

JOHNSON & JOHNSON  
Form 10-Q  
August 04, 2016

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

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the quarterly period ended July 3, 2016  
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 22-1024240  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

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.  Yes  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).  Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  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 29, 2016, 2,735,876,843 shares of Common Stock, \$1.00 par value, were outstanding.

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## Part I — FINANCIAL INFORMATION

## Item 1 — FINANCIAL STATEMENTS

## JOHNSON &amp; JOHNSON AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

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

	July 3, 2016	January 3, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,640	13,732
Marketable securities	23,944	24,644
Accounts receivable, trade, less allowances for doubtful accounts \$270 (2015, \$268)	12,062	10,734
Inventories (Note 2)	8,523	8,053
Prepaid expenses and other	3,122	3,047
Total current assets	66,291	60,210
Property, plant and equipment at cost	37,779	36,648
Less: accumulated depreciation	(21,807 )	(20,743 )
Property, plant and equipment, net	15,972	15,905
Intangible assets, net (Note 3)	25,694	25,764
Goodwill (Note 3)	22,104	21,629
Deferred taxes on income	5,776	5,490
Other assets	3,977	4,413
Total assets	\$ 139,814	133,411
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Loans and notes payable	\$ 1,708	7,004
Accounts payable	6,061	6,668
Accrued liabilities	5,650	5,411
Accrued rebates, returns and promotions	5,259	5,440
Accrued compensation and employee related obligations	2,168	2,474
Accrued taxes on income	690	750
Total current liabilities	21,536	27,747
Long-term debt (Note 4)	24,535	12,857
Deferred taxes on income	2,849	2,562
Employee related obligations	8,359	8,854
Other liabilities	10,062	10,241
Total liabilities	67,341	62,261
Shareholders' equity:		
Common stock — par value \$1.00 per share (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	\$ 3,120	3,120
Accumulated other comprehensive income (loss) (Note 7)	(12,707 )	(13,165 )
Retained earnings	106,738	103,879
Less: common stock held in treasury, at cost (382,189,000 and 364,681,000 shares)	24,678	22,684
Total shareholders' equity	72,473	71,150
Total liabilities and shareholders' equity	\$ 139,814	133,411
See Notes to Consolidated Financial Statements		



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CONSOLIDATED STATEMENTS OF EARNINGS

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

	Fiscal Second Quarters Ended			
	July 3, 2016	Percent to Sales	June 28, 2015	Percent to Sales
Sales to customers (Note 9)	\$18,482	100.0 %	\$17,787	100.0 %
Cost of products sold	5,336	28.9	5,357	30.1
Gross profit	13,146	71.1	12,430	69.9
Selling, marketing and administrative expenses	5,176	28.0	5,384	30.3
Research and development expense	2,264	12.2	2,129	12.0
In-process research and development	29	0.2	—	—
Interest income	(88 )	(0.5 )	(24 )	(0.1 )
Interest expense, net of portion capitalized	190	1.1	131	0.7
Other (income) expense, net	557	3.0	(931 )	(5.3 )
Restructuring (Note 12)	114	0.6	—	—
Earnings before provision for taxes on income	4,904	26.5	5,741	32.3
Provision for taxes on income (Note 5)	907	4.9	1,225	6.9
NET EARNINGS	\$3,997	21.6 %	\$4,516	25.4 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$1.46		\$1.63	
Diluted	\$1.43		\$1.61	
CASH DIVIDENDS PER SHARE	\$0.80		\$0.75	
AVG. SHARES OUTSTANDING				
Basic	2,745.4		2,772.3	
Diluted	2,794.2		2,812.0	
See Notes to Consolidated Financial Statements				

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JOHNSON & JOHNSON AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF EARNINGS  
(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal Six Months Ended			
	July 3, 2016	Percent to Sales	June 28, 2015	Percent to Sales
Sales to customers (Note 9)	\$35,964	100.0 %	\$35,161	100.0 %
Cost of products sold	10,665	29.6	10,639	30.2
Gross profit	25,299	70.4	24,522	69.8
Selling, marketing and administrative expenses	9,864	27.4	10,231	29.1
Research and development expense	4,277	11.9	4,028	11.5
In-process research and development	29	0.1	—	—
Interest income	(171 )	(0.5 )	(43 )	(0.1 )
Interest expense, net of portion capitalized	350	1.0	269	0.7
Other (income) expense, net	518	1.4	(1,279 )	(3.6 )
Restructuring expense (Note 12)	234	0.7	—	—
Earnings before provision for taxes on income	10,198	28.4	11,316	32.2
Provision for taxes on income (Note 5)	1,744	4.9	2,480	7.1
NET EARNINGS	\$8,454	23.5 %	\$8,836	25.1 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$3.07		\$3.18	
Diluted	\$3.02		\$3.13	
CASH DIVIDENDS PER SHARE	\$1.55		\$1.45	
AVG. SHARES OUTSTANDING				
Basic	2,751.4		2,777.7	
Diluted	2,800.9		2,821.0	

See Notes to Consolidated Financial Statements

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

	Fiscal Second Quarters Ended		Fiscal Six Months Ended	
	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015
Net earnings	\$3,997	4,516	8,454	8,836
Other comprehensive income (loss), net of tax				
Foreign currency translation	(295 )	903	584	(1,660 )
Securities:				
Unrealized holding gain (loss) arising during period	156	196	100	311
Reclassifications to earnings	(12 )	(24 )	(94 )	(81 )
Net change	144	172	6	230
Employee benefit plans:				
Prior service cost amortization during period	(6 )	(6 )	(10 )	(11 )
Gain (loss) amortization during period	101	159	207	318
Net change	95	153	197	307
Derivatives & hedges:				
Unrealized gain (loss) arising during period	(250 )	61	(441 )	(134 )
Reclassifications to earnings	(10 )	(43 )	112	(75 )
Net change	(260 )	18	(329 )	(209 )
Other comprehensive income (loss)	(316 )	1,246	458	(1,332 )
Comprehensive income	\$3,681	5,762	8,912	7,504

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal second quarters were as follows for 2016 and 2015, respectively: Securities: \$77 million and \$92 million; Employee Benefit Plans: \$56 million and \$75 million; Derivatives & Hedges: \$140 million and \$9 million.

The tax effects in other comprehensive income for the fiscal six months were as follows for 2016 and 2015, respectively: Securities: \$3 million and \$124 million; Employee Benefit Plans: \$104 million and \$151 million; Derivatives & Hedges: \$177 million and \$113 million.

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JOHNSON & JOHNSON AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited; Dollars in Millions)

	Fiscal Six Months Ended	
	July 3, 2016	June 28, 2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$8,454	8,836
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	1,791	1,784
Stock based compensation	479	474
Asset write-downs	187	11
Net gain on sale of assets/businesses	(185)	(1,034)
Deferred tax provision	115	284
Accounts receivable allowances	(4)	5
Changes in assets and liabilities, net of effects from acquisitions and divestitures:		
Increase in accounts receivable	(1,098)	(1,186)
Increase in inventories	(443)	(537)
Decrease in accounts payable and accrued liabilities	(1,047)	(1,931)
(Increase)/Decrease in other current and non-current assets	(630)	602
(Decrease)/Increase in other current and non-current liabilities	(866)	1,036
<b>NET CASH FLOWS FROM OPERATING ACTIVITIES</b>	<b>6,753</b>	<b>8,344</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Additions to property, plant and equipment	(1,396)	(1,308)
Proceeds from the disposal of assets/businesses, net	685	1,193
Acquisitions, net of cash acquired	(730)	(233)
Purchases of investments	(17,511)	(20,813)
Sales of investments	18,775	15,829
Other	(38)	(11)
<b>NET CASH USED BY INVESTING ACTIVITIES</b>	<b>(215)</b>	<b>(5,343)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends to shareholders	(4,266)	(4,025)
Repurchase of common stock	(4,751)	(3,094)
Proceeds from short-term debt	118	1,024
Retirement of short-term debt	(4,687)	(345)
Proceeds from long-term debt, net of issuance costs	11,951	3
Retirement of long-term debt	(936)	(21)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	929	506
Other	—	(50)
<b>NET CASH USED BY FINANCING ACTIVITIES</b>	<b>(1,642)</b>	<b>(6,002)</b>
Effect of exchange rate changes on cash and cash equivalents	12	(883)
Increase/(Decrease) in cash and cash equivalents	4,908	(3,884)



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Cash and Cash equivalents, beginning of period	13,732	14,523	
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$18,640	10,639	
Acquisitions			
Fair value of assets acquired	\$744	477	
Fair value of liabilities assumed and noncontrolling interests	(14	) (244	)
Net cash paid for acquisitions	730	233	
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 3, 2016. 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 Pronouncements

Recently Adopted Accounting Pronouncements

During the fiscal first quarter of 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2016-09 Compensation - Stock Compensation: Improvements to Employee Share Based Payment Accounting. The amendments in the update are effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. During the fiscal second quarter of 2016, the Company elected to early adopt this standard. The update requires the following changes to presentation of the financial statements:

All excess tax benefits and deficiencies to be recognized as a reduction or an increase to the provision for taxes on income. Previously, the Company recorded these benefits directly to Retained Earnings. The tax benefit for the Company was \$123 million and \$288 million for the fiscal second quarter and fiscal six months ended for 2016, respectively. The standard does not permit retroactive presentation of this benefit to prior fiscal years on the Consolidated Statement of Earnings.

The tax benefit or deficiency is required to be classified and presented as a cash flow to/from operating activities. It was previously required to be presented as a cash flow to/from financing activities on the Consolidated Statement of Cash Flows. As permitted in the standard, the Company has elected to adopt this reclassification on a prospective basis and therefore prior fiscal years for the Consolidated Statement of Cash Flows have not been recast for this provision.

Clarifies that all cash payments made to taxing authorities on employees' share-based compensation should be classified as a cash outflow from financing activities. This reclassification is required to be recast retrospectively. As a result, \$262 million and \$272 million of cash outflow was reclassified from an operating activity to a financing activity (Proceeds from the exercise of stock options/employee withholding tax on stock awards, net) for the first fiscal six months of 2016 and 2015, respectively.

- In the diluted net earnings per share calculation, when applying the treasury stock method for shares that could be repurchased, the assumed proceeds no longer include the amount of excess tax benefit. This did not have a material impact on the Company's diluted net earnings per share calculation.

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

During the fiscal second quarter of 2015, the FASB issued Accounting Standards Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update is effective for the Company for all annual and interim periods beginning after December 15, 2015 and is

required to be applied retroactively for all periods presented. This update did not have a material impact on the presentation of the Company's financial position.

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

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Recently Issued Accounting Standards  
Not Adopted as of July 3, 2016

During the fiscal first quarter of 2016, the 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. Earlier adoption is permitted for any entity in any interim or annual period. The adoption of this standard is not expected to have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal 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 previous 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 Company is currently assessing the impact of the future adoption of this standard on its financial statements.

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 currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting 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 will be effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2017. During the fiscal first quarter of 2016, the FASB issued additional guidance and clarification relating to Identifying

Performance Obligations, Licensing, and Principal versus Agent Considerations. During the second quarter of 2016, the FASB issued additional guidance and clarification relating to assessing collectability, presentation of sales taxes, noncash consideration, and contract modifications & completed contracts at transition. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal third quarter of 2014, the FASB issued Accounting Standards Update No. 2014-15: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise

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substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update will become effective for all annual periods and interim reporting periods ending after December 15, 2016. This standard is not expected to have any impact on current disclosures in the financial statements.

## NOTE 2 — INVENTORIES

(Dollars in Millions)	July 3, 2016	January 3, 2016
Raw materials and supplies	\$952	936
Goods in process	1,984	2,241
Finished goods	5,587	4,876
Total inventories	\$8,523	8,053

## 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 2015. 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)	July 3, 2016	January 3, 2016
Intangible assets with definite lives:		
Patents and trademarks — gross	\$8,633	8,299
Less accumulated amortization	4,974	4,745
Patents and trademarks — net	3,659	3,554
Customer relationships and other intangibles — gross	17,799	17,583
Less accumulated amortization	6,242	5,816
Customer relationships and other intangibles — net	11,557	11,767
Intangible assets with indefinite lives:		
Trademarks	7,085	7,023
Purchased in-process research and development	3,393	3,420
Total intangible assets with indefinite lives	10,478	10,443
Total intangible assets — net	\$25,694	25,764

Goodwill as of July 3, 2016 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Devices	Total
Goodwill, net at January 3, 2016	\$ 7,240	2,889	11,500	21,629
Goodwill, related to acquisitions	225	—	180	405
Goodwill, related to divestitures	—	(10 )	—	(10 )
Currency translation/Other	50	11	19	80
Goodwill, net at July 3, 2016	\$ 7,515	2,890	11,699	22,104

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 18 years and 24 years, respectively. The amortization expense of amortizable intangible assets included in

cost of products sold was \$576 million and \$619 million for the fiscal six months ended July 3, 2016 and June 28, 2015, respectively. The estimated amortization expense for the five succeeding years approximates \$1.2 billion, before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

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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 or requirements to post collateral (excluding equity collar contracts) by either the Company or the counter-party. 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 3, 2016, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps, interest rate swaps and equity collar contracts of \$31.6 billion, \$2.3 billion, \$2.2 billion, and \$0.5 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.

During the fiscal second quarter of 2016, the change in the carrying value due to remeasurement of these Euro notes resulted in a \$116 million pretax gain reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

As of July 3, 2016, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was \$365 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.

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The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal second quarters in 2016 and 2015:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI <sup>(1)</sup>	Gain/(Loss) Reclassified From Accumulated OCI Into Income <sup>(1)</sup>		Gain/(Loss) Recognized In Other Income/Expense <sup>(2)</sup>		
		July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015	July 3, 2016
Cash Flow Hedges By Income Statement Caption						
Sales to customers <sup>(3)</sup>	\$(27 )	37	(3 )	(30 )	—	(1 )
Cost of products sold <sup>(3)</sup>	(178 )	52	13	47	(2 )	14
Research and development expense <sup>(3)</sup>	12	(7 )	(1 )	7	(1 )	—
Interest (income)/Interest expense, net <sup>(4)</sup>	(3 )	7	7	—	—	—
Other (income) expense, net <sup>(3) (5)</sup>	(54 )	(28 )	(6 )	19	—	1
Total	\$(250)	61	10	43	(3 )	14

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the first fiscal six months in 2016 and 2015:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI <sup>(1)</sup>	Gain/(Loss) Reclassified From Accumulated OCI Into Income <sup>(1)</sup>		Gain/(Loss) Recognized In Other Income/Expense <sup>(2)</sup>		
		July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015	July 3, 2016
Cash Flow Hedges By Income Statement Caption						
Sales to customers <sup>(3)</sup>	\$(27 )	(55 )	(21 )	(71 )	—	(2 )
Cost of products sold <sup>(3)</sup>	(222 )	(116)	(8 )	116	(6 )	14
Research and development expense <sup>(3)</sup>	(95 )	(3 )	(96 )	(9 )	(1 )	—
Interest (income)/Interest expense, net <sup>(4)</sup>	9	(29 )	15	(3 )	—	—
Other (income) expense, net <sup>(3) (5)</sup>	(106 )	69	(2 )	42	(3 )	1
Total	\$(441)	(134)	(112 )	75	(10 )	13

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

- (1) Effective portion
- (2) Ineffective portion
- (3) Forward foreign exchange contracts
- (4) Cross currency interest rate swaps
- (5) Includes equity collar contracts

For the fiscal second quarters ended July 3, 2016 and June 28, 2015, a loss of \$36 million and a gain of \$124 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 3, 2016 and June 28, 2015, a loss of \$41 million and a gain of \$40 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

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subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of July 3, 2016 and January 3, 2016 were as follows:

(Dollars in Millions)	July 3, 2016			January 3, 2016
	Level 1	Level 2	Level 3	Total
Derivatives designated as hedging instruments:				
Assets:				
Forward foreign exchange contracts <sup>(7)</sup>	\$—	279	—	452
Interest rate contracts <sup>(2)(4)(7)</sup>	—	55	—	28
Total	—	334	—	480
Liabilities:				
Forward foreign exchange contracts <sup>(8)</sup>	—	569	—	358
Interest rate contracts <sup>(3)(4)(8)</sup>	—	314	—	241
Equity collar contracts <sup>(8)(9)</sup>	—	108	—	—
Total	—	991	—	599
Derivatives not designated as hedging instruments:				
Assets:				
Forward foreign exchange contracts <sup>(7)</sup>	—	28	—	33
Liabilities:				
Forward foreign exchange contracts <sup>(8)</sup>	—	62	—	41
Available For Sale Other Investments:				
Equity investments <sup>(5)</sup>	1,276	—	—	1,494
Debt securities <sup>(6)</sup>	\$—	12,046	—	8,316

(1) 2015 assets and liabilities are all classified as Level 2 with the exception of equity investments of \$1,494 million, which are classified as Level 1.

(2) Includes \$41 million and \$20 million of non-current other assets for July 3, 2016 and January 3, 2016, respectively.

(3) Includes \$314 million and \$239 million of non-current other liabilities for July 3, 2016 and January 3, 2016, respectively.

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

(5) Classified as non-current other assets with the exception of \$272 million of current other assets for July 3, 2016.

The carrying amount of the equity investments were \$530 million and \$528 million as of July 3, 2016 and January 3, 2016, respectively. The unrealized gains were \$767 million and \$979 million as of July 3, 2016 and January 3,

2016, respectively. The unrealized losses were \$21 million and \$13 million as of July 3, 2016 and January 3, 2016, respectively.

(6) Classified as current marketable securities.

(7) Classified as other current assets.

(8) Classified as accounts payable.

(9) Includes \$41 million of non-current other liabilities for July 3, 2016.

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The Company's cash, cash equivalents and current marketable securities as of July 3, 2016 comprised:

(Dollars in Millions)	July 3, 2016			Estimated Fair Value	Cash & Equivalents	Current Marketable Securities
	Carrying Amount	Unrecognized Gain	Unrecognized Loss			
Cash	\$1,619	—	—	1,619	1,619	
U.S. Gov't Securities <sup>(1)</sup>	6,548	1	—	6,549	900	5,648
Other Sovereign Securities <sup>(1)</sup>	2,494	—	—	2,494	1,359	1,135
U.S. Reverse repurchase agreements <sup>(1)</sup>	11,288	—	—	11,288	9,587	1,701
Other Reverse repurchase agreements <sup>(1)</sup>	1,600	—	—	1,600	1,600	
Corporate debt securities <sup>(1)</sup>	4,598	1	—	4,599	1,456	3,142
Money market funds	882	—	—	882	882	
Time deposits <sup>(1)</sup>	1,237	—	—	1,237	1,237	
Subtotal	30,266	2	—	30,268	18,640	11,626
		Unrealized Gain	Unrealized Loss			
Gov't securities	10,036	176	—	10,212	—	10,212
Corporate debt securities	1,818	17	(1 )	1,834	—	1,834
Equity investments	37	246	(11 )	272	—	272
Subtotal Available for Sale <sup>(2)</sup>	\$11,891	439	(12 )	12,318	—	12,318
Total cash, cash equivalents and current marketable securities					18,640	23,944

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

<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.

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 current marketable securities.

The estimated fair value was the same as the amortized cost as of January 3, 2016.

The contractual maturities of substantially all available for sale securities were from one year to five years at July 3, 2016.

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Financial Instruments not measured at Fair Value:

The following financial liabilities are held at carrying amount on the consolidated balance sheet as of July 3, 2016:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
<b>Financial Liabilities</b>		
Current Debt	\$ 1,708	1,708
<b>Non-Current Debt</b>		
5.55% Debentures due 2017	999	1,053
1.125% Notes due 2017	703	709
5.15% Debentures due 2018	899	975
1.65% Notes due 2018	609	620
4.75% Notes due 2019 (1B Euro 1.1098)	1,105	1,286
1.875% Notes due 2019	514	528
0.89% Notes due 2019	299	300
1.125% Notes due 2019	698	704
3% Zero Coupon Convertible Subordinated Debentures due in 2020	110	183
2.95% Debentures due 2020	545	585
3.55% Notes due 2021	447	492
2.45% Notes due 2021	348	371
1.65% Notes due 2021	997	1,015
0.250% Notes due 2022 (1B Euro 1.1098)	1,105	1,123
6.73% Debentures due 2023	249	335
3.375% Notes due 2023	808	905
2.05% Notes due 2023	497	510
0.650% Notes due 2024 (750MM Euro 1.1098)	827	848
5.50% Notes due 2024 (500 MM GBP 1.3418)	664	879
2.45% Notes due 2026	1,989	2,063
1.150% Notes due 2028 (750MM Euro 1.1098)	823	857
6.95% Notes due 2029	296	444
4.95% Debentures due 2033	497	643
4.375% Notes due 2033	857	1,039
1.650% Notes due 2035 (1.5B Euro 1.1098)	1,645	1,811
3.55% Notes due 2036	986	1,096
5.95% Notes due 2037	990	1,472
5.85% Debentures due 2038	695	1,031
4.50% Debentures due 2040	537	680
4.85% Notes due 2041	296	387
4.50% Notes due 2043	495	617
3.70% Notes due 2046	1,970	2,251
Other	36	36
Total Non-Current Debt	\$ 24,535	27,848

The weighted average effective interest rate on non-current debt is 3.30%.

The excess of the estimated fair value over the carrying value of debt was \$1.7 billion at January 3, 2016.



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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 first fiscal six months of 2016 and 2015 were 17.1% and 21.9%, respectively. In the fiscal six months of 2016, the Company had higher income in lower tax jurisdictions relative to higher tax jurisdictions as compared to 2015, which decreased the effective tax rate by approximately 1.7%. As described in Note 1, the Company adopted a new accounting standard for the reporting of tax benefits on share-based compensation. The adoption of this new standard reduced the tax rate for the first six months of fiscal 2016 by approximately 2.8% versus 2015. The remainder of the change from prior year was primarily related to the U.S. Research & Development tax credit and the Controlled Foreign Corporation look-through provisions, which were not enacted into law until the fiscal fourth quarter of 2015, and the settlement of certain open tax positions in several international jurisdictions.

As of July 3, 2016, the Company had approximately \$3.1 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 2016 and 2015 include the following components:

(Dollars in Millions)	Fiscal Second Quarters Ended			
	Retirement Plans		Other Benefit Plans	
	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015
Service cost	\$226	249	55	65
Interest cost	233	248	39	46
Expected return on plan assets	(493)	(455)	(1)	(1)
Amortization of prior service cost/(credit)	(1)	1	(8)	(9)
Recognized actuarial losses	124	187	34	50
Curtailments and settlements	4	—	—	—
Net periodic benefit cost	\$93	230	119	151

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the first fiscal six months of 2016 and 2015 include the following components:

(Dollars in Millions)	Fiscal Six Months Ended			
	Retirement Plans		Other Benefit Plans	
	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015
Service cost	\$452	497	110	129

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Interest cost	466	497	79	93
Expected return on plan assets	(985 )	(910 )	(3 )	(3 )
Amortization of prior service cost/(credit)	—	1	(16)	(17 )
Recognized actuarial losses	248	374	68	100
Curtailments and settlements	5	4	—	—
Net periodic benefit cost	\$186	463	238	302

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## Company Contributions

For the fiscal six months ended July 3, 2016, the Company contributed \$283 million and \$14 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 Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/(Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
(Dollars in Millions)					
January 3, 2016	\$ (8,435 )	604	(5,298 )	(36 )	(13,165 )
Net change	584	6	197	(329 )	458
July 3, 2016	\$ (7,851 )	610	(5,101 )	(365 )	(12,707 )

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 3, 2016 and June 28, 2015:

(Shares in Millions)	Fiscal Second Quarters Ended	
	July 3, 2016	June 28, 2015
Basic net earnings per share	\$1.46	1.63
Average shares outstanding — basic	2,745.4	2,772.3
Potential shares exercisable under stock option plans	146.3	151.4
Less: shares which could be repurchased under treasury stock method	(99.2 )	(113.9 )
Convertible debt shares	1.7	2.2
Average shares outstanding — diluted	2,794.2	2,812.0
Diluted net earnings per share	\$1.43	1.61

The diluted net earnings per share calculation for both the fiscal second quarters ended July 3, 2016 and June 28, 2015 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 3, 2016 and June 28, 2015 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

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The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal six months ended July 3, 2016 and June 28, 2015:

(Shares in Millions)	Fiscal Six Months Ended	
	July 3, 2016	June 28, 2015
Basic net earnings per share	\$3.07	3.18
Average shares outstanding — basic	2,751.4	2,777.7
Potential shares exercisable under stock option plans	145.8	151.4
Less: shares which could be repurchased under treasury stock method	(98.0 )	(110.3 )
Convertible debt shares	1.7	2.2
Average shares outstanding — diluted	2,800.9	2,821.0
Diluted net earnings per share	\$3.02	3.13

The diluted net earnings per share calculation for both the fiscal six months ended July 3, 2016 and June 28, 2015 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 3, 2016 and June 28, 2015 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 SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Second Quarters Ended		
	July 3, 2016	June 28, 2015	Percent Change
Consumer			
United States	\$1,384	1,355	2.1 %
International	2,035	2,128	(4.4 )
Total	3,419	3,483	(1.8 )
Pharmaceutical			
United States	5,144	4,543	13.2
International	3,510	3,403	3.1
Total	8,654	7,946	8.9
Medical Devices			
United States	3,044	3,013	1.0
International	3,365	3,345	0.6
Total	6,409	6,358	0.8
Worldwide			
United States	9,572	8,911	7.4
International	8,910	8,876	0.4
Total	\$18,482	17,787	3.9 %



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(Dollars in Millions)	Fiscal Six Months Ended		
	July 3, 2016	June 28, 2015	Percent Change
Consumer			
United States	\$2,742	2,714	1.0 %
International	3,872	4,159	(6.9 )
Total	6,614	6,873	(3.8 )
Pharmaceutical			
United States	10,081	8,914	13.1
International	6,751	6,758	(0.1 )
Total	16,832	15,672	7.4
Medical Devices			
United States	6,070	5,975	1.6
International	6,448	6,641	(2.9 )
Total	12,518	12,616	(0.8 )
Worldwide			
United States	18,893	17,603	7.3
International	17,071	17,558	(2.8 )
Total	\$35,964	35,161	2.3 %

## INCOME BEFORE TAX BY SEGMENT

(Dollars in Millions)	Fiscal Second Quarters Ended		
	July 3, 2016	June 28, 2015	Percent Change
Consumer	\$571	317	80.1 %
Pharmaceutical <sup>(1)</sup>	3,687	4,122	(10.6)
Medical Devices <sup>(2)</sup>	939	1,584	(40.7)
Segments operating profit	5,197	6,023	(13.7)
Less: Expense not allocated to segments <sup>(3)</sup>	293	282	
Worldwide income before tax	\$4,904	5,741	(14.6)%

(Dollars in Millions)	Fiscal Six Months Ended		
	July 3, 2016	June 28, 2015	Percent Change
Consumer	\$1,137	961	18.3 %
Pharmaceutical <sup>(1)</sup>	7,031	7,084	(0.7 )
Medical Devices <sup>(2)</sup>	2,515	3,805	(33.9)
Segments operating profit	10,683	11,850	(9.8 )
Less: Expense not allocated to segments <sup>(3)</sup>	485	534	
Worldwide income before taxes	\$10,198	11,316	(9.9 )%

(1) Includes litigation expense of \$136 million recorded in the fiscal six months of 2015. Includes a gain of \$981 million recorded in the fiscal second quarter and first fiscal six months of 2015 from the divestiture of the U.S. license rights to NUCYNTA<sup>®</sup> (tapentadol), NUCYNTA<sup>®</sup> ER (tapentadol extended-release tablets), and NUCYNTA<sup>®</sup> (tapentadol) oral solution. Includes a positive adjustment of \$539 million and \$403 million to previous reserve estimates in the fiscal six months of 2016 and 2015, respectively. Includes a positive adjustment of \$342 million and \$199 million to previous reserve estimates in the fiscal second quarter of 2016 and 2015, respectively.

(2) Includes a restructuring charge of \$141 million and \$278 million in the fiscal second quarter and fiscal six months of 2016, respectively. Includes litigation expense of \$570 million and \$676 million recorded in the fiscal second quarter and fiscal six months of 2016, respectively. Includes litigation expense of \$134 million in the fiscal second quarter of 2015 and a net

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litigation gain of \$404 million primarily related to a litigation settlement agreement with Guidant recorded in the fiscal six months of 2015. The fiscal six months of 2015 included \$148 million for costs associated with the DePuy ASR™ Hip program.

(3) Amounts not allocated to segments include interest income/expense and general corporate income/expense.

**SALES BY GEOGRAPHIC AREA**

(Dollars in Millions)	Fiscal Second Quarters Ended		
	July 3, 2016	June 28, 2015	Percent Change
United States	\$9,572	8,911	7.4 %
Europe	4,090	4,151	(1.5 )
Western Hemisphere, excluding U.S.	1,542	1,501	2.7
Asia-Pacific, Africa	3,278	3,224	1.7
Total	\$18,482	17,787	3.9 %

(Dollars in Millions)	Fiscal Six Months Ended		
	July 3, 2016	June 28, 2015	Percent Change
United States	\$18,893	17,603	7.3 %
Europe	7,937	8,191	(3.1 )
Western Hemisphere, excluding U.S.	2,873	3,140	(8.5 )
Asia-Pacific, Africa	6,261	6,227	0.5
Total	\$35,964	35,161	2.3 %

**NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES**

Subsequent to the quarter the Company completed the acquisition of Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products for \$3.3 billion in cash. The Company is in the process of finalizing the purchase price allocation.

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 \$650 million.

During the fiscal second quarter of 2015, the Company completed the divestiture of its U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution for approximately \$1.05 billion. The pre-tax gain on the divestiture was \$981 million and was recognized in Other (income) expense, net.

During the fiscal first quarter of 2015, the Company acquired XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody.



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

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

PRODUCT LIABILITY

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. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, XARELTO® and JOHNSON'S® Baby Powder. As of July 3, 2016, in the U.S. there were approximately 2,900 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 9,100 with respect to the PINNACLE® Acetabular Cup System, 50,100 with respect to pelvic meshes, 13,000 with respect to RISPERDAL®, 13,900 with respect to XARELTO® and 1,700 with respect to JOHNSON'S® Baby Powder.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to

fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR<sup>®</sup>Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement, which effectively extends the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,800 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the United States. However, many lawsuits in the United States will remain, and the settlement program does not address litigation outside of the United States. In Australia, a settlement has been reached with representatives of a class action lawsuit pending in the Federal Court of New South Wales

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that resolves the claims of the majority of ASR Hip patients in that country. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Changes to these accruals may be required in the future as additional information becomes available.

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

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

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

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of XARELTO®, an oral anticoagulant. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States and many cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with XARELTO®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® 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 and New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby

Powder. Changes to this accrual may be required in the future as additional information becomes available.

#### INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, 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.

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Medical Devices

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

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE ADVANCE® and ACUVUE OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the '327 patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt asked the District Court to grant it a new trial based on alleged new evidence, and in July 2014, the District Court denied Rembrandt's motion. Rembrandt appealed and the Court of Appeals overturned that ruling in April 2016 and remanded the case to the District Court for a new trial. JJVC filed a motion to reconsider the decision, which was denied.

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

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, LLC (Shasta), Instacare Corp (now Pharmatech Solutions, Inc. (Pharmatech)) and Conductive Technologies, Inc. (Conductive) in the United States District Court for the Northern District of California for patent infringement and false advertising for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. The defendants alleged that the three LifeScan patents-in-suit are invalid and challenged the validity of the asserted patents in the United States Patent and Trademark Office (USPTO). In April 2013, the defendants brought counterclaims for alleged antitrust violations and false advertising and those claims were stayed pending resolution of the patent infringement case. The validity of two of the patents was confirmed by the USPTO, but the USPTO determined that the third patent, U.S. Patent No. 7,250,105, is invalid. LifeScan lost an appeal of that decision, but is seeking a rehearing. LifeScan entered into a settlement agreement with Shasta and Conductive. A motion brought by Pharmatech for summary judgment of patent invalidity was denied. In April 2016, LifeScan and Pharmatech entered into a settlement agreement and the case was dismissed.

LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip) in the United States District Court for the District of North Carolina in May 2014, alleging that the making and marketing of UniStrip's strips for use in LifeScan's blood glucose monitors infringe U.S. Patent Nos. 6,241,862 (the '862 patent) and 7,250,105 (the '105 patent). In August 2014, the USPTO determined that the '105 patent is invalid. In January 2016, the invalidity decision was upheld on appeal. LifeScan filed a motion for rehearing, which was denied. In July 2014, UniStrip brought a lawsuit against LifeScan in the United States District Court for the Eastern District of Pennsylvania,

alleging antitrust violations relating to marketing practices for LifeScan strips.

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



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## Pharmaceutical

In 2012 and 2013, Noramco, Inc. (Noramco) moved to intervene in several patent infringement lawsuits filed in the United States District Court for the Southern District of New York by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), Watson Laboratories, Inc.- Florida (Watson) and Andrx Labs, LLC (Andrx). The lawsuits are in response to the defendants' respective Abbreviated New Drug Applications seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco agreed to defend the lawsuits on behalf of Impax, Teva, Amneal, Watson, and Andrx. In April 2013, Watson and Andrx entered into a settlement with Purdue. The trial against Impax and Teva (and others) took place in September 2013, and Noramco defended Teva and Impax. In November 2013, Impax entered into a settlement with Purdue, and in December 2014, Teva entered into a settlement with Purdue. The District Court issued a decision in January 2014 invalidating the relevant Purdue patents and, based on that decision, subsequently dismissed the lawsuit against Amneal (and other parties not defended by Noramco). Purdue appealed the Court's decision. In February 2016, the Federal Circuit affirmed the District Court decision invalidating the Purdue patents. Purdue filed a petition for rehearing and the petition was denied. In December 2015, Purdue filed another patent infringement action against Amneal in the District of Delaware asserting, among others, the three above-referenced patents and a newly issued patent relating to oxycodone and processes for making oxycodone. Noramco was divested in July 2016 and, as a result, the Company is no longer involved in the defense of these actions.

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

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, alleging that JBI's manufacture and sale of DARZALEX<sup>®</sup> (daratumumab) willfully infringes its U.S. Patent No. 8,263,746. Morphosys is seeking money damages. JBI licenses patents and the commercial rights to DARZALEX<sup>®</sup> from Genmab. In June 2016, JBI filed a motion to dismiss the lawsuit.

REMICADE<sup>®</sup> 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<sup>®</sup> (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU, and NYU granted JBI an exclusive license to NYU's rights under the patent. The '471 patent in the United States expires in September 2018. 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. In May 2015, JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board, and the appeal is currently pending. The '471 patent remains a valid and enforceable patent as it undergoes reexamination at the USPTO.

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 biosimilar version of REMICADE<sup>®</sup>. 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 biosimilar

version of REMICADE<sup>®</sup>, seeking a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents and that defendants failed to comply with certain procedural requirements of the Biologics Price Competition and Innovation Act (BPCIA). In addition, JBI moved for an injunction to prohibit Celltrion and Hospira from launching their biosimilar product until 180 days after they had given JBI a Notice of Commercial Marketing under the BPCIA, such notice not to be given before FDA approval of Celltrion's product. JBI's motion to stay all proceedings in the District Court with respect to the '471 patent, pending the outcome of the USPTO reexamination proceeding discussed above, was denied in May 2016. In February 2016, Celltrion and Hospira filed two motions for summary judgment of invalidity of the '471 patent, which will be argued in August 2016.

In April 2016, the FDA approved Celltrion's biosimilar version of REMICADE<sup>®</sup> for sale in the United States. Celltrion and Hospira have agreed not to launch their biosimilar product before October 3, 2016, 180 days after the FDA's approval of their

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biosimilar product, thereby eliminating litigation of the issue of the 180-day Notice of Commercial Marketing under the BPCIA.

In June 2016, JBI filed two new patent infringement lawsuits asserting U.S. Patent No. 7,598,083 (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 new lawsuit against Celltrion expands the claims to include any use of the cell media made in the United States to manufacture Celltrion's biosimilar. The new lawsuit against Celltrion has been consolidated with the existing Massachusetts lawsuit. The Court has scheduled a claim construction hearing regarding the '083 patent for August 2016.

In the United States, if either of the REMICADE<sup>®</sup> related patents discussed above is found to be invalid following all appeals, such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE<sup>®</sup>. Biosimilar versions of REMICADE<sup>®</sup> have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE<sup>®</sup> in those markets. The timing of the possible introduction of a biosimilar version of REMICADE<sup>®</sup> in the United States is subject to enforcement of patent rights and compliance with the 180-day Notice of Commercial Marketing provisions of the BPCIA. There is a risk that Celltrion and Hospira could launch their biosimilar version of REMICADE<sup>®</sup> on or after October 3, 2016, even though one or more valid patents are in place and JBI will continue to assert its patent rights. Introduction to the U.S. market of a biosimilar version of REMICADE<sup>®</sup> will result in a reduction in U.S. sales of REMICADE<sup>®</sup>.

### Canadian Proceedings

In March 2013, Hospira filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE<sup>®</sup> (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<sup>®</sup> would infringe the Feldman patents owned by Kennedy. Discovery in the patent action is ongoing, and trial has been scheduled for September 2016.

In January 2014, Health Canada approved Celltrion's SEB to REMICADE<sup>®</sup>, allowing Celltrion to market its biosimilar version of REMICADE<sup>®</sup> in Canada, regardless of the pending patent action. In June 2014, Health Canada approved Hospira's SEB to REMICADE<sup>®</sup>. In July 2014, Janssen filed a lawsuit to compel the Canadian Minister of Health to withdraw the Notice of Compliance for Hospira's SEB because Hospira did not serve a Notice of Allegation on Janssen to address the patent listed by Janssen on the Patent Register. In March 2015, the parties entered into a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira's Notice of Compliance, subject to Health Canada's appeal, which was filed in June 2015. Nevertheless, Hospira began marketing a biosimilar version of REMICADE<sup>®</sup> as a distributor under Celltrion's Notice of Compliance. A hearing on the appeal concluded in June 2016 and the parties are awaiting a decision.

In Canada, if any of the REMICADE<sup>®</sup> related patents discussed above is found to be invalid following all appeals, such patent could not be relied upon to prevent the further introduction of biosimilar versions of REMICADE<sup>®</sup>.

### 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.

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**PREZISTA®**

In November 2010, Tibotec, Inc. (predecessor-in-interest to Janssen Products, LP) and Tibotec Pharmaceuticals (predecessor-in-interest to Janssen Sciences Ireland UC) (individually or collectively, with one or more affiliates and successors-in-interest, Janssen) filed a series of patent infringement lawsuits, relating to several patents owned by Janssen or licensed to Janssen from G.D. Searle, against Lupin, Ltd. and Lupin Pharmaceuticals, Inc. (together, Lupin) in the United States District Court for the District of New Jersey in response to Lupin's ANDA seeking approval to market a generic version of Tibotec's PREZISTA® product in various dosage strengths before the expiration of patents relating to PREZISTA®. In June 2013, Lupin, agreed not to seek FDA approval of its ANDA until the November 2017 expiration of the G.D. Searle patents. After a trial regarding the remaining patents, the Court issued a decision in August 2014, holding that the asserted patents are valid and would be infringed by Lupin's marketing of its proposed products. Lupin appealed.

In May 2013, Lupin notified Janssen that it filed an ANDA seeking approval to market a new dosage strength of its generic version of PREZISTA®. In response, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey, alleging that Lupin's new dosage strength would infringe the same patents that Janssen is asserting against Lupin in the original action. In March 2014, Janssen filed a patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No. 8,518,987 (the '987 patent). In January 2015, the Court stayed these cases pending Lupin's appeal of the Court's August 2014 decision in the first action. In April 2015, Lupin filed a petition for Inter Partes review in the United States Patent and Trademark Office (USPTO) seeking to invalidate the '987 patent, which was denied in October 2015. In January 2016, Lupin amended its ANDA to reflect a new formulation of darunavir that Lupin alleges does not infringe the relevant Janssen patents. In February 2016, Janssen filed a lawsuit in the United States District Court for the District of New Jersey asserting that Lupin's new formulation of darunavir infringes the relevant Janssen patents.

In the above lawsuits, Janssen sought orders enjoining Lupin from marketing its generic versions of PREZISTA® before the expiration of the relevant patents. In May 2016, Janssen and Lupin entered into a confidential settlement agreement, pursuant to which the above lawsuits have been dismissed.

**CONCERTA®**

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

**ZYTIGA®**

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. (Janssen Oncology) and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 (the '213 patent) (expiring December 2016) and/or 8,822,438 (the '438 patent) (expiring August 2027). The generic companies include Actavis Laboratories, FL, Inc. (Actavis); Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively,

Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward); and Hikma Pharmaceuticals, LLC (Hikma). The Court entered a stay of the lawsuit against Par and Citron, as each agreed to be bound by the decision against the other defendants in the action. In February 2016, the Court set a trial date of October 2017.

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

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

In March 2016, Janssen filed a motion to correct inventorship of the '438 patent to add an inventor and requested that, should the Court order the requested correction, it grant Janssen leave to amend the complaint to recognize BTG as a co-owner of the '438 patent and a co-plaintiff with Janssen with regard to the '438 patent infringement claims.

In March 2016, Janssen received a notice from Amerigen Pharmaceuticals Limited (Amerigen) advising of Amerigen's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In response, Janssen and BTG filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amerigen in May 2016.

In May 2016, Janssen received a notice of paragraph IV certification from Glenmark Pharmaceuticals Inc., on behalf of Glenmark Pharmaceuticals SA, a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd. (collectively, Glenmark) advising of Glenmark's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In response, in June 2016, Janssen and BTG filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Glenmark.

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

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

In December 2015, Amerigen filed a petition for an Inter Partes Review in the USPTO seeking to invalidate the '438 patent. In May 2016, the USPTO granted the Inter Partes Review, and a decision as to the validity of the '438 patent is expected by May 2017. In June 2016, Argentum Pharmaceuticals LLC and Mylan Pharmaceuticals Inc. filed petitions for Inter Partes Review in the USPTO seeking to invalidate the '438 patent and moved to join the Inter Partes Review filed by Amerigen.

**COMPLERA®**

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Courts for the District of Delaware and the District of West Virginia, respectively, against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to Mylan's ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310 (the '310 patent), 7,125,879 (the '879 patent) and 8,101,629 (the '629 patent).

In the West Virginia action, in September 2015, Mylan filed an answer and counterclaims asserting invalidity and non-infringement of the '310 patent, '879 patent, and '629 patent, as well as United States Patent No. 8,080,551 (the '551 patent). In March 2016, the District of West Virginia Court stayed the lawsuit and scheduled a conditional trial date in February 2018, in accordance with the schedule in the first-filed Delaware lawsuit described below.

In the Delaware action, in January and March 2016, Janssen and Gilead amended their complaint to add claims for patent infringement with respect to the '551 patent and United States Patent Nos. 7,399,856 (the '856 patent),

7,563,922 (the '922 patent), 8,101,752 (the '752 patent) and 8,618,291 (the '291 patent). In February 2016, Mylan moved to dismiss the suit for lack of personal jurisdiction and, in April 2016, Mylan filed a motion to dismiss, strike or sever the infringement claims regarding the '752 and '291 patents. 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<sup>®</sup> before the expiration of the relevant patents.

#### XARELTO<sup>®</sup>

A number of generic companies have filed ANDAs seeking approval to market generic versions of XARELTO<sup>®</sup>. In October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against Aurobindo Pharma



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Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Micro Labs USA Inc. and Micro Labs Ltd. (collectively, Micro), Mylan Pharmaceuticals Inc., Mylan Inc. (Mylan), Princeton Pharmaceutical, Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc., in response to those parties' respective ANDAs seeking approval to market generic versions of XARELTO® before the expiration of Bayer's United States Patent Nos. 7,157,456 (the '456 patent), 7,585,860 (the '860 patent) and 7,592,339 (the '339 patent) relating to XARELTO®. JPI is the exclusive licensee of the asserted patents.

In November 2015, Mylan moved to dismiss the action. In December 2015, JPI, Bayer, and Mylan stipulated and agreed to dismiss the claims against Mylan, and suspend further briefing and argument on Mylan's motion to dismiss, pending appeals relating to personal jurisdiction over Mylan Pharmaceuticals Inc. in the District of Delaware. In February 2016, a similar patent infringement action by JPI and Bayer against Invagen Pharmaceuticals Inc. (Invagen), in response to Invagen's notice of paragraph IV certification advising of its ANDA seeking FDA approval for a generic XARELTO® product before expiration of the relevant patents, was consolidated with the original case. The District Court has set a trial date of March 2018.

In April 2016, JPI and Bayer filed a separate patent infringement action in the District of Delaware against Micro, in response to their notice of paragraph IV certification advising of their ANDA seeking FDA approval for a generic XARELTO® product before expiration of the '860 and '339 patents. In May 2016, this action was consolidated with the original action.

In July 2016, JPI and Bayer filed a separate patent infringement action in the District of Delaware against Breckenridge Pharmaceutical, Inc., in response to its notice of paragraph IV certification advising of its ANDA seeking FDA approval for a generic XARELTO® product before expiration of the '456 and '339 patents.

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.

### GOVERNMENT PROCEEDINGS

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

#### Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWP's in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain Johnson & Johnson subsidiaries have been settled, including the case in Wisconsin, which settled in February 2016. Cases are still pending in Illinois, New Jersey, and Utah. The cases in Illinois and New Jersey have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. In the AWP case against the J&J AWP Defendants brought by the Commonwealth of Pennsylvania, following a trial in 2010, the Pennsylvania Commonwealth Court found in favor of the Commonwealth with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law, and in favor of the J&J AWP Defendants on the Commonwealth's remaining claims. Following an appeal to the Pennsylvania Supreme Court that vacated that judgment, the Commonwealth Court entered a subsequent judgment in favor of the J&J AWP Defendants on all claims. That subsequent judgment has been upheld by the Pennsylvania Supreme Court in a successive appeal.

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McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division) (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (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 in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL-PPC, Inc. (now JJCI) agreed to pay a \$20 million fine and a \$5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC, 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. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In November 2015, the Court of Appeals of the State of Oregon reversed the trial court and reinstated Oregon's consumer protection claims. In February 2016, the Oregon Supreme Court denied the Companies' petition for review, and the case was sent back to the trial court.

Opioids Litigation

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

In June 2014, the City of Chicago filed a complaint in Cook County Circuit Court against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices, including consumer fraud violations and false claims, and seeking injunctive and monetary relief. The case was later removed to the United States District Court for the Northern District of Illinois. In December 2014, J&J and JPI filed a motion to dismiss the City of Chicago's First Amended Complaint, which was granted with leave to file an amended complaint. The City filed an amended complaint, and in November 2015, J&J and JPI filed a motion to dismiss the Second Amended Complaint.

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

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI and other pharmaceutical companies related to opioids marketing practices. In October 2015, the State filed a motion in the State of New Hampshire Superior Court to enforce the subpoena. JPI and the other pharmaceutical companies subsequently filed a joint motion for injunctive relief and a protective order to preclude the State from engaging private contingent fee counsel to participate in the State's investigation or any subsequent enforcement

action. In March 2016, the Court denied the State's motion to enforce the subpoena and granted the protective order on the grounds that the State had not obtained requisite executive and legislative approvals to retain private counsel, but rejected the contention that the contingency fee agreement was otherwise unlawful. All parties have appealed the March 2016 ruling to the New Hampshire Supreme Court. In the interim, in May 2016, the New Hampshire Attorney General's office obtained executive and legislative approvals to retain private counsel for the State's investigation. In June 2016, in response to the State's renewed demand (through its private counsel) to produce documents responsive to the subpoenas, JPI and the other pharmaceutical companies filed a joint motion to enforce the protective order.

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In December 2015, the State of Mississippi filed a complaint in the Chancery Court of the First Judicial District of Hinds County against substantially the same group of pharmaceutical manufacturers as in the suits brought by the California counties and City of Chicago, including J&J and JPI, alleging a number of claims related to opioid marketing practices and seeking penalties and injunctive and monetary relief. In March 2016, defendants filed motions to dismiss the complaint.

**Other**

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

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of the RELIEVA STRATUS<sup>®</sup> MicroFlow Spacer product (the RELIEVA STRATUS<sup>®</sup> 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<sup>®</sup> 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 ASR<sup>™</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' subsequent motion for reconsideration was denied and they have filed a notice of appeal. In addition, in October 2013, a group of State Attorneys General issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. 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<sup>™</sup> 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 and Ethicon alleging violations of their consumer protection statutes. The companies have entered into a new tolling agreement with the remaining 45 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<sup>®</sup> (methoxsalen) and the Uvar Xts<sup>®</sup> System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States

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

In 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. 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 Johnson & Johnson) and seeks injunctive and monetary relief. This matter is currently scheduled for trial in February 2017.

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

GENERAL LITIGATION

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as *In re Blood Reagent Antitrust Litigation*. Following the divestiture of OCD, Johnson & Johnson retains any liability that may result from these cases. In August 2012, the District Court granted a motion filed by the plaintiffs for class certification. In April 2015, the United States Court of Appeals for the Third Circuit reversed the class certification ruling and remanded the case to the District Court for further proceedings. In October 2015, the District Court again granted the motion by the plaintiffs for class certification. In July 2016, OCD filed a motion for summary judgment.

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

In May 2014, two purported class actions were filed against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) 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 Johnson & Johnson). The cases are pending in United States District Court for the Eastern District of California and United States District Court for the Southern District of Illinois. Both cases seek injunctive relief and monetary damages. Neither case includes a claim for personal injuries.

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.

In March 2015, Costco Wholesale Corporation (Costco) filed a complaint against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court of the Northern District of California, alleging antitrust claims of an unlawful vertical price fixing agreement between JJVCI, Costco and unnamed other distributors and retailers. Costco alleges that the alleged agreements harmed competition by causing increases in the price Costco customers pay for JJVCI contact lenses. Costco is seeking an injunction and monetary damages. In June 2015, the case was transferred to the United States District Court for the Middle District of Florida along with related class action cases described below. In May 2016, Costco dismissed its claims without prejudice.

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



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Consolidated Class Action complaint in November 2015, and in December 2015, JJVCI and other defendants filed motions to dismiss. In June 2016, the Court denied the motions to dismiss.

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

In April 2015, Adimmune Corporation Ltd (Adimmune) commenced an arbitration in the International Court of Arbitration - International Chamber of Commerce against Crucell Switzerland AG (now Janssen Vaccines AG) and Crucell Holland 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 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<sup>®</sup> as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages in an unspecified amount.

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

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## 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 charges of approximately \$2.0 billion to \$2.4 billion, most of which are expected to be incurred by 2017. In the fiscal six months of 2016, the Company recorded a pre-tax charge of \$278 million, of which \$24 million was included in cost of products sold and \$20 million was included in other (income) expense. See table below for additional details. Total restructuring charges of \$868 million have been recorded since the restructuring has been announced.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next two years, subject to any consultation procedures in countries, where required. Approximately 900 positions have been eliminated since the restructuring has been announced.

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

The following table summarizes the severance related reserves and the associated spending under this initiative through the first fiscal six months of 2016:

(Dollars in Millions)	Severance	Asset Write-offs	Other	Total
Reserve balance, January 3, 2016	\$ 484	—	17	501
Current year activity:				
Charges	—	150	128	278
Cash payments	(56)	) —	(142)	(198)
Settled without cash	—	(150)	) —	(150)
Reserve balance, July 3, 2016*	\$ 428	—	3	431

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

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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 2016, worldwide sales were \$36.0 billion, a total increase of 2.3%, including operational growth of 4.6% as compared to 2015 first fiscal six months sales of \$35.2 billion. Currency fluctuations had a negative impact of 2.3% for the first fiscal six months of 2016. In the first fiscal six months of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the worldwide operational sales growth was negative 2.8%. Operations in Venezuela negatively impacted the worldwide operational sales growth by 0.5%.

Sales by U.S. companies were \$18.9 billion in the first fiscal six months of 2016, which represented an increase of 7.3% as compared to the prior year. In the first fiscal six months of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the U.S. operational sales growth was negative 2.0%. Sales by international companies were \$17.1 billion, a decline of 2.8%, including operational growth of 1.8%, offset by a negative currency impact of 4.6% as compared to the first fiscal six months sales of 2015. In the first fiscal six months of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the international operational sales growth was negative 3.6%. Operations in Venezuela negatively impacted the international operational sales growth by 0.9%.

In the first fiscal six months of 2016, sales by companies in Europe experienced a decline of 3.1%, which included an operational decline of 0.6% and a negative currency impact of 2.5%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 8.5%, which included operational growth of 7.1%, offset by a negative currency impact of 15.6%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 0.5%, which including operational growth of 2.5% and a negative currency impact of 2.0%.

For the fiscal second quarter of 2016, worldwide sales were \$18.5 billion, a total increase of 3.9%, including operational growth of 5.3% as compared to 2015 fiscal second quarter sales of \$17.8 billion. Currency fluctuations had a negative impact of 1.4% for the fiscal second quarter of 2016. In the fiscal second quarter of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the worldwide operational sales growth was negative 2.6%. Operations in Venezuela negatively impacted the worldwide operational sales growth by 0.3%.

Sales by U.S. companies were \$9.6 billion in the fiscal second quarter of 2016, which represented an increase of 7.4% as compared to the prior year. In the fiscal second quarter of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the U.S. operational sales growth was negative 1.4%. Sales by international companies were \$8.9 billion, an increase of 0.4%, including operational growth of 3.1%, partially offset by a negative currency impact of 2.7% as compared to the fiscal second quarter sales of 2015. In the fiscal second quarter of 2016, the impact of acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), on the international operational sales growth was negative 3.8%. Operations in Venezuela negatively impacted the international operational sales growth by 0.7%.

In the fiscal second quarter of 2016, sales by companies in Europe experienced a decline of 1.5%, which included an operational decline of 0.6% and a negative currency impact of 0.9%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 2.7%, which included operational growth of 15.4%, and a negative currency impact of 12.7%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 1.7%, including operational growth of 2.1% and a negative currency impact of 0.4%.

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## ANALYSIS OF SALES BY BUSINESS SEGMENTS

## Consumer

Consumer segment sales in the first fiscal six months of 2016 were \$6.6 billion, a decrease of 3.8% as compared to the same period a year ago, including operational growth of 0.6% offset by a negative currency impact of 4.4%. U.S. Consumer segment sales increased by 1.0%. International Consumer segment sales decreased by 6.9%, including operational growth of 0.4% offset by a negative currency impact of 7.3%. In the fiscal six months of 2016, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was negative 2.3%. Operations in Venezuela negatively impacted the Consumer segment operational sales growth by 1.6%.

## Major Consumer Franchise Sales — Fiscal Six Months Ended

(Dollars in Millions)	July 3, 2016	June 28, 2015	Total Change	Operations Change	Currency Change
OTC	\$2,027	\$1,967	3.1 %	6.8 %	(3.7 )%
Skin Care	1,815	1,797	1.0	3.9	(2.9 )
Baby Care	951	1,054	(9.8 )	(2.6 )	(7.2 )
Oral Care	788	794	(0.8 )	3.8	(4.6 )
Women's Health	534	607	(12.0)	(2.9 )	(9.1 )
Wound Care/Other	499	654	(23.7)	(21.9 )	(1.8 )
Total Consumer Sales	\$6,614	\$6,873	(3.8 )%	0.6 %	(4.4 )%

Consumer segment sales in the fiscal second quarter of 2016 were \$3.4 billion, a decrease of 1.8% as compared to the same period a year ago, including operational growth of 1.5% and a negative currency impact of 3.3%. U.S. Consumer segment sales increased by 2.1%. International Consumer segment sales decreased by 4.4%, including an operational growth of 1.0% and a negative currency impact of 5.4%. In the fiscal second quarter of 2016, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was negative 2.4%. Operations in Venezuela negatively impacted the Consumer segment operational sales growth by 1.2%.

## Major Consumer Franchise Sales — Fiscal Second Quarters Ended

(Dollars in Millions)	July 3, 2016	June 28, 2015	Total Change	Operations Change	Currency Change
OTC	\$1,008	\$974	3.5 %	6.2 %	(2.7 )%
Skin Care	953	894	6.6	8.7	(2.1 )
Baby Care	500	543	(7.9 )	(2.1 )	(5.8 )
Oral Care	403	391	3.1	6.6	(3.5 )
Women's Health	283	320	(11.6)	(4.8 )	(6.8 )
Wound Care/Other	272	361	(24.7)	(23.6 )	(1.1 )
Total Consumer Sales	\$3,419	\$3,483	(1.8 )%	1.5 %	(3.3 )%

The OTC franchise achieved operational growth of 6.2% as compared to the prior year fiscal second quarter. The growth was primarily driven by analgesics, digestive health products and anti-smoking aids.

The Skin Care franchise achieved operational growth of 8.7% as compared to the prior year fiscal second quarter primarily due to sales growth of AVEENO and NEUTROGENA products.

The Baby Care franchise experienced an operational decline of 2.1% as compared to the prior year fiscal second quarter due to operations in Venezuela, lower sales in China and competitive pressure.

The Oral Care franchise achieved operational growth of 6.6% as compared to the prior year fiscal second quarter. Growth was driven by increased sales of LISTERINE® as a result of new product launches and successful marketing campaigns partially offset by operations in Venezuela.

The Women's Health franchise experienced an operational decline of 4.8% as compared to the prior year fiscal second quarter. Strong sales of new products was offset by operations in Venezuela.

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The Wound Care/Other franchise experienced an operational decline of 23.6% as compared to the prior year fiscal second quarter primarily due to the SPLENDA® divestiture.

## Pharmaceutical

Pharmaceutical segment sales in the first fiscal six months of 2016 were \$16.8 billion, an increase of 7.4% as compared to the same period a year ago, with an operational increase of 9.1% and a negative currency impact of 1.7%. U.S. Pharmaceutical sales increased 13.1% as compared to the same period a year ago. International Pharmaceutical sales decreased by 0.1%, including operational growth of 3.8% offset by a negative currency impact of 3.9%. Acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 3.4% on the operational growth of the Pharmaceutical segment in the fiscal six months of 2016. In the fiscal six months of 2016 the Pharmaceutical segment was impacted approximately 0.6% by a positive adjustment to previous reserve estimates as compared to the same period a year ago.

## Major Pharmaceutical Therapeutic Area Sales — Fiscal Six Months Ended

(Dollars in Millions)	July 3, 2016	June 28, 2015	Total Change	Operations Change	Currency Change
Total Immunology	\$5,948	\$5,017	18.6 %	20.2 %	(1.6 )%
REMICADE®	3,559	3,268	8.9	10.5	(1.6 )
SIMPONI®/ SIMPONI ARIA®	838	608	37.8	39.5	(1.7 )
STELARA®	1,539	1,119	37.5	38.7	(1.2 )
Other Immunology	12	22	(45.5)	(36.4 )	(9.1 )
Total Infectious Diseases	1,605	2,007	(20.0)	(18.6 )	(1.4 )
EDURANT®	259	192	34.9	35.6	(0.7 )
OLYSIO®/SOVRIAD®	75	498	(84.9)	(84.5 )	(0.4 )
PREZISTA®/ PREZCOBIX®/REZOLSTA®	911	875	4.1	5.5	(1.4 )
Other Infectious Diseases	360	442	(18.6)	(15.8 )	(2.8 )
Total Neuroscience	3,151	3,182	(1.0 )	0.6	(1.6 )
CONCERTA®/methylphenidate	469	430	9.1	11.7	(2.6 )
INVEGA®/paliperidone	168	321	(47.7)	(47.3 )	(0.4 )
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®	1,073	847	26.7	28.0	(1.3 )
RISPERDAL® CONSTA®	461	501	(8.0 )	(6.6 )	(1.4 )
Other Neuroscience	980	1,083	(9.5 )	(7.5 )	(2.0 )
Total Oncology	2,828	2,252	25.6	28.1	(2.5 )
IMBRUVICA®	556	270	*	*	**
VELCADE®	646	683	(5.4 )	(2.0 )	(3.4 )
ZYTIGA®	1,159	1,102	5.2	6.8	(1.6 )
Other Oncology	467	197	*	*	**
Cardiovascular / Metabolism / Other	3,300	3,214	2.7	4.2	(1.5 )
XARELTO®	1,161	913	27.2	27.2	—
INVOKANA®/ INVOKAMET®	708	596	18.8	19.5	(0.7 )
PROCRI®/EPREX®	596	545	9.4	10.9	(1.5 )
Other	835	1,160	(28.0)	(25.0 )	(3.0 )
Total Pharmaceutical Sales	\$16,832	\$15,672	7.4 %	9.1 %	(1.7 )%

\* Percentage greater than 100%

\*\*Not meaningful

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Pharmaceutical segment sales in the fiscal second quarter of 2016 were \$8.7 billion, an increase of 8.9% as compared to the same period a year ago, with an operational increase of 9.7% and a negative currency impact of 0.8%. U.S. Pharmaceutical sales increased 13.2% as compared to the same period a year ago. International Pharmaceutical sales increased by 3.1%, including operational growth of 4.9% and a negative currency impact of 1.8%. Acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 3.1% on the operational growth of the Pharmaceutical segment in the fiscal second quarter of 2016. In the fiscal second quarter of 2016, the Pharmaceutical segment was impacted approximately 1.6% due to a higher positive adjustment to previous reserve estimates as compared to the same period a year ago.

## Major Pharmaceutical Therapeutic Area Sales — Fiscal Second Quarters Ended

(Dollars in Millions)	July 3, 2016	June 28, 2015	Total Change	Operations Change	Currency Change
			%	%	%
Total Immunology	\$3,038	\$2,554	19.0	19.8	(0.8)
REMICADE®	1,780	1,668	6.7	7.7	(1.0)
SIMPONI®/ SIMPONI ARIA®	448	308	45.5	45.4	0.1
STELARA®	804	570	41.1	41.4	(0.3)
Other Immunology	6	8	(25.0)	(15.2)	(9.8)
Total Infectious Diseases	829	1,032	(19.7)	(19.1)	(0.6)
EDURANT®	140	101	38.6	36.9	1.7
OLYSIO®/ SOVRIAD®	43	264	(83.7)	(83.5)	(0.2)
PREZISTA®/ PREZCOBIX®/ REZOLSTA®	459	448	2.5	3.1	(0.6)
Other Infectious Diseases	187	219	(14.6)	(12.5)	(2.1)
Total Neuroscience	1,602	1,564	2.4	2.8	(0.4)
CONCERTA®/ methylphenidate	238	206	15.5	17.3	(1.8)
INVEGA®/ paliperidone	82	166	(50.6)	(51.2)	0.6
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®	560	436	28.4	28.6	(0.2)
RISPERDAL CONSTA®	230	247	(6.9)	(6.7)	(0.2)
Other Neuroscience	492	509	(3.3)	(3.0)	(0.3)
Total Oncology	1,474	1,144	28.8	29.8	(1.0)
IMBRUVICA®	295	154	91.6	93.1	(1.5)
VELCADE®	342	344	(0.6)	1.4	(2.0)
ZYTIGA®	601	546	10.1	10.2	(0.1)
Other Oncology	236	100	*	*	**
Cardiovascular / Metabolism / Other	1,711	1,652	3.6	4.7	(1.1)
XARELTO®	594	472	25.8	25.8	—
INVOKANA®/ INVOKAMET®	383	318	20.4	21.0	(0.6)
PROCRIT®/ EPREX®	322	276	16.7	17.5	(0.8)
Other	412	586	(29.7)	(27.4)	(2.3)
Total Pharmaceutical Sales	\$8,654	\$7,946	8.9	9.7	(0.8)

\* Percentage greater than 100%

\*\*Not meaningful

Immunology products achieved operational sales growth of 19.8% as compared to the same period a year ago due to strong market growth and increased share for both STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab). Additionally, in the fiscal second quarter of 2016, total immunology sales growth was positively impacted by approximately 6.0% due to an adjustment to previous reserve estimates. On a product basis, growth of REMICADE® (infliximab), SIMPONI®/SIMPONI ARIA® (golimumab) and STELARA® (ustekinumab) were

positively impacted by approximately 5.5%, 7.0%, and 7.0%, respectively. 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

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in REMICADE® sales in markets outside the United States. The timing of the possible introduction of any 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 (the BPCIA). In April 2016, the FDA approved a biosimilar version of REMICADE® for sale in the United States. There is a risk that this approved biosimilar version of REMICADE® could be introduced to the U.S. market on or after October 3, 2016 (180 days after the FDA's approval), even though one or more valid patents are in place and the Company will continue to assert its patent rights. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®. The launch of a biosimilar version of REMICADE® in the U.S. is not expected to have a material adverse effect on the Company's results of operations and cash flows in 2016. See Note 11 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

Infectious disease products experienced an operational decline of 19.1% as compared to the same period a year ago. Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on sales. The decline of Hepatitis C sales was partially offset by sales growth of EDURANT®(rilpivirine) and PREZISTA®/ PREZCOBIX®/ REZOLSTA® (darunavir/cobicistat).

Neuroscience products achieved operational sales growth of 2.8% as compared to the same period a year ago primarily due to strong sales of INVEGA SUSTENNA®/XEPLION®/ INVEGA TRINZA®(paliperidone palmitate). Neuroscience products sales were negatively impacted by lower sales of INVEGA® (paliperidone) due to generic competition and RISPERDAL CONSTA® (risperidone).

Oncology products achieved strong operational sales growth of 29.8% 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 the launch of DARZALEX® (daratumumab) in Europe. Sales of ZYTIGA® (abiraterone acetate) grew in the U.S. and Asia primarily due to market growth and the launch in China. Additionally, sales growth of ZYTIGA® (abiraterone acetate) was positively impacted by approximately 3.5% due to an adjustment to previous reserve estimates.

Cardiovascular / Metabolism / Other products achieved operational sales growth of 4.7% as compared to the same period a year ago primarily due to strong sales of XARELTO®(rivaroxaban) and INVOKANA®/INVOKAMET® (canagliflozin). The sales growth of Cardiovascular / Metabolism / Other was negatively impacted by approximately 2.0% due to a higher adjustment to previous reserve estimates in 2015. A positive adjustment to previous reserve estimates in the fiscal second quarter of 2015 was primarily related to hormonal contraceptives while a positive adjustment to previous reserve estimates in the fiscal second quarter of 2016 was primarily related to PROCREDIT®/ EPREX® (Epoetin alfa).

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## Medical Devices

The Medical Devices segment sales in the first fiscal six months of 2016 were \$12.5 billion, a decrease of 0.8% as compared to the same period a year ago, with operational growth of 1.2% and a negative currency impact of 2.0%. U.S. Medical Devices sales increased 1.6%. International Medical Devices sales decreased by 2.9%, including an operational increase of 0.8% and a negative currency impact of 3.7%. In the first fiscal six months of 2016, acquisitions and divestitures had a negative impact of 2.2% on the operational sales growth of the Medical Devices segment.

## Major Medical Devices Franchise Sales\* — Fiscal Six Months Ended

(Dollars in Millions)	July 3, 2016	June 28, 2015	Total Change	Operations Change	Currency Change
Orthopaedics	\$4,696	\$4,658	0.8 %	2.4 %	(1.6 )%
Hips	691	669	3.3	5.3	(2.0 )
Knees	774	748	3.5	5.1	(1.6 )
Trauma	1,278	1,277	0.1	1.8	(1.7 )
Spine & Other	1,953	1,964	(0.6 )	0.9	(1.5 )
Surgery	4,625	4,584	0.9	3.4	(2.5 )
Advanced	1,725	1,610	7.1	9.7	(2.6 )
General	2,197	2,252	(2.4 )	0.2	(2.6 )
Specialty	703	722	(2.6 )	(0.4 )	(2.2 )
Vision Care	1,325	1,277	3.8	5.0	(1.2 )
Cardiovascular	913	1,073	(14.9)	(14.0 )	(0.9 )
Diabetes Care	900	978	(8.0 )	(5.8 )	(2.2 )
Diagnostics	59	46	28.3	47.8	(19.5 )
Total Medical Devices Sales	\$12,518	\$12,616	(0.8 )%	1.2 %	(2.0 )%

\*Prior year amounts have been reclassified to conform to current year product disclosure.

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The Medical Devices segment sales in the fiscal second quarter of 2016 were \$6.4 billion, an increase of 0.8% as compared to the same period a year ago, with operational growth of 1.8% and a negative currency impact of 1.0%. U.S. Medical Devices sales increased 1.0%. International Medical Devices sales increased by 0.6%, including an operational increase of 2.6% and a negative currency impact of 2.0%. In the fiscal second quarter of 2016, acquisitions and divestitures had a negative impact of 2.1% on the operational sales growth of the Medical Devices segment.

## Major Medical Devices Franchise Sales\* — Fiscal Second Quarters Ended

(Dollars in Millions)	July 3, June 28, Total		Operations		Currency
	2016	2015	Change	Change	Change
Orthopaedics	\$2,355	\$2,330	1.1	% 2.0	% (0.9)
Hips	349	336	3.9	5.3	(1.4)
Knees	385	372	3.5	4.6	(1.1)
Trauma	636	621	2.4	3.2	(0.8)
Spine & Other	985	1,001	(1.6)	(0.9)	(0.7)
Surgery	2,397	2,328	3.0	4.6	(1.6)
Advanced	909	840	8.2	9.7	(1.5)
General	1,127	1,119	0.7	2.3	(1.6)
Specialty	361	369	(2.2)	(0.7)	(1.5)
Vision Care	685	646	6.0	5.8	0.2
Cardiovascular	470	544	(13.6)	(13.6)	0.0
Diabetes Care	471	494	(4.7)	(3.5)	(1.2)
Diagnostics	31	16	93.8	**	***
Total Medical Devices Sales	\$6,409	\$6,358	0.8	% 1.8	% (1.0)

\*Prior year amounts have been reclassified to conform to current year product disclosure.

\*\* Percentage greater than 100%

\*\*\*Not meaningful

The Orthopaedics franchise achieved operational sales growth of 2.0% as compared to the prior year fiscal second quarter. Sales growth was primarily driven by worldwide sales of the hip primary stem platform, U.S. sales of the trauma TFNA nailing system, the ATTUNE® Knee System, and sports medicine ORTHOVISC®/MONOVISC® products. Growth was negatively impacted by softer demand and a reduction in customer inventory levels primarily in China and continued pricing pressures.

The Surgery franchise achieved operational sales growth of 4.6% as compared to the prior year fiscal second quarter. Operational growth in Advanced Surgery was driven by endocutter, biosurgery and energy products, primarily attributable to market growth, increased penetration in certain markets and new product launches. The acquisition of NeuWave Medical, Inc. also contributed to growth this quarter. Operational growth in General Surgery was driven by sutures partially offset by lower sales of women's health and urology products. Growth of Mentor products was offset by lower sales of Advanced Sterilization Products in Specialty Surgery.

The Vision Care franchise achieved operational sales growth of 5.8% as compared to the prior year fiscal second quarter due to sales growth across all the major regions driven by new product launches and line extensions. Growth was partially offset in the U.S. by a customer reward program.

The Cardiovascular Care franchise experienced an operational sales decline of 13.6% as compared to the prior year fiscal second quarter. Strong operational growth in the electrophysiology business driven by market growth and new

product launches was offset by the impact of divesting the Cordis business. The Company completed the divestiture of the Cordis business to Cardinal Health on October 4, 2015. The Cordis business generated annual net revenues of approximately \$535 million in 2015.

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The Diabetes Care franchise experienced an operational sales decline of 3.5% as compared to the prior year fiscal second quarter primarily due to price decline of self-monitoring blood glucose (SMBG) products and competition in the U.S., partially offset by the success of the ANIMAS® VIBE® in Europe and Canada and SMBG products in emerging markets.

### 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 2016 was \$10.2 billion as compared to \$11.3 billion in the first fiscal six months of 2015, a decrease of 9.9%. The decrease was primarily due to litigation expense of \$0.7 billion included in the fiscal six months of 2016 versus the fiscal six months of 2015, which included a net litigation gain of \$0.3 billion primarily related to a settlement agreement of \$0.6 billion with Guidant. Additionally, the fiscal six months of 2016 had lower gains of \$0.8 billion on the sale of assets/businesses as compared to the fiscal six months of 2015 and included a restructuring charge of \$0.3 billion. The fiscal six months of 2016 included the divestiture of the controlled substance raw material and active pharmaceutical ingredient (API) business. The fiscal six months of 2015 included the U.S. divestiture of NUCYNTA®. This was partially offset by higher sales volume, favorable mix in the business and lower selling, marketing and administrative costs as compared to the fiscal six months of 2015.

Consolidated earnings before provision for taxes on income for the fiscal second quarter of 2016 was \$4.9 billion as compared to \$5.7 billion in the fiscal second quarter of 2015, a decrease of 14.6%. The decrease was primarily due to lower gains of \$0.8 billion on the sale of assets/businesses and higher litigation expense of \$0.5 billion recorded in 2016, as compared to the fiscal second quarter of 2015. The fiscal second quarter of 2016 included the divestiture of the controlled substance raw material and API business. The fiscal second quarter of 2015 included the U.S. divestiture of NUCYNTA®. Additionally, the fiscal second quarter of 2016 included a restructuring charge of \$0.1 billion. This was partially offset by higher sales volume, favorable mix and lower selling, marketing and administrative costs as compared to the fiscal second quarter of 2015.

### Cost of Products Sold

Consolidated costs of products sold for the first fiscal six months of 2016 decreased to 29.6% from 30.2% of sales as compared to the same period a year ago. Consolidated costs of products sold for the fiscal second quarter of 2016 decreased to 28.9% from 30.1% of sales as compared to the same period a year ago. The decrease in both periods was primarily due to favorable mix in the business and manufacturing efficiencies partially offset by the unfavorable impact of transactional currency. The intangible asset amortization expense for the fiscal six months of 2016 and 2015 was \$576 million and \$619 million, respectively.

### Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the first fiscal six months of 2016 decreased to 27.4% from 29.1% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal second quarter of 2016 decreased to 28.0% from 30.3% of sales as compared to the same period a year ago. The decrease in both periods was primarily due to cost management and favorable mix, primarily due to faster growth in the Pharmaceutical segment.

### Research and Development Expense

Worldwide costs of research and development activities for the first fiscal six months of 2016 increased to 11.9% from 11.5% of sales as compared to the same period a year ago. Worldwide costs of research and development activities for the fiscal second quarter of 2016 increased to 12.2% from 12.0% of sales as compared to the same period

a year ago. The increase was primarily due to increased investment spending in the Pharmaceutical segment to advance the pipeline.

#### In-Process Research and Development (IPR&D)

During the first fiscal six months of 2016, the Company recorded a charge of \$29 million for the discontinuation of a development program related to Crucell.

#### Interest (Income) Expense

Interest income in the fiscal six months and fiscal second quarter of 2016 was higher than the same periods a year ago due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. The ending balance of cash, cash equivalents and marketable securities was \$42.6 billion at the end of the fiscal second quarter of 2016, which is an



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increase of \$8.6 billion as compared to the same period a year ago. The increase in the balance of cash, cash equivalents and marketable securities was primarily due to cash generated from operating activities.

Interest expense in the fiscal six months and fiscal second quarter of 2016 was higher as compared to the same periods a year ago. At the end of the fiscal second quarter of 2016, the Company's debt position was \$26.2 billion as compared to \$19.3 billion the same period a year ago. The higher debt balance of approximately \$6.9 billion was primarily due to increased borrowings in February and May of 2016. 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 is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc., gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income.

The change in other (income) expense, net for the first fiscal six months of 2016 was unfavorable by \$1.8 billion as compared to the same period a year ago. The fiscal six months of 2015 included higher gains of \$0.8 billion on the sale of assets/businesses. The first fiscal six months of 2016 included the divestiture of the controlled substance raw material and API business. The first fiscal six months of 2015 included the U.S. divestiture of NUCYNTA®. Additionally, the fiscal six months of 2016 included litigation expense of \$0.7 billion as compared to a net litigation gain of \$0.3 billion in the fiscal six months of 2015, primarily due to a litigation settlement agreement of \$0.6 billion with Guidant.

The change in other (income) expense, net for the fiscal second quarter of 2016 was unfavorable by \$1.5 billion as compared to the same period a year ago. The fiscal second quarter of 2015 included higher gains of \$0.8 billion on the sale of assets/businesses and lower litigation expense of \$0.5 billion, as compared to the fiscal second quarter of 2016. The fiscal second quarter of 2016 included the divestiture of the controlled substance raw material and API business. The fiscal second quarter of 2015 included the U.S. divestiture of NUCYNTA®.

## INCOME BEFORE TAX BY SEGMENT

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

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015
Consumer	\$1,137	\$961	\$6,614	\$6,873	17.2%	14.0%
Pharmaceutical	7,031	7,084	16,832	15,672	41.8	45.2
Medical Devices	2,515	3,805	12,518	12,616	20.1	30.2
Segment total	10,683	11,850	35,964	35,161	29.7	33.7
Less: Expenses not allocated to segments <sup>(1)</sup>	485	534				
Worldwide total	\$10,198	\$11,316	\$35,964	\$35,161	28.4%	32.2%

<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:

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015

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	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015	July 3, 2016	June 28, 2015
Consumer	\$571	\$ 317	\$3,419	\$3,483	16.7%	9.1 %
Pharmaceutical	3,687	4,122	8,654	7,946	42.6	51.9
Medical Devices	939	1,584	6,409	6,358	14.7	24.9
Segment operating profit	5,197	6,023	18,482	17,787	28.1	33.9
Less: Expenses not allocated to segments <sup>(1)</sup>	293	282				
Worldwide income before tax	\$4,904	\$ 5,741	\$18,482	\$17,787	26.5%	32.3 %

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

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### Consumer Segment

The Consumer segment income before tax as a percent of sales in the first fiscal six months of 2016 was 17.2% versus 14.0% for the same period a year ago. The Consumer segment income before tax as a percent of sales in the fiscal second quarter of 2016 was 16.7% versus 9.1% for the same period a year ago. The increase in the income before tax as a percent to sales for both periods was primarily due to favorable selling, marketing and administrative expenses due to cost management and higher gross profit margins due to cost improvement projects and favorable mix. This was partially offset by operations in Venezuela.

### Pharmaceutical Segment

The Pharmaceutical segment income before tax as a percent of sales in the first fiscal six months of 2016 was 41.8% versus 45.2% for the same period a year ago. The Pharmaceutical segment income before tax as a percent of sales in the fiscal second quarter of 2016 was 42.6% versus 51.9% for the same period a year ago. The decrease in the income before tax as a percent to sales for both periods was primarily due to higher divestiture gains of \$0.8 million in 2015 as compared to 2016. The second quarter and first fiscal six months of 2016 included the divestiture of the controlled substance raw material and API business. The second quarter and first fiscal six months of 2015 included the U.S. divestiture of NUCYNTA®. This was partially offset by strong sales volume growth, a higher positive adjustment of \$0.1 billion to previous reserve estimates as compared to the prior year and favorable selling, marketing and administrative expenses. Additionally, the fiscal six months of 2016, had a lower net litigation expense of \$0.2 billion as compared to the prior year.

### Medical Devices Segment

The Medical Devices segment income before tax as a percent of sales in the first fiscal six months of 2016 was 20.1% versus 30.2% for the same period a year ago. The decrease in the income before tax as a percent to sales for the fiscal six months was primarily due to litigation expense of \$0.7 billion in the fiscal six months of 2016 as compared to the fiscal six months of 2015, which included a net litigation gain of \$0.4 billion primarily related to a litigation settlement agreement of \$0.6 billion with Guidant. Additionally, the fiscal six months of 2016 included a restructuring charge of \$0.3 billion and was impacted by unfavorable transactional currency. This was partially offset by lower costs of \$0.1 billion associated with the DePuy ASR<sup>TH</sup>Hip program as compared to the fiscal six months of 2015.

The Medical Devices segment income before tax as a percent of sales in the fiscal second quarter of 2016 was 14.7% versus 24.9% for the same period a year ago. The decrease in the income before tax as a percent to sales for the fiscal second quarter was primarily due to higher litigation expense of \$0.4 billion in the fiscal second quarter of 2016 as compared to the fiscal second quarter of 2015. Additionally, the fiscal second quarter of 2016 included a restructuring charge of \$0.1 billion and was impacted by unfavorable transactional currency.

### Restructuring

The Company announced restructuring actions in its Medical Devices segment that are expected to result in annualized pre-tax cost savings of \$800 million to \$1.0 billion, the majority of which is expected to be realized by the end of 2018, including approximately \$200 million savings in 2016. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately \$2.0 billion to \$2.4 billion, most of which are expected to be incurred by 2017. In the fiscal second quarter of 2016, the Company recorded a pre-tax charge of \$141 million, of which \$7 million is included in cost of products sold and \$20 million is included in other (income) expense. In the first fiscal six months of 2016, the Company recorded a pre-tax charge of \$278 million, of which \$24 million was included in cost of products sold and

\$20 million was included in other (income) expense. Restructuring charges of \$868 million 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 2016 and 2015 were 17.1% and 21.9%, respectively. In the first fiscal six months of 2016, the Company had higher income in lower tax jurisdictions relative to higher tax jurisdictions as compared to 2015, which decreased the effective tax rate by approximately 1.7%. The Company adopted the new accounting standard for the reporting of tax benefits on share-based compensation. As described in Note 1 to the Consolidated Financial Statements, the adoption of this new standard reduced the tax rate for the first six months of fiscal

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2016, by approximately 2.8% versus 2015. The remainder of the change from prior year was primarily related to the U.S. Research & Development tax credit and the Controlled Foreign Corporation look-through provisions, which were not enacted into law until the fiscal fourth quarter of 2015, and the settlement of certain open tax positions in several international jurisdictions.

As of July 3, 2016, the Company had approximately \$3.1 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 3, 2016 for more detailed information regarding unrecognized tax benefits.

## LIQUIDITY AND CAPITAL RESOURCES

### Cash Flows

Cash and cash equivalents were \$18.6 billion at the end of the fiscal second quarter of 2016 as compared with \$13.7 billion at the fiscal year end of 2015. The primary sources of cash were approximately \$6.8 billion net cash generated from operating activities offset by \$0.2 billion used by investing activities and \$1.6 billion used by financing activities. In addition, the Company had \$23.9 billion in marketable securities at the end of the fiscal second quarter of 2016 and \$24.6 billion at the end of 2015.

Cash flow from operations of \$6.8 billion was the result of \$8.5 billion of net earnings, \$2.5 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation and asset write-downs, and \$0.1 billion related to deferred taxes. Cash flow from operations was reduced by \$1.0 billion related to accounts payable and accrued liabilities, primarily due to the timing of payments and receipts for tax and legal liabilities, \$1.5 billion related to accounts receivable and inventories, \$1.5 billion of other assets and liabilities and \$0.2 billion from net gains on sale of assets/businesses.

Investing activities use of \$0.2 billion of cash was primarily used for additions to property, plant and equipment of \$1.4 billion and \$0.7 billion for acquisitions. Investing activities also included a source of \$1.2 billion from the net sales of investments in marketable securities and proceeds from the disposal of assets/businesses of \$0.7 billion.

Financing activities use of \$1.6 billion of cash was primarily for dividends to shareholders of \$4.3 billion and \$4.8 billion for the repurchase of common stock. Financing activities also included a source of \$6.5 billion from the net proceeds of short and long-term debt and \$0.9 billion of proceeds from stock options exercised/employee withholding tax on stock awards, net.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 15, 2016, 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 2016, the Company continued to have access to liquidity through the commercial paper market. The Company anticipates that operating cash flows, existing credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs. However, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are

favorable. In the fiscal first quarter and fiscal second quarter of 2016, the Company issued bonds for a total of \$7.5 billion and \$4.4 billion, respectively, 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 3, 2016, \$4.3 billion has been repurchased under the program. The repurchase program has no time limit and may be delayed or suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets.

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### Dividends

On April 28, 2016, the Board of Directors declared a regular cash dividend of \$0.80 per share, payable on June 7, 2016 to shareholders of record as of May 24, 2016.

On July 18, 2016, the Board of Directors declared a regular cash dividend of \$0.80 per share, payable on September 6, 2016 to shareholders of record as of August 23, 2016. The Company expects to continue the practice of paying regular quarterly cash dividends.

### Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately \$1.4 billion as of July 3, 2016 and \$1.3 billion as of January 3, 2016. Approximately \$0.9 billion as of July 3, 2016 and approximately \$0.8 billion as of January 3, 2016 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers, which are in line with historical collection patterns.

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

### 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.

As described above, while the Company continues to do business in Greece, the Company closely monitors the economic situation. As of July 3, 2016, the business of the Company's Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and fiscal six months revenues, respectively.

On June 23, 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.” 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 3, 2016, 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.



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

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

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 11 to the Consolidated Financial Statements.

## CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-Q contains forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. Forward-looking statements may be identified by the use of words like "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things, discussions of future operations, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures.

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

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

delays, internally or within the supply chain; complex global supply chains with increasing regulatory requirements; product efficacy or safety concerns resulting in product recalls or regulatory action; disruptions due to natural disasters; and the potential failure to meet obligations in compliance agreements with government bodies.

The Company's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including Exhibit 99 thereto, contains a discussion of additional factors that could cause actual results to differ from expectations. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

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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 3, 2016.

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, Board of Directors and Chief Executive Officer, and Dominic J. Caruso, Vice President, Finance and Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

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.

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 has no time limit and may be delayed or suspended for periods or discontinued at any time.

The following table provides information with respect to Common Stock purchases by the Company during the fiscal second quarter of 2016. The repurchases below also include the stock-for-stock option exercises that settled in the

fiscal second quarter.

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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 4, 2016 through May 1, 2016	4,178,207	110.15	—	—
May 2, 2016 through May 29, 2016	7,611,271	113.14	5,675,241	—
May 30, 2016 through July 3, 2016	9,037,789	115.79	8,537,333	—
Total	20,827,267		14,212,574	47,361,210

(1) During the fiscal second quarter of 2016, the Company repurchased an aggregate of 20,827,267 shares of Johnson & Johnson Common Stock in open-market transactions, of which 14,212,574 shares were purchased pursuant to the repurchase program that was publicly announced on October 13, 2015, and of which 6,614,693 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 3, 2016, an aggregate of 39,679,023 shares were purchased for a total of \$4.3 billion since the inception of the repurchase program announced on October 13, 2015.

(3) As of July 3, 2016, the maximum number of shares that may yet be purchased under the plan is 47,361,210 based on the closing price of the Company's Common Stock on the New York Stock Exchange on July 1, 2016 of \$121.29 per share.

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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 3, 2016, formatted in Extensive Business Reporting Language (XBRL), (i) consolidated balance sheets, (ii) consolidated statements of earnings, (iii) consolidated statements of comprehensive income (iv) consolidated statements of 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 4, 2016 By /s/ D. J. CARUSO  
D. J. CARUSO  
Executive Vice President, Chief Financial Officer (Principal Financial Officer)

Date: August 4, 2016 By /s/ R. A. KAPUSTA  
R. A. KAPUSTA  
Controller (Principal Accounting Officer)