of

REMICADE® by a vote of 21-3 across all eligible indications in the United States. There is a risk that a competitor could launch a biosimilar version of REMICADE® following FDA approval (subject to compliance with the 180-day notice provisions of the BPCIA), even though one or more valid patents are in place. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

PREZISTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of PREZISTA®. In November 2010, Tibotec, Inc. (now Tibotec, LLC) and Tibotec Pharmaceuticals (now Janssen R&D Ireland) (collectively, Tibotec) filed a patent infringement lawsuit against Lupin, Ltd., Lupin Pharmaceuticals, Inc. (collectively, Lupin), Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in the United States District Court for the District of New Jersey in response to Lupin's and Mylan's respective ANDAs seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of Tibotec's patent relating to PREZISTA®. Lupin and Mylan each filed counterclaims alleging non-infringement and invalidity. In July 2011, Tibotec filed another patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of two additional patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle. In September 2011, the Court consolidated the above lawsuits (referred to here as the First Consolidated Action).

The approved New Drug Application for PREZISTA® was transferred from Tibotec, Inc. to Janssen Products, LP in December 2011. In 2012 and 2013, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) added several patents that they own or exclusively license from G.D. Searle to the First Consolidated Action against Mylan and Lupin. In June 2013, Janssen and G.D. Searle dismissed their claims relating to the patents owned by G.D. Searle against Lupin and Mylan, based on those parties’ agreement not to seek FDA approval of their respective ANDAs until the November 2017 expiration of the G.D. Searle patents. After a trial regarding the remaining patents in the First Consolidated Action, the Court issued a decision in August 2014 in favor of Janssen, holding that the asserted patents are valid and would be infringed by Lupin's and Mylan's marketing of their proposed products. Mylan and Lupin filed an appeal.

In July 2014, Janssen filed a patent infringement lawsuit against Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No. 8,153,829. In November 2015, Janssen and Mylan entered into a confidential settlement. Pursuant to the settlement agreement, the parties are in the process of

seeking a dismissal of this action. In addition, the appeal of the August 2014 decision as it relates to Mylan has been dismissed and remanded to the District Court where the parties are seeking a modification of the Court’s 2014 order in accordance with the settlement agreement.

In May 2013, Lupin notified Janssen that it filed an ANDA seeking approval to market a new dosage strength of its generic version of PREZISTA®. In response, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey, alleging that Lupin's new dosage strength would infringe the same patents that Janssen is asserting against Lupin in the original action. In March 2014, Janssen filed a patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No 8,518,987 (the ‘987 patent). In January 2015, the Court consolidated these lawsuits (referred to here as the Second Consolidated Action), and stayed them pending Lupin's appeal of the Court's decision in the First Consolidated Action. In April 2015, Lupin filed an Inter

Partes Review in the USPTO seeking to invalidate the ‘987 patent and in October 2015, the USPTO denied Lupin's petition. In January 2016, Janssen received a patent notice from Lupin advising that Lupin has amended its ANDA to reflect a new formulation of darunavir that Lupin alleges does not infringe the relevant Janssen patents, and in February 2016, Janssen filed a lawsuit asserting those patents against Lupin in the United States District Court for the District of New Jersey. In addition, in January 2016, Lupin filed a motion to stay and deactivate its appeal of the above-referenced August 2014 decision, and to remand the matter to the District Court where Lupin intends to modify the 2014 District Court order and injunction to allow Lupin to market its new formulation of darunavir before the expiration of the relevant patents.

Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. in March 2013 in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408. In October 2015, the parties stipulated to a Consent Judgment wherein the Hetero defendants admitted that the patents-in-suit are valid and would be infringed by the manufacture, importation, use or sale of Hetero’s ANDA product, and agreed to an injunction with respect to such product during the life of the patents-in-suit. Hetero reserved the right to develop non-infringing darunavir products and processes.

In August 2014, Janssen filed patent infringement lawsuits against Cipla Ltd. and Cipla USA, Inc. (collectively, Cipla) in the United States District Courts for the Districts of New Jersey and Delaware in response to Cipla’s ANDA seeking approval to market a generic version of Janssen’s PREZISTA® product before the expiration of certain of Janssen’s patents relating to PREZISTA®. Cipla filed counterclaims seeking declarations of noninfringement and invalidity of the patents-in-suit. In May 2015, Janssen and Cipla entered into a settlement agreement.

In response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® in Canada before the expiration of Canadian Patent No. 2,485,834, Janssen Inc. and Janssen R&D Ireland filed a Notice of Application against Mylan Pharmaceuticals ULC in July 2014. In December 2014, Janssen R&D Ireland transferred its PREZISTA® patents to Janssen Sciences Ireland UC, and Janssen Sciences Ireland UC was substituted for Janssen R&D Ireland as plaintiff in the above-referenced actions. In February 2016, the parties entered into a confidential settlement and the Notice of Application has been dismissed.

In January 2015, Janssen Inc. and Janssen Sciences Ireland UC filed a Notice of Application against Teva Canada Limited in response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent No. 2,485,834. In October 2015, the parties entered into a settlement wherein Teva Canada Limited agreed to withdraw its Notice of Allegation without prejudice to file a new one in the future, and Janssen Inc. and Janssen Sciences Ireland UC agreed to dismiss their Notice of Application.

In each of the above lawsuits, Janssen sought or is seeking an Order enjoining the defendants from marketing their generic versions of PREZISTA® before the expiration of the relevant patents.

CONCERTA®

In May 2014, ALZA Corporation (ALZA) and Janssen Pharmaceuticals, Inc. (JPI) filed a patent infringement lawsuit in the United States District Court for the District of West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (Mylan) in response to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent No. 8,163,798 (the '798 patent). Mylan filed counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit. In May 2015, Mylan sought leave to add a counterclaim for invalidity and non-infringement of U.S. Patent No. 8,629,179 (the '179 patent) and the Court denied Mylan's motion. In July 2015, Mylan filed a declaratory judgment action in the Eastern District of Pennsylvania seeking a declaration of invalidity and non-infringement of the '179 patent. In October 2015, the parties entered into a confidential settlement of both the West Virginia and Pennsylvania actions.

In December 2014, Janssen Inc. and ALZA filed a Notice of Application against Actavis Pharma Company (Actavis) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of Canadian Patent No. 2,264,852 (the ‘852 patent). The hearing is scheduled for September 2016.

In February 2015, Janssen Inc. and ALZA filed a Notice of Application against Apotex Inc. (Apotex) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of the '852 patent. In August 2015, Janssen Inc. and ALZA voluntarily dismissed the Notice of Application.

In each of the above lawsuits, ALZA and/or JPI sought or are seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA® before the expiration of the relevant patents.

ZYTIGA®

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 (the '213 patent) (expiring December 2016) and/or 8,822,438 (the '438 patent) (expiring August 2027). The generic companies include Actavis Laboratories, FL, Inc. (Actavis); Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward); and Hikma Pharmaceuticals, LLC (Hikma). The Court entered a stay of the New Jersey lawsuit against each of Par and Citron, as each agreed to be bound by the decision against the other defendants in the New Jersey action. In February 2016, the New Jersey Court set a trial date of October 2017.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia. In October 2015, Mylan filed a motion to dismiss the New Jersey lawsuit for lack of personal jurisdiction and improper venue. In February 2016, the West Virginia Court stayed the West Virginia case pending a decision on Mylan's motion to dismiss in the New Jersey lawsuit, but set a conditional trial date of February 2018. The Court will dismiss the West Virginia lawsuit if Mylan's motion to dismiss in New Jersey is denied.

In August 2015, JBI received a notice of paragraph IV certification from Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, a division of Hetero Labs Limited (collectively, Hetero) advising of Hetero’s ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In September 2015, Janssen and BTG filed an amended complaint in the New Jersey lawsuit to allege infringement of the '438 patent by Hetero.

The filing of the above-referenced lawsuits triggered a stay until October 2018 during which the FDA will not grant final approval of the generics' ANDAs unless there is an earlier district court decision finding the patents-in-suit invalid or not infringed.

In December 2015, Amerigen Pharmaceuticals Limited filed a petition for an Inter Partes Review in the USPTO seeking to invalidate the '438 patent.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the relevant patents.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Court for the District of Delaware and West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to their ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310; 7,125,879; and 8,101,629. In September 2015, Mylan filed an Answer in the West Virginia action that included counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit as well as United States Patent No. 8,080,551. In September 2015, Mylan filed a motion to dismiss the Delaware lawsuit for lack of personal jurisdiction. In January 2016, Janssen and Gilead filed a first amended complaint in the New Jersey Action adding claims for patent infringement with respect to United States Patent Nos. 7,399,856 and 7,563,922. In addition, in the New Jersey Action, the Court dismissed Mylan's motion to dismiss and set a trial date of February 2018, and in the West Virginia Action, the Court set a trial date of December 2017. In February 2016, Mylan renewed its motion to dismiss for lack of jurisdiction.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of COMPLERA® before the expiration of the relevant patents.

XARELTO®

A number of generic companies have filed ANDAs seeking approval to market generic versions of XARELTO®. In October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed a patent infringement lawsuit against Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Micro Labs USA Inc., Micro Labs Ltd., Mylan Pharmaceuticals Inc., Mylan Inc., Prinston Pharmaceutical, Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. in the United States District Court for the District of Delaware in response to those parties' respective ANDAs seeking approval to market generic versions of XARELTO® before the expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive licensee of the asserted patents. JPI is seeking an Order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents. In November 2015, Mylan moved to dismiss the action. In December 2015, JPI, Bayer, and Mylan stipulated and agreed to dismiss the claims against Mylan Inc. and suspend further briefing and argument on Mylan's motion to dismiss pending appeals relating to personal jurisdiction over Mylan Pharmaceuticals Inc. in the District of Delaware.

In January 2016, JPI and Bayer received a paragraph IV notice from Invagen Pharmaceuticals Inc. (Invagen) advising that it is seeking FDA approval for a generic XARELTO® product before expiration of the relevant patents. In February 2016, JPI and Bayer filed a patent infringement action against Invagen asserting the same XARELTO® patents asserted in the original case, and the Invagen case has been consolidated with the original case. The Court set a trial date of March 2018.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts.

The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and cases are still pending in Illinois, New Jersey, Wisconsin and Utah. The cases in Illinois, New Jersey and Wisconsin have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. The AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPL”), entered an injunction, and awarded $45 million in restitution and $6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants appealed the Commonwealth Court's UTPL ruling, and in June 2014, the Pennsylvania Supreme Court

vacated the judgment entered by the Commonwealth Court and remanded the case for further proceedings. On remand, in January 2015, the Commonwealth Court dismissed the monetary awards against the J&J AWP Defendants. In March 2015, the ruling was appealed back to the Pennsylvania Supreme Court. In December 2015, the Pennsylvania Supreme Court affirmed the Order of the Commonwealth Court dismissing the monetary awards against the J&J AWP Defendants.

RISPERDAL®

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL® from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL® with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL®, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL®. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above. The cases brought by the Attorneys General of Mississippi and Kentucky were settled in December 2015, without any admission of wrongdoing on the part of JPI. State cases that went to judgment after trial are discussed below.

In 2004, the Attorney General of West Virginia commenced a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) based on claims of alleged consumer fraud as to DURAGESIC®, as well as RISPERDAL®. JPI was found liable and damages were assessed at $4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court of Appeals reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen Pharmaceutica, Inc. (now JPI). Johnson & Johnson was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether Johnson & Johnson or JPI had violated the State's Medical Assistance Program Integrity Law (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Professional letter regarding RISPERDAL®. The jury returned a verdict that JPI and Johnson & Johnson had violated the Act and awarded $257.7 million in damages. The trial judge subsequently awarded the Attorney General counsel fees and expenses in the amount of $73 million. In January 2014, the Louisiana Supreme Court reversed the District Court’s judgment in favor of the Attorney General, and rendered judgment in favor of Johnson & Johnson and JPI. In April 2014, the Louisiana Supreme Court denied the Attorney General's petition seeking a rehearing of the appellate arguments, resulting in final dismissal of the case.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's Medicaid program. The trial occurred in June 2010. The trial judge dismissed the case after the close of the plaintiff's evidence. The Commonwealth filed an appeal and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica, Inc. (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at

which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately $327.1 million against JPI. JPI appealed this judgment and in February 2015, the South Carolina Supreme Court affirmed the trial court’s decision in part, reversed it in part and remanded the case back to the trial court. The net effect of the decision was to reduce the judgment to approximately $136 million, plus interest. In the first fiscal quarter of 2015, the Company accrued $136 million. In March 2015, JPI filed a Petition for Rehearing. In July 2015, the South Carolina Supreme Court granted the Petition and filed a substituted opinion. The new opinion reduced the judgment from approximately $136 million to approximately $124 million. In January 2016, the United States Supreme Court denied JPI's request for review, putting an end to this case.

In April 2012, in the lawsuit brought by the Attorney General of Arkansas, the jury found against both JPI and Johnson & Johnson, and the Court imposed penalties in the amount of approximately $1.2 billion. In January 2013, the trial court awarded attorney fees of approximately $181 million. JPI and Johnson & Johnson appealed both awards to the Arkansas Supreme Court, and in March 2014, the Arkansas Supreme Court dismissed the State's claim under the Arkansas Medicaid Fraud False Claims Act, as well as the approximately $1.2 billion in penalties, and reversed and remanded a claim under the Arkansas Deceptive Trade Practices Act. In April 2014, the Arkansas Supreme Court rejected a petition by the State for rehearing on the case. In May 2015, the matter settled for $7.75 million.

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division) (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. In March 2015, McNEIL-PPC entered a guilty plea in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL-PPC agreed to pay a $20 million fine and a $5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice, and Oregon appealed that decision. In November 2015, the Court of Appeals of the State of Oregon reversed the trial court and reinstated Oregon's consumer protection claims. In December 2015, the Companies filed a petition for review with the Oregon Supreme Court.

Opioids Litigation

Along with other pharmaceutical companies, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI) have been named in two lawsuits alleging claims related to marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. In May 2014, Santa Clara and Orange Counties in California (the Counties) filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including J&J and JPI, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. The Counties seek injunctive and monetary relief. In February 2015, the defendants filed motions challenging the sufficiency of the complaint. In August 2015, the Court stayed the case until the FDA concludes its ongoing inquiry into the safety and effectiveness of long-term opioid treatment.

In June 2014, the City of Chicago filed a complaint in Cook County Circuit Court against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices, including consumer fraud violations and false claims, and seeking injunctive and monetary relief. The case was later removed to the United States District Court for the Northern District of Illinois, and in December 2014, J&J and JPI filed a motion to dismiss the City of Chicago's First Amended Complaint for failure to state a claim. In

November 2015, J&J and JPI filed a motion to dismiss the City of Chicago's Second Amended Complaint for failure to state a claim.

In September 2014, the Tennessee Attorney General Division of Consumer Affairs issued a Request for Information to JPI and other pharmaceutical companies related to opioids marketing practices.

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI and other pharmaceutical companies related to opioids marketing practices. JPI objected to private contingent fee counsel’s participation in the investigation on the State’s behalf, and in October 2015, the State moved to enforce the subpoena.

In December 2015, the State of Mississippi filed a complaint in the Chancery Court of the First Judicial District of Hinds County against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices. The State of Mississippi is seeking penalties and injunctive and monetary relief.

Other

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The Demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the Demand and is cooperating with the inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of the RELIEVA STRATUS® MicroFlow Spacer product (the STRATUS® Spacer). In April 2015, an Indictment was filed in the United States District Court for the District of Massachusetts charging the former President/CEO and Vice President of Sales of Acclarent (the former Acclarent officers). The Indictment charges the former Acclarent officers with various violations related to the off-label promotion of the STRATUS® Spacer. The allegations against the former Acclarent officers relate to the development, sale and marketing of the STRATUS® Spacer, as well as actions allegedly taken by the former Acclarent officers in connection with the acquisition of Acclarent by Ethicon, Inc. in 2010. There are no charges against Acclarent, Ethicon, Inc. or Johnson & Johnson.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (the Companies) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the Companies. The District Court issued an order in August 2014 that publicly unsealed the United States' declination notice; however, the complaint in the matter remains under seal. In addition, in October 2013, a group of state Attorneys General issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.’s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation for a total payment of $4 million to the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014, the United States Attorney’s

Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with the request. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos.

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

GENERAL LITIGATION

In September 2006, Johnson & Johnson filed a lawsuit against Guidant Corporation (Guidant) in the United States District Court for the Southern District of New York, alleging that Guidant breached provisions of a merger agreement between Johnson & Johnson and Guidant. In June 2011, Guidant filed a motion for summary judgment and in July 2014, the judge denied Guidant's motion. The trial concluded in January 2015 and in February 2015, before a decision was issued by the Court, Johnson & Johnson and Guidant entered into a settlement agreement, pursuant to which Guidant agreed to pay Johnson & Johnson $600 million and agreed that it will not sue Johnson & Johnson or its affiliates for patent infringement regarding certain stent products. Johnson & Johnson dismissed its action against Guidant with prejudice. The Company recorded a gain associated with this transaction in fiscal first quarter of 2015.

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as In re Blood Reagent Antitrust Litigation. Following the divestiture of OCD, Johnson & Johnson retains any liability that may result from these cases. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In April 2015, the United States Court of Appeals for the Third Circuit reversed the class certification ruling and remanded the case to the District Court for further proceedings. In October 2015, the District Court again granted the motion by Plaintiffs for class certification.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and there is currently no date set for that hearing.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed its Petition for Relief in July 2015.

In March 2015, Costco Wholesale Corporation (Costco) filed a complaint against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court of the Northern District of California, alleging antitrust claims of an unlawful vertical price fixing agreement between JJVCI, Costco and unnamed other distributors and retailers. Costco alleges that the alleged agreements harmed competition by causing increases in the price Costco customers pay for JJVCI contact lenses. Costco is seeking an injunction and monetary damages. In June 2015, the case was transferred to the United States District Court for the Middle District of Florida along with related class action cases described below. In November 2015, the Court denied a JJVCI motion to dismiss.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI), other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints alleged that the manufacturers reached agreements between each other and certain distributors

and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015 along with the related case filed by Costco Wholesale Corporation described above. The plaintiffs filed a Consolidated Class Action complaint in November 2015, and in December 2015, JJVCI and other defendants filed motions to dismiss.

In April 2015, Johnson & Johnson Vision Care, Inc. (JJVCI) filed a complaint in the United States District Court for the District of Utah against the State of Utah seeking a declaratory judgment that a law passed by the state to ban unilateral pricing policies solely in the contact lens market violates the Commerce Clause of the United States Constitution. The Court denied JJVCI's motion for a preliminary injunction. JJVCI appealed. Argument on the appeal was held in August 2015.

In April 2015, Adimmune Corporation Ltd (Adimmune) commenced an arbitration in the International Court of Arbitration - International Chamber of Commerce against Crucell Switzerland AG (now Janssen Vaccines AG) and Crucell Holland BV (collectively, Crucell). Adimmune claims that Crucell breached certain agreements relating to the supply of flu antigen when Crucell ceased purchasing flu antigen from Adimmune. In December 2015, Adimmune filed its Statement of Claim seeking monetary damages.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages in an unspecified amount.

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

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by 2017. In the fiscal fourth quarter of 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million is included in cost of products sold. The $590 million restructuring charge consists of severance costs of $484 million, asset write-offs of $86 million and $20 million in other costs, primarily related to supply contracts.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next two years, subject to any consultation procedures in countries, where required.

The Company estimates that approximately one half of the cumulative pre-tax costs will result in cash outlays, including
approximately $500 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash,
relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending for the fiscal year ended 2015:

(Dollars in Millions)	Severance	Asset Write-offs	Other	Total
2015 restructuring charge	$484	86	20	590
Current year activity	—	86	3	89
Reserve balance, January 3, 2016*	$484	—	17	501

*Cash outlays for severance are expected to be substantially paid out over the next 24 months in accordance with the Company's plans and local laws.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of earnings, statements of comprehensive income, statements of equity, and statements of cash flows present fairly, in all material respects, the financial position of Johnson & Johnson and its subsidiaries at January 3, 2016 and December 28, 2014, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 3, 2016, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it classifies deferred tax assets and liabilities in 2015.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Florham Park, New Jersey

February 24, 2016

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Management’s Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company’s internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company’s internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company’s internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company’s financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company’s management has assessed the effectiveness of the Company’s internal control over financial reporting as of January 3, 2016. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in “Internal Control-Integrated Framework (2013).” These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company’s assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company’s processes and assessment, as described above, management has concluded that, as of January 3, 2016, the Company’s internal control over financial reporting was effective.

The effectiveness of the Company’s internal control over financial reporting as of January 3, 2016 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky	/s/ Dominic J. Caruso
Alex Gorsky	Dominic J. Caruso
Chairman, Board of Directors	Vice President, Finance
Chief Executive Officer	Chief Financial Officer

Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2015, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2010 and December 31, 2005 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

	2010	2011	2012	2013	2014	2015
Johnson & Johnson	$100.00	$109.89	$121.79	$163.95	$192.37	$194.59
S&P 500 Index	$100.00	$102.11	$118.44	$156.78	$178.22	$180.67
S&P Pharmaceutical Index	$100.00	$117.76	$134.75	$182.22	$222.70	$235.59
S&P Healthcare Equipment Index	$100.00	$99.20	$116.33	$148.54	$187.58	$198.78

10 Year Shareholder Return Performance J&J vs. Indices

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Johnson & Johnson	$100.00	$112.44	$116.50	$107.45	$119.57	$118.87	$130.63	$144.77	$194.89	$228.67	$231.32
S&P 500 Index	$100.00	$115.78	$122.23	$77.00	$97.37	$112.03	$114.39	$132.68	$175.64	$199.67	$202.41
S&P Pharmaceutical Index	$100.00	$115.85	$121.25	$99.18	$117.65	$118.56	$139.62	$159.76	$216.04	$264.04	$279.32
S&P Healthcare Equipment Index	$100.00	$104.12	$109.47	$79.20	$102.01	$99.24	$98.45	$115.45	$147.42	$186.16	$197.28

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

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

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

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 3, 2016, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at www.investor.jnj.com/gov/policies.cfm, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at www.investor.jnj.com/gov.cfm within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and

Executive Officers is available on the Company's website at www.investor.jnj.com/gov/policies.cfm, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at www.investor.jnj.com/gov.cfm within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1: Election of Directors – Director Compensation – Fiscal 2015," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

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

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

The information called for by this item is incorporated herein by reference to the material under the caption "Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 3, 2016 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	143,479,580	$62.05	485,801,441
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	143,479,580	$62.05	485,801,441

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

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

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

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

The information called for by this item is incorporated herein by reference to the material under the captions "Corporate Governance - Director Independence" and "Related Party Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. Financial Statements

Consolidated Balance Sheets at end of Fiscal Years 2015 and 2014

Consolidated Statements of Earnings for Fiscal Years 2015, 2014 and 2013

Consolidated Statements of Comprehensive Income for Fiscal Years 2015, 2014 and 2013

Consolidated Statements of Equity for Fiscal Years 2015, 2014 and 2013

Consolidated Statements of Cash Flows for Fiscal Years 2015, 2014 and 2013

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

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

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

SIGNATURES

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

Date: February 24, 2016

JOHNSON & JOHNSON

(Registrant)

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

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

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors, Chief Executive Officer, and Director (Principal Executive Officer)	February 24, 2016
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer and Vice President, Finance (Principal Financial Officer)	February 24, 2016
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 24, 2016
/s/ M. C. Beckerle M. C. Beckerle	Director	February 24, 2016
/s/ M. S. Coleman M. S. Coleman	Director	February 24, 2016
/s/ D. S. Davis D. S. Davis	Director	February 24, 2016
/s/ I. E. L. Davis I. E. L. Davis	Director	February 24, 2016

Signature	Title	Date
/s/ S. L. Lindquist S. L. Lindquist	Director	February 24, 2016
/s/ M. B. McClellan M. B. McClellan	Director	February 24, 2016
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 24, 2016
/s/ W. D. Perez W. D. Perez	Director	February 24, 2016
/s/ C. Prince C. Prince	Director	February 24, 2016
/s/ A. E. Washington A. E. Washington	Director	February 24, 2016
/s/ R. A. Williams R. A. Williams	Director	February 24, 2016

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Filed with this document.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Restricted Shares to Non-Employee Directors under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed August 25, 2005.*
10(c)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(d)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 14, 2012 .*
10(e)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(f)	Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the year ended December 31, 2000.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(k)	Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(n)	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(p)	

	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2014.*
10(q)	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Johnson & Johnson Retirement Savings Plan, Johnson & Johnson Savings Plan for Union Represented Employees, and Johnson & Johnson Savings Plan - Incorporated herein by reference to Exhibits 99.1, 99.2 and 99.3 of the Registrant's Form S-8 filed with the Commission on May 6, 2013.*
10(t)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(u)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(v)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(w)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(x)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Filed with this document.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31(a)	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31(b)	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32(a)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32(b)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
99	Cautionary Statement Pursuant to Private Securities Litigation Reform Act of 1995 — “Safe Harbor” for Forward-Looking Statements — Filed with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended January 3, 2016, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.