# 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<sup>®</sup> /SOVRIAD<sup>®</sup> (simeprevir) and INCIVO<sup>®</sup> (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<sup>®</sup> /SOVRIAD<sup>®</sup> (simeprevir) and INCIVO<sup>®</sup> (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.

# **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<sup>®</sup>, 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<sup>®</sup> and AVEENO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and BENECOL<sup>®</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (simeprevir) and INCIVO<sup>®</sup> (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.

				% 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 <sup>®</sup> /SIMPONI ARIA <sup>®</sup>	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 <sup>®</sup>	410	365	236	12.3	54.7	
OLYSIO <sup>®</sup> /SOVRIAD <sup>®</sup>	621	2,302	23	(73.0)	**	
PREZISTA <sup>®</sup> / PREZCOBIX <sup>®</sup> /REZOLSTA <sup>®</sup>	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 <sup>®</sup> /methylphenidate	821	599	782	37.1	(23.4)	
INVEGA <sup>®</sup> /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 <sup>®</sup>	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	

## Major Pharmaceutical Therapeutic Area Sales:\*

\* 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<sup>®</sup> (ustekinumab) and SIMPONI<sup>®</sup> /SIMPONI ARIA<sup>®</sup> (golimumab) were due to market growth and increased penetration of SIMPONI ARIA<sup>®</sup>. Growth was partially offset by lower REMICADE<sup>®</sup> (infliximab) sales to the Company's distributor primarily due to the weakening of the euro and biosimilar competition in Europe. The

patents for REMICADE<sup>®</sup> in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE<sup>®</sup> have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE<sup>®</sup> in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE<sup>®</sup> sales in markets outside the United States. The timing of the possible introduction of a biosimilar version of REMICADE<sup>®</sup> 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 version of REMICADE<sup>®</sup> 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<sup>®</sup> will result in a reduction in U.S. sales of REMICADE<sup>®</sup>. In 2015, U.S. sales of REMICADE<sup>®</sup> were \$4.5 billion. The launch of a biosimilar version of REMICADE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (simeprevir) and INCIVO<sup>®</sup> (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<sup>®</sup> (rilpivirine) and sales of PREZISTA<sup>®</sup> / PREZCOBIX<sup>®</sup> /REZOLSTA<sup>®</sup> (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<sup>®</sup> /methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors by the FDA in November 2014. Strong sales of INVEGA SUSTENNA<sup>®</sup> /XEPLION<sup>®</sup> /INVEGA TRINZA<sup>®</sup> (paliperidone palmitate) were primarily due to increased market share and the launch of INVEGA TRINZA<sup>®</sup>. Neuroscience products sales were negatively impacted by the U.S. divestiture of NUCYNTA<sup>®</sup> (tapentadol) and lower sales of RISPERDAL<sup>®</sup> CONSTA<sup>®</sup> (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<sup>®</sup> (ibrutinib) due to the approval of new indications, additional country launches and strong patient uptake. Additionally, sales of ZYTIGA<sup>®</sup> (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<sup>®</sup> (rivaroxaban) and INVOKANA<sup>®</sup> /INVOKAMET<sup>®</sup> (canagliflozin). PROCRIT<sup>®</sup> /EPREX<sup>®</sup> (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	1			1
EDURANT <sup>®</sup> (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	1	1		
IMBRUVICA <sup>®</sup> (ibrutinib)	Treatment of Waldenström's Macroglobulinemia	1	1		
	Treatment for patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma in combination with bendamustine and rituximab			1	1
	For use in treatment-naïve patients with chronic lymphocytic leukemia			1	1
INVEGA TRINZA <sup>®</sup> (paliperidone palmitate)	An atypical antipsychotic injection administered four times a year for the treatment of schizophrenia	1			1
INVOKAMET <sup>®</sup> 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			1	
PREZCOBIX <sup>®</sup> (darunavir/ cobicistat)	For use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1)	1			
SIMPONI <sup>®</sup> (golimumab)	Treatment of non-radiographic axial spondyloarthritis		1		
STELARA® (ustekinumab)	For the treatment of adolescents with moderate-to-severe psoriasis		1		
	For the treatment of adult patients with moderately to severely active Crohn's disease			1	1
VELCADE <sup>®</sup> (bortezomib)	For use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma		1		
YONDELIS <sup>®</sup> (trabectedin)	For the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma	1			

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<sup>®</sup> / SOVRIAD<sup>®</sup> (simeprevir) and INCIVO<sup>®</sup> (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<sup>®</sup> Knee System, trauma TFNA nailing system and sports medicine ORTHOVISC<sup>®</sup> /MONOVISC<sup>®</sup> 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<sup>®</sup> SMARTTOUCH<sup>®</sup> 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<sup>®</sup> VIBE<sup>®</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>®</sup> brand and the U.S. divestiture of NUCYNTA<sup>®</sup> versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y<sup>®</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>™</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>®</sup> /SOVRIAD<sup>®</sup> (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.

	2015 2014 2		2015 2014		2015		2014		2013
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*	Amount	% 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				

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

\* 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, Corlmmun 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<sup>®</sup> (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 Sale	
(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 <sup>(2)</sup>	1,151	1,027		
Earnings before provision for taxes on income	\$19,196	20,563	27.4%	27.7

<sup>(1)</sup> See Note 18 to the Consolidated Financial Statements for more details.

<sup>(2)</sup> 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<sup>®</sup> brand. In 2014, the Consumer segment included a gain of \$0.5 billion from divestitures, primarily the divestiture of the K-Y<sup>®</sup> 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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>®</sup>, 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<sup>®</sup> (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<sup>®</sup> /SOVRIAD<sup>®</sup> (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<sup>®</sup> (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

<sup>(1)</sup> 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 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 fair market on the date of grant using the fair market on the date of grant using the fair market 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.