JOHNSON & JOHNSON
Form 10-Q
October 30, 2015

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

þ	Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 27, 2015

or

o	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 incorporation or organization)	(I.R.S. Employer 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. þ Yes o No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). þ Yes o 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 þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes þ No
Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.
On October 23, 2015, 2,766,943,629 shares of Common Stock, $1.00 par value, were outstanding.

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Part I — FINANCIAL INFORMATION

Item 1 — FINANCIAL STATEMENTS

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited; Dollars in Millions Except Share and Per Share Data)

	September 27, 2015	December 28, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$13,639	14,523
Marketable securities	23,667	18,566
Accounts receivable, trade, less allowances for doubtful accounts $260 (2014, $275)	11,366	10,985
Inventories (Note 2)	8,206	8,184
Deferred taxes on income	3,606	3,567
Prepaid expenses and other	3,010	3,486
Total current assets	63,494	59,311
Property, plant and equipment at cost	36,397	36,685
Less: accumulated depreciation	(20,846)	(20,559)
Property, plant and equipment, net	15,551	16,126
Intangible assets, net (Note 3)	25,988	27,222
Goodwill (Note 3)	21,279	21,832
Deferred taxes on income	3,150	3,396
Other assets	3,804	3,232
Total assets	$133,266	131,119
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Loans and notes payable	$5,677	3,638
Accounts payable	5,928	7,633
Accrued liabilities	5,062	6,553
Accrued rebates, returns and promotions	5,338	4,010
Accrued compensation and employee related obligations	2,324	2,751
Accrued taxes on income	931	500
Total current liabilities	25,260	25,085
Long-term debt (Note 4)	14,073	15,122
Deferred taxes on income	3,561	3,154
Employee related obligations	9,515	9,972
Other liabilities	9,303	8,034
Total liabilities	61,712	61,367
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)	(12,861)	(10,722)
Retained earnings	102,748	97,245
Less: common stock held in treasury, at cost (352,562,000 and 336,620,000 shares)	21,453	19,891

Total shareholders’ equity	71,554	69,752
Total liabilities and shareholders' equity	$133,266	131,119

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 Third Quarters Ended					
	September 27, 2015	Percent to Sales		September 28, 2014	Percent to Sales	
Sales to customers (Note 9)	$17,102	100.0	%	$ 18,467	100.0	%
Cost of products sold	5,224	30.5		5,399	29.2	
Gross profit	11,878	69.5		13,068	70.8	
Selling, marketing and administrative expenses	5,081	29.7		5,468	29.6	
Research and development expense	2,154	12.6		2,023	11.0	
In-process research and development	10	0.1		—	—	
Interest income	(32)	(0.2)		(18)	(0.1)	
Interest expense, net of portion capitalized	123	0.7		130	0.7	
Other (income) expense, net	420	2.5		(1,345)	(7.3)	
Earnings before provision for taxes on income	4,122	24.1		6,810	36.9	
Provision for taxes on income (Note 5)	764	4.5		2,061	11.2	
NET EARNINGS	$3,358	19.6	%	$ 4,749	25.7	%
NET EARNINGS PER SHARE (Note 8)						
Basic	$1.21			$ 1.69		
Diluted	$1.20			$ 1.66		
CASH DIVIDENDS PER SHARE	$0.75			$ 0.70		
AVG. SHARES OUTSTANDING						
Basic	2,768.4			2,814.4		
Diluted	2,807.2			2,864.3		

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 Nine Months Ended					
	September 27, 2015	Percent to Sales		September 28, 2014	Percent to Sales	
Sales to customers (Note 9)	$ 52,263	100.0	%	$ 56,077	100.0	%
Cost of products sold	15,863	30.4		16,893	30.1	
Gross profit	36,400	69.6		39,184	69.9	
Selling, marketing and administrative expenses	15,312	29.3		16,132	28.8	
Research and development expense	6,182	11.8		5,859	10.5	
In-process research and development	10	0.0		22	0.0	
Interest income	(75)	(0.1)		(50)	(0.1)	
Interest expense, net of portion capitalized	392	0.7		394	0.7	
Other (income) expense, net	(859)	(1.6)		(1,033)	(1.8)	
Earnings before provision for taxes on income	15,438	29.5		17,860	31.8	
Provision for taxes on income (Note 5)	3,244	6.2		4,058	7.2	
NET EARNINGS	$ 12,194	23.3	%	$ 13,802	24.6	%
NET EARNINGS PER SHARE (Note 8)						
Basic	$ 4.39			$ 4.89		
Diluted	$ 4.33			$ 4.81		
CASH DIVIDENDS PER SHARE	$ 2.20			$ 2.06		
AVG. SHARES OUTSTANDING						
Basic	2,774.8			2,822.0		
Diluted	2,817.1			2,871.2		

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

	Fiscal Third Quarters Ended		Fiscal Nine Months Ended	
	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014
Net earnings	$3,358	4,749	12,194	13,802
Other comprehensive income (loss), net of tax				
Foreign currency translation	(1,069)	(2,400)	(2,729)	(2,499)
Securities:				
Unrealized holding gain (loss) arising during period	(44)	(35)	267	6
Reclassifications to earnings	(46)	(1)	(127)	(1)
Net change	(90)	(36)	140	5
Employee benefit plans:				
Prior service cost amortization during period	(5)	(5)	(16)	(14)
Gain (loss) amortization during period	159	101	477	301
Net change	154	96	461	287
Derivatives & hedges:				
Unrealized gain (loss) arising during period	160	14	26	(139)
Reclassifications to earnings	38	(49)	(37)	(176)
Net change	198	(35)	(11)	(315)
Other comprehensive income (loss)	(807)	(2,375)	(2,139)	(2,522)
Comprehensive income	$2,551	2,374	10,055	11,280

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal third quarters were as follows for 2015 and 2014, respectively: Securities: $48 million and $19 million; Employee Benefit Plans: $75 million and $46 million; Derivatives & Hedges: $107 million and $19 million.

The tax effects in other comprehensive income for the fiscal nine months were as follows for 2015 and 2014, respectively: Securities: $76 million and $3 million; Employee Benefit Plans: $226 million and $139 million; Derivatives & Hedges: $6 million and $170 million.

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

	Fiscal Nine Months Ended	
	September 27, 2015	September 28, 2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	$12,194	13,802
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	2,713	2,904
Stock based compensation	677	646
Venezuela adjustments	—	89
Asset write-downs	367	259
Net gain on sale of assets/businesses	(1,274)	(2,336)
Deferred tax provision	233	297
Accounts receivable allowances	2	(54)
Changes in assets and liabilities, net of effects from acquisitions:		
Increase in accounts receivable	(910)	(399)
Increase in inventories	(719)	(1,098)
Decrease in accounts payable and accrued liabilities	(1,558)	(827)
Decrease in other current and non-current assets	986	72
Increase in other current and non-current liabilities	1,486	751
NET CASH FLOWS FROM OPERATING ACTIVITIES	14,197	14,106
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(2,097)	(2,218)
Proceeds from the disposal of assets/businesses, net	1,620	4,481
Acquisitions, net of cash acquired	(233)	(291)
Purchases of investments	(28,766)	(25,784)
Sales of investments	23,167	14,576
Other	(35)	(147)
NET CASH USED BY INVESTING ACTIVITIES	(6,344)	(9,383)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(6,101)	(5,812)
Repurchase of common stock	(3,394)	(4,381)
Proceeds from short-term debt	2,107	629
Retirement of short-term debt	(930)	(1,713)
Proceeds from long-term debt	3	17
Retirement of long-term debt	(27)	(1,787)
Proceeds from the exercise of stock options/excess tax benefits	837	1,406
Other	(50)	—
NET CASH USED BY FINANCING ACTIVITIES	(7,555)	(11,641)
Effect of exchange rate changes on cash and cash equivalents	(1,182)	(191)
Decrease in cash and cash equivalents	(884)	(7,109)

Cash and Cash equivalents, beginning of period	14,523	20,927
CASH AND CASH EQUIVALENTS, END OF PERIOD	$13,639	13,818
Acquisitions		
Fair value of assets acquired	$477	305
Fair value of liabilities assumed and noncontrolling interests	(244)	(14)
Net fair value of acquisitions	233	291

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 December 28, 2014. 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.

During the fiscal third quarter of 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update 2015-16 Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015. The amendments in this update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. This update is not expected to have a material impact on the Company's consolidated financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-11: Simplifying the Measurement of Inventory. This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. 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 2015, the FASB issued Accounting Standard Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be applied retroactively for all periods presented. This update will not have a material impact on the presentation of the Company's financial position.

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

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date of Accounting Standards Update No. 2014-09 to be adopted by all public companies for all annual periods and interim reporting

periods beginning after December 15, 2017. Early adoption of this standard is permitted but not before the original effective for the year beginning after December 15, 2016. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

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

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 beginning after December 15, 2016. This standard is not expected to have any impact on current disclosures in the financial statements.

Annual Closing Date

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

NOTE 2 — INVENTORIES

(Dollars in Millions)	September 27, 2015	December 28, 2014
Raw materials and supplies	$1,198	1,214
Goods in process	2,026	2,461
Finished goods	4,982	4,509
Total inventories	$8,206	8,184

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 2014. 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)	September 27, 2015	December 28, 2014
Intangible assets with definite lives:		
Patents and trademarks — gross	$8,298	9,074
Less accumulated amortization	4,687	4,700
Patents and trademarks — net	3,611	4,374
Customer relationships and other intangibles — gross	17,739	17,970
Less accumulated amortization	5,637	5,227
Customer relationships and other intangibles — net	12,102	12,743
Intangible assets with indefinite lives:		
Trademarks	7,084	7,263
Purchased in-process research and development	3,191	2,842
Total intangible assets with indefinite lives	10,275	10,105
Total intangible assets — net	$25,988	27,222

Goodwill as of September 27, 2015 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Devices	Total
Goodwill, net at December 28, 2014	$7,675	2,626	11,531	21,832
Goodwill, related to acquisitions	—	64	22	86
Goodwill, related to divestitures	(117)	(17)	(1)	(135)
Currency translation/Other	(350)	(56)	(98) (1)	(504)
Goodwill, net as of September 27, 2015	$7,208	2,617	11,454	21,279

See Note 10 to the Consolidated Financial Statements for more details related to business combinations and divestitures.

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(1)Includes $98 million classified as held for sale, a component of other assets on the Consolidated Balance Sheet, related to the divestiture of Cordis which was pending as of September 27, 2015.

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 17 years and 24 years, respectively. The amortization expense of amortizable intangible assets included in cost of products sold was $912 million and $1,033 million for the fiscal nine months ended September 27, 2015 and September 28, 2014, 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.

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. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company may use forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral by either the Company or the counter-party. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an "A" (or equivalent) credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this note for receivables and payables with these commercial institutions. As of September 27, 2015, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $27.8 billion, $2.4 billion and $2.2 billion, respectively.

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

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts and cross currency interest rate swaps. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting

period, hedge ineffectiveness associated with interest rate swaps were not material.

As of September 27, 2015, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was $130 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. 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 third quarters in 2015 and 2014:

	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
(Dollars in Millions)	Fiscal Third Quarters Ended					
Cash Flow Hedges By Income Statement Caption	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014
Sales to customers[3]	$3	(43)	(24)	(2)	(3)	—
Cost of products sold[3]	222	(37)	(34)	37	1	(2)
Research and development expense[3]	(10)	25	7	8	—	—
Interest (income)/Interest expense, net[4]	(13)	11	1	(6)	—	—
Other (income) expense, net[3]	(42)	58	12	12	(1)	—
Total	$160	14	(38)	49	(3)	(2)

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the first fiscal nine months in 2015 and 2014:

	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
(Dollars in Millions)	Fiscal Nine Months Ended					
Cash Flow Hedges By Income Statement Caption	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014
Sales to customers[3]	$(52)	(73)	(95)	6	(5)	1
Cost of products sold[3]	106	(187)	82	196	15	(4)
Research and development expense[3]	(13)	28	(2)	(5)	—	(1)
Interest (income)/Interest expense, net[4]	(42)	21	(2)	(12)	—	—
Other (income) expense, net[3]	27	72	54	(9)	—	—
Total	$26	(139)	37	176	10	(4)

All amounts shown in the table above are net of tax.
(1) Effective portion
(2) Ineffective portion
(3) Forward foreign exchange contracts
(4) Cross currency interest rate swaps

For the fiscal third quarters ended September 27, 2015 and September 28, 2014, a loss of $8 million and a loss of $2 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

For the fiscal nine months ended September 27, 2015 and September 28, 2014, a gain of $32 million and a loss of $48 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

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

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or

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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 September 27, 2015 and December 28, 2014 were as follows:

	September 27, 2015				December 28, 2014
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total[1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts[7]	$—	791	—	791	996
Interest rate contracts [2][4][7]	—	51	—	51	31
Total	—	842	—	842	1,027
Liabilities:					
Forward foreign exchange contracts[8]	—	472	—	472	751
Interest rate contracts [3][4]	—	185	—	185	8
Total	—	657	—	657	759
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts[7]	—	56	—	56	29
Liabilities:					
Forward foreign exchange contracts[8]	—	39	—	39	51
Available For Sale Other Investments:					
Equity investments[5]	1,130	—	—	1,130	679
Debt securities[6]	$—	5,269	—	5,269	—

(1) 2014 assets and liabilities are all classified as Level 2 with the exception of equity investments of $679 million, which are classified as Level 1.
(2) Includes $45 million and $29 million of non-current other assets for September 27, 2015 and December 28, 2014, respectively.
(3) Includes $185 million and $8 million of non-current other liabilities for September 27, 2015 and December 28, 2014, respectively.
(4) Includes cross currency interest rate swaps and interest rate swaps.
(5) Classified as non-current other assets. The carrying amount of the equity investments were $531 million and $284 million as of September 27, 2015 and December 28, 2014, respectively. The unrealized gains were $648 million and $406 million as of September 27, 2015 and December 28, 2014, respectively. The unrealized losses were $49 million and $11 million as of September 27, 2015 and December 28, 2014, respectively.
(6) Classified as current marketable securities.
(7) Classified as other current assets.
(8) Classified as accounts payable.

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The Company's cash, cash equivalents and current marketable securities as of September 27, 2015 comprised:

	September 27, 2015					
(Dollars in Millions)	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$1,976	—	—	1,976	1,976	
U.S. Gov't Securities[1]	15,694	5	—	15,699	1,700	13,994
Other Sovereign Securities[1]	2,737	—	—	2,737	1,192	1,545
U.S. Reverse repurchase agreements[1]	3,015	—	—	3,015	3,015	
Other Reverse repurchase agreements[1]	2,179	—	—	2,179	2,179	
Corporate debt securities[1]	4,237	—	—	4,237	1,378	2,859
Money market funds	1,358	—	—	1,358	1,358	
Time deposits[1]	841	—	—	841	841	
Subtotal	32,037	5	—	32,042	13,639	18,398
Gov't Securities	4,255	14	(1)	4,268	—	4,268
Corporate debt securities	1,002	2	(3)	1,001	—	1,001
Subtotal Available for Sale[2]	$5,257	16	(4)	5,269	—	5,269
Total cash, cash equivalents and current marketable securities					13,639	23,667

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

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 December 28, 2014.
The contractual maturities of the debt securities available for sale at September 27, 2015 are due from one year through five years.

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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 September 27, 2015:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Liabilities		
Current Debt	$5,677	5,677
Non-Current Debt		
3 month LIBOR+0.07% FRN due 2016	800	800
0.70% Notes due 2016	399	400
5.55% Debentures due 2017	1,000	1,084
1.125% Notes due 2017	706	710
5.15% Debentures due 2018	899	995
1.65% Notes due 2018	609	616
4.75% Notes due 2019 (1B Euro 1.1267)	1,123	1,322
1.875% Notes due 2019	510	517
3% Zero Coupon Convertible Subordinated Debentures due in 2020	140	181
2.95% Debentures due 2020	545	585
3.55% Notes due 2021	448	487
2.45% Notes due 2021	350	357
6.73% Debentures due 2023	250	326
3.375% Notes due 2023	811	856
5.50% Notes due 2024 (500 MM GBP 1.5215)	756	940
6.95% Notes due 2029	297	426
4.95% Debentures due 2033	500	571
4.375% Notes due 2033	864	932
5.95% Notes due 2037	996	1,275
5.85% Debentures due 2038	700	898
4.50% Debentures due 2040	541	585
4.85% Notes due 2041	298	345
4.50% Notes due 2043	499	539
Other	32	32
Total Non-Current Debt	$14,073	15,779

The weighted average effective interest rate on non-current debt is 4.18%.

The excess of the fair value over the carrying value of debt was $2.2 billion at December 28, 2014.

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

NOTE 5 — INCOME TAXES

The worldwide effective income tax rates for the fiscal nine months of 2015 and 2014 were 21.0% and 22.7%, respectively. The lower effective tax rate in 2015 as compared to 2014 was primarily due to the 2014 divestiture of the Ortho-Clinical Diagnostics business at an approximate 41.0% effective tax rate and the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible. This additional 2014 tax expense was partially offset by a benefit from the Conor Medsystems divestiture, a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009 and the federal appeals court’s decision in OMJ Pharmaceuticals, Inc.’s litigation regarding

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credits under former Section 936 of the Internal Revenue Code. Additionally, the effective tax rate is lower in 2015 as compared to 2014 as a result of the mix in foreign earnings to lower tax jurisdictions.

As of September 27, 2015, the Company had approximately $2.6 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 other 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 third quarters of 2015 and 2014 include the following components:

	Fiscal Third Quarters Ended			
	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014
Service cost	$247	197	64	52
Interest cost	246	255	46	50
Expected return on plan assets	(451)	(403)	(2)	(2)
Amortization of prior service cost/(credit)	—	1	(8)	(8)
Recognized actuarial losses	186	115	50	33
Curtailments and settlements	—	(11)	—	—
Net periodic benefit cost	$228	154	150	125

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal nine months of 2015 and 2014 include the following components:

	Fiscal Nine Months Ended			
	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	September 27, 2015	September 28, 2014	September 27, 2015	September 28, 2014
Service cost	$744	594	193	158
Interest cost	743	768	139	149
Expected return on plan assets	(1,361)	(1,212)	(5)	(5)
Amortization of prior service cost/(credit)	1	4	(25)	(25)
Recognized actuarial losses	560	346	150	101
Curtailments and settlements	4	(11)	—	—
Net periodic benefit cost	$691	489	452	378

Company Contributions

For the fiscal nine months ended September 27, 2015, the Company contributed $316 million and $23 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.

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NOTE 7 — ACCUMULATED OTHER COMPREHENSIVE INCOME

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

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/(Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 28, 2014	$ (4,803)	257	(6,317)	141	(10,722)
Net change	(2,729)	140	461	(11)	(2,139)
September 27, 2015	$ (7,532)	397	(5,856)	130	(12,861)

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 hedged 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 third quarters ended September 27, 2015 and September 28, 2014:

(Shares in Millions)	Fiscal Third Quarters Ended September 27, 2015	September 28, 2014
Basic net earnings per share	$ 1.21	1.69
Average shares outstanding — basic	2,768.4	2,814.4
Potential shares exercisable under stock option plans	129.4	148.4
Less: shares which could be repurchased under treasury stock method	(92.8)	(101.2)
Convertible debt shares	2.2	2.7
Average shares outstanding — diluted	2,807.2	2,864.3
Diluted earnings per share	$ 1.20	1.66

The diluted earnings per share calculation for both the fiscal third quarters ended September 27, 2015 and September 28, 2014 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 the fiscal third quarter ended September 27, 2015 excluded 20 million shares related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share. Diluted earnings per share calculation for the fiscal third quarter ended September 28, 2014 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 nine months ended September 27, 2015 and September 28, 2014:

(Shares in Millions)	Fiscal Nine Months Ended September 27, 2015	September 28, 2014
Basic net earnings per share	$4.39	4.89
Average shares outstanding — basic	2,774.8	2,822.0
Potential shares exercisable under stock option plans	129.1	148.8
Less: shares which could be repurchased under treasury stock method	(89.0)	(102.3)
Convertible debt shares	2.2	2.7
Average shares outstanding — diluted	2,817.1	2,871.2
Diluted earnings per share	$4.33	4.81

The diluted earnings per share calculation for both the fiscal nine months ended September 27, 2015 and September 28, 2014 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 the fiscal nine months ended September 27, 2015 excluded 20 million shares related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share. Diluted net earnings per share calculation for the fiscal nine months ended September 28, 2014 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 Third Quarters Ended September 27, 2015	September 28, 2014	Percent Change
Consumer			
United States	$1,277	1,173	8.9 %
International	2,037	2,416	(15.7)
Total	3,314	3,589	(7.7)
Pharmaceutical			
United States	4,509	4,723	(4.5)
International	3,185	3,584	(11.1)
Total	7,694	8,307	(7.4)
Medical Devices			
United States	3,005	2,946	2.0
International	3,089	3,625	(14.8)
Total	6,094	6,571	(7.3)

Worldwide				
United States	8,791	8,842	(0.6	)
International	8,311	9,625	(13.7	)
Total	$17,102	18,467	(7.4	)%

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(Dollars in Millions)	Fiscal Nine Months Ended September 27, 2015	September 28, 2014	Percent Change	
Consumer				
United States	$3,991	3,802	5.0	%
International	6,196	7,088	(12.6	)
Total	10,187	10,890	(6.5	)
Pharmaceutical				
United States	13,423	13,076	2.7	
International	9,943	11,238	(11.5	)
Total	23,366	24,314	(3.9	)
Medical Devices				
United States	8,980	9,300	(3.4	)
International	9,730	11,573	(15.9	)
Total	18,710	20,873	(10.4	)
Worldwide				
United States	26,394	26,178	0.8	
International	25,869	29,899	(13.5	)
Total	$52,263	56,077	(6.8	)%

SEGMENT PRE-TAX PROFIT

(Dollars in Millions)	Fiscal Third Quarters Ended September 27, 2015	September 28, 2014	Percent Change	
Consumer [1]	$811	407	99.3	%
Pharmaceutical[2]	2,732	3,247	(15.9	)
Medical Devices[3]	835	3,399	(75.4	)
Segments operating profit	4,378	7,053	(37.9	)
Less: Expense not allocated to segments [4]	256	243		
Worldwide income before taxes	$4,122	6,810	(39.5	)%

(Dollars in Millions)	Fiscal Nine Months Ended September 27, 2015	September 28, 2014	Percent Change	
Consumer [1]	$1,772	1,588	11.6	%
Pharmaceutical[2]	9,816	9,921	(1.1	)
Medical Devices[3]	4,640	7,069	(34.4	)
Segments operating profit	16,228	18,578	(12.6	)
Less: Expense not allocated to segments [4]	790	718		
Worldwide income before taxes	$15,438	17,860	(13.6	)%

(1) Includes a gain of $229 million from the divestiture of the SPLENDA® brand recorded in the fiscal third quarter and fiscal nine months of 2015. Includes a gain of $388 million from the divestiture of the K-Y® brand recorded in the fiscal nine months of 2014.

(2) Includes litigation expense of $136 million in the fiscal nine months of 2015. Includes a gain of $981 million recorded in the fiscal nine months of 2015 from the divestiture of the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. Includes an

additional year of the Branded Prescription Drug Fee of $220 million recorded in the fiscal third quarter and fiscal nine months of 2014.

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(3) Includes litigation expense of $409 million related to product liability and a $0.3 billion intangible asset write-down related to Acclarent recorded in the fiscal third quarter of 2015. Includes a net gain of $1,948 million from the divestiture of the Ortho-Clinical Diagnostics business, litigation expense of $225 million, Synthes integration costs of $167 million and $126 million for costs associated with the DePuy ASR™ Hip program recorded in the fiscal third quarter of 2014. Includes $148 million for costs associated with the DePuy ASR™ Hip program, Synthes integration costs of $113 million and a $0.3 billion intangible asset write-down related to Acclarent recorded in the fiscal nine months of 2015. Includes a net gain of $1,948 million from the divestiture of the Ortho-Clinical Diagnostics business, litigation expense of $501 million, Synthes integration costs of $429 million and $126 million for costs associated with the DePuy ASR™ Hip program recorded in the fiscal nine months of 2014.
(4) Amounts not allocated to segments include interest income/expense and general corporate income/expense.
SALES BY GEOGRAPHIC AREA

(Dollars in Millions)	Fiscal Third Quarters Ended			
	September 27, 2015	September 28, 2014	Percent Change	
United States	$8,791	8,842	(0.6	)%
Europe	3,802	4,446	(14.5	)
Western Hemisphere, excluding U.S.	1,463	1,820	(19.6	)
Asia-Pacific, Africa	3,046	3,359	(9.3	)
Total	$17,102	18,467	(7.4	)%

(Dollars in Millions)	Fiscal Nine Months Ended			
	September 27, 2015	September 28, 2014	Percent Change	
United States	$26,394	26,178	0.8	%
Europe	11,993	14,387	(16.6	)
Western Hemisphere, excluding U.S.	4,603	5,378	(14.4	)
Asia-Pacific, Africa	9,273	10,134	(8.5	)
Total	$52,263	56,077	(6.8	)%

NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES
Subsequent to the quarter, on October 2, 2015, the Company completed the divestiture of the Cordis business to Cardinal Health for an approximate value of $2.0 billion subject to customary adjustments. The Company will record the gain in the fiscal fourth quarter of 2015. As of September 27, 2015, the assets classified as held for sale relating to the Cordis business were $173 million of inventory classified as prepaid expenses and other on the Consolidated Balance Sheet. The non-current assets classified as held for sale relating to the Cordis business were $104 million of property, plant and equipment, net, $59 million of intangible assets and $98 million of goodwill classified as other assets on the Consolidated Balance Sheet.

During the fiscal third quarter of 2015, the Company completed the divestiture of its SPLENDA® brand to Heartland Food Products Group. The pre-tax gain on the divestiture was $229 million and was recognized in Other (income) expense, net.

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 the anti-thrombin antibody, ichorcumab.

During the fiscal third quarter of 2014, the Company divested its Ortho-Clinical Diagnostics business to The Carlyle Group, for approximately $4.0 billion. The Company recorded a pre-tax net gain of approximately $1.9 billion in the fiscal third quarter of 2014. As of September 27, 2015, the assets classified as held for sale relating to the Ortho-Clinical Diagnostics companies in countries that have not completely closed due to local regulatory requirements were $42 million of inventory, classified as prepaid expenses and other on the Consolidated Balance Sheet and $107 million of property, plant and equipment, classified as other assets on the Consolidated Balance Sheet. Additional countries are expected to close by the end of the year.

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During the fiscal third quarter of 2014, the Company completed the acquisition of Covagen AG, a privately-held, biopharmaceutical company specializing in the development of multispecific protein therapeutics through the FynomAb® technology platform.

During the fiscal second quarter of 2014, McNEIL-PPC, Inc., a subsidiary of Johnson & Johnson, completed the divestiture of the K-Y® brand to Reckitt Benckiser Group PLC in the U.S. and certain other markets. The pre-tax gain on the divestiture in the countries that closed as of the fiscal third quarter of 2014 was $388 million and was recognized in Other (income) expense, net.

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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 such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of September 27, 2015, 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 determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters 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. 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.

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 in any reporting period of one or more of these matters, either alone or in the aggregate, may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While these subsidiaries believe they have substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. In addition, product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, and XARELTO®. As of September 27, 2015, in the U.S. there were approximately 6,300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 8,300 with respect to the PINNACLE® Acetabular Cup System, 44,400 with respect to pelvic meshes, 5,400 with respect to RISPERDAL®, and 3,000 with respect to XARELTO®.

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

District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement which would effectively extend the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is now 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 U.S. However, many lawsuits in the U.S. will remain, and the settlement program does not address litigation outside of the U.S. 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. Updates to these accruals may be required in the future as additional information becomes available.

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

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

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

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

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products. Although these subsidiaries believe that they have substantial defenses to these challenges with respect to all material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could potentially adversely affect the ability of these subsidiaries to sell their products, or require the payment of past damages and future royalties. The most significant of

these matters are described below.

Medical Devices

In January 2010, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that EES's HARMONIC® shears infringed three Tyco patents. The case was tried in July 2012, and in March 2013, the Court ruled that some of EES's HARMONIC® shears infringed Tyco's patents and ordered EES to pay damages of approximately $176 million, but declined to order injunctive relief. EES appealed and in December 2014, the United States Court of Appeals for the Federal Circuit reversed the District Court's ruling and found all the asserted claims invalid. Tyco filed a motion for rehearing, which was denied in February 2015. In July 2015, Tyco filed a motion for review with the U.S. Supreme Court. In July 2014, Covidien filed another patent infringement lawsuit against EES in the United States District Court for the District of

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Connecticut seeking damages and a preliminary injunction, alleging that EES's newest version of its harmonic scalpels, the HARMONIC ACE®+ 7 Shears and the HARMONIC ACE®+ Shears, infringed the three Tyco patents asserted in the previous case. Covidien brought a motion for a preliminary injunction against the HARMONIC ACE®+7 Shears, and in October 2014, the District Court granted Covidien's motion for a preliminary injunction. EES appealed and the Court of Appeals for the Federal Circuit granted EES an interim stay of the injunction, and then in March 2015, reversed the grant of the preliminary injunction. The claims asserted by Covidien in this case are the same claims that were declared invalid in December 2014 by the Court of Appeals in the Tyco case discussed above.

In November 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.

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

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

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, LLC, Instacare Corp (now known as Pharmatech Solutions, Inc. (Pharmatech)) and Conductive Technologies, Inc. (collectively, Shasta) in the United States District Court for the Northern District of California for patent infringement for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. Shasta has alleged that the three LifeScan patents-in-suit are invalid. Shasta also challenged the validity of the asserted patents in the United States Patent and Trademark Office (USPTO) and the patent infringement case has been stayed pending the outcome of the USPTO proceedings. The validity of two of the patents was confirmed by the USPTO and in August 2014, the USPTO determined that the third patent, U.S. Patent No. 7,250,105 (the '105 patent), is invalid. LifeScan is appealing that decision, and oral argument on the appeal is scheduled for December 2015. The patent case has resumed on the two other patents. In April 2013, Shasta brought counterclaims for alleged antitrust violations and false advertising and those claims have been stayed pending resolution of the patent infringement case. LifeScan entered into a settlement agreement with Shasta Technologies and Conductive Technologies and in March 2015, the Court entered a consent judgment against Shasta Technologies and Conductive Technologies. The litigation with Pharmatech continues. In May 2014, LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip)

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

In September 2012, Bonutti Skeletal Innovations LLC (Bonutti), a non-practicing entity, filed a patent infringement lawsuit against DePuy Mitek, LLC, The DePuy Institute, LLC (now DePuy Synthes Institute, LLC), DePuy, Inc. (now DePuy Synthes, Inc.) and DePuy Orthopaedics, Inc. (collectively, DePuy) in the United States District Court for the District of Massachusetts, alleging that DePuy's manufacture, sale and/or method of using the SIGMA® Family of Partial and Total Knee Systems and the LCS® COMPLETE™ Knee System willfully infringe three of Bonutti's patents. Bonutti also alleges that the method of using certain of DePuy's suture anchors willfully infringe four of Bonutti's other patents. In August 2014, the parties entered into a settlement of the portion of the lawsuit relating to suture anchors, and in March 2015, the parties entered into a settlement agreement relating to the remaining portion of the case.

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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 is appealing this decision. Following the divestiture of Cordis, the Company retains any liability that may result from this case.

In January 2014, Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare S.A. (collectively, Baxter) filed a lawsuit against Johnson & Johnson, Ethicon, Inc. (Ethicon), Ferrosan Medical Devices A/S and Packaging Coordinators Inc. in the United States District Court for the Northern District of Illinois, alleging that the manufacture, importation, sale and/or use of Ethicon's SURGIFLO® Hemostatic Matrix Family of Products infringes six of Baxter's patents. Baxter is seeking monetary damages and injunctive relief. In February 2014, Baxter also filed a complaint before the United States International Trade Commission (ITC) against the same defendants alleging that the importation into the United States of Ethicon's SURGIFLO® Hemostatic Matrix Family of Products violates Section 337 of the Tariff Act of 1930 due to the alleged infringement of four of its products, and is seeking an exclusion order to enjoin the importation into the United States of such products. The ITC case was tried in January 2015 and in March 2015, the parties entered into an agreement settling the ITC and District Court cases.

In June 2014, My Health, Inc. (My Health) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the Eastern District of Texas, alleging LifeScan's OneTouch® Verio®IQ Blood Glucose Monitoring System infringes My Health's patent related to a method for monitoring and treating patients. My Health sought monetary damages and injunctive relief. In October 2014, Lifescan filed an Inter Partes review proceeding in the United States Patent and Trademark Office seeking to invalidate My Health's patent. In December 2014, LifeScan moved to stay the lawsuit pending a decision in the Inter Partes review proceeding. In May 2015, LifeScan and My Health entered into a settlement agreement and LifeScan terminated its petition for Inter Partes Review.

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

Pharmaceutical

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

prevails in its appeal of the invalidity decision, it can reinstitute its action against Amneal. In December 2014, Teva entered into a confidential settlement with Purdue, and Teva subsequently moved to have the appeal dismissed as moot in view of the settlement. The Federal Circuit deferred judgment on Teva’s motion to dismiss, and oral argument on Purdue’s appeal is set for November 2015.

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.

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REMICADE® Related Cases

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

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

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

In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®. In February 2015, JBI received a Notice of Commercial Marketing from Celltrion purportedly in accordance with the Biologics Price Competition and Innovation Act (the BPCIA), notifying JBI that Celltrion and/or Hospira intended to begin commercial marketing of a biosimilar product as early as 180 days from the date of the notice. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira seeking a declaratory judgment that their biosimilar product for which they are seeking FDA approval under the new BPCIA statute infringes or potentially infringes six JBI patents. JBI is also seeking a declaratory judgment that defendants have failed to comply with certain procedural requirements of the BPCIA. In addition, JBI has moved for a preliminary and permanent injunction to prohibit Celltrion and Hospira from launching their biosimilar product until 180 days after they have given JBI a Notice of Commercial Marketing. Subsequently in March 2015, JBI moved to stay all proceedings in the District Court with respect to the '471 patent, pending the USPTO re-examination proceeding.

If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States would be subject to approval by the FDA. Loss of exclusivity will likely result in a further reduction in sales as additional biosimilar versions of REMICADE® are introduced to the market.

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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.

PREZISTA®

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

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

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

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

In July 2014, Janssen filed a patent infringement lawsuit against Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No. 8,153,829. Discovery in the case in ongoing.

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

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

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

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

CONCERTA®

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

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

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

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

ZYTIGA®

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. and Janssen

Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 and/or 8,822,438. 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). In

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August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia. In October 2015, Mylan filed a motion to dismiss the New Jersey lawsuit for lack of personal jurisdiction and improper venue. In October 2015, Janssen and Par entered into an agreement staying the New Jersey lawsuit as to Par, wherein Par agreed to be bound by any judgment concerning the validity or enforceability of the relevant patent.

In August 2015, JBI received a notice of paragraph IV certification from Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, a division of Hetero Labs Limited (collectively, Hetero) advising of Hetero's ANDA seeking approval for a generic version of ZYTIGA® before expiration of United States Patent No. 8,822,438. In September 2015, Janssen and BTG filed an amended complaint in the New Jersey lawsuit to allege infringement of United States Patent No. 8,822,438 by Hetero.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Court for the District of Delaware and West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to their ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310; 7,125,879; and 8,101,629. In September 2015, Mylan filed an Answer in the West Virginia action that included counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit as well United States Patent No. 8,080,551. In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of COMPLERA® before the expiration of the relevant patents. In September 2015, Mylan filed a motion to dismiss the Delaware lawsuit for lack of personal jurisdiction.

XARELTO®

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

GOVERNMENT PROCEEDINGS

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

Average Wholesale Price (AWP) Litigation

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

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

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and cases are still pending in Illinois, New Jersey, Wisconsin, Utah and Pennsylvania. The cases in Illinois, New Jersey and Wisconsin have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. The AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPL”), entered an injunction, and awarded $45 million in restitution and $6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants appealed the Commonwealth Court's UTPL ruling, and in June 2014, the Pennsylvania Supreme Court vacated the judgment entered by the Commonwealth Court and remanded the case for further proceedings. On remand, in January 2015, the Commonwealth Court dismissed the monetary awards against the J&J AWP Defendants. In March 2015, the ruling was appealed back to the Pennsylvania Supreme Court.

RISPERDAL®

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL® from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL® with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL®, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL®. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above.

Three states have remaining claims in litigation related to RISPERDAL®: in South Carolina, JPI intends to seek U.S. Supreme Court review of the South Carolina judgment; in Kentucky, a trial has been set for April 2016; and in Mississippi, the case has not progressed to trial. State cases that went to judgment after trial are discussed below.

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

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

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

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The Commonwealth filed an appeal and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica, Inc. (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately $327.1 million against JPI. JPI appealed this judgment and in February 2015, the South Carolina Supreme Court affirmed the trial court’s decision in part, reversed it in part and remanded the case back to the trial court. The net effect of the decision was to reduce the judgment to approximately $136 million, plus interest. In the first fiscal quarter of 2015, the Company accrued $136 million. In March 2015, JPI filed a Petition for Rehearing. In July 2015, the South Carolina Supreme Court granted the Petition and filed a substituted opinion. The new opinion reduced the judgment from approximately $136 million to approximately $124 million. JPI intends to seek U.S. Supreme Court review of the South Carolina judgment.

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

McNeil Consumer Healthcare

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

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In December 2012, Oregon filed a Notice of Appeal in the Court of Appeals of the State of Oregon. Oral argument took place in July 2014 and the parties are awaiting a decision.

Opioids Litigation

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

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

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

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI related to opioids marketing practices.

Other

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

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

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

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

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

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

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

GENERAL LITIGATION

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

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

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

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

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

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transferred to the United States District Court for the Middle District of Florida in June 2015 along with the related case filed by Costco Wholesale Corporation described above.

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

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

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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 fiscal nine months of 2015, worldwide sales were $52.3 billion, a total decrease of 6.8%, including operational growth of 1.0% as compared to 2014 fiscal nine months sales of $56.1 billion. Currency fluctuations had a negative impact of 7.8% for the fiscal nine months of 2015. The introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 3.0% on the fiscal nine months of 2015 worldwide operational sales growth. The divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 1.6% on the worldwide operational sales growth on the fiscal nine months of 2015.

Sales by U.S. companies were $26.4 billion in the fiscal nine months of 2015, which represented an increase of 0.8% as compared to the prior year. Sales by international companies were $25.9 billion, a decline of 13.5%, including operational growth of 1.1%, offset by a negative currency impact of 14.6% as compared to the fiscal nine months sales of 2014.

Sales by companies in Europe experienced a decline of 16.6%, which included an operational increase of 1.3%, offset by a negative currency impact of 17.9%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 14.4%, including operational growth of 2.6%, offset by a negative currency impact of 17.0%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 8.5%, including operational growth of 0.1%, offset by a negative currency impact of 8.6%.

For the fiscal third quarter of 2015, worldwide sales were $17.1 billion, a total decrease of 7.4%, including operational growth of 0.8% as compared to 2014 fiscal third quarter sales of $18.5 billion. Currency fluctuations had a negative impact of 8.2% for the fiscal third quarter of 2015. The introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 4.3% on the fiscal third quarter of 2015 worldwide operational sales growth.

Sales by U.S. companies were $8.8 billion in the fiscal third quarter of 2015, which represented a decrease of 0.6% as compared to the prior year. Sales by international companies were $8.3 billion, a decline of 13.7%, including operational growth of 2.1%, offset by a negative currency impact of 15.8% as compared to the fiscal third quarter sales of 2014.

Sales by companies in Europe experienced a decline of 14.5%, including operational growth of 2.7%, offset by a negative currency impact of 17.2%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 19.6%, which included operational growth of 2.7%, and a negative currency impact of 22.3%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 9.3%, including operational growth of 1.2% offset by a negative currency impact of 10.5%.

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ANALYSIS OF SALES BY BUSINESS SEGMENTS

Consumer

Consumer segment sales in the fiscal nine months of 2015 were $10.2 billion, a decrease of 6.5% as compared to the same period a year ago, including operational growth of 2.9% offset by a negative currency impact of 9.4%. U.S. Consumer segment sales increased by 5.0%. International Consumer segment sales decreased by 12.6%, including operational growth of 1.9% offset by a negative currency impact of 14.5%.

Major Consumer Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
OTC	$2,930	$3,033	(3.4)%	8.1 %	(11.5)%
Skin Care	2,660	2,802	(5.1)	2.0	(7.1)
Baby Care	1,560	1,715	(9.0)	0.5	(9.5)
Oral Care	1,172	1,233	(4.9)	4.4	(9.3)
Wound Care/Other	948	1,113	(14.8)	(10.3)	(4.5)
Women's Health	917	994	(7.7)	7.6	(15.3)
Total Consumer Sales	$10,187	$10,890	(6.5)%	2.9 %	(9.4)%

Consumer segment sales in the fiscal third quarter of 2015 were $3.3 billion, a decrease of 7.7% as compared to the same period a year ago, including an operational increase of 3.1% offset by a negative currency impact of 10.8%. U.S. Consumer segment sales increased by 8.9%. International Consumer segment sales decreased by 15.7%, including operational growth of 0.4% offset by a negative currency impact of 16.1%.

Major Consumer Franchise Sales — Fiscal Third Quarters Ended

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
OTC	$963	$1,019	(5.5)%	6.3 %	(11.8)%
Skin Care	863	920	(6.2)	2.5	(8.7)
Baby Care	506	563	(10.1)	2.0	(12.1)
Oral Care	378	409	(7.6)	3.5	(11.1)
Wound Care/Other	294	353	(16.7)	(11.9)	(4.8)
Women's Health	310	325	(4.6)	13.3	(17.9)
Total Consumer Sales	$3,314	$3,589	(7.7)%	3.1 %	(10.8)%

The OTC franchise achieved operational growth of 6.3% as compared to the prior year fiscal third quarter. The growth was primarily driven by analgesics and ZYRTEC® in the U.S.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) continues to operate under a consent decree, signed in 2011 with the U.S. Food and Drug Administration (FDA), which governs certain McNeil Consumer Healthcare manufacturing operations and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania; Fort Washington, Pennsylvania; and Las Piedras, Puerto Rico (the Consent Decree). In February 2015, a third-party expert submitted written certification to the FDA for all three manufacturing sites. Following FDA inspections, McNEIL-PPC received notification that all three manufacturing facilities are in conformity with applicable laws and regulations and, at this point, no independent third-party is needed for day-to-day oversight. A third-party expert will reassess those sites at various times during the next five years.

The Skin Care franchise achieved operational growth of 2.5% as compared to the prior year, primarily due to strong sales growth of NEUTROGENA® and AVEENO® products partially offset by soft sales in China.

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The Baby Care franchise achieved operational growth of 2.0% as compared to the prior year, primarily due to new product launches partially offset by competition in China.

The Oral Care franchise achieved operational growth of 3.5% as compared to the prior year. The growth was driven by increased sales of LISTERINE®, as a result of new product launches and successful marketing campaigns.

The Wound Care/Other franchise experienced an operational decline of 11.9% as compared to the prior year primarily due to the BENECOL® divestiture outside the U.S.

The Women's Health franchise achieved operational growth of 13.3% as compared to the prior year primarily due to new product launches outside the U.S.

Pharmaceutical

Pharmaceutical segment sales in the fiscal nine months of 2015 were $23.4 billion, a total decrease of 3.9% as compared to the same period a year ago, with an operational increase of 3.4% and a negative currency impact of 7.3%. U.S. Pharmaceutical sales increased by 2.7% as compared to the same period a year ago. International Pharmaceutical sales decreased by 11.5%, including operational growth of 4.3% offset by a negative currency impact of 15.8%. In the fiscal nine months of 2015, the Pharmaceutical segment operational growth was negatively impacted by 7.3% due to the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), and positively impacted by 1.6% due to an adjustment to previous reserve estimates, including managed medicaid rebates primarily in the Cardiovascular/Metabolism/Other therapeutic area.

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Major Pharmaceutical Therapeutic Area Sales — Fiscal Nine Months Ended*

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
Total Immunology	$ 7,631	$ 7,615	0.2 %	5.2 %	(5.0)%
REMICADE®	4,881	5,196	(6.1)	(2.7)	(3.4)
SIMPONI®/ SIMPONI ARIA®	988	841	17.5	28.4	(10.9)
STELARA®	1,732	1,527	13.4	20.5	(7.1)
Other Immunology	30	51	(41.2)	(31.4)	(9.8)
Total Infectious Diseases	2,855	4,523	(36.9)	(29.4)	(7.5)
EDURANT®	303	275	10.2	31.3	(21.1)
OLYSIO®/SOVRIAD®	577	1,981	(70.9)	(66.6)	(4.3)
PREZISTA®/ PREZCOBIX®/REZOLSTA®	1,343	1,383	(2.9)	5.5	(8.4)
Other Infectious Diseases	632	884	(28.5)	(19.4)	(9.1)
Total Neuroscience	4,658	4,836	(3.7)	5.3	(9.0)
CONCERTA®/methylphenidate	608	430	41.4	51.9	(10.5)
INVEGA®/paliperidone	460	479	(4.0)	2.6	(6.6)
INVEGA® SUSTENNA®/XEPLION®/INVEGA TRINZA™	1,306	1,170	11.6	20.4	(8.8)
RISPERDAL® CONSTA®	736	896	(17.9)	(8.4)	(9.5)
Other Neuroscience	1,548	1,861	(16.8)	(7.5)	(9.3)
Total Oncology	3,422	3,245	5.5	18.9	(13.4)
IMBRUVICA®	454	108	**	**	***
VELCADE®	1,012	1,200	(15.7)	(1.0)	(14.7)
ZYTIGA®	1,650	1,642	0.5	11.0	(10.5)
Other Oncology	306	295	3.7	19.5	(15.8)
Cardiovascular / Metabolism / Other	4,800	4,095	17.2	21.7	(4.5)
XARELTO®	1,374	1,094	25.6	25.6	—
INVOKANA®/ INVOKAMET®	936	385	**	**	***
PROCRIT®/EPREX®	808	936	(13.7)	(8.2)	(5.5)
Other	1,682	1,680	0.1	7.6	(7.5)
Total Pharmaceutical Sales	$ 23,366	$ 24,314	(3.9)%	3.4 %	(7.3)%

*Prior year amounts have been reclassified to conform to current year product disclosure.
** Percentage greater than 100%
***Not meaningful

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Pharmaceutical segment sales in the fiscal third quarter of 2015 were $7.7 billion, a total decrease of 7.4% as compared to the same period a year ago, with an operational decrease of 0.3% and a negative currency impact of 7.1%. U.S. Pharmaceutical sales decreased by 4.5% as compared to the same period a year ago. International Pharmaceutical sales decreased by 11.1%, including operational growth of 5.5% offset by a negative currency impact of 16.6%. The introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 10.0% on the operational growth of the Pharmaceutical segment in the fiscal third quarter of 2015.

Major Pharmaceutical Therapeutic Area Sales — Fiscal Third Quarters Ended*

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
Total Immunology	$ 2,614	$2,641	(1.0)%	4.4 %	(5.4)%
REMICADE®	1,613	1,782	(9.5)	(5.9)	(3.6)
SIMPONI®/ SIMPONI ARIA®	380	300	26.7	39.6	(12.9)
STELARA®	613	543	12.9	19.7	(6.8)
Other Immunology	8	16	(50.0)	(37.2)	(12.8)
Total Infectious Diseases	848	1,561	(45.7)	(39.9)	(5.8)
EDURANT®	111	102	8.8	27.6	(18.8)
OLYSIO®/ SOVRIAD®	79	796	(90.1)	(88.8)	(1.3)
PREZISTA®/ PREZCOBIX®/REZOLSTA®	468	446	4.9	13.4	(8.5)
Other Infectious Diseases	190	217	(12.4)	(1.6)	(10.8)
Total Neuroscience	1,476	1,571	(6.0)	3.4	(9.4)
CONCERTA®/methylphenidate	178	135	31.9	43.7	(11.8)
INVEGA®/paliperidone	139	156	(10.9)	(4.7)	(6.2)
INVEGA® SUSTENNA®/XEPLION®/INVEGA TRINZA™	459	403	13.9	22.4	(8.5)
RISPERDAL® CONSTA®	235	284	(17.3)	(8.1)	(9.2)
Other Neuroscience	465	593	(21.6)	(11.2)	(10.4)
Total Oncology	1,170	1,112	5.2	18.4	(13.2)
IMBRUVICA®	184	56	**	**	***
VELCADE®	329	389	(15.4)	0.1	(15.5)
ZYTIGA®	548	568	(3.5)	6.1	(9.6)
Other Oncology	109	99	10.1	26.2	(16.1)
Cardiovascular / Metabolism / Other	1,586	1,422	11.5	16.1	(4.6)
XARELTO®	461	414	11.4	11.4	—
INVOKANA®/ INVOKAMET®	340	174	95.4	97.3	(1.9)
PROCRIT®/EPREX®	263	307	(14.3)	(9.1)	(5.2)
Other	522	527	(0.9)	7.9	(8.8)
Total Pharmaceutical Sales	$ 7,694	$8,307	(7.4)%	(0.3)%	(7.1)%

*Prior year amounts have been reclassified to conform to current year product disclosure.
** Percentage greater than 100%
***Not meaningful

Immunology products achieved operational sales growth of 4.4% as compared to the same period a year ago. Growth of STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab) were due to market growth and increased penetration of SIMPONI ARIA®. Growth was partially offset by lower REMICADE® (infliximab) sales to the Company's distributor in Japan primarily due to an inventory drawdown in preparation for label expansion. Additionally, the weakening of the euro and loss of exclusivity in Europe negatively impacted sales. The patents for

REMICADE® in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Loss of exclusivity will likely result in a further reduction in sales as additional biosimilar versions of REMICADE® are introduced to the market. See Note 11 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

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Infectious disease products experienced an operational decline of 39.9% as compared to the same period a year ago primarily due to lower sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir). Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on U.S. sales and will continue to have a negative impact on future sales. The decline in sales was partially offset by sales growth of PREZCOBIX® (darunavir/cobicistat), which was launched earlier this year.

Neuroscience products achieved operational sales growth of 3.4% as compared to the same period a year ago. U.S. sales growth of CONCERTA®/methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors by the FDA in November 2014. Strong sales of INVEGA® SUSTENNA®/XEPLION®/INVEGA TRINZA™(paliperidone palmitate) were primarily due to increased market share. The growth was negatively impacted by the U.S. divestiture of NUCYNTA® (tapentadol).

Oncology products achieved strong operational sales growth of 18.4% as compared to the same period a year ago. Major contributors to the growth were strong sales of IMBRUVICA® (ibrutinib) due to the approval of new indications and strong patient uptake. Additionally, sales of ZYTIGA®(abiraterone acetate) grew in the U.S. due to market growth partially offset by share decline and strong growth in Asia and Latin America were partially offset by lower sales in Europe due to competition.

Cardiovascular / Metabolism / Other products achieved operational sales growth of 16.1% as compared to the same period a year ago due to strong sales of XARELTO®(rivaroxaban) and INVOKANA®/INVOKAMET® (canagliflozin).

Medical Devices

The Medical Devices segment sales in the fiscal nine months of 2015 were $18.7 billion, a decrease of 10.4% as compared to the same period a year ago, with an operational decrease of 2.9% and a negative currency impact of 7.5%. U.S. Medical Devices sales decreased 3.4%. International Medical Devices sales decreased by 15.9%, including an operational decrease of 2.4% and a negative currency impact of 13.5%. In the fiscal nine months of 2015, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 4.2% on the operational growth of the Medical Devices segment.

Major Medical Devices Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
Orthopaedics	$ 6,839	$ 7,234	(5.5)%	0.8 %	(6.3)%
Surgical Care	4,271	4,604	(7.2)	1.3	(8.5)
Specialty Surgery/Other	2,533	2,637	(3.9)	3.3	(7.2)
Vision Care	1,960	2,172	(9.8)	(0.2)	(9.6)
Cardiovascular Care	1,597	1,650	(3.2)	5.4	(8.6)
Diabetes Care	1,448	1,628	(11.1)	(1.6)	(9.5)
Diagnostics	62	948	(93.5)	(91.0)	(2.5)
Total Medical Devices Sales	$ 18,710	$ 20,873	(10.4)%	(2.9)%	(7.5)%

The Medical Devices segment sales in the fiscal third quarter of 2015 were $6.1 billion, a decrease of 7.3% as compared to the same period a year ago, with operational growth of 0.9% and a negative currency impact of 8.2%.

U.S. Medical Devices sales increased 2.0%. International Medical Devices sales decreased by 14.8%, including an operational increase of 0.1% and a negative currency impact of 14.9%. In the fiscal third quarter of 2015, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 0.3% on the operational growth of the Medical Devices segment.

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Major Medical Devices Franchise Sales — Fiscal Third Quarters Ended

(Dollars in Millions)	September 27, 2015	September 28, 2014	Total Change	Operations Change	Currency Change
Orthopaedics	$ 2,181	$ 2,344	(7.0)%	(0.7)%	(6.3)%
Surgical Care	1,399	1,521	(8.0)	0.9	(8.9)
Specialty Surgery/Other	821	858	(4.3)	3.5	(7.8)
Vision Care	683	704	(3.0)	8.1	(11.1)
Cardiovascular Care	524	542	(3.3)	5.2	(8.5)
Diabetes Care	470	558	(15.8)	(6.4)	(9.4)
Diagnostics	16	44	(63.6)	(39.8)	(23.8)
Total Medical Devices Sales	$ 6,094	$ 6,571	(7.3)%	0.9 %	(8.2)%

The Orthopaedics franchise experienced an operational decline of 0.7% as compared to the prior year fiscal third quarter. Growth outside the U.S. was negatively impacted by softer demand and a reduction in customer inventory levels primarily in China and continued pricing pressures. This was partially offset by solid growth in the U.S. driven by sales of trauma and sports medicine products.

The Surgical Care franchise achieved operational sales growth of 0.9% as compared to the prior year fiscal third quarter primarily due to the success of the ECHELON FLEX™ products partially offset by pricing pressures.

The Specialty Surgery/Other franchise achieved operational sales growth of 3.5% as compared to the prior year fiscal third quarter. Growth was primarily driven by sales of biosurgical, energy and Mentor products attributable to market growth, increased penetration in certain markets and new product launches.

The Vision Care franchise achieved operational sales growth of 8.1% as compared to the prior year fiscal third quarter. Growth in all the major regions was primarily driven by new product launches.

The Cardiovascular Care franchise, composed of the Cordis and Biosense Webster businesses, achieved operational sales growth of 5.2% as compared to the prior year fiscal third quarter driven by a 9% operational increase in the electrophysiology business. Subsequent to the quarter on October 4, 2015, the Company completed the divestiture of the Cordis business to Cardinal Health. The Cordis business generated annual net revenues of approximately $780 million in 2014. For additional details see Note 10 to the Consolidated Financial Statements.

The Diabetes Care franchise experienced an operational sales decline of 6.4% as compared to the prior year fiscal third quarter primarily due to lower price partially offset by the success of the ANIMAS® VIBE™ products.

On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) to The Carlyle Group. For additional details see Note 10 to the Consolidated Financial Statements.

ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income for the fiscal nine months of 2015 decreased to $15.4 billion as compared to $17.9 billion in the fiscal nine months of 2014, a decrease of 13.6%. The decrease was primarily due to lower gains of $1.1 billion on the sale of assets/businesses, the loss of OLYSIO®(simeprevir) sales and currency impacts. The fiscal nine months of 2015 included a gain of $1.2 billion from the divestitures of the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the fiscal nine months of 2014, which included a gain of $2.3 billion from the divestitures of the Ortho-Clinical Diagnostics business and the divestiture of the K-Y®

brand. The decrease was partially offset by lower net litigation expense of $0.4 billion, which included a litigation settlement agreement of $0.6 billion with Guidant Corporation (Guidant), a positive adjustment of $0.4 billion to previous reserve estimates including managed medicaid rebates, and lower Synthes integration costs of $0.3 billion as compared to the fiscal nine months of 2014. Additionally, the fiscal nine months of 2014 included an additional year of the Branded Prescription Drug Fee of $0.2 billion.

Consolidated earnings before provision for taxes on income for the fiscal third quarter of 2015 decreased to $4.1 billion as compared to $6.8 billion in the fiscal third quarter of 2014, a decrease of 39.5%. The decrease was attributable to lower gains

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of $1.7 billion on the sale of assets/businesses, loss of OLYSIO®(simeprevir) sales, a higher intangible asset write-down of $0.3 billion related to Acclarent and higher litigation expense of $0.1 billion versus the fiscal third quarter of 2014. The fiscal third quarter of 2014 included a net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business versus the fiscal third quarter of 2015, which included the gain of $0.2 billion from the divestiture of the SPLENDA® brand. The decrease was partially offset by lower costs of $0.3 billion related to Synthes integration costs and costs associated with the DePuy ASR™ Hip program as compared to the fiscal third quarter of 2014. Additionally, the fiscal third quarter of 2014 included an additional year of the Branded Prescription Drug Fee of $0.2 billion.

Cost of Products Sold

Consolidated costs of products sold for the fiscal nine months of 2015 increased to 30.4% from 30.1% of sales as compared to the same period a year ago. Consolidated costs of products sold for the fiscal third quarter of 2015 increased to 30.5% from 29.2% of sales as compared to the same period a year ago. The increase in both periods was primarily due to lower net sale prices, product mix and lower sales of OLYSIO®(simeprevir) in 2015. The intangible asset amortization expense for the fiscal nine months of 2015 and 2014 was $912 million and $1,033 million, respectively.

Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the fiscal nine months of 2015 increased to 29.3% from 28.8% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal third quarter of 2015 increased to 29.7% from 29.6% of sales as compared to the same period a year ago. The increase in both periods was primarily due to incremental investment spending mainly in the Pharmaceutical and Medical Devices segments and the impact from lower sales of OLYSIO®(simeprevir). This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of $220 million in the fiscal third quarter of 2014.

Research and Development Expense

Worldwide costs of research and development activities for the fiscal nine months of 2015 increased to 11.8% from 10.5% of sales as compared to the same period a year ago. Worldwide costs of research and development activities for the fiscal third quarter of 2015 increased to 12.6% from 11.0% of sales as compared to the same period a year ago. The increase in both periods was primarily due to increased investment spending in the Pharmaceutical segment.

Interest (Income) Expense

Interest income in the fiscal nine months of 2015 and the fiscal third quarter of 2015 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 $37.3 billion at the end of the fiscal third quarter of 2015, which is an increase of $4.3 billion as compared to the same period a year ago. The increase in the balance of cash, cash equivalents and marketable securities was due primarily to cash generated from operating activities.

Interest expense in fiscal nine months of 2015 and the fiscal third quarter of 2015 was slightly lower as compared to the same periods a year ago due to lower effective interest rate partially offset by a higher average debt balance. At the end of the fiscal third quarter of 2015, the Company’s debt position was $19.8 billion as compared to $15.3 billion the same period a year ago.

Other (Income) Expense, Net

Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (formerly Johnson & Johnson Development Corporation), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal nine months of 2015 was unfavorable by $0.2 billion, primarily due to lower gains of $1.1 billion on the sale of assets/businesses as compared to the prior year. The fiscal nine months of 2015 included a gain of $1.2 billion from the divestiture of the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the fiscal nine months of 2014, which included a gain of $2.3 billion from the divestiture of the Ortho-Clinical Diagnostics business and the divestiture of the K-Y® brand. The decrease was partially offset by lower net litigation expense of $0.4 billion, lower Synthes integration costs of $0.3 billion and higher JJDC portfolio gains of $0.2 billion as compared to the fiscal nine months of 2014.

The change in other (income) expense, net for the fiscal third quarter of 2015 was unfavorable by $1.8 billion as compared to the same period a year ago primarily due to higher gains of $1.7 billion on the sale of assets/businesses recorded in the fiscal

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third quarter of 2014. The fiscal third quarter of 2014 included a net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business versus the fiscal third quarter of 2015, which included the gain of $0.2 billion from the divestiture of the SPLENDA® brand. Additionally, the fiscal third quarter of 2015 included higher intangible asset write-downs of $0.3 billion related to Acclarent and higher litigation expense of $0.1 billion. The decrease was partially offset by lower costs of $0.3 billion related to Synthes integration costs and costs associated with the DePuy ASR™ Hip program as compared to the fiscal third quarter of 2014.

SEGMENT PRE-TAX PROFIT

Consumer Segment

Pre-tax profit for the Consumer segment as a percent to sales in the fiscal nine months of 2015 was 17.4% versus 14.6% for the same period a year ago. Pre-tax profit for the Consumer segment as a percent to sales in the fiscal third quarter of 2015 was 24.5% versus 11.3% for the same period a year ago. The favorable pre-tax profit in both periods was primarily due to product mix. The fiscal third quarter and fiscal nine months of 2015 included a gain of $0.2 billion on the divestiture of the SPLENDA® brand. The fiscal nine months of 2014 included a gain of $0.4 billion on the divestiture of the K-Y® brand.

Pharmaceutical Segment

Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal nine months of 2015 was 42.0% versus 40.8% for the same period a year ago. The favorable pre-tax profit in the fiscal nine months of 2015 was primarily due to higher gains recognized in the fiscal nine months of 2015 partially offset by a sales decline of OLYSIO®(simeprevir). The fiscal nine months of 2015 included $1.5 billion from a gain on the U.S. divestiture of NUCYNTA®, receipt of a contingent payment and a positive adjustment to previous reserve estimates, including managed medicaid rebates. Additionally, the pre-tax profit in the fiscal nine months of 2014 was negatively impacted by $0.2 billion for an additional year of the Branded Prescription Drug Fee and a $0.1 billion intangible asset write-down related to INCIVO® (telaprevir). Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal third quarter of 2015 was 35.5% versus 39.1% for the same period a year ago. The fiscal third quarter of 2014 was favorably impacted by strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive sales mix of higher margin products and cost containment initiatives realized in selling, marketing and administrative expenses partially offset by $0.2 billion for an additional year of the Branded Prescription Drug Fee.

Medical Devices Segment

Pre-tax profit for the Medical Devices segment as a percent to sales in the fiscal nine months of 2015 was 24.8% versus 33.9% for the same period a year ago. The unfavorable pre-tax profit in the fiscal nine months of 2015 was primarily attributable to a net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business recorded in the fiscal third quarter of 2014 partially offset by higher expenses of $0.8 billion related to net litigation and Synthes integration costs as compared to the fiscal nine months of 2015. Additionally, the fiscal nine months of 2015 included a $0.3 billion intangible asset write-down related to Acclarent.

Pre-tax profit for the Medical Devices segment as a percent to sales in the fiscal third quarter of 2015 was 13.7% versus 51.7% for the same period a year ago. The unfavorable pre-tax profit in the fiscal third quarter of 2015 was primarily attributable to a net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business recorded in the fiscal third quarter of 2014 partially offset by higher expenses of $0.3 billion related to Synthes integration costs and costs associated with the DePuy ASR™ Hip program as compared to the fiscal third quarter of 2015. Additionally, the fiscal third quarter of 2015 included a $0.3 billion intangible asset write-down related to

Acclarent and higher litigation expense of $0.2 billion as compared to the fiscal third quarter of 2014.

Provision for Taxes on Income

The worldwide effective income tax rates for the fiscal nine months of 2015 and 2014 were 21.0% and 22.7%, respectively. The lower effective tax rate in 2015 as compared to 2014 was primarily due the 2014 divestiture of the Ortho-Clinical Diagnostics business at an approximate 41% effective tax rate and the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible. This additional 2014 tax expense was partially offset by a benefit from the Conor Medsystems divestiture, a settlement of substantially all issues related to the Company's U.S. Internal Revenue

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Service audit of tax years 2006 - 2009 and the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code. Additionally, the effective tax rate is lower in 2015 as compared to 2014 as a result of the mix in foreign earnings to lower tax jurisdictions.

As of September 27, 2015, the Company had approximately $2.6 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 other 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 December 28, 2014 for more detailed information regarding unrecognized tax benefits.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

Cash and cash equivalents were $13.6 billion at the end of the fiscal third quarter of 2015 as compared with $14.5 billion at the fiscal year end of 2014. The primary sources of cash were approximately $14.2 billion net cash generated from operating activities offset by $6.3 billion used by investing activities and $7.6 billion used by financing activities and $1.2 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $23.7 billion in marketable securities at the end of the fiscal third quarter of 2015 and $18.6 billion at the end of 2014.

Cash flow from operations of $14.2 billion was the result of $12.2 billion of net earnings and $3.8 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, primarily related to Acclarent, $1.3 billion from net gains on sale of assets/businesses and $2.7 billion related to deferred taxes, other current and non-current assets and other current and non-current liabilities. Cash flow from operations was reduced by $1.6 billion related to accounts payable and accrued liabilities and $1.6 billion related to account receivables and inventories.

Investing activities use of $6.3 billion of cash was primarily for net purchases of investments in marketable securities of $5.6 billion, additions to property, plant and equipment of $2.1 billion and acquisitions of $0.2 billion partially offset by proceeds from the disposal of assets/businesses of $1.6 billion.

Financing activities use of $7.6 billion of cash was primarily for dividends to shareholders of $6.1 billion and $3.4 billion for the repurchase of common stock. Financing activities also included a source of $0.8 billion of net proceeds from stock options exercised and associated tax benefits and net proceeds of short and long-term debt of $1.2 billion.

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 third quarter of 2015, 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.

Subsequent to the quarter, on October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes.

Dividends

On July 20, 2015, the Board of Directors declared a regular cash dividend of $0.75 per share, payable on September 8, 2015 to shareholders of record as of August 25, 2015.

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On October 22, 2015, the Board of Directors declared a regular cash dividend of $0.75 per share, payable on December 8, 2015 to shareholders of record as of November 24, 2015. 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 $1.7 billion as of September 27, 2015 and $1.8 billion as of December 28, 2014. Approximately $1.1 billion as of September 27, 2015 and December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers, which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers was approximately $0.6 billion at September 27, 2015 and $0.7 billion as of December 28, 2014. The Company continues to receive payments from these customers and in some cases late payment premiums. 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.

The Venezuelan government has established alternative systems and offerings of various foreign currency exchanges. In 2015, the Company continues to have access to an official government rate of 6.3 Bolivares Fuertes to one U.S. dollar to settle imports of various products into Venezuela. During 2014, the Company applied to settle an outstanding dividend payable at one of the alternative foreign exchange rates. As a result, the Company has applied this alternative exchange rate to translate certain transactions, as appropriate. Through the third quarter of 2015, the Company has primarily utilized the official government rate of 6.3 Bolivares Fuertes to one U.S. dollar in preparing its consolidated financial statements. Beginning in the third quarter of 2015, the number of the Company’s transactions conducted at the official rate has declined from prior quarters. If the Company’s ability to have consistent access to the official government rate continues to decline, the Company would consider the use of one of the alternative rates in preparing its consolidated financial statements. As of September 27, 2015, the Company’s Venezuelan subsidiaries represented

less than 0.4% of the Company's consolidated assets, liabilities, revenues, profits and net equity; therefore, the effect of any possible action related to the Company’s Venezuelan businesses is not expected to have a material adverse effect on the Company's 2015 full-year results.

As described above, while the Company continues to do business in Greece, the Company closely monitors the economic situation. As of September 27, 2015, the Company’s Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and revenues, respectively.

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.

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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 inherent in new product development, including obtaining regulatory approvals; challenges to patents; the impact of patent expirations; uncertainty of commercial success of new and existing products; significant adverse litigation or government action, including related to product liability claims; impact of business combinations and divestitures; 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 laws and regulations and 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 sovereign risk; manufacturing difficulties or delays; 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 December 28, 2014, 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.

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 December 28, 2014.

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

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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.

Subsequent to the quarter, 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. Share repurchases may be made at management's discretion from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes.

The following table provides information with respect to Common Stock purchases by the Company during the fiscal third quarter of 2015. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal third quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
June 29, 2015 through July 26, 2015	433,486	100.25	—	—
July 27, 2015 through August 23, 2015	1,299,021	98.76	—	—
August 24, 2015 through September 27, 2015	1,359,986	95.69	—	—
Total	3,092,493		—	

(1) During the fiscal third quarter of 2015, the Company repurchased an aggregate of 3,092,493 shares of Johnson & Johnson Common Stock in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) The previous repurchase program announced on July 21, 2014 concluded on April 28, 2015.

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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 September 27, 2015, 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: October 30, 2015	By /s/ D. J. CARUSO D. J. CARUSO Vice President, Finance; Chief Financial Officer (Principal Financial Officer)
Date: October 30, 2015	By /s/ R. A. KAPUSTA R. A. KAPUSTA Controller (Principal Accounting Officer)