JOHNSON & JOHNSON Form 10-Q August 03, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

p Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended July 2, 2017 or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the transition period from to

Commission file number 1-3215

(Exact name of registrant as specified in its charter)

NEW JERSEY

(State or other jurisdiction of incorporation or organization)

22-1024240

(I.R.S. Employer incorporation or organization)

One Johnson & Johnson Plaza

New Brunswick, New Jersey 08933

(Address of principal executive offices)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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. b Yes o No Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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). b Yes o No

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

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company o Emerging growth company o

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

On July 28, 2017, 2,683,999,728 shares of Common Stock, \$1.00 par value, were outstanding.

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### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success; Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the U.S. and other important markets;

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

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

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

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

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

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

Risks Related to Product Liability, Litigation and Regulatory Activity

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

Impact of significant litigation or government action adverse to the Company, including product liability claims; Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

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

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

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

Global climate changes, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and The impact of armed conflicts and terrorist attacks in the U.S. and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

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

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

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

Investors also should carefully read the Risk Factors described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2017, for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to identify or predict all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

# Part I — FINANCIAL INFORMATION

# Item 1 — FINANCIAL STATEMENTS

# JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited; Dollars in Millions Except Share and Per Share Data)

	July 2, 2017	January 1, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$12,598	18,972
Marketable securities	255	22,935
Accounts receivable, trade, less allowances for doubtful accounts \$292 (2016, \$252)	13,283	11,699
Inventories (Note 2)	9,699	8,144
Prepaid expenses and other	2,954	3,282
Total current assets	38,789	65,032
Property, plant and equipment at cost	40,075	37,773
Less: accumulated depreciation	(23,617)	(21,861)
Property, plant and equipment, net	16,458	15,912
Intangible assets, net (Note 3)	54,942	26,876
Goodwill (Note 3)	31,234	22,805
Deferred taxes on income	6,111	6,148
Other assets	5,273	4,435
Total assets	\$152,807	141,208
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Loans and notes payable	\$7,209	4,684
Accounts payable	6,135	6,918
Accrued liabilities	6,076	5,635
Accrued rebates, returns and promotions	6,319	5,403
Accrued compensation and employee related obligations	2,374	2,676
Accrued taxes on income	759	971
Total current liabilities	28,872	26,287
Long-term debt (Note 4)	27,363	22,442
Deferred taxes on income	4,846	2,910
Employee related obligations	9,687	9,615
Other liabilities	10,117	9,536
Total liabilities	80,885	70,790
Shareholders' equity:		
Common stock — par value \$1.00 per share (authorized 4,320,000,000 shares; issued	\$3,120	3,120
3,119,843,000 shares)	Ψ3,120	3,120
Accumulated other comprehensive income (loss) (Note 7)		(14,901)
Retained earnings	113,208	110,551
Less: common stock held in treasury, at cost (434,653,000 and 413,332,000 shares)	31,172	28,352
Total shareholders' equity	71,922	70,418
Total liabilities and shareholders' equity	\$152,807	141,208
See Notes to Consolidated Financial Statements		

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS

(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal Second Quarters Ended			l
	July 2, Percent		July 3,	Percent
	2017	to Sales	2016	to Sales
Sales to customers (Note 9)	\$18,839	100.0 %	\$18,482	100.0 %
Cost of products sold	5,823	30.9	5,336	28.9
Gross profit	13,016	69.1	13,146	71.1
Selling, marketing and administrative expenses	5,262	28.0	5,176	28.0
Research and development expense	2,285	12.1	2,264	12.2
In-process research and development	_	_	29	0.2
Interest income	(105)	(0.6)	(88)	(0.5)
Interest expense, net of portion capitalized	227	1.2	190	1.1
Other (income) expense, net	588	3.1	557	3.0
Restructuring (Note 12)	11	0.1	114	0.6
Earnings before provision for taxes on income	4,748	25.2	4,904	26.5
Provision for taxes on income (Note 5)	921	4.9	907	4.9
NET EARNINGS	\$3,827	20.3 %	\$3,997	21.6 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$1.42		\$1.46	
Diluted	\$1.40		\$1.43	
CASH DIVIDENDS PER SHARE	\$0.84		\$0.80	
AVG. SHARES OUTSTANDING				
Basic	2,691.9		2,745.4	
Diluted	2,741.5		2,794.2	
See Notes to Consolidated Financial Statements				

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS

(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal Six Months Ended			
	July 2,	Percent	July 3,	Percent
	2017	to Sales	2016	to Sales
Sales to customers (Note 9)	\$36,605	100.0 %	\$35,964	100.0 %
Cost of products sold	11,209	30.6	10,665	29.6
Gross profit	25,396	69.4	25,299	70.4
Selling, marketing and administrative expenses	9,999	27.3	9,864	27.4
Research and development expense	4,345	11.9	4,277	11.9
In-process research and development		_	29	0.1
Interest income	(226)	(0.6)	(171)	(0.5)
Interest expense, net of portion capitalized	431	1.2	350	1.0
Other (income) expense, net	428	1.2	518	1.4
Restructuring expense (Note 12)	96	0.2	234	0.7
Earnings before provision for taxes on income	10,323	28.2	10,198	28.4
Provision for taxes on income (Note 5)	2,074	5.7	1,744	4.9
NET EARNINGS	\$8,249	22.5 %	\$8,454	23.5 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$3.06		\$3.07	
Diluted	\$3.00		\$3.02	
CASH DIVIDENDS PER SHARE	\$1.64		\$1.55	
AVG. SHARES OUTSTANDING				
Basic	2,699.3		2,751.4	
Diluted	2,749.4		2,800.9	

See Notes to Consolidated Financial Statements

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (Unaudited; Dollars in Millions)

	Fiscal So Quarters July 2, 2017	Ended July 3,	Month	s Ended July 3,
Net earnings	\$3,827	3,997	8,249	8,454
Other comprehensive income (loss), net of tax Foreign currency translation	843	(295)	1,238	584
Securities: Unrealized holding gain (loss) arising during period Reclassifications to earnings Net change		156 (12 ) 144	136 (193) (57)	100 (94 ) 6
Employee benefit plans: Prior service cost amortization during period Gain (loss) amortization during period Net change	(5 ) 123 118	(6 ) 101 95	(9 ) 246 237	(10 ) 207 197
Derivatives & hedges: Unrealized gain (loss) arising during period Reclassifications to earnings Net change	154 140 294	(250 ) (10 ) (260 )	319	(441 ) 112 (329 )
Other comprehensive income (loss)	1,288	(316)	1,667	458
Comprehensive income	\$5,115	3,681	9,916	8,912

### See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal second quarters were as follows for 2017 and 2016, respectively: Securities: \$17 million and \$77 million; Employee Benefit Plans: \$60 million and \$56 million; Derivatives & Hedges: \$158 million and \$140 million.

The tax effects in other comprehensive income for the fiscal six months were as follows for 2017 and 2016, respectively: Securities: \$31 million and \$3 million; Employee Benefit Plans: \$120 million and \$104 million; Derivatives & Hedges: \$134 million and \$177 million.

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# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; Dollars in Millions)

	Fiscal Si Ended		
	July 2, 2017	July 3, 2016	
CASH FLOWS FROM OPERATING ACTIVITIES	2017	2010	
Net earnings	\$8,249	8,454	
Adjustments to reconcile net earnings to cash flows from operating activities:	, ,	,	
Depreciation and amortization of property and intangibles	2,062	1,791	
Stock based compensation	522	479	
Asset write-downs	270	187	
Net gain on sale of assets/businesses	(53	) (185	)
Deferred tax provision	(72	) 115	
Accounts receivable allowances	24	(4	)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Increase in accounts receivable	(476	) (1,098	)
Increase in inventories	(421	) (443	)
Decrease in accounts payable and accrued liabilities	-	) (1,047	)
Increase in other current and non-current assets	`		)
Increase/(Decrease) in other current and non-current liabilities	322	(702	)
NET CASH FLOWS FROM OPERATING ACTIVITIES	8,685	6,753	
CASH FLOWS FROM INVESTING ACTIVITIES			
Additions to property, plant and equipment	(1,249	) (1,396	)
Proceeds from the disposal of assets/businesses, net	125	685	
Acquisitions, net of cash acquired	(34,072		)
Purchases of investments	(5,227)		
Sales of investments	27,320		j
Other	(80	) (38	)
NET CASH USED BY INVESTING ACTIVITIES	(13,183	) (215	)
CASH FLOWS FROM FINANCING ACTIVITIES			
Dividends to shareholders	(4,433	) (4,266	)
Repurchase of common stock	(5,232	) (4,751	)
Proceeds from short-term debt	2,635	118	
Retirement of short-term debt	(180	) (4,687	)
Proceeds from long-term debt, net of issuance costs	4,464	11,951	L
Retirement of long-term debt	,	) (936	)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	719	929	
Other	(25	) —	
NET CASH USED BY FINANCING ACTIVITIES	(2,067	) (1,642	)
Effect of exchange rate changes on cash and cash equivalents	191	12	
(Decrease)/Increase in cash and cash equivalents	(6,374	) 4,908	

Cash and Cash equivalents, beginning of period CASH AND CASH EQUIVALENTS, END OF PERIOD	18,972 13,732 \$12,598 18,640
Acquisitions	
Fair value of assets acquired	\$36,161 744
Fair value of liabilities assumed and noncontrolling interests	(2,089 ) (14 )
Net cash paid for acquisitions	\$34,072 730
Prior year amounts have been reclassified to conform to current year presentation	
See Notes to Consolidated Financial Statements	
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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2017. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented.

New Accounting Standards Adopted as of July 2, 2017

During the fiscal first quarter of 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2016-07 Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting. The amendments in the update eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step by step basis as if the equity method had been in effect during all previous periods that the investment had been held. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The amendments should be applied prospectively upon their effective date to increases in the level of ownership interest or degree of influence that result in the application of the equity method. The adoption of this standard did not have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standards 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 is effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively. This update did not have any material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

Not Adopted as of July 2, 2017

During the fiscal first quarter of 2017, the FASB issued Accounting Standards Update 2017-07: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost. This update requires that an employer disaggregate the service cost component from the other components of net periodic benefit cost ("NPBC"). In addition, only the service cost component will be eligible for capitalization. This update is effective for the Company for all annual and interim periods beginning after December 15, 2017. Early adoption is permitted as of the beginning of an annual period for which financial statements (interim or annual) have not been issued or made available for issuance. The Company will adopt this new standard in 2018. The amendments in this Update should be applied retrospectively for the presentation of the service cost component and the other components of NPBC in the income statement and prospectively, on and after the effective date, for the capitalization of the service cost component of NPBC in assets. The Company is assessing the retroactive restatement methodology and impact to the individual line items on Consolidated Statement of Earnings. The Company does not expect there to be a material impact to net earnings.

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-05: Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets. This update clarifies the scope of asset derecognition guidance, adds guidance for partial sales of nonfinancial assets and clarifies recognizing gains and losses from the transfer of nonfinancial assets in contracts with noncustomers. This update will be effective for the Company for its

annual and interim reporting periods beginning after December 15, 2017, the same time as the amendments in Update 2014-09 Revenue from Contracts with Customers. This update allows the Company to choose either a full retrospective method or modified retrospective method upon adoption. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-04: Simplifying the Test for Goodwill Impairment. This update simplifies how an entity is required to test goodwill for impairment. A goodwill impairment will now be measured by the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This update will be effective for the Company for its annual or any interim goodwill impairment

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tests in fiscal years beginning after December 15, 2019. Early adoption is permitted. This update should be applied prospectively. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-01: Clarifying the Definition of a Business. This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted. This update should be applied prospectively. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal fourth quarter of 2016, the FASB issued Accounting Standards Update 2016-16 Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory. This update removes the current exception in US GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The amendments in this update are effective for public entities for annual reporting periods beginning after December 15, 2017. Early adoption is permitted and should be in the first interim period if an entity issues interim financial statements. The Company is currently assessing the impact of the future adoption of this standard on its consolidated financial statements and based upon the preliminary assessment expects to record a credit to retained earnings based on timing differences that exist as of the date of adoption.

During the fiscal third quarter of 2016, the FASB issued Accounting Standards Update 2016-15 Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This update addresses whether to present certain specific cash flow items as operating, investing or financing activities. The amendments in this update are effective for public entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The Company is currently assessing the impact of the future adoption of this standard on its consolidated Statements of Cash Flows.

During the fiscal first quarter of 2016, the FASB issued Accounting Standards Update 2016-02 Leases (Topic 842). This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The update is required to be adopted using a modified retrospective approach. The Company anticipates that most of its operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets, however does not expect to have a material impact on the financial position. The actual impact will depend on the Company's lease portfolio at the time of adoption. The Company continues to assess all implications of the standard and related financial disclosures.

During the fiscal first quarter of 2016, the FASB issued Accounting Standards Update 2016-01 Financial Instruments: 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 unable to estimate the impact of the future adoption of this standard on its financial statements as it will depend on the equity investments as of the adoption date.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers, which, along with amendments issued in 2015 and 2016, will replace substantially all current U.S. GAAP guidance on this topic and eliminate industry-specific guidance. 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, 2017. The guidance permits two methods of adoption: full retrospective method (retrospective application to each prior reporting period presented) or modified retrospective method (retrospective application with the cumulative effect of initially applying the guidance recognized at the date of initial application and providing certain additional disclosures). The Company plans to adopt the standard using the modified retrospective method. While the Company continues to evaluate the effect of the standard, preliminarily, it does not anticipate a material impact on its financial statements including the potential impact of additional disclosure requirements. To complete the assessment of the impact of the standard, the Company continues to assess all

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implications of the standard on its financial statements and disclosures. Additionally, the Company continues to monitor modifications, clarifications and interpretations issued by the FASB that may affect current conclusions.

### NOTE 2 — INVENTORIES

(Dollars in Millions)	July 2,	January 1,
	2017	2017
Raw materials and supplies	\$1,138	952
Goods in process	2,515	2,185
Finished goods	6,046	5,007
Total inventories	\$9,699	8,144

Inventory of \$58 million was classified as held for sale, and reported in prepaid expenses and other on the Consolidated Balance Sheet, related to the divestiture of the Codman Neurosurgery business which was pending as of July 2, 2017.

See Note 10 to the Consolidated Financial Statements for additional details on inventory related to the Actelion acquisition.

### NOTE 3 — INTANGIBLE ASSETS AND GOODWILL

Intangible assets that have finite useful lives are amortized over their estimated useful lives. The latest annual impairment assessment of goodwill and indefinite lived intangible assets was completed in the fiscal fourth quarter of 2016. Future impairment tests for goodwill and indefinite lived intangible assets will be performed annually in the fiscal fourth quarter, or sooner, if warranted.

(Dollars in Millions)		January 1,
		2017
Intangible assets with definite lives:		
Patents and trademarks — gross	\$35,804	10,521
Less accumulated amortization	5,546	5,076
Patents and trademarks — net	30,258	5,445
Customer relationships and other intangibles — gros	s20,048	17,615
Less accumulated amortization	7,053	6,515
Customer relationships and other intangibles — net	12,995	11,100
Intangible assets with indefinite lives:		
Trademarks	7,069	6,888
Purchased in-process research and development	4,620	3,443
Total intangible assets with indefinite lives	11,689	10,331
Total intangible assets — net	\$54,942	26,876

Goodwill as of July 2, 2017 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Devices	Total
Goodwill, net at January 1, 2017	\$ 8,263	2,840	11,702	22,805
Goodwill, related to acquisitions*	11	5,986	2,081	8,078
Goodwill, related to divestitures	(13)			(13)
Currency translation/Other	369	64	(69)(1)	)364
Goodwill, net at July 2, 2017	\$ 8,630	8,890	13,714	31,234

(1) Net of \$106 million classified as held for sale, reported in other assets on the Consolidated Balance Sheet, related to the divestiture of the Codman Neurosurgery business which was pending as of July 2, 2017.

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 12 years and 23 years, respectively. The amortization expense of amortizable intangible assets included in cost of products

<sup>\*</sup> Includes measurement period adjustments

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sold was \$809 million and \$576 million for the fiscal six months ended July 2, 2017 and July 3, 2016, respectively. The estimated amortization expense for the five succeeding years approximates \$4.3 billion, before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

The primary driver of the increase to intangible assets and goodwill is related to the Actelion acquisition in the fiscal second quarter of 2017, which resulted in the recording of \$25.0 billion to intangible assets and approximately \$6.0 billion to goodwill. Additionally, the Abbott Medical Optics (AMO) acquisition in the fiscal first quarter of 2017, resulted in the recording of \$2.3 billion to intangible assets and \$1.8 billion to goodwill. The intangible assets and goodwill amounts related to the Actelion and AMO acquisitions are based on the preliminary purchase price allocation. See Note 10 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

#### NOTE 4 — 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.

The Company also uses equity collar contracts to manage exposure to market risk associated with certain equity investments.

All three types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses 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. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with our derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of July 2, 2017 the total amount of collateral received under the credit support agreements (CSA) amounted to \$20 million. For equity collar contracts, the Company pledged the underlying hedged marketable equity securities to the counter-party as collateral. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of July 2, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps, interest rate swaps and equity collar contracts of \$35.8 billion, \$2.3 billion, \$1.8 billion, and \$0.2 billion, \$1.8 billion, and \$0.3 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. 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, cross currency interest rate swaps, net investment hedges and equity collar contracts. 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.

During the fiscal second quarter of 2016, the Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

The change in the carrying value due to remeasurement of these Euro notes resulted in a \$268 million pretax loss during the fiscal second quarter of 2017 reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

The change in the carrying value due to remeasurement of these Euro notes resulted in a \$378 million pretax loss during the fiscal six months of 2017, resulting in a cumulative \$3 million pretax loss from hedge inception through the fiscal six months of 2017 reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

As of July 2, 2017, 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 7. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal second quarters in 2017 and 2016:

	Gain/(Loss) Recognized In Accumulated OCI <sup>(1)</sup>	Gain/(Loss) Reclassified From Accumulated OCI Into Income <sup>(1)</sup>	Income/E	ed In
(Dollars in Millions)	Fiscal Second	d Quarters End	ed	
Cash Flow Hedges By Income Statement Caption	July July 2, 3, 2017 2016	July 2, July 3, 2017 2016	July 2, 2017	July 3, 2016
Sales to customers <sup>(3)</sup>	\$36 (27)	(6 ) (3 )	(1)	
Cost of products sold <sup>(3)</sup>	218 (178)	(68) 13	1	(2)
Research and development expense <sup>(3)</sup>	(19) 12	1 (1)	1	(1)
Interest (income)/Interest expense, net <sup>(4)</sup>	(69)(3)	(65) 7		
Other (income) expense, net <sup>(3) (5)</sup>	(12) (54)	(2 ) (6 )	(1)	
Total	\$154 (250)	(140 ) 10	_	(3)

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal six months in 2017 and 2016:

Gain/(Loss)	Gain/(Loss)	Gain/(Loss)
Recognized	Reclassified	Recognized In
In	From	Other
Accumulated	1	Income/Expense <sup>(2)</sup>

	OCI(1)	)	Accun	nulated				
			OCI					
			Into					
			Incom	$e^{(1)}$				
(Dollars in Millions)	Fiscal	Six M	onths E	Ended				
	July	July	July	July	Turley '	2	Inly	2
Cash Flow Hedges By Income Statement Caption	2,	3,	2,	3,	July 2 2017	۷,	July 2016	
	2017	2016	2017	2016	2017		2010	)
Sales to customers <sup>(3)</sup>	\$22	(27)	(39)	(21)	(1	)	_	
Cost of products sold <sup>(3)</sup>	121	(222)	(99)	(8)	(16	)	(6	)
Research and development expense <sup>(3)</sup>	(128)	(95)	(101)	(96)	6		(1	)
Interest (income)/Interest expense, net <sup>(4)</sup>	(41)	9	(43)	15	—		_	
Other (income) expense, net <sup>(3) (5)</sup>	(44)	(106)	(37)	(2)	—		(3	)
Total	\$(70)	(441)	(319)	(112)	(11	)	(10	)

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

- (1) Effective portion
- (2) Ineffective portion

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- (3) Forward foreign exchange contracts
- (4) Cross currency interest rate swaps
- (5) Includes equity collar contracts

For the fiscal second quarters ended July 2, 2017 and July 3, 2016, a gain of \$63 million and loss \$36 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

For the fiscal six months ended July 2, 2017 and July 3, 2016, a gain of \$34 million and a loss of \$41 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.

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The Company's significant financial assets and liabilities measured at fair value as of July 2, 2017 and January 1, 2017 were as follows:

	July 2, 2			January 1, 2017
(Dollars in Millions)	Lekelvel 1 2	Level 3	Total	Total <sup>(1)</sup>
Derivatives designated as hedging instruments:				
Assets:				
Forward foreign exchange contracts <sup>(7)</sup>	<b>\$-4</b> 18	_	418	747
Interest rate contracts (2)(4)(7)	<del></del> 15		15	31
Total	<del>433</del>	_	433	778
Liabilities:				
Forward foreign exchange contracts <sup>(8)</sup>	<del>454</del>		454	723
Interest rate contracts (3)(4)(8)	<del>273</del>		273	382
Equity collar contracts (8)	<b>—</b> 50		50	57
Total	<del></del> 777		777	1,162
Derivatives not designated as hedging instruments:				
Assets:				
Forward foreign exchange contracts <sup>(7)</sup>	<b>—</b> 56	_	56	34
Liabilities:				
Forward foreign exchange contracts <sup>(8)</sup>	<del>31</del>		31	57
Available For Sale Other Investments:				
Equity investments <sup>(5)</sup>	1,040	_	1,040	1,209
Debt securities <sup>(6)</sup>	\$-3,599	_	3,599	12,087

- (1) 2016 assets and liabilities are all classified as Level 2 with the exception of equity investments of \$1,209 million, which are classified as Level 1.
- (2) Includes \$11 million and \$23 million of non-current other assets for July 2, 2017 and January 1, 2017, respectively.
- (3) Includes \$273 million and \$382 million of non-current other liabilities for July 2, 2017 and January 1, 2017, respectively.
- (4) Includes cross currency interest rate swaps and interest rate swaps.

  Classified as non-current other assets with the exception of \$204 million of current assets for July 2, 2017. The original cost of the equity investments were \$496 million and \$520 million as of July 2, 2017 and January 1, 2017,
- (5) respectively. The unrealized gains were \$548 million and \$757 million as of July 2, 2017 and January 1, 2017, respectively. The unrealized losses were \$4 million and \$68 million as of July 2, 2017 and January 1, 2017, respectively.
- (6) Classified as cash equivalents and current marketable securities.
- (7) Classified as other current assets, including the net effect of the CSA
- (8) Classified as accounts payable, including the net effect of the CSA.

July 2 2017

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The Company's cash, cash equivalents and current marketable securities as of July 2, 2017 comprised:

	July 2,					
(Dollars in Millions)	Carryin Amoun	gUnrecogniz tGain	e <b>U</b> nrecogniz Loss	Estimate ed Fair Value	dCash & Cash Equivalents	Current Marketable Securities
Cash	\$2,547			2,547	2,547	
U.S. Gov't Securities <sup>(1)</sup>	_	_	_	_		
Other Sovereign Securities <sup>(1)</sup>	210			210	210	
U.S. Reverse repurchase agreements	2,841			2,841	2,841	
Other Reverse repurchase agreements	271			271	271	
Corporate debt securities <sup>(1)</sup>	979			979	979	
Money market funds	1,076			1,076	1,076	
Time deposits <sup>(1)</sup>	1,126			1,126	1,126	
Subtotal	9,050			9,050	9,050	
		Unrealized	Unrealized			
		Gain	Loss			
Gov't securities	3,548			3,548	3,548	
Other Sovereign Securities	1			1		1
Corporate debt securities	50			50		50
Equity investments	17	187		204		204
Subtotal Available for Sale <sup>(2)</sup>	\$3,616	187	_	3,803	3,548	255
Total cash, cash equivalents and current marketable securities					12,598	255

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

Fair value of government securities and obligations and corporate debt securities was estimated using quoted broker prices and significant other observable inputs.

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. Available for sale securities with stated maturities of greater than one year from the date of purchase are available for current operations and are classified as cash equivalents and current marketable securities.

The excess of the estimated fair value over the carrying value of cash equivalents and current marketable securities was \$0.2 billion at January 1, 2017.

The contractual maturities of the available for sale securities at July 2, 2017 are as follows:

(Dollars in Millions)	Cost	Fair
(Donars in Willions)	Basis	Value
Due within one year	\$3,588	3,588
Due after one year through five years	11	11
Due after five years through ten years		
Total debt securities	\$3,599	3,599

<sup>(2)</sup> Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

# Financial Instruments not measured at Fair Value:

The following financial liabilities are held at carrying amount on the consolidated balance sheet as of July 2, 2017:

Estimated

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Liabilities		
Current Debt	\$7,209	7,209
Non-Current Debt		
5.15% Debentures due 2018	899	933
1.65% Notes due 2018	599	601
4.75% Notes due 2019 (1B Euro 1.1397)	1,136	1,266
1.875% Notes due 2019	500	508
0.89% Notes due 2019	300	301
1.125% Notes due 2019	699	696
3% Zero Coupon Convertible Subordinated Debentures due in 2020	69	126
2.95% Debentures due 2020	546	566
3.55% Notes due 2021	448	476
2.45% Notes due 2021	349	357
1.65% Notes due 2021	997	991
0.250% Notes due 2022 (1B Euro 1.1397)	1,136	1,136
2.25% Notes due 2022	995	1,003
6.73% Debentures due 2023	250	311
3.375% Notes due 2023	807	866
2.05% Notes due 2023	497	493
0.650% Notes due 2024 (750MM Euro 1.1397)	850	852
5.50% Notes due 2024 (500 MM GBP 1.2965)	642	823
2.45% Notes due 2026	1,990	1,946
2.95% Notes due 2027	995	1,034
1.150% Notes due 2028 (750MM Euro 1.1397)	846	848
6.95% Notes due 2029	296	409
4.95% Debentures due 2033	498	596
4.375% Notes due 2033	857	982
1.650% Notes due 2035 (1.5B Euro 1.1397)	1,691	1,717
3.55% Notes due 2036	987	1,027
5.95% Notes due 2037	990	1,334
3.625% Notes due 2037	1,485	1,556
5.85% Debentures due 2038	695	933
4.50% Debentures due 2040	537	608
4.85% Notes due 2041	296	358
4.50% Notes due 2043	495	578
3.70% Notes due 2046	1,971	2,030
3.75% Notes due 2047	990	1,033
Other	25	25
Total Non-Current Debt	\$27,363	

The weighted average effective interest rate on non-current debt is 3.27%.

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The excess of the estimated fair value over the carrying value of debt was \$1.6 billion at January 1, 2017.

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

#### NOTE 5 — INCOME TAXES

The worldwide effective income tax rates for the fiscal six months of 2017 and 2016 were 20.1% and 17.1%, respectively. The Company completed its acquisition of AMO in the first fiscal quarter of 2017, and incurred incremental tax costs that were discretely recorded in the first quarter, which has increased the effective tax rate by 2.1% for the first six months of 2017 compared to the same period in 2016. Additionally, the Company had more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2016. These increases to the effective tax rate were partially offset by additional tax benefits received from stock-based compensation that either vested or were exercised during the first fiscal six months of 2017 and 2016, which reduced the effective tax rate by 2.7% and 2.8%, respectively.

As of July 2, 2017, the Company had approximately \$3.2 billion of liabilities from unrecognized tax benefits. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. The Company is not able to provide a reasonably reliable estimate of the timing of any future tax payments relating to uncertain tax positions.

#### NOTE 6 — PENSIONS AND OTHER POSTRETIREMENT BENEFITS

#### Components of Net Periodic Benefit Cost

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal second quarters of 2017 and 2016 include the following components:

	Fiscal Second Quarters			
	Ended			
	Retirement	Other		
	Plans	Benefit		
	rialis	Plans		
(Dollars in Millions)	July 2, July 3,	July 2July 3,		
	2017 2016	2017 2016		
Service cost	\$255 226	62 55		
Interest cost	231 233	40 39		
Expected return on plan assets	(509) (493)	(1)(1)		
Amortization of prior service cost/(credit)	1 (1)	(8)(8)		
Recognized actuarial losses	150 124	35 34		
Curtailments and settlements	(1) 4			
Net periodic benefit cost	\$127 93	128 119		

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Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal six months of 2017 and 2016 include the following components:

	Fiscal Six Months Ended				
	Retirement Plans		Other		
			Benefit		
			Plans		
(Dollars in Millions)	July 2,	July 3,	July 2	2July	3,
(Dollars in Millions)	2017	2016	2017	2016	6
Service cost	\$506	452	123	110	
Interest cost	461	466	79	79	
Expected return on plan assets	(1,014	(985)	(3)	(3	)
Amortization of prior service cost/(credit)	1	_	(15)	(16	)
Recognized actuarial losses	302	248	69	68	
Curtailments and settlements	(1)	5			
Net periodic benefit cost	\$255	186	253	238	

### **Company Contributions**

For the fiscal six months ended July 2, 2017, the Company contributed \$34 million and \$20 million to its U.S. and international retirement plans, respectively. The Company plans to continue to fund its U.S. defined benefit plans to comply with the Pension Protection Act of 2006. International plans are funded in accordance with local regulations.

#### NOTE 7 — ACCUMULATED OTHER COMPREHENSIVE INCOME

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

	Foreign	Gain/(Loss)	Employee	Gain/(Loss)	Total Accumulated
	_			On	Other
	Currency	On	Benefit	_	
	,			Derivatives	Comprehensive
(Dollars in Millions)	Translation	Securities	Plans	& Hedges	Income (Loss)
January 1, 2017	\$ (9,047 )	411	(5,980 )	(285)	(14,901)
Net change	1,238	(57)	237	249	1,667
July 2, 2017	\$ (7,809 )	354	(5,743)	(36)	(13,234 )

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 6 for additional details. Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the underlying transaction. See Note 4 for additional details.

#### NOTE 8 — EARNINGS PER SHARE

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal second quarters ended July 2, 2017 and July 3, 2016:

	Fiscal Second
	Quarters Ended
(Shares in Millions)	July 2, July 3,
(Shares in Millions)	2017 2016
Basic net earnings per share	\$1.42 1.46
Average shares outstanding — basic	2,691.9 2,745.4
Potential shares exercisable under stock option plans	143.2 146.3
Less: shares which could be repurchased under treasury stock method	(94.6) (99.2)
Convertible debt shares	1.0 1.7
Average shares outstanding — diluted	2,741.5 2,794.2
Diluted net earnings per share	\$1.40 1.43

The diluted net earnings per share calculation for both the fiscal second quarters ended July 2, 2017 and July 3, 2016 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted net earnings per share calculation for both the fiscal second quarters ended July 2, 2017 and July 3, 2016 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal six months ended July 2, 2017 and July 3, 2016:

	Fiscal Six
	Months Ended
(Shares in Millions)	July 2, July 3,
(Shares in Willions)	2017 2016
Basic net earnings per share	\$3.06 3.07
Average shares outstanding — basic	2,699.3 2,751.4
Potential shares exercisable under stock option plans	142.2 145.8
Less: shares which could be repurchased under treasury stock method	(93.1) (98.0)
Convertible debt shares	1.0 1.7
Average shares outstanding — diluted	2,749.4 2,800.9
Diluted net earnings per share	\$3.00 3.02

The diluted net earnings per share calculation for both the fiscal six months ended July 2, 2017 and July 3, 2016 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted net earnings per share calculation for both the fiscal six months ended July 2, 2017 and July 3, 2016 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

# NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

SALES BY SEGME	NT OF BU	JSINES	S
	Fiscal Se	cond Q	uarters
	Ended		
(D-11 '- M'11')	July 2,	July 3,	Percent
(Dollars in Millions)	2017	2016	Change
Consumer			
United States	\$1,487	1,384	7.4 %
International	1,991	2,035	(2.2)
Total	3,478	3,419	1.7
Pharmaceutical			
United States	5,010	5,144	(2.6)
International	3,625	3,510	3.3
Total	8,635	8,654	(0.2)
Medical Devices			
United States	3,229	3,044	6.1
International	3,497	3,365	3.9
Total	6,726	6,409	4.9
Worldwide	,	,	
United States	9,726	9,572	1.6
International	9,113	8,910	2.3
Total	\$18,839	-	
	, -,	-, -	
	Fiscal Si	x Month	s Ended
(Dallars in Millians)	July 2,	July 3,	Percent
(Dollars in Millions)	2017	2016	Change
Consumer			
United States	\$2,901	2,742	5.8 %
International	3,805	3,872	(1.7)
Total	6,706	6,614	1.4
Pharmaceutical			
United States	9,882	10,081	(2.0)
International	6,998	6,751	3.7
Total	16,880	16,832	0.3
Medical Devices			
United States	6,321	6,070	4.1
International	6,698	6,448	3.9
Total	13,019	12,518	4.0
Worldwide			
Worldwide United States	19,104	18,893	1.1
	19,104 17,501	-	
United States	19,104 17,501 \$36,605	18,893 17,071 35,964	2.5

#### INCOME BEFORE TAX BY SEGMENT

	Fiscal Second Quarters			
	Ended			
(Dollars in Millions)		July 3,	Percent	
(Donars in Willions)	2017	2016	Change	
Consumer	\$658	571	15.2 %	
Pharmaceutical <sup>(1)</sup>	3,414	3,687	(7.4)	
Medical Devices <sup>(2)</sup>	992	939	5.6	
Segments operating profit	5,064	5,197	(2.6)	
Less: Expense not allocated to segments (3)	316	293		
Worldwide income before tax	\$4,748	4,904	(3.2)%	

	Fiscal Si	ix Months Ended		
(Dollars in Millions)	July 2,	July 3,	Percent	
(Donars in Minions)	2017	2016	Change	
Consumer	\$1,254	1,137	10.3 %	
Pharmaceutical <sup>(1)</sup>	7,077	7,031	0.7	
Medical Devices <sup>(2)</sup>	2,555	2,515	1.6	
Segments operating profit	10,886	10,683	1.9	
Less: Expense not allocated to segments (3)	563	485		
Worldwide income before taxes	\$10,323	10,198	1.2 %	

- (1) Includes a positive adjustment of \$0.3 billion to previous reserve estimates in the fiscal second quarter of 2016. Includes a positive adjustment of \$0.5 billion to previous reserve estimates in the fiscal six months of 2016. Includes acquisition costs related to the Actelion acquisition of \$0.2 billion in the fiscal second quarter and fiscal six months of 2017. Includes a gain of \$0.2 billion related to monetization of future royalty receivables in the fiscal second quarter and fiscal six months of 2017. Includes a gain of \$0.2 billion and \$0.1 billion in the fiscal six months of 2017 and 2016, respectively, related to the sale of certain investments in equity securities held by Johnson & Johnson Innovation JJDC, Inc.
- (2) Includes a restructuring related charge of \$0.1 billion and \$0.1 billion in the fiscal second quarters of 2017 and 2016, respectively. Includes a restructuring related charge of \$0.3 billion and \$0.3 billion in the fiscal six months of 2017 and 2016, respectively. Includes litigation expense of \$0.4 billion and \$0.6 billion in the fiscal second quarter of 2017 and 2016, respectively. Includes litigation expense of \$0.4 billion and \$0.7 billion in the fiscal six months of 2017 and 2016, respectively. Includes an asset impairment of \$0.2 billion primarily related to the insulin pump business in the fiscal second quarter and fiscal six months of 2017.
- (3) Amounts not allocated to segments include interest income/expense and general corporate income/expense. SALES BY GEOGRAPHIC AREA

	Fiscal Second Quarters			
	Ended			
(Dollars in Millions)	July 2,	July 3,	Percent	
	2017	2016	Change	
United States	\$9,726	9,572	1.6 %	
Europe	4,232	4,090	3.5	
Western Hemisphere, excluding U.S.	1,499	1,542	(2.8)	
Asia-Pacific, Africa	3,382	3,278	3.2	
Total	\$18,839	18,482	1.9 %	

	Fiscal Six Months Ended			
(Dollars in Millions)	July 2,	July 3,	Percent	
	2017	2016	Change	
United States	\$19,104	18,893	1.1 %	
Europe	8,090	7,937	1.9	
Western Hemisphere, excluding U.S.	2,953	2,873	2.8	
Asia-Pacific, Africa	6,458	6,261	3.1	
Total	\$36,605	35,964	1.8 %	

#### NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

On June 16, 2017, the Company completed the acquisition of Actelion Ltd. through an all cash tender offer in Switzerland for \$280 per share, payable in U.S. dollars. As of July 2, 2017, the Company paid \$28.8 billion, net of cash acquired, representing 97.86% of the shares to which the offer was extended. The Company recorded a current liability of \$0.7 billion for the shares not tendered as of July 2, 2017, which the Company expects to pay in the second half of 2017 as it takes steps to acquire the remaining outstanding shares of Actelion. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). The Company currently holds 9.9% of the shares of Idorsia and has rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately \$0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a ten year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also acquired an option on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia with a Swiss franc denominated credit facility of approximately \$250 million. As of July 2, 2017, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion's specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

Due to the timing of the close of the transaction, the Company is still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. To assist management in the allocation, the Company engaged valuation specialists to prepare independent appraisals. The Company will finalize the amounts recognized as the information necessary to complete the analysis is obtained. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The following table presents the preliminary amounts recognized for assets acquired and liabilities assumed as of the acquisition date on June 16, 2017:

(Dollars in Millions)

Cash & Cash equivalents \$469 Inventory<sup>(1)</sup> 759 Accounts Receivable 485 93 Other current assets Property, plant and equipment 104 Goodwill 5,986 Intangible assets 25,010 **Deferred Taxes** 3 Other non-current assets 19 Total Assets Acquired 32,928

Current liabilities 531
Deferred Taxes 1,960
Other non-current liabilities 383
Total Liabilities Assumed 2,874

Net Assets Acquired \$30,054

(1) Includes adjustment of \$642 million to write-up the acquired inventory to its estimated fair value.

The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately \$6.0 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)

Intangible assets with definite lives:

Patents and trademarks \$24,230 Total amortizable intangibles 24,230

In-process research and development 780 Total intangible assets \$25,010

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. Total sales and a net loss for Actelion for the second quarter ended July 2, 2017 were \$91 million and \$116 million, respectively.

The following table provides pro forma results of operations for the fiscal second quarters and the fiscal six months ended July 2, 2017 and July 3, 2016, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects

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of the planned integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

Unaudited Pro forma Consolidated Results

Fiscal Six Fiscal Second Months Quarters Ended Ended

(Dollars in Millions Except Per Share Data) July 2, July 3, July 2, July 3, 2017 2016 2017 2016

 Net Sales
 37,83637,165
 19,42619,090

 Net Earnings
 7,890
 6,875
 3,788
 3,495

 Diluted Net Earnings per Common Share
 2.87
 2.45
 1.38
 1.25

In the fiscal second quarter of 2017, the Company recorded acquisition related costs of approximately \$0.2 billion before tax, which was recorded in Other (income)/expense.

Additionally, during the fiscal second quarter of 2017, the Company completed the acquisition of Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy.

During the fiscal first quarter of 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for \$4.4 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for \$2.3 billion and goodwill for \$1.8 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.5 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the preliminary purchase price allocation which is under review by the Company and is subject to change. The assets acquired were recorded in the Medical Devices segment.

Additionally, during the fiscal first quarter of 2017, the Company completed the acquisition of Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX<sup>TM</sup> Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

During the fiscal first quarter of 2017, the Company received a binding offer from Integra LifeSciences Holdings Corporation to purchase the Company's Codman Neurosurgery business for approximately \$1.0 billion. As of July 2, 2017, the assets held for sale were \$58 million of inventory, classified as prepaid expenses and other on the Consolidated Balance Sheet. The non-current assets classified as held for sale were \$33 million of property, plant and equipment, net and \$106 million of goodwill, classified as other assets on the Consolidated Balance Sheet.

During the fiscal first quarter of 2017, the Company announced it is engaging in a process to evaluate potential strategic options for the Johnson & Johnson Diabetes Care Companies, specifically LifeScan, Inc., Animas Corporation, and Calibra Medical, Inc. Strategic options may include the formation of operating partnerships, joint ventures or strategic alliances, a sale of the businesses, or other alternatives either separately or together. During the fiscal second quarter of 2017, the Company recorded an impairment charge of \$0.2 billion, primarily related to the insulin pump business. All strategic options are still being evaluated to determine the best opportunity to drive future growth and maximize shareholder value. There can be no assurance that this process will result in any transaction or other strategic alternative of any kind therefore, there were no assets held for sale as of July 2, 2017 related to the

## announcement.

During the fiscal second quarter of 2016, the Company completed the acquisitions of NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems and NeoStrata Company, Inc., a global leader in dermocosmetics. Additionally, during the fiscal second quarter of 2016, the Company completed the divestiture of its controlled substance raw material and active pharmaceutical ingredient (API) business. The proceeds from the divestiture were \$0.6 billion.

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## NOTE 11 — 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 July 2, 2017, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

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

## PRODUCT LIABILITY

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

The most significant of these cases include: the DePuy ASR<sup>TM</sup> XL Acetabular System and DePuy ASR<sup>TM</sup> Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; and INVOKANA®. As of July 2, 2017, in the U.S. there were approximately 2,000 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR<sup>TM</sup> XL Acetabular System and DePuy ASR<sup>TM</sup> Hip Resurfacing System; 9,700 with respect to the PINNA®LE Acetabular Cup System; 55,500 with respect to pelvic meshes; 13,800 with respect to RISPERDAL®; 20,000 with respect to XARELTO®; 4,800 with respect to body powders containing talc; and 800 with respect to INVOKANA®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR<sup>T</sup>XL Acetabular System and DePuy ASR<sup>T</sup>Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 9,500 claims, with more expected from the recent extension, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However,

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lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the U.S. settlement program and DePuy ASR Thip-related product liability litigation.

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

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 various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established an accrual with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with XARELTO®.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri,

New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. 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 District of New Jersey. In addition, there are federal cases pending in the Southern District of California and the Eastern District of Missouri. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with INVOKANA®.

## INTELLECTUAL PROPERTY

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

#### Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt's U.S. Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the District Court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the District Court for a new trial. A new trial is scheduled for August 2017.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER Mand CYPHER SELECT stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit, then dismissed the appeal in order to file a petition for review with the United States Supreme Court. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases and remanded this case to the U.S. Court of Appeals for the Federal Circuit for further proceedings. Cordis was divested in 2015, and the Company retained any liability that may result from this case.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. MedIdea alleges infringement of U.S. Patent Nos. 6,558,426; 8,273,132; 8,721,730 and 9,492,280 relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM<sup>TM</sup> Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that U.S. Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAI® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and U.S. Patent Nos. 8,323,310; 9,084,608; 9,241,759 and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction,

and a hearing on the motion is set for September 2017.

## Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleges that JBI's manufacture and sale of DARZALEX® (daratumumab) willfully infringes MorphoSys' U.S. Patent Nos. 8,263,746 and 9,200,061. MorphoSys is seeking money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. Trial in the case is scheduled to commence in August 2018.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC (a Pfizer company) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/

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GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the UK pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the UK. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the Court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the Court's decision and the injunction will be stayed pending the appeal.

## REMICADE® Related Cases

## U.S. Proceedings

In September 2013, Janssen Biotech, Inc. (JBI) and NYU Langone Medical Center (NYU) 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® (infliximab) (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent expires in September 2018 and is co-owned by JBI and NYU, with NYU having granted JBI an exclusive license to NYU's rights under the patent. Following several office actions by the patent examiner, including two further rejections, and responses by JBI, the USPTO issued a further action maintaining its rejection of the '471 patent. JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board, which issued a decision in November 2016 upholding the examiner's rejection. JBI has filed an appeal to the United States Court of Appeals for the Federal Circuit.

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (together, Celltrion) filed an application with the U.S. Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive U.S. marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including the '471 patent and U.S. Patent No. 7,598,083 (the '083 patent). In August 2016, the District Court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the '471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. This case and the appeal of the reexamination of the '471 patent have been designated companion cases and will be heard by the same panel of judges at the Federal Circuit.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the '083 patent, one against Celltrion in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. Although the '083 patent is already asserted in the existing lawsuit against Celltrion, the additional lawsuit expands the claims to include any use of the cell culture media made in the United States to manufacture Celltrion's biosimilar. This additional lawsuit against Celltrion has been consolidated with the existing lawsuit discussed above. Hospira has moved to dismiss all counts of the lawsuit related to the '083 patent as to it. Celltrion has moved to dismiss all counts of the lawsuit related to the '083 patent without prejudice for failure to join all the co-owners of the '083 patent as plaintiffs. The trial has been postponed pending resolution of these motions.

The FDA approved Celltrion's infliximab biosimilar for sale in the United States in April 2016. Hospira's parent company, Pfizer Inc., launched Celltrion's infliximab biosimilar in the United States in late 2016.

In April 2017, JBI received notice that the FDA approved a marketing application submitted by Samsung Bioepis Co. Ltd. (Samsung) for the sale of its infliximab biosimilar in the United States. In May 2017, JBI filed a patent infringement lawsuit against Samsung in the United States District Court for the District of New Jersey alleging that the sale of its biosimilar product may infringe three of JBI's patents. In July 2017, Samsung announced the U.S. launch

of its biosimilar, which is being commercialized by Merck in the United States.

## **Canadian Proceedings**

In March 2013, Hospira filed an impeachment proceeding in the Federal Court of Canada 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 JBI. In October 2013, Kennedy, along with JBI, Janssen Inc. (Janssen) and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against 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. Janssen and Kennedy are seeking damages and an injunction against Hospira. A trial in this patent action concluded in October 2016, and closing arguments took place in January 2017. The parties are awaiting a decision. The remaining REMICADE® patent at issue in the action expired August 1, 2017.

In January 2014, Health Canada approved Celltrion's SEB to REMICADE®, allowing Celltrion to market its infliximab biosimilar in Canada, regardless of the pending patent action. In June 2014, Health Canada approved Hospira's SEB to REMICADE®. In July 2014, Janssen filed a lawsuit in the Federal Court of Canada challenging the Canadian Minister of Health's marketing approval (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 a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira's Notice of Compliance, subject to Health Canada's appeal, which was filed in June 2015. Nevertheless, Hospira began marketing an infliximab biosimilar as a distributor under Celltrion's Notice of Compliance. In October 2016, the appeals court reversed the Consent Judgment. In June 2017, the Supreme Court of Canada denied Janssen's application for leave to appeal. The REMICADE® patent at issue in the lawsuit expired August 1, 2017. Hospira continues to market and sell Celltrion's infliximab biosimilar in Canada.

## 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. The inter partes review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used by generic companies in conjunction with these ANDAs and lawsuits to challenge patents held by the Company's subsidiaries.

## **CONCERTA®**

In October 2016, ALZA Corporation and Janssen Pharmaceuticals, Inc. (together, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals LLC (together, Amneal), who filed an ANDA seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent Nos. 8,163,798 and 9,144,549. Janssen is seeking an order enjoining Amneal from marketing its generic version of CONCERTA® before the expiration of the patents. In July 2017, the parties filed a stipulation of dismissal based on Amneal's agreement not to market its generic version of CONCERTA® before the expiration of the patents.

## **ZYTIGA®**

In July 2015, Janssen Biotech, Inc. (JBI), Janssen Oncology, Inc. (Janssen Oncology) and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent No. 8,822,438 (the '438 patent). The generic companies currently 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 has set a trial date of October 2017. Subsequently, Janssen and BTG initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the '438 patent.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

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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 '438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy's, Sun, Teva, West-Ward and Hikma have filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the '438 patent. The Company is awaiting final written decisions in all of the IPRs.

## **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) initiated patent infringement lawsuits in the United States District Courts for the District of Delaware and the District of West Virginia, respectively, against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan), who filed an ANDA seeking approval to market a generic version of COMPLERA® before the expiration of U.S. Patent Nos. 8,841,310, 7,125,879 and 8,101,629. In July 2017, the West Virginia lawsuit was dismissed without prejudice by stipulation of the parties.

In the Delaware lawsuit, Janssen and Gilead amended their complaint to add claims for patent infringement with respect to U.S. Patent Nos. 8,080,551; 7,399,856; 7,563,922; 8,101,752 and 8,618,291. A trial in the Delaware action has been scheduled for February 2018.

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

## **XARELTO®**

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (together, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer's U.S. Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (together, Aurobindo); Breckenridge Pharmaceutical, Inc.; Invagen Pharmaceuticals Inc. (Invagen); Micro Labs USA Inc. and Micro Labs Ltd (together, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. Trial is scheduled for March 2018.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (together, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's U.S. Patent No. 9,539,218 relating to XARELTO®. The following generic companies are named defendants: Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (together, Taro); Aurobindo; Micro; Mylan; Sigmapharm; Invagen; Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

## RISPERDAL® CONSTA®

On November 30, 2016, the United States Patent and Trademark Office (USPTO) instituted an Inter Partes Review filed by Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Sandong Luye Pharmaceutical Co., Ltd. and Nanjing

Luye Pharmaceutical Co., Ltd., seeking to invalidate U.S. Patent No. 6,667,061 relating to RISPERDAL CONSTA®. Janssen Pharmaceuticals, Inc. markets RISPERDAL CONSTA® pursuant to a license from Alkermes Pharma Ireland Ltd. A decision by the USPTO is expected in November 2017.

## INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (together, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's U.S. Patent Nos. 7,943,582 and 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp.; Aurobindo Pharma USA Inc.; Macleods Pharmaceuticals Ltd.; Invagen Pharmaceuticals, Inc.; Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz) and Teva Pharmaceuticals USA, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Zydus and Sandoz, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's U.S. Patent Nos. 7,943,788 and 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC's U.S. Patent No. 8,785,403 relating to INVOKAMET®. Janssen is the exclusive licensee of the asserted patents.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA® and/or INVOKAMET® before the expiration of the relevant patents.

## **VELETRI®**

In July 2017, Actelion Pharmaceuticals Ltd. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Limited (collectively, Sun Pharmaceutical), who filed an ANDA seeking approval to market a generic version of VELETRI® before the expiration of United States Patent No. 8,598,227. Actelion is seeking an order enjoining Sun Pharmaceutical from marketing its generic version of VELETRI® before the expiration of the patent. GOVERNMENT PROCEEDINGS

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

## Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court,

were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, the parties are awaiting assignment of a trial date. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

#### 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 FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities. In addition, in February 2011, the government served McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI) 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, Inc. (now JJCI) entered a guilty plea to a misdemeanor violation of the U.S. Food, Drug, and Cosmetic Act and agreed to pay a fine to resolve the matter.

The Companies received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies cooperated with these inquiries, which were coordinated through a multi-state coalition. In May 2017, the Companies and the multi-state coalition agreed to a settlement that resolves these matters.

In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC, Inc. (now JJCI) 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. Following the appeal and reversal of the trial court's grant of the Companies' motion to dismiss, the case was sent back to the trial court. In March 2017, JJCI and McNeil Consumer Healthcare served an "Offer to Allow Judgment" in the case without any admission or finding of fact or wrongdoing. The offer allows the court to enter a judgment with specified relief without a trial. Oregon accepted the offer, and in May 2017 the court entered a stipulated judgment.

# Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in numerous lawsuits brought by certain states, counties and cities related to marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief.

JPI and other pharmaceutical companies have received subpoenas or requests for information related to opioids marketing practices from three state Attorneys General: New Hampshire, New Jersey and Tennessee. JPI has also received a request for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

To date, complaints against pharmaceutical manufacturers, including J&J and JPI, were filed by the following state and local governments: the State of Mississippi, in the Chancery Court of the First Judicial District of Hinds County; the State of Missouri in the Circuit Court of St. Louis City; the State of Ohio, in the Ross County Court of Common Pleas; the State of Oklahoma, in the District Court of Cleveland County; the California Counties of Santa Clara and Orange, in state court in Orange County, California; San Joaquin County and the City of Stockton and the Montezuma Fire Protection District, in state court in San Joaquin County, California; the Illinois Counties of Jersey and Union, in the Illinois Circuit Court; the New York Counties of Broome, Dutchess, Erie, Nassau, Orange, Schenectady, Seneca, Suffolk and Sullivan, which have been consolidated in the New York Supreme Court in Suffolk County; the City of Chicago, initially in Cook County Circuit Court and later removed to the United States District Court for the Northern District of Illinois; the City of Dayton, Ohio and the City of Lorain, Ohio, each in the Ohio Court of Common Pleas. These cases are in early stages of litigation.

Other

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 RELIEVA STRATUS® Spacer). In March 2016, Acclarent executed a civil settlement with the United States Justice Department and other agencies to resolve this investigation. Johnson & Johnson was not a party to this settlement and there was no admission of liability. In a separate matter, in July 2016, the former President/CEO and Vice President of Sales of Acclarent (the former Acclarent officers), were convicted of misdemeanor violations in connection with the sale and marketing of the RELIEVA STRATUS® Spacer. There are no charges against Acclarent, Ethicon, Inc. or Johnson & Johnson in this matter.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR<sup>TM</sup> XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the District Court's dismissal in part and affirmed the decision to deny the relators' request to file a third amended complaint. Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. The states are seeking monetary and injunctive relief. 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 May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon Inc. and Ethicon US, LLC alleging violations of their consumer protection statutes. In August 2016, Kentucky filed a similar complaint against the companies. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 44 states and the District of Columbia. In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests. In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI) and seeks injunctive and monetary relief. The parties have agreed to adjourn the trial date and currently expect the trial to be re-scheduled to the spring of 2018.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice (DOJ) relating to allegations concerning the sales and marketing practices of OLYSIO<sup>TM</sup>.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests in June and December 2016, from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients.

In March 2017, Janssen Biotech, Inc. (JBI) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April 2017, Johnson & Johnson received a subpoena from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for OLYSIO<sup>TM</sup>, SIMPONI® and STELARA®. The subpoena also seeks documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes spinal implants at three hospitals in Boston as well as interactions of Company employees with physicians at these hospitals.

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

## **GENERAL LITIGATION**

In 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 appeal and reversal of its initial grant of a motion for class certification, on remand, the District Court in October 2015 again granted a motion by the plaintiffs for class certification. OCD's motion for summary judgment was argued before the Court in January 2017 and the parties are awaiting a decision. OCD was divested in 2014 and Johnson & Johnson retained any liability that may result from these cases.

In September 2011, Johnson & Johnson & Johnson 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, Pennsylvania 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 addition, in April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in May 2017, the Court denied a motion to dismiss the amended complaint.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson (J&J) and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI), alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal

injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the Court granted J&J and JJCI's motion to dismiss one of the cases.

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

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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 allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the Court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification.

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 B.V. (now Janssen Vaccines & Prevention B.V.) (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 April 2017, the Arbitration Panel ruled that Crucell breached its agreement with Adimmune, but awarded Adimmune zero 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, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against Lifescan Inc., Johnson & Johnson, other diabetes test strip manufacturers, and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC. Lonza alleges that Janssen breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages.

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.

#### NOTE 12— 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 and other charges of approximately \$2.0 billion to \$2.4 billion. In the fiscal six months of 2017, the Company recorded a pre-tax charge of \$289 million, of which \$17 million was included in cost of products sold and \$176 million was included in other (income) expense. In the fiscal second quarter of 2017, the Company recorded a pre-tax charge of \$128 million, of which \$13 million was included in cost of products sold and \$104 million was included in other (income) expense. In the fiscal second quarter of 2017, the Company recorded a \$90 million accrual adjustment to the severance reserve due to higher voluntary separation than anticipated. See the following table for additional details. Total project costs of \$1.6 billion have been recorded since the restructuring announcement.

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 18 months, subject to any consultation procedures in countries, where required. Approximately 2,100 positions have been eliminated of which 1,650 received separation payments since the restructuring announcement.

The Company estimates that approximately one half of the cumulative pre-tax costs will result in cash outlays, including

approximately \$400 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 related reserves and the associated spending under this initiative through the first fiscal six months of 2017:

(Dollars in Millions)	Severance	Asset Write-offs	Other**	Total
Reserve balance, January 1, 2017	\$ 380	_	1	381

## Current year activity:

Charges	_	112	267	379
Cash payments	(39	) —	(264	) (303)
Settled non cash	_	(112	) —	(112)
Accrual adjustment	(90	) —		(90)

Reserve balance, July 2, 2017\* \$ 251 — 4 255

<sup>\*</sup>Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.

<sup>\*\*</sup>Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Item 2 — MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## **RESULTS OF OPERATIONS**

## **Analysis of Consolidated Sales**

For the first fiscal six months of 2017, worldwide sales were \$36.6 billion, a total increase of 1.8%, including operational growth of 2.5% as compared to 2016 first fiscal six months sales of \$36.0 billion. Currency fluctuations had a negative impact of 0.7% for the first fiscal six months of 2017. In the first fiscal six months of 2017, the net impact of acquisitions and divestitures on worldwide operational sales growth was a positive 1.7%.

Sales by U.S. companies were \$19.1 billion in the first fiscal six months of 2017, which represented an increase of 1.1% as compared to the prior year. In the first fiscal six months of 2017, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a positive 2.0%. Sales by international companies were \$17.5 billion, an increase of 2.5%, including operational growth of 4.0%, partially offset by a negative currency impact of 1.5% as compared to the first fiscal six months sales of 2016. In the first fiscal six months of 2017, the net impact of acquisitions and divestitures on the international operational sales growth was a positive 1.3%.

In the first fiscal six months of 2017, sales by companies in Europe achieved growth of 1.9%, which included operational growth of 5.4% and a negative currency impact of 3.5%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 2.8%, which included an operational decline of 0.2%, and a positive currency impact of 3.0%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 3.1%, including operational growth of 4.1% partially offset by a negative currency impact of 1.0%.

For the fiscal second quarter of 2017, worldwide sales were \$18.8 billion, a total increase of 1.9%, including operational growth of 2.9% as compared to 2016 fiscal second quarter sales of \$18.5 billion. Currency fluctuations had a negative impact of 1.0% for the fiscal second quarter of 2017. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on worldwide operational sales growth was a positive 2.4%.

Sales by U.S. companies were \$9.7 billion in the fiscal second quarter of 2017, which represented an increase of 1.6% as compared to the prior year. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a positive 2.6%. Sales by international companies were \$9.1 billion, an increase of 2.3%, including operational growth of 4.4%, partially offset by a negative currency impact of 2.1% as compared to the fiscal second quarter sales of 2016. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on the international operational sales growth was a positive 2.4%.

In the fiscal second quarter of 2017, sales by companies in Europe achieved growth of 3.5%, which included operational growth of 6.7% and a negative currency impact of 3.2%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 2.8%, which included an operational decrease of 2.7%, and a negative currency impact of 0.1%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 3.2%, including operational growth of 4.9% partially offset by a negative currency impact of 1.7%.

## ANALYSIS OF SALES BY BUSINESS SEGMENTS

#### Consumer

Consumer segment sales in the first fiscal six months of 2017 were \$6.7 billion, an increase of 1.4% as compared to the same period a year ago, including operational growth of 1.6% partially offset by a negative currency impact of 0.2%. U.S. Consumer segment sales increased by 5.8%. International Consumer segment sales decreased by 1.7%, including an operational decrease of 1.3% and a negative currency impact of 0.4%. In the first fiscal six months of 2017, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was a positive 3.2%.

Major Consumer Franchise Sales\* — Fiscal Six Months Ended

(Dollars in Millions)	July 2,	July 3,	Total	Operations	Currency	
(Dollars III Willions)	2017	2016	Change	Change	Change	
OTC	\$2,019	\$1,995	1.2 %	1.8 %	(0.6)%	
Beauty	2,057	1,855	10.9	11.4	(0.5)	
Baby Care	949	1,013	(6.3)	(6.3)	0.0	
Oral Care	756	788	(4.1)	(3.9)	(0.2)	
Women's Health	518	534	(3.0)	(4.2)	1.2	
Wound Care/Other	407	429	(5.1)	(5.0)	(0.1)	
<b>Total Consumer Sales</b>	\$6,706	\$6,614	1.4 %	1.6 %	(0.2)%	

<sup>\*</sup>Prior year amounts have been reclassified to conform to current year presentation.

Consumer segment sales in the fiscal second quarter of 2017 were \$3.5 billion, an increase of 1.7% as compared to the same period a year ago, including operational growth of 2.3% and a negative currency impact of 0.6%. U.S. Consumer segment sales increased by 7.4%. International Consumer segment sales decreased by 2.2%, including an operational decline of 1.1% and a negative currency impact of 1.1%. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on the Consumer segment operational sales growth was a positive 3.1%.

Major Consumer Franchise Sales\* — Fiscal Second Quarters Ended

(Dollars in Millions)	July 2,	July 3,	Total	Operations	Currency	
(Donars in Willions)	2017	2016	Change	Change	Change	
OTC	\$1,006	\$996	1.0 %	2.1 %	(1.1)%	
Beauty	1,076	976	10.2	11.0	(0.8)	
Baby Care	494	530	(6.8)	(6.5)	(0.3)	
Oral Care	394	403	(2.2)	(1.7)	(0.5)	
Women's Health	276	283	(2.5)	(3.3)	0.8	
Wound Care/Other	232	231	0.4	0.9	(0.5)	
<b>Total Consumer Sales</b>	\$3,478	\$3,419	1.7 %	2.3 %	(0.6)%	

<sup>\*</sup>Prior year amounts have been reclassified to conform to current year presentation.

The OTC franchise achieved operational growth of 2.1% as compared to the prior year fiscal second quarter. Growth was primarily driven by sales of upper respiratory products, primarily ZYRTEC®, and sales outside the U.S. of anti-smoking aids.

The Beauty franchise achieved operational growth of 11.0% as compared to the prior year fiscal second quarter. Growth was primarily driven by sales from recent acquisitions, primarily Vogue International LLC, which contributed approximately 9.6% of the operational growth. Additionally, sales of NEUTROGENA® sun protection products

contributed to the growth.

The Baby Care franchise experienced an operational decline of 6.5% as compared to the prior year fiscal second quarter due to competitive pressure.

The Oral Care franchise experienced an operational decline of 1.7% as compared to the prior year fiscal second quarter primarily driven by category declines in the U.S. partially offset by growth in Asia Pacific.

The Women's Health franchise experienced an operational decline of 3.3% as compared to the prior year fiscal second quarter primarily due to category slowdown in Europe and the U.S. divestiture of TUCKS<sup>®</sup>.

The Wound Care/Other franchise grew operationally by 0.9% as compared to the prior year fiscal second quarter primarily due to U.S. increased promotional activity partially offset by competitive pressure outside the U.S.

#### Pharmaceutical

Pharmaceutical segment sales in the first fiscal six months of 2017 were \$16.9 billion, an increase of 0.3% as compared to the same period a year ago, with an operational increase of 1.2% and a negative currency impact of 0.9%. U.S. Pharmaceutical sales decreased 2.0% as compared to the same period a year ago. International Pharmaceutical sales increased by 3.7%, including operational growth of 5.9% partially offset by a negative currency impact of 2.2%. In the first fiscal six months of 2017, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a negative 0.1%. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the Pharmaceutical segment operational growth for the first fiscal six months of 2017, by approximately 3.0%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales* — Fiscal Six Months I	nths Ended	Six Month	<ul> <li>Fiscal Six</li> </ul>	Sales* —	Area	Therapeutic	harmaceutical	Maior	N
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Wajor Filarmaceurical Therapeuric Area Sales — Pr				_	_	
(Dollars in Millions)	July 2, 2017	July 3,	Total	-		Currency
·		2016	Change	_	•	Change
Total Immunology	\$5,889	\$5,948	(1.0)%	(0.7)	)%	(0.3)%
$REMICADE^{@}$	3,202	3,559	(10.0)	(9.9)	)	(0.1)
SIMPONI®/ SIMPONI ARIA®	867	838	3.5	3.8		(0.3)
STELARA®	1,806	1,539	17.3	18.3		(1.0)
Other Immunology	14	12	16.7	14.0		2.7
Total Infectious Diseases	1,541	1,605	(4.0)	(3.0)	)	(1.0)
EDURANT®/rilpivirine	220	250	26.6	20.2		(0.6.)
•	328	259	26.6	29.2		(2.6)
PREZISTA®/ PREZCOBIX®/REZOLSTA®	884	911	(3.0)	(2.0	)	(1.0)
Other Infectious Diseases	329	435	(24.4)	(24.4	)	0.0
Total Neuroscience	2,964	3,151	(5.9)	(4.9	)	(1.0)
CONCERTA®/methylphenidate	390	469	(16.8)	(16.2	)	(0.6)
INVEGA SUSTENNA®/XEPLION®/TRINZA®	1,233	1,073	14.9	16.2		(1.3)
RISPERDAL® CONSTA®	414	461	(10.2)	(8.9)	)	(1.3)
Other Neuroscience	927	1,148	(19.3)	(18.4	)	(0.9)
Total Oncology	3,321	2,828	17.4	19.2		(1.8)
DARZALEX®	554	209	**	**		***
IMBRUVICA®	859	556	54.5	56.8		(2.3)
VELCADE®	570	646	(11.8)	(9.0	)	(2.8)
ZYTIGA®	1,081	1,159	(6.7)	(5.7	)	(1.0)
Other Oncology	257	258	(0.4)	1.3		(1.7)
Pulmonary Hypertension	91	_	****	****		
OPSUMIT®	45		****	****		_
TRACLEER®	26		****	****		_
UPTRAVI®	9		****	****		_
Other	11		****	****		_
Cardiovascular / Metabolism / Other	3,074	3,300	(6.8)	(6.0	)	(0.8)
XARELTO®	1,155	1,161	(0.5)	(0.5	)	_
INVOKANA®/ INVOKAMET®	579	708	(18.2)	(17.9	)	(0.3)
PROCRIT®/EPREX®	502	596	(15.8)		)	(0.5)
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Other	838	835	0.4	3.1		(2.7)
Total Pharmaceutical Sales	\$16,880	\$16,832	0.3	% 1.2	%	(0.9)%

Pharmaceutical segment sales in the fiscal second quarter of 2017 were \$8.6 billion, a decrease of 0.2% as compared to the same period a year ago, with an operational increase of 1.0% offset by a negative currency impact of 1.2%. U.S. Pharmaceutical sales decreased 2.6% as compared to the same period a year ago. International Pharmaceutical sales increased by 3.3%, including operational growth of 6.1% partially offset by a negative currency impact of 2.8%. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a positive 0.5%. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the Pharmaceutical segment operational growth for the fiscal second quarter of 2017, by approximately 4.0%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales\* — Fiscal Second Quarters Ended

(Dollars in Millions)		y 2, July 3, Total Operation		tions	s Currency		
		2016	Change	Chang	e	Char	ıge
Total Immunology	\$2,959	\$3,038	(2.6)%	(1.9	)%	(0.7)	)%
REMICADE®	1,530	1,780	(14.0)	(13.6	)	(0.4)	)
SIMPONI®/ SIMPONI ARIA®	439	448	(2.0)	(1.0	)	(1.0	)
STELARA®	983	804	22.3	23.4		(1.1	)
Other Immunology	7	6	16.7	15.8		0.9	
Total Infectious Diseases	792	829	(4.5)	(3.4	)	(1.1	)
EDURANT®/rilpivirine	179	140	27.9	30.0		(2.1	)
PREZISTA®/ PREZCOBIX®/ REZOLSTA®	454	459	(1.1)	(0.1	)	(1.0	)
Other Infectious Diseases	159	230	(30.9)	(30.4	)	(0.5)	)
Total Neuroscience	1,467	1,602	(8.4)	(7.0	)	(1.4	)
CONCERTA®/ methylphenidate	181	238	(23.9)	(22.8)	)	(1.1	)
INVEGA SUSTENNA®/XEPLION®/TRINZA®	629	560	12.3	13.7		(1.4	)
RISPERDAL CONSTA®	207	230	(10.0)	(8.5	)	(1.5	)
Other Neuroscience	450	574	(21.6)	(20.0	)	(1.6	)
Total Oncology	1,727	1,474	17.2	19.2		(2.0	)
DARZALEX®	299	108	**	**		***	
IMBRUVICA®	450	295	52.5	55.1		(2.6	)
VELCADE®	290	342	(15.2)	(12.6	)	(2.6	)
ZYTIGA®	558	601	(7.2)	(5.8	)	(1.4	)
Other Oncology	130	128	1.6	3.1		(1.5	)
Pulmonary Hypertension	91	_	****	****			
OPSUMIT®	45	_	****	****			
TRACLEER®	26	_	****	****		_	
UPTRAVI®	9	_	****	****		_	
Other	11	_	****	****			
Cardiovascular / Metabolism / Other	1,599	1,711	(6.5)	(5.5	)	(1.0	)
XARELTO <sup>®</sup>	642	594	8.1	8.1		_	
INVOKANA®/ INVOKAMET®	295	383	(23.0)	(22.5)	)	(0.5)	)
PROCRIT®/ EPREX®	255	322	(20.8)	(20.1	)	(0.7)	)
Other	407	412	(1.2)	1.9		(3.1	)
Total Pharmaceutical Sales	\$8,635	\$8,654	(0.2)%	1.0	%	(1.2	)%
*Driver year amounts have been realessified to conform	to our	ant rican	mmo direct	licalas.			

<sup>\*</sup>Prior year amounts have been reclassified to conform to current year product disclosure.

<sup>\*</sup>Prior year amounts have been reclassified to conform to current year product disclosure.

<sup>\*\*</sup>Percentage greater than 100%

<sup>\*\*\*</sup> Not meaningful

<sup>\*\*\*\*</sup>On June 16, 2017, the Company acquired Actelion.

\*\*Percentage greater than 100%

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\*\*\* Not meaningful

\*\*\*\*On June 16, 2017, the Company acquired Actelion.

Immunology products experienced an operational decline of 1.9% as compared to the same period a year ago. Immunology was negatively impacted by approximately 6.0% by a positive adjustment to previous reserve estimates recorded in the fiscal second quarter of 2016 and lower sales of REMICADE®(infliximab) due to biosimilar competition. The decline was partially offset by strong growth of STELARA® (ustekinumab).

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the 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 introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the U.S. Food and Drug Administration (FDA) and compliance with the 180-day notice provisions of the Biologics Price Competition and Innovation Act. In April 2016, the FDA approved for sale in the United States an infliximab biosimilar to be marketed by a subsidiary of Pfizer Inc., which was launched in the United States in late 2016. In addition in April 2017, the FDA approved for sale in the United States an infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. The Company continues to assert REMICADE® related patent rights. See Note 11 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products experienced an operational decline of 3.4% as compared to the same period a year ago. Lower sales of OLYSIO® (simeprevir) and PREZISTA® (darunavir/cobicistat) were partially offset by strong sales growth of PREZCOBIX®/REZOLSTA®(darunavir/cobicistat) and sales of EDURANT®/rilpivirine.

Neuroscience products experienced an operational decline of 7.0% as compared to the same period a year ago. Strong sales of INVEGA SUSTENNA®/XEPLION®/ TRINZA®(paliperidone palmitate) were offset by lower sales of CONCERTA®/methylphenidate in the U.S. due to generic competition and the impact of divestitures in the Neuroscience therapeutic area.

Oncology products achieved strong operational sales growth of 19.2% as compared to the same period a year ago. Contributors to the growth were strong sales of IMBRUVICA® (ibrutinib) and DARZALEX® (daratumumab) due to increased patient uptake and new launches of DARZALEX® (daratumumab) in Europe. Lower sales of ZYTIGA® (abiraterone acetate) in the U.S. were partially offset by growth in Japan.

Pulmonary Hypertension is a new therapeutic area which was established with the acquisition of Actelion on June 16, 2017. See Note 10 to the Consolidated Financial Statements for additional details regarding the acquisition.

Cardiovascular / Metabolism / Other products experienced an operational decline of 5.5% as compared to the same period a year ago. Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. primarily due to an increase in price discounts were partially offset by sales growth of XARELTO®(rivaroxaban) due to increased market share. Additionally, Cardiovascular / Metabolism / Other was negatively impacted by a positive adjustment to previous reserve estimates, primarily PROCRIT®, recorded in the fiscal second quarter of 2016.

## **Medical Devices**

The Medical Devices segment sales in the first fiscal six months of 2017 were \$13.0 billion, an increase of 4.0% as compared to the same period a year ago, with operational growth of 4.7% and a negative currency impact of 0.7%. U.S. Medical Devices sales increased 4.1%. International Medical Devices sales increased by 3.9%, including an operational increase of 5.3% and a negative currency impact of 1.4%. In the first fiscal six months of 2017, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a positive 3.3%.

Major Medical Devices Franchise Sales — Fiscal Six Months Ended

(Dallars in Millians)	July 2,	July 3,	Total	Operations	Currency
(Dollars in Millions)	2017	2016	Change	Change	Change
Orthopaedics	\$4,668	\$4,696	(0.6)%	0.1 %	(0.7)%
Hips	702	691	1.6	2.4	(0.8)
Knees	783	774	1.2	2.0	(0.8)
Trauma	1,285	1,278	0.5	1.0	(0.5)
Spine & Other	1,898	1,953	(2.8)	(2.1)	(0.7)
Surgery	4,655	4,625	0.6	1.5	(0.9)
Advanced	1,810	1,725	4.9	6.0	(1.1)
General	2,188	2,197	(0.4)	0.5	(0.9)
Specialty	657	703	(6.5)	(6.5)	0.0
Vision Care	1,853	1,325	39.8	40.2	(0.4)
Contact Lenses/Other	1,436	1,325	8.4	8.8	(0.4)
Surgical	417	_	*	*	
Cardiovascular	1,022	913	11.9	12.8	(0.9)
Diabetes Care	820	900	(8.9)	(8.1)	(0.8)
Diagnostics	1	59	**	**	**
Total Madical Davisco Cales	¢ 12 010	¢ 12 5 10	10 01	17 07	(0.7.)0/

Total Medical Devices Sales \$13,019 \$12,518 4.0 % 4.7 % (0.7 )%

The Medical Devices segment sales in the fiscal second quarter of 2017 were \$6.7 billion, an increase of 4.9% as compared to the same period a year ago, with operational growth of 5.9% partially offset by a negative currency impact of 1.0%. U.S. Medical Devices sales increased 6.1%. International Medical Devices sales increased by 3.9%, including an operational increase of 5.8% partially offset by a negative currency impact of 1.9%. In the fiscal second quarter of 2017, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a positive 4.8%.

<sup>\*</sup>On February 27, 2017, the Company acquired Abbott Medical Optics (AMO)

<sup>\*\*</sup>On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise)

Major Medical Devices Franchise Sales — Fiscal Second Quarters Ended

(Dollars in Millians)	July 2,	July 3,	Total	Operations	Currency
(Dollars in Millions)	2017	2016	Change	Change	Change
Orthopaedics	\$2,343	\$2,355	(0.5)%	0.4 %	(0.9)%
Hips	350	349	0.3	1.3	(1.0)
Knees	385	385	0.0	0.8	(0.8)
Trauma	643	636	1.1	1.9	(0.8)
Spine & Other	965	985	(2.0)	(1.1)	(0.9)
Surgery	2,384	2,397	(0.5)	0.6	(1.1)
Advanced	933	909	2.6	4.0	(1.4)
General	1,114	1,127	(1.2)	0.0	(1.2)
Specialty	337	361	(6.6)	(6.2)	(0.4)
Vision Care	1,055	685	54.0	55.0	(1.0)
Contact Lenses/Other	753	685	9.9	10.9	(1.0)
Surgical	302	_	*	*	_
Cardiovascular	523	470	11.3	12.6	(1.3)
Diabetes Care	421	471	(10.6)	(9.5)	(1.1)
Diagnostics	_	31	**	**	**
Total Medical Devices Sales	\$6,726	\$6,409	4.9 %	5.9 %	(1.0)%

Total Medical Devices Sales \$6,726 \$6,409 4.9 % 5.9

The Orthopaedics franchise achieved operational sales growth of 0.4% as compared to the prior year fiscal second quarter. Sales growth was primarily driven by U.S. sales of the hip primary stem platform, the trauma TFNA nailing system, the ATTUNE® Knee System, and sports medicine products. Growth was negatively impacted by competitive and pricing pressures.

The Surgery franchise achieved operational sales growth of 0.6% as compared to the prior year fiscal second quarter. Operational growth in Advanced Surgery was primarily driven by endocutter, energy, including recent acquisitions, and biosurgery products. General Surgery was flat as compared to the prior year fiscal second quarter. Sales growth of sutures was offset by declines in mechanical products. The operational decline in Specialty Surgery was primarily driven by aesthetic products and Advanced Sterilization Products.

The Vision Care franchise achieved operational sales growth of 55.0% as compared to the prior year fiscal second quarter. Operational growth was driven by sales from the recent acquisition of AMO, with the majority of AMO sales in the surgical category, and new product launches in the contact lenses category.

The Cardiovascular Care franchise achieved strong operational sales growth of 12.6% as compared to the prior year fiscal second quarter. Strong operational growth in the electrophysiology business was driven by market growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

The Diabetes Care franchise experienced an operational sales decline of 9.5% as compared to the prior year fiscal second quarter primarily due to price declines and competitive pressure.

## ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income for the first fiscal six months of 2017 was \$10.3 billion representing 28.2% of sales as compared to \$10.2 billion in the first fiscal six months of 2016, representing 28.4% of

<sup>\*</sup>On February 27, 2017, the Company acquired Abbott Medical Optics (AMO) \*\*On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise)

sales. Consolidated earnings before provision for taxes on income for the fiscal second quarter of 2017 was \$4.7 billion representing 25.2% of sales as compared to \$4.9 billion in the fiscal second quarter of 2016, representing 26.5% of sales. The decrease as a percent to sales in both periods was primarily due to higher amortization and other costs related to the recent acquisitions, primarily Actelion and AMO and an asset impairment charge of \$0.2 billion primarily related to the insulin pump business as compared to the prior period. This was partially offset by lower litigation costs in 2017 and a lower restructuring charge of

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\$0.1 billion as compared to 2016. Additionally, the fiscal second quarter and six months of 2017 included a gain of \$0.2 billion related to monetization of future royalty receivables.

#### Cost of Products Sold

Consolidated costs of products sold for the first fiscal six months of 2017 increased to 30.6% from 29.6% of sales as compared to the same period a year ago. Consolidated costs of products sold for the fiscal second quarter of 2017 increased to 30.9% from 28.9% of sales as compared to the same period a year ago. The unfavorable increase in both periods was primarily driven by higher amortization expense related to the recent acquisitions, transactional currency impacts and product mix. The intangible asset amortization expense for the fiscal six months of 2017 and 2016 was \$809 million and \$576 million, respectively.

### Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the first fiscal six months of 2017 decreased slightly to 27.3% from 27.4% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal second quarter of 2017 was 28.0% of sales, which is flat as compared to the same period a year ago.

### Research and Development Expense

Worldwide costs of research and development activities for the first fiscal six months of 2017 was 11.9% of sales, which was flat as compared to the same period a year ago. Worldwide costs of research and development activities for the fiscal second quarter of 2017 decreased slightly to 12.1% from 12.2% of sales as compared to the same period a year ago. Both periods in 2017 are consistent with the prior year.

### Interest (Income) Expense

Interest income in the first fiscal six months and fiscal second quarter of 2017 was higher than the same period a year ago due to higher cash, cash equivalents and marketable securities balances during the period and higher average interest rates. The ending balance of cash, cash equivalents and marketable securities was \$12.9 billion at the end of the fiscal second quarter of 2017, which is a decrease of \$29.7 billion as compared to the same period a year ago. The decrease in the balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes including, acquisitions, primarily the Actelion acquisition for \$28.8 billion, net of cash acquired, on June 16, 2017.

Interest expense in the first fiscal six months and fiscal second quarter of 2017 was higher as compared to the same periods a year ago. At the end of the fiscal second quarter of 2017, the Company's debt position was \$34.6 billion as compared to \$26.2 billion the same period a year ago. The higher debt balance of approximately \$8.4 billion was primarily due to increased borrowings. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, primarily the stock repurchase program.

### Other (Income) Expense, Net

Other (income) expense, net for the first fiscal six months of 2017 was slightly favorable by \$0.1 billion as compared to the same period a year ago. The first fiscal six months of 2017 included a gain of \$0.2 billion related to monetization of future royalty receivables, lower litigation expense of \$0.2 billion and a higher gain of \$0.1 billion related to the sale of certain investments in equity securities as compared to the same period a year ago. This was

offset by \$0.2 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of \$0.2 billion primarily related to the insulin pump business and a higher restructuring related charge of \$0.1 billion as compared to the same period a year ago.

Other (income) expense, net for the fiscal second quarter of 2017 was slightly unfavorable as compared to the same period a year ago. The fiscal second quarter of 2017 included \$0.2 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of \$0.2 billion primarily related to the insulin pump business and a higher restructuring related charge of \$0.1 billion as compared to the same period a year ago. This was partially offset by a gain of \$0.2 billion related to monetization of future royalty receivables, lower litigation expense of \$0.1 billion and lower asset write-downs of \$0.1 billion as compared to the fiscal second quarter of 2016.

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#### INCOME BEFORE TAX BY SEGMENT

Income before tax by segment of business for the first fiscal six months were as follows:

	Income 1	Before	Comment Colos		Percent of	
	Tax		Segment Sales		Segment Sales	
(Dollars in Millions)	July 2,	July 3,	July 2,	July 3,	July 2,	July 3,
	2017	2016	2017	2016	2017	2016
Consumer	\$1,254	\$1,137	\$6,706	\$6,614	18.7%	17.2%
Pharmaceutical	7,077	7,031	16,880	16,832	41.9	41.8
Medical Devices	2,555	2,515	13,019	12,518	19.6	20.1
Segment total	10,886	10,683	36,605	35,964	29.7	29.7
Less: Expenses not allocated to segments (1)	563	485				
Worldwide total	\$10,323	\$10,198	\$36,605	\$35,964	28.2%	28.4%

<sup>(1)</sup> Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Income before tax by segment of business for the fiscal second quarters were as follows:

	Income	Before	Carmont	Colos	Percent of	
	Tax		Segment Sales		Segment Sales	
(Dollars in Millions)	July 2,	July 3,	July 2,	July 3,	July 2,	July 3,
	2017	2016	2017	2016	2017	2016
Consumer	\$658	\$571	\$3,478	\$3,419	18.9%	16.7%
Pharmaceutical	3,414	3,687	8,635	8,654	39.5	42.6
Medical Devices	992	939	6,726	6,409	14.7	14.7
Segment operating profit	5,064	5,197	18,839	18,482	26.9	28.1
Less: Expenses not allocated to segments (1)	316	293				
Worldwide income before tax	\$4,748	\$4,904	\$18,839	\$18,482	25.2%	26.5%

<sup>(1)</sup> Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

# Consumer Segment

The Consumer segment income before tax as a percent of sales in the first fiscal six months of 2017 was 18.7% versus 17.2% for the same period a year ago. The Consumer segment income before tax as a percent of sales in the fiscal second quarter of 2017 was 18.9% versus 16.7% for the same period a year ago. The increase in the income before tax as a percent to sales in both the first fiscal six months and fiscal second quarter of 2016 was primarily due to higher gains on divestitures in 2017 as compared to 2016 and favorable selling, marketing and administrative expenses due to cost efficiencies. This was partially offset by higher amortization expense in 2017 related to acquisitions. Additionally, the fiscal six months of 2016 were negatively impacted by operations in Venezuela.

### Pharmaceutical Segment

The Pharmaceutical segment income before tax as a percent of sales in the first fiscal six months of 2017 was 41.9% versus 41.8% for the same period a year ago. The Pharmaceutical segment income before tax as a percent of sales in the fiscal second quarter of 2017 was 39.5% versus 42.6% for the same period a year ago. The decrease in the income before tax as a percent to sales for the fiscal second quarter of 2017 was primarily due to \$0.3 billion of higher

amortization expense and other costs related to the Actelion acquisition. This was partially offset by a gain of \$0.2 billion related to monetization of future royalty receivables. Additionally, the fiscal second quarter of 2016 included a positive adjustment of \$0.3 billion to previous reserve estimates.

Medical Devices Segment

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The Medical Devices segment income before tax as a percent of sales in the first fiscal six months of 2017 was 19.6% versus 20.1% for the same period a year ago. The Medical Devices segment income before tax as a percent of sales was flat at 14.7% for both the fiscal second quarter of 2017 and 2016. The decrease in the income before tax as a percent to sales for the fiscal six months of 2017 as compared to 2016 was primarily due to an asset impairment charge of \$0.2 billion primarily related to the insulin pump business, \$0.2 billion of higher amortization expense and other acquisition costs related to AMO and the impact of unfavorable transactional currency and mix as compared to the fiscal six months of 2016. This was partially offset by sales volume growth and favorable selling, marketing and administrative expenses due to cost efficiencies in 2017. Additionally, the fiscal six months of 2016 included \$0.2 billion of higher litigation expense as compared to 2017.

### 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. Approximately \$250 million in savings were realized in 2016 and approximately \$200 million additional savings is expected in 2017. 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 related charges of approximately \$2.0 billion to \$2.4 billion, most of which are expected to be incurred by the end of 2017. In the fiscal second quarter of 2017, the Company recorded a pre-tax charge of \$128 million, of which \$13 million is included in cost of products sold and \$104 million is included in other (income) expense. In the first fiscal six months of 2017, the Company recorded a pre-tax charge of \$289 million, of which \$17 million is included in cost of products sold and \$176 million is included in other (income) expense. Restructuring charges of \$1.6 billion have been recorded since the restructuring was announced. See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

#### Provision for Taxes on Income

The worldwide effective income tax rates for the first fiscal six months of 2017 and 2016 were 20.1% and 17.1%, respectively. The Company completed its acquisition of AMO in the first fiscal quarter of 2017, and incurred incremental tax costs that were discretely recorded in the first quarter, which has increased the effective tax rate by 2.1% for the first six months of 2017, as compared to the same period in 2016. Additionally, the Company had more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2016. These increases to the effective tax rate were partially offset by additional tax benefits received from stock-based compensation that either vested or were exercised during the first fiscal six months of 2017 and 2016, which reduced the effective tax rate by 2.7% and 2.8%, respectively.

As of July 2, 2017, the Company had approximately \$3.2 billion of liabilities from unrecognized tax benefits. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. The Company is not able to provide a reasonably reliable estimate of the timing of any future tax payments relating to uncertain tax positions.

See Note 8 to the Consolidated Financial Statements in the Annual Report on Form 10-K for the fiscal year ended January 1, 2017 for more detailed information regarding unrecognized tax benefits.

### LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

Cash and cash equivalents were \$12.6 billion at the end of the fiscal second quarter of 2017 as compared with \$19.0 billion at the end of fiscal year 2016. The primary sources of cash were approximately \$8.7 billion net cash generated from operating activities offset by \$13.2 billion used by investing activities and \$2.1 billion used by financing activities. In addition, the Company had \$0.3 billion in marketable securities at the end of the fiscal second quarter of 2017 and \$22.9 billion at the end of 2016.

Cash flow from operations of \$8.7 billion was the result of \$8.2 billion of net earnings, \$2.9 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation and asset write-downs and a \$0.3 billion increase in other liabilities. Cash flow from operations was reduced by \$1.2 billion related to accounts payable and accrued

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liabilities, primarily due to the timing of accounts payable, \$0.9 billion related to accounts receivable and inventories and \$0.5 billion of other assets.

Investing activities use of \$13.2 billion of cash was primarily used for acquisitions of \$34.1 billion and additions to property, plant and equipment of \$1.2 billion. Investing activities also included a source of \$22.1 billion from the net sales of investments in marketable securities.

Financing activities use of \$2.1 billion of cash was primarily for the repurchase of common stock of \$5.2 billion and dividends to shareholders of \$4.4 billion. Financing activities also included a source of \$6.9 billion from the net proceeds of short and long-term debt and \$0.7 billion of proceeds from stock options exercised/employee withholding tax on stock awards, net.

During the fiscal second quarter of 2017, the Company acquired Actelion Ltd. for approximately \$28.8 billion net of cash acquired. The Company used cash held by its foreign subsidiaries to pay for the acquisition.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2016, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 14, 2017, approximates \$10.0 billion. 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.

In the fiscal second quarter of 2017, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs. The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a new shelf registration on February 27, 2017. In the fiscal first quarter of 2017, the Company issued bonds for a total of \$4.5 billion for general corporate purposes.

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 July 2, 2017, \$10.0 billion has been repurchased under the program and the program has been completed. Any shares acquired will be available for general corporate purposes. The Company financed the share repurchase program through available cash and access to the capital markets.

#### Dividends

On April 27, 2017, the Board of Directors declared a regular cash dividend of \$0.84 per share, payable on June 13, 2017 to shareholders of record as of May 30, 2017.

On July 17, 2017, the Board of Directors declared a regular cash dividend of \$0.84 per share, payable on September 12, 2017 to shareholders of record as of August 29, 2017. The Company expects to continue the practice of paying regular quarterly cash dividends.

#### OTHER INFORMATION

**New Accounting Pronouncements** 

Refer to Note 1 to the Consolidated Financial Statements for new accounting pronouncements.

### **Economic and Market Factors**

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 and currency exchange rates continue to have an effect on worldwide economies and, consequently, on the way the Company operates. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

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In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and in March 2017 the U.K. formally started the process for the U.K. to leave the E.U. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of July 2, 2017, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal six months revenues.

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, 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, initiated inter partes review proceedings in the United States Patent and Trademark Office, 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 these actions, generic or biosimilar versions of the products at issue may 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. For further information, see the discussion on "REMICAD® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 11 to the Consolidated Financial Statements.

# Item 3 — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in its Annual Report on Form 10-K for the fiscal year ended January 1, 2017.

#### Item 4 — 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 Securities 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 Securities 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, Executive Vice President, 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.

Internal control. During the period covered by this report, there were no changes in the Company's internal control over financial reporting 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.

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#### Part II — OTHER INFORMATION

# Item 1 — LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to Note 11 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Consolidated Financial Statements.

### Item 2 — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

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 was completed on June 16, 2017.

The following table provides information with respect to Common Stock purchases by the Company during the fiscal second quarter of 2017. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal second quarter.

Period	Total Number of Shares Purchased <sup>(1)</sup>	Avg. Price Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(2)</sup>	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(3)</sup>
April 3, 2017 through April 30, 2017	1,814,412	123.35	1,805,461	_
May 1, 2017 through May 28, 2017	2,200,986	125.37	2,196,268	_
May 29, 2017 through July 2, 2017	10,497,064	132.70	6,547,611	_
Total	14,512,462		10,549,340	

- (1) During the fiscal second quarter of 2017, the Company repurchased an aggregate of 14,512,462 shares of Johnson & Johnson Common Stock in open-market transactions, of which 10,549,340 shares were purchased pursuant to the repurchase program that was publicly announced on October 13, 2015, and of which 3,963,122 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 July 2, 2017, an aggregate of 86,592,946 shares were purchased for a total of \$10.0 billion since the inception of the repurchase program announced on October 13, 2015.
- (3) As of July 2, 2017 the repurchase program was completed.

Item 6 — EXHIBITS

Exhibit 31.1 Certifications under Rule 13a-14(a) of the Securities Exchange Act pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 — Filed with this document.

Exhibit 32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 — Furnished with this document.

Exhibit 101 XBRL (Extensible Business Reporting Language) The following materials from Johnson & Johnson's Quarterly Report on Form 10-Q for the quarter ended July 2, 2017, 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 cash flows, and (v) the notes to the consolidated financial statements.

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### **SIGNATURES**

Pursuant to the requirements 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.

JOHNSON & JOHNSON (Registrant)

Date: August 3, 2017 By /s/ D. J. CARUSO

D. J. CARUSO

Executive Vice President, Chief Financial Officer (Principal Financial Officer)

Date: August 3, 2017 By /s/R. A. KAPUSTA

R. A. KAPUSTA

Controller (Principal Accounting Officer)