

JOHNSON & JOHNSON
Form 10-Q
October 30, 2014

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

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the quarterly period ended September 28, 2014
or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from _____ to _____

Commission file number 1-3215

(Exact name of registrant as specified in its charter)

NEW JERSEY

22-1024240

(State or other jurisdiction of
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. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

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

On October 24, 2014, 2,799,110,362 shares of Common Stock, \$1.00 par value, were outstanding.

JOHNSON & JOHNSON AND SUBSIDIARIES
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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 28, 2014	December 29, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$13,818	20,927
Marketable securities	19,187	8,279
Accounts receivable, trade, less allowances for doubtful accounts \$262 (2013, \$333)	11,615	11,713
Inventories (Note 2)	8,419	7,878
Deferred taxes on income	3,827	3,607
Prepaid expenses and other	3,107	4,003
Total current assets	59,973	56,407
Property, plant and equipment at cost	36,448	37,133
Less: accumulated depreciation	(20,644) (20,423
Property, plant and equipment, net	15,804	16,710
Intangible assets, net (Note 3)	26,304	27,947
Goodwill (Note 3)	21,636	22,798
Deferred taxes on income	3,347	3,872
Other assets	5,033	4,949
Total assets	\$132,097	132,683
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Loans and notes payable	\$2,115	4,852
Accounts payable	6,603	6,266
Accrued liabilities	6,188	7,685
Accrued rebates, returns and promotions	4,208	3,308
Accrued compensation and employee related obligations	2,333	2,794
Accrued taxes on income	1,535	770
Total current liabilities	22,982	25,675
Long-term debt (Note 4)	13,152	13,328
Deferred taxes on income	4,063	3,989
Employee related obligations	7,551	7,784
Other liabilities	7,758	7,854
Total liabilities	55,506	58,630
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)	(5,382) (2,860
Retained earnings	96,560	89,493
Less: common stock held in treasury, at cost (315,787,000 and 299,215,000 shares)	17,707	15,700

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Total shareholders' equity	76,591	74,053
Total liabilities and shareholders' equity	\$132,097	132,683
See Notes to Consolidated Financial Statements		

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CONSOLIDATED STATEMENTS OF EARNINGS

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

	Fiscal Third Quarters Ended					
	September 28, 2014		September 29, 2013		Percent to Sales	
		Percent to Sales		Percent to Sales		
Sales to customers (Note 9)	\$ 18,467	100.0	%	\$ 17,575	100.0	%
Cost of products sold	5,399	29.2		5,344	30.4	
Gross profit	13,068	70.8		12,231	69.6	
Selling, marketing and administrative expenses	5,468	29.6		5,314	30.2	
Research and development expense	2,023	11.0		2,042	11.6	
In-process research and development	—	—		178	1.0	
Interest income	(18) (0.1)	(18) (0.1)
Interest expense, net of portion capitalized	130	0.7		105	0.6	
Other (income) expense, net	(1,345) (7.3)	943	5.4	
Earnings before provision for taxes on income	6,810	36.9		3,667	20.9	
Provision for taxes on income (Note 5)	2,061	11.2		685	3.9	
NET EARNINGS	\$ 4,749	25.7	%	\$ 2,982	17.0	%
NET EARNINGS PER SHARE (Note 8)						
Basic	\$ 1.69			\$ 1.06		
Diluted	\$ 1.66			\$ 1.04		
CASH DIVIDENDS PER SHARE	\$ 0.70			\$ 0.66		
AVG. SHARES OUTSTANDING						
Basic	2,814.4			2,818.4		
Diluted	2,864.3			2,881.2		
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 28, 2014	Percent to Sales		September 29, 2013	Percent to Sales	
Sales to customers (Note 9)	\$ 56,077	100.0	%	\$ 52,957	100.0	%
Cost of products sold	16,893	30.1		16,387	30.9	
Gross profit	39,184	69.9		36,570	69.1	
Selling, marketing and administrative expenses	16,132	28.8		15,913	30.0	
Research and development expense	5,859	10.5		5,772	10.9	
In-process research and development	22	0.0		242	0.5	
Interest income	(50) (0.1)	(56) (0.1)
Interest expense, net of portion capitalized	394	0.7		348	0.7	
Other (income) expense, net	(1,033) (1.8)	1,630	3.1	
Earnings before provision for taxes on income	17,860	31.8		12,721	24.0	
Provision for taxes on income (Note 5)	4,058	7.2		2,409	4.5	
NET EARNINGS	\$ 13,802	24.6	%	\$ 10,312	19.5	%
NET EARNINGS PER SHARE (Note 8)						
Basic	\$ 4.89			\$ 3.68		
Diluted	\$ 4.81			\$ 3.58		
CASH DIVIDENDS PER SHARE	\$ 2.06			\$ 1.93		
AVG. SHARES OUTSTANDING						
Basic	2,822.0			2,805.6		
Diluted	2,871.2			2,879.0		

See Notes to Consolidated Financial Statements

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

	Fiscal Third Quarters Ended		Fiscal Nine Months Ended	
	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013
Net earnings	\$4,749	2,982	13,802	10,312
Other comprehensive income (loss), net of tax				
Foreign currency translation	(2,400) 1,278	(2,499) (48
Securities:				
Unrealized holding gain (loss) arising during period	(35) 59	6	238
Reclassifications to earnings	(1) —	(1) (289
Net change	(36) 59	5	(51
Employee benefit plans:				
Prior service cost amortization during period	(5) —	(14) 2
Gain (loss) amortization during period	101	130	301	390
Net change	96	130	287	392
Derivatives & hedges:				
Unrealized gain (loss) arising during period	14	41	(139) 224
Reclassifications to earnings	(49) (44) (176) (53
Net change	(35) (3) (315) 171
Other comprehensive income (loss)	(2,375) 1,464	(2,522) 464
Comprehensive income	\$2,374	4,446	11,280	10,776

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal third quarters were as follows for 2014 and 2013, respectively: Securities: \$19 million and \$32 million; Employee Benefit Plans: \$46 million and \$68 million; Derivatives & Hedges: \$19 million and \$1 million.

The tax effects in other comprehensive income for the fiscal nine months were as follows for 2014 and 2013, respectively: Securities: \$3 million and \$28 million; Employee Benefit Plans: \$139 million and \$204 million; Derivatives & Hedges: \$170 million and \$92 million.

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

	Fiscal Nine Months Ended	
	September 28, 2014	September 29, 2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 13,802	10,312
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	2,904	3,002
Stock based compensation	646	584
Venezuela adjustments	89	108
Asset write-downs	259	247
Net gain on sale of assets/businesses	(2,336)	(55)
Net gain on equity investment transactions	—	(380)
Deferred tax provision	297	(224)
Accounts receivable allowances	(54)	(32)
Changes in assets and liabilities, net of effects from acquisitions:		
Increase in accounts receivable	(399)	(971)
Increase in inventories	(1,098)	(799)
(Decrease)/increase in accounts payable and accrued liabilities	(827)	589
Decrease/(increase) in other current and non-current assets	72	(348)
Increase in other current and non-current liabilities	751	1,242
NET CASH FLOWS FROM OPERATING ACTIVITIES	14,106	13,275
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(2,218)	(2,166)
Proceeds from the disposal of assets/businesses, net	4,481	192
Acquisitions, net of cash acquired	(291)	(819)
Purchases of investments	(25,784)	(13,583)
Sales of investments	14,576	12,891
Other	(147)	(40)
NET CASH USED BY INVESTING ACTIVITIES	(9,383)	(3,525)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(5,812)	(5,424)
Repurchase of common stock	(4,381)	(3,050)
Proceeds from short-term debt	629	1,770
Retirement of short-term debt	(1,713)	(1,416)
Proceeds from long-term debt	17	51
Retirement of long-term debt	(1,787)	(1,531)
Proceeds from the exercise of stock options/excess tax benefits	1,406	2,271
Other	—	56
NET CASH USED BY FINANCING ACTIVITIES	(11,641)	(7,273)
Effect of exchange rate changes on cash and cash equivalents	(191)	(184)

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(Decrease)/Increase in cash and cash equivalents	(7,109) 2,293	
Cash and Cash equivalents, beginning of period	20,927		14,911
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$13,818		17,204
Acquisitions			
Fair value of assets acquired	\$305		1,012
Fair value of liabilities assumed and noncontrolling interests	(14) (193)
Net fair value of acquisitions	291		819
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 29, 2013. 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 first quarter of 2014, the Company adopted the Financial Accounting Standards Board (FASB) guidance clarifying the release of accumulated Foreign Currency Translation from other comprehensive income (OCI), into current year Net Earnings. The amendment requires that when the parent company ceases to have a controlling interest in a subsidiary or a business within a foreign entity the parent is to release accumulated Foreign Currency Translation from OCI. This update became effective for all annual periods and interim reporting periods beginning after December 15, 2013. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2014, the Company adopted the FASB guidance on the presentation of unrecognized tax benefits when various qualifying tax credits exist. The amendment requires that unrecognized tax benefits be presented on the Consolidated Balance Sheet as a reduction to deferred tax assets created by net operating losses or other tax credits from prior periods that occur in the same taxing jurisdiction. To the extent that the unrecognized tax benefit exceeds these credits, it shall be presented as a liability. This update became effective for all annual periods and interim reporting periods beginning after December 15, 2013. The adoption of this standard did not have a material impact on the presentation of the Company's financial position.

During the fiscal second quarter of 2014, the FASB issued amended guidance on the use and presentation of discontinued operations in an entity's financial statements. The new guidance restricts the presentation of discontinued operations to business circumstances when the disposal of business operations represents a strategic shift that has or will have a major effect on an entity's operations and financial results. Examples of a strategic shift could include, but not be limited to: disposal of major geographic segments, a major line of business or other major business component of an entity. The new guidance also expands the required disclosures for entities that have assets held for sale but do not meet the new definition of discontinued operations. This amendment includes early adoption provisions allowing the Company to implement this update immediately for the first quarter of 2014. The Company elected to adopt this standard for the first quarter of 2014. The balances and updated disclosures required by the amended guidance are included in Note 10 in the Notes to the 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. This update is required to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2016. Early adoption of this standard is not permitted. 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 second quarter of 2014, the FASB issued Accounting Standards Update 2014-12: Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period. This standard clarifies the current accounting guidance for entities that issue share-based payment awards that require a specific performance target be achieved for employees to become eligible to vest in the awards, which may occur subsequent to a required service period. Current accounting guidance does not explicitly address how to account for these types of awards. The new standard provides explicit guidance and clarifies that these types of performance targets should be treated as performance conditions. The accounting for share-based awards with performance conditions is already specified in current accounting guidance. This update is required to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2015. Early adoption of this standard is permitted and the Company has elected to adopt this standard for the second quarter of 2014. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

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

Reclassification

Certain prior period amounts on the Consolidated Statements of Cash Flows have been reclassified to conform to current year presentation.

NOTE 2 — INVENTORIES

(Dollars in Millions)	September 28, 2014	December 29, 2013
Raw materials and supplies	\$1,165	1,224
Goods in process	2,303	2,612
Finished goods	4,951	4,042
Total inventories	\$8,419	7,878

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 2013. 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 28, 2014	December 29, 2013
Intangible assets with definite lives:		
Patents and trademarks — gross	\$8,991	9,164
Less accumulated amortization	4,614	4,146
Patents and trademarks — net	4,377	5,018
Customer relationships and other intangibles — gross	18,256	19,027
Less accumulated amortization	5,075	4,872
Customer relationships and other intangibles — net	13,181	14,155
Intangible assets with indefinite lives:		
Trademarks	7,425	7,619
Purchased in-process research and development	1,321	1,155
Total intangible assets with indefinite lives	8,746	8,774
Total intangible assets — net	\$26,304	27,947

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Goodwill as of September 28, 2014 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Dev & Diag	Total
Goodwill, net at December 29, 2013	\$8,531	2,068	12,199	22,798
Goodwill, related to acquisitions	—	92	—	92
Goodwill, related to divestitures	(101)	—	(600)	(701)
Currency translation/Other	(446)	(68)	(39)	(553)
Goodwill, net as of September 28, 2014	\$7,984	2,092	11,560	21,636

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

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 was \$1,033 million and \$980 million for the fiscal nine months ended September 28, 2014 and September 29, 2013, respectively. The estimated amortization expense for the five succeeding years approximates \$1,350 million, before tax, per year. Amortization expense is included in cost of products sold. 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 product 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 also uses forward foreign exchange contracts to manage its exposure to the variability of cash flows for repatriation of foreign dividends. These contracts are 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. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company enters into agreements with commercial institutions that have at least an "A" (or equivalent) credit rating. As of September 28, 2014, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of \$32.6 billion, \$2.4 billion and \$1.0 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 are recorded to interest expense in the period in which they occurred. 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 are not material.

As of September 28, 2014, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was \$70 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

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earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal third quarters in 2014 and 2013:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI ⁽¹⁾		Gain/(Loss) Reclassified From Accumulated OCI Into Income ⁽¹⁾		Gain/(Loss) Recognized In Other Income/Expense ⁽²⁾	
	Fiscal Third Quarters Ended					
Cash Flow Hedges By Income Statement Caption	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013
Sales to customers ⁽³⁾	\$(43)	25	(2)	17	—	—
Cost of products sold ⁽³⁾	(37)	42	37	51	(2)	—
Research and development expense ⁽³⁾	25	(20)	8	(14)	—	—
Interest (income)/Interest expense, net ⁽⁴⁾	11	7	(6)	(2)	—	—
Other (income) expense, net ⁽³⁾	58	(13)	12	(8)	—	—
Total	\$14	41	49	44	(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 2014 and 2013:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI ⁽¹⁾		Gain/(Loss) Reclassified From Accumulated OCI Into Income ⁽¹⁾		Gain/(Loss) Recognized In Other Income/Expense ⁽²⁾	
	Fiscal Nine Months Ended					
Cash Flow Hedges By Income Statement Caption	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013
Sales to customers ⁽³⁾	\$(73)	22	6	24	1	—
Cost of products sold ⁽³⁾	(187)	220	196	72	(4)	4
Research and development expense ⁽³⁾	28	(27)	(5)	(31)	(1)	(3)
Interest (income)/Interest expense, net ⁽⁴⁾	21	15	(12)	(6)	—	—
Other (income) expense, net ⁽³⁾	72	(6)	(9)	(6)	—	(1)
Total	\$(139)	224	176	53	(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 quarter ended September 28, 2014, a loss of \$2 million was recognized and for the fiscal third quarter ended September 29, 2013, no gain or loss 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 28, 2014 and September 29, 2013, a loss of \$48 million and a gain of \$50 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

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

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 because they are traded in an active exchange market. 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 28, 2014 and December 29, 2013 were as follows:

(Dollars in Millions)	September 28, 2014				December 29, 2013
	Level 1	Level 2	Level 3	Total	Total ⁽¹⁾
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	\$—	534	—	534	537
Interest rate contracts ⁽²⁾	—	111	—	111	169
Total	—	645	—	645	706
Liabilities:					
Forward foreign exchange contracts	—	579	—	579	133
Interest rate contracts ⁽³⁾⁽⁴⁾	—	4	—	4	26
Total	—	583	—	583	159
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	28	—	28	25
Liabilities:					
Forward foreign exchange contracts	—	40	—	40	29
Other Investments ⁽⁵⁾	\$396	—	—	396	333

(1) As of December 29, 2013, these assets and liabilities are classified as Level 2 with the exception of Other investments of \$333 million, which are classified as Level 1.

(2) Includes \$110 million and \$169 million of non-current assets for September 28, 2014 and December 29, 2013, respectively.

(3) Includes \$4 million and \$19 million of non-current liabilities for September 28, 2014 and December 29, 2013, respectively.

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

(5) Classified as non-current other assets.

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Financial Instruments not measured at Fair Value:

The following financial assets and liabilities are held at carrying amount on the consolidated balance sheet as of September 28, 2014:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Assets		
Current Investments		
Cash	\$2,226	2,226
Government securities and obligations	19,247	19,249
Reverse repurchase agreements	8,138	8,138
Corporate debt securities	1,280	1,281
Money market funds	1,364	1,364
Time deposits	750	750
Total cash, cash equivalents and current marketable securities	\$33,005	33,008

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.

The estimated fair value was the same as the amortized cost as of December 29, 2013.

Financial Liabilities

Current Debt	\$2,115	2,115
Non-Current Debt		
2.15% Notes due 2016	898	922
3 month LIBOR+0.07% FRN due 2016	800	801
0.70% Notes due 2016	399	398
5.55% Debentures due 2017	1,000	1,124
5.15% Debentures due 2018	898	1,026
1.65% Notes due 2018	598	598
4.75% Notes due 2019 (1B Euro 1.2726)	1,268	1,534
3% Zero Coupon Convertible Subordinated Debentures due in 2020	164	288
2.95% Debentures due 2020	542	564
3.55% Notes due 2021	446	481
6.73% Debentures due 2023	250	324
3.375% Notes due 2023	550	573
5.50% Notes due 2024 (500 MM GBP 1.6332)	812	993
6.95% Notes due 2029	296	413
4.95% Debentures due 2033	500	586
4.375% Notes due 2033	646	704
5.95% Notes due 2037	995	1,288
5.85% Debentures due 2038	700	912

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4.50% Debentures due 2040	539	574
4.85% Notes due 2041	298	343
4.50% Notes due 2043	499	545
Other	54	54
Total Non-Current Debt	\$13,152	15,045

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The weighted average effective interest rate on non-current debt is 4.41%.

The excess of the fair value over the carrying value of debt was \$1.4 billion at December 29, 2013.

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 2014 and 2013 were 22.7% and 18.9%, respectively. The higher effective tax rate in 2014 as compared to 2013 was primarily due to the divestiture of the Ortho-Clinical Diagnostics business at an approximate 41% effective tax rate, litigation accruals at low tax rates, the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. Also, the mix of earnings into higher tax jurisdictions, primarily the United States, increased the tax rate. Additionally, the 2014 tax rate was adversely impacted by the expiration, at year end 2013, of the U.S. Research & Development (R&D) tax credit and the Controlled Foreign Corporation (CFC) look-through provision as compared to 2013. The 2013 fiscal nine months tax rate included both the 2012 benefit and the 2013 benefit from the R&D tax credit and the CFC look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

These increases to the year to date 2014 tax rate were partially offset by a tax benefit of \$398 million associated with the Conor Medsystems divestiture. The tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 11 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009.

As of September 28, 2014, the Company had approximately \$2.3 billion of liabilities from unrecognized tax benefits, which reflects the adjustments described above. 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 2014 and 2013 include the following components:

(Dollars in Millions)	Fiscal Third Quarters Ended			
	Retirement Plans		Other Benefit Plans	
	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013
Service cost	\$197	204	52	49
Interest cost	255	226	50	37
Expected return on plan assets	(403) (360) (2) (1
Amortization of prior service cost/(credit)	1	1	(8) (1
Recognized actuarial losses	115	169	33	29

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Curtailments and settlements	(11) —	—	—
Net periodic benefit cost	\$154	240	125	113

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Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal nine months of 2014 and 2013 include the following components:

(Dollars in Millions)	Fiscal Nine Months Ended			
	Retirement Plans		Other Benefit Plans	
	September 28, 2014	September 29, 2013	September 28, 2014	September 29, 2013
Service cost	\$594	615	158	147
Interest cost	768	681	149	112
Expected return on plan assets	(1,212) (1,084) (5) (4
Amortization of prior service cost/(credit)	4	4	(25) (2
Recognized actuarial losses	346	509	101	84
Curtailments and settlements	(11) —	—	—
Net periodic benefit cost	\$489	725	378	337

Company Contributions

For the fiscal nine months ended September 28, 2014, the Company contributed \$36 million and \$27 million to its U.S. and international retirement plans, respectively. The Company plans to continue to fund its U.S. defined benefit plans to comply with the Pension Protection Act of 2006. International plans are funded in accordance with local regulations.

NOTE 7 — ACCUMULATED OTHER COMPREHENSIVE INCOME

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

(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 29, 2013	\$ (202) 106	(3,009) 245	(2,860
Net change	(2,499) 5	287	(315) (2,522
September 28, 2014	\$ (2,701) 111	(2,722) (70) (5,382

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.

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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 28, 2014 and September 29, 2013:

(Shares in Millions)	Fiscal Third Quarters Ended	
	September 28, 2014	September 29, 2013
Basic net earnings per share	\$1.69	1.06
Average shares outstanding — basic	2,814.4	2,818.4
Potential shares exercisable under stock option plans	148.4	154.1
Less: shares which could be repurchased under treasury stock method	(101.2) (107.9
Convertible debt shares	2.7	3.0
Accelerated share repurchase program	—	13.6
Average shares outstanding — diluted	2,864.3	2,881.2
Diluted earnings per share	\$1.66	1.04

The diluted earnings per share calculation for both the fiscal third quarters ended September 28, 2014 and September 29, 2013 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted earnings per share calculation for the fiscal third quarter ended September 29, 2013 included the dilutive effect of 13.6 million shares related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc.

The diluted earnings per share calculation for both the fiscal third quarters ended September 28, 2014 and September 29, 2013 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal nine months ended September 28, 2014 and September 29, 2013:

(Shares in Millions)	Fiscal Nine Months Ended	
	September 28, 2014	September 29, 2013
Basic net earnings per share	\$4.89	3.68
Average shares outstanding — basic	2,822.0	2,805.6
Potential shares exercisable under stock option plans	148.8	154.7
Less: shares which could be repurchased under treasury stock method	(102.3) (110.4
Convertible debt shares	2.7	3.0
Accelerated share repurchase program	—	26.1
Average shares outstanding — diluted	2,871.2	2,879.0
Diluted earnings per share	\$4.81	3.58

The diluted earnings per share calculation for both the fiscal nine months ended September 28, 2014 and September 29, 2013 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted earnings per share calculation for the fiscal nine months ended September 29, 2013 included the dilutive effect of 26.1 million shares related to the accelerated share repurchase program, associated with the acquisition of

Synthes, Inc.

The diluted net earnings per share calculation for both the fiscal nine months ended September 28, 2014 and September 29, 2013 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

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NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

SALES BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Third Quarters Ended			Percent Change
	September 28, 2014	September 29, 2013		
Consumer				
United States	\$1,173	1,225	(4.2)%
International	2,416	2,386	1.3	
Total	3,589	3,611	(0.6)
Pharmaceutical				
United States	4,723	3,549	33.1	
International	3,584	3,487	2.8	
Total	8,307	7,036	18.1	
Medical Devices & Diagnostics				
United States	2,946	3,151	(6.5)
International	3,625	3,777	(4.0)
Total	6,571	6,928	(5.2)
Worldwide				
United States	8,842	7,925	11.6	
International	9,625	9,650	(0.3)
Total	\$18,467	17,575	5.1	%
(Dollars in Millions)	Fiscal Nine Months Ended			Percent Change
	September 28, 2014	September 29, 2013		
Consumer				
United States	\$3,802	3,899	(2.5)%
International	7,088	7,045	0.6	
Total	10,890	10,944	(0.5)
Pharmaceutical				
United States	13,076	10,397	25.8	
International	11,238	10,432	7.7	
Total	24,314	20,829	16.7	
Medical Devices & Diagnostics				
United States	9,300	9,600	(3.1)
International	11,573	11,584	(0.1)
Total	20,873	21,184	(1.5)
Worldwide				
United States	26,178	23,896	9.5	
International	29,899	29,061	2.9	
Total	\$56,077	52,957	5.9	%

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SEGMENT PRE-TAX PROFIT

(Dollars in Millions)	Fiscal Third Quarters Ended			Percent Change)%
	September 28, 2014	September 29, 2013	Percent Change	
Consumer ⁽¹⁾	\$407	467	(12.8)%
Pharmaceutical ⁽²⁾	3,247	2,449	32.6	
Medical Devices & Diagnostics ⁽³⁾	3,399	956	255.5	
Segments operating profit	7,053	3,872	82.2	
Less: Expense not allocated to segments ⁽⁴⁾	243	205		
Worldwide income before taxes	\$6,810	3,667	85.7	%

(Dollars in Millions)	Fiscal Nine Months Ended			Percent Change)%
	September 28, 2014	September 29, 2013	Percent Change	
Consumer ⁽¹⁾	\$1,588	1,525	4.1	%
Pharmaceutical ⁽²⁾	9,921	7,858	26.3	
Medical Devices & Diagnostics ⁽³⁾	7,069	3,991	77.1	
Segments operating profit	18,578	13,374	38.9	
Less: Expense not allocated to segments ⁽⁴⁾	718	653		
Worldwide income before taxes	\$17,860	12,721	40.4	%

(1) Includes litigation expense of \$60 million recorded in the fiscal third quarter of 2014.

Includes a gain of \$388 million from the divestiture of the K-Y[®] brand and litigation expense of \$60 million recorded in the fiscal nine months of 2014. Includes a gain on the sale of intangible and other assets of \$55 million recorded in the fiscal nine months of 2013.

(2) Includes an additional year of the Branded Prescription Drug Fee of \$220 million recorded in the fiscal third quarter of 2014. Includes in-process research and development charge of \$178 million recorded in the fiscal third quarter of 2013.

Includes an additional year of the Branded Prescription Drug Fee of \$220 million recorded in the fiscal nine months of 2014. Includes litigation expense of \$206 million, an in-process research and development charge of \$178 million and a net gain of \$400 million on equity investment transactions, primarily the sale of Elan American Depositary Shares, in the fiscal nine months of 2013.

(3) Includes a net gain of \$1,948 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration/transaction costs of \$167 million, litigation expense of \$225 million and \$126 million for costs associated with the DePuy ASR[™] Hip program recorded in the fiscal third quarter of 2014. Includes Synthes integration/transaction costs of \$122 million, litigation expense of \$844 million and \$35 million for costs associated with the DePuy ASR[™] Hip program recorded in the fiscal third quarter of 2013.

Includes a net gain of \$1,948 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration/transaction costs of \$429 million, litigation expense of \$501 million and \$126 million for costs associated with the DePuy ASR[™] Hip program recorded in the fiscal nine months of 2014. Includes Synthes integration/transaction costs of \$502 million, litigation expense of \$1,564 million, an in-process research and development charge of \$64 million and \$117 million for costs associated with the DePuy ASR[™] Hip program recorded in the fiscal nine months of 2013.

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

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SALES BY GEOGRAPHIC AREA

(Dollars in Millions)	Fiscal Third Quarters Ended			Percent Change	
	September 28, 2014	September 29, 2013			
United States	\$8,842	7,925	11.6	%	
Europe	4,446	4,478	(0.7))	
Western Hemisphere, excluding U.S.	1,820	1,842	(1.2))	
Asia-Pacific, Africa	3,359	3,330	0.9		
Total	\$18,467	17,575	5.1	%	

(Dollars in Millions)	Fiscal Nine Months Ended			Percent Change	
	September 28, 2014	September 29, 2013			
United States	\$26,178	23,896	9.5	%	
Europe	14,387	13,631	5.5		
Western Hemisphere, excluding U.S.	5,378	5,530	(2.7))	
Asia-Pacific, Africa	10,134	9,900	2.4		
Total	\$56,077	52,957	5.9	%	

NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

Subsequent to the quarter, on September 30, 2014, the Company announced a definitive agreement to acquire Alios BioPharma, Inc., a privately-held, clinical stage biopharmaceutical company focused on developing therapies for viral diseases, for approximately \$1.75 billion in cash. The closing is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. The transaction is expected to close during the fiscal fourth quarter of 2014.

During the fiscal third quarter of 2014, the Company completed the divestiture of 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.

Ortho-Clinical Diagnostics' results are included in the Company's Medical Devices and Diagnostics segment pre-tax profit.

As of September 28, 2014 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 \$43 million of inventory, classified as prepaid expenses and other on the Consolidated Balance Sheet and \$114 million of property plant and equipment, classified as other assets on the Consolidated Balance Sheet.

Additionally, 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 gain on the divestiture in the countries that have closed was \$388 million and was recognized in Other (income) expense, net in the fiscal nine months of 2014.

During the fiscal third quarter of 2013, the Company completed the acquisition of Aragon Pharmaceuticals, Inc., a privately-held, pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers.

During the fiscal first quarter of 2013, the Company completed the acquisitions of Flexible Stenting Solutions, Inc., a leading developer of innovative flexible peripheral arterial, venous and biliary stents and Shanghai Elsker Mother & Baby Co., Ltd, a baby care company in China.

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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 28, 2014, 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. 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, and RISPERDAL®. As of September 28, 2014, in the U.S. there were approximately 12,300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 6,900 with respect to the PINNACLE® Acetabular Cup System, 35,600 with respect to pelvic meshes, and 1,000 with respect to RISPERDAL®.

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. We expect the number of pending lawsuits 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 patients in the

United States who had surgery to replace their ASR hip, known as revision surgery, as of August 31, 2013. The U.S. settlement is valued at approximately \$2.5 billion, based on an estimate of 8,000 patients participating in the program. This settlement program is expected to bring to a close significant ASR 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. During the fiscal third quarter of 2014, the Company increased its accruals for the DePuy ASR™ Hip program and related product liability litigation based on additional information. Updates to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District

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Court for the Northern District of Texas. 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 to cover defense costs in connection with product liability litigation associated with RISPERDAL®. 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 and Diagnostics

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 several features of some of 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 the decision to the United States Court of Appeals for the Federal Circuit. Oral argument on appeal took place in September 2014 and the parties are awaiting a decision. The Company believes EES has strong arguments supporting its appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the case. In July 2014, Covidien filed another patent infringement lawsuit against EES in the United States District Court for the District of Connecticut seeking damages and a preliminary injunction, alleging that several features of EES's newest version of its harmonic scalpel, the HARMONIC ACE®+ 7 Shears, infringed the three Tyco patents asserted in the previous case. In August 2014, Covidien amended its complaint to include the HARMONIC ACE®+ Shears. Covidien brought a motion for a preliminary injunction against

the HARMONIC ACE®+ 7 Shears. In October 2014, the District Court entered a decision granting Covidien's motion for a preliminary injunction. EES appealed the decision and sought a stay of the preliminary injunction from the Court of Appeals for the Federal Circuit. The Court of Appeals granted EES an interim stay and lifted the injunction while briefing on a long-term stay takes place. Briefing on the appeal of the injunction will continue.

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. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. The Court entered judgment against Roche in July 2010 and Roche appealed. 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. The issue was argued in September 2012 and the parties are awaiting a ruling. Roche is seeking monetary damages and injunctive relief.

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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 Chang 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. In October 2014, the District Court denied a motion by Rembrandt to re-open discovery.

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 first mediation session was held in September 2014.

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, Instacare Corp and Conductive Technologies (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 validity 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. 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. 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 November 2011, Howmedica Osteonics Corp. (Howmedica) and Stryker Ireland Ltd. (Stryker) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. (DePuy) in the United States District Court for the District of New Jersey alleging infringement by DePuy's PINNACLE® Acetabular Cup System and DURALOC® Acetabular Cup System of a patent relating to a dual-locking mechanism feature in an acetabular cup system. Howmedica and Stryker sought monetary damages and injunctive relief. DePuy filed a counterclaim in February 2012 asserting that Stryker's Trident Acetabular Hip System infringes DePuy's U.S. Patent No. 6,610,097. DePuy sought damages and injunctive relief. In June 2014, the case was settled and dismissed.

In May 2012, Medtronic MiniMed, Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic MiniMed) filed a patent infringement lawsuit against Animas Corporation (Animas) in the United States District Court for the Central District of California alleging that Animas's OneTouch® Ping® Glucose Management System and the IR 1250, IR 2020 and IR 2000 insulin pumps infringe nine of their patents. Medtronic MiniMed since withdrew two of the patents from the lawsuit and is seeking monetary damages and injunctive relief with respect to the remaining patents. In July 2014, Animas entered into a settlement of this lawsuit.

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, 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. Discovery is underway. In August 2014, the parties entered into a settlement of the portion of the lawsuit relating to suture anchors.

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

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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. Medinol is appealing this decision.

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 (USITC) 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 patent infringement, and is seeking an exclusion order to enjoin the importation into the United States of such products. The District Court case has been stayed pending the outcome of the USITC case. The USITC case is set for trial in January 2015.

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. In August 2014, LifeScan filed a motion to dismiss the lawsuit. 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.

Pharmaceutical

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor, Inc. (Centocor) (now Janssen Biotech, Inc. (JBI)) in the United States District Court for the District of Massachusetts alleging that SIMPONI[®] infringes Abbott's U.S. Patent Nos. 7,223,394 and 7,541,031 (the Salfeld patents). Abbott is seeking monetary damages and injunctive relief. Trial is set for January 2015.

In August 2009, Abbott GmbH & Co. (Abbott GmbH) and Abbott Bioresearch Center (collectively now referred to as, AbbVie) filed a patent infringement lawsuit against Centocor (now JBI) in the United States District Court for the District of Massachusetts alleging that STELARA[®] infringes two United States patents assigned to Abbott GmbH. JBI filed a complaint in the United States District Court for the District of Columbia for a declaratory judgment of non-infringement and invalidity of the Abbott GmbH patents, as well as a Complaint for Review of a Patent Interference Decision that granted priority of invention on one of the two asserted patents to Abbott GmbH. The cases were transferred from the District of Columbia to the District of Massachusetts. Trial was held in September 2012 and a jury returned a verdict in favor of JBI, invalidating AbbVie's patent claims. In March 2013, the Court denied AbbVie's post-trial motions challenging the outcome and granted JBI's motion on the appeal of the interference decision. AbbVie appealed, and in July 2014, the Court of Appeals for the Federal Circuit affirmed the lower court's ruling.

Also in August 2009, Abbott GmbH and Abbott Laboratories Limited (collectively now referred to as, AbbVie) brought a patent infringement lawsuit in The Federal Court of Canada alleging that STELARA[®] infringes Abbott GmbH's Canadian patent. A trial was held in December 2013 in the Canadian case. In January 2014, the Court ruled in favor of AbbVie, finding that the asserted claims were valid and infringed by STELARA[®]. JBI appealed that decision. In May 2014, AbbVie's motion for an injunction was granted in part, and JBI has also appealed that decision. In October 2014, the appellate court overturned the finding of liability, remanded the case to the trial court for re-trial, and lifted the injunction. In addition to the U.S. and Canadian litigations, in August 2012, AbbVie filed patent infringement lawsuits related to STELARA[®] in the Netherlands, Switzerland and Germany. In each of these cases,

briefing has commenced or recently completed and hearings on the merits will take place later this year or early in 2015. In each of the above cases, AbbVie is seeking monetary damages and injunctive relief.

In March 2012, Noramco, Inc. (Noramco), a subsidiary of Johnson & Johnson, moved to intervene in three patent infringement lawsuits filed in the United States District Court for the Southern District of New York (SDNY) by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva) and Amneal Pharmaceuticals, LLC (Amneal). In February 2013, Noramco appeared on behalf of Noramco customers Watson Laboratories, Inc.- Florida and Andrx Labs, LLC (collectively, Watson/Andrx) in a similar lawsuit filed by Purdue in the SDNY. 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 and Watson/Andrx. In April 2013, Watson/Andrx entered into a settlement with Purdue. The trial against

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Impax and Teva (as well as two parties not defended by Noramco) 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. Purdue has appealed the decision.

In August 2012, Dr. James M. Swanson filed a lawsuit against ALZA Corporation (ALZA) in the Northern District of California seeking to be added as an inventor on three ALZA-owned patents relating to CONCERTA®. Alternatively, Dr. Swanson has alleged, among other things, that the patents-in-suit are invalid and/or unenforceable as a result of ALZA's alleged omission of Dr. Swanson as a named inventor on the patents. The lawsuit also includes claims of fraud, breach of fiduciary duty and unfair competition. Dr. Swanson is seeking damages and an award of unjust enrichment. ALZA filed a motion to dismiss Dr. Swanson's claims, as well as counterclaims for breach of contract and negligent misrepresentation. The Court granted the motion in part, and denied it in part. Discovery in the case is ongoing. ALZA filed a motion for summary judgment on the issue of inventorship, which is scheduled for hearing in November 2014.

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 the summary judgment rulings.

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. If the Notice of Compliance is withdrawn, Hospira would have to serve a Notice of Allegation and Janssen could commence an application to prohibit issuance of the Notice of Compliance until expiry of the relevant patent. A hearing has been scheduled for February 2015.

In September 2013, JBI and New York University Medical Center (NYU) received an Office Action from the United States Patent Office 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, and NYU granted JBI an exclusive license to NYU'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 received a further rejection. JBI believes the '471 patent is valid and has responded to the latest Office Action to defend the patent, and if necessary, JBI will pursue all available appeals.

In March 2014, Celltrion filed a declaratory judgment lawsuit against JBI in the United States District Court for the District of Massachusetts seeking to invalidate the '471 patent and two other U.S. patents that relate to REMICADE® and are co-owned by JBI and NYU, and exclusively licensed to JBI (collectively, the Le patents). JBI moved to dismiss the case for lack of jurisdiction. Also in March 2014, Celltrion filed a lawsuit in the United States District Court for the Southern District of New York against Kennedy seeking to invalidate three patents owned by Kennedy (the Feldman patents). The Feldman patents are licensed to JBI and also relate to REMICADE®. In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®.

In August 2014, Hospira, Inc. (Hospira) filed a lawsuit in the United States District Court for the Southern District of New York against JBI, NYU, NYU Medical Center and Kennedy seeking to invalidate the Feldman patents. Hospira alleges that it has co-exclusive rights to market Celltrion's biosimilar version of REMICADE® in the United States if it is approved by the FDA. In October 2014, JBI, NYU and NYU Medical Center moved to dismiss this case or transfer it to the United States District Court for the District of Massachusetts.

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If any of the Le or Feldman patents is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States would be subject to approval by the FDA. If a biosimilar version of REMICADE® were to be approved and introduced to the market, loss of exclusivity would likely result in a reduction in sales.

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, resulting in substantial market share and revenue losses for those products.

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. 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 consolidated action against Mylan and Lupin.

In March 2013, Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. 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. Discovery in this case is ongoing and a trial date is set for October 2015.

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. Discovery in these cases is ongoing.

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. A trial regarding the remaining patents in the consolidated action was completed in April 2014. In August 2014, the Court issued a decision 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.

Janssen and G.D. Searle also filed patent infringement lawsuits against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd. (collectively, Teva) in the United States District Court for the District of New Jersey in response to Teva's ANDA seeking approval to market a generic version of PREZISTA[®] before the expiration of certain patents relating to PREZISTA[®] that Janssen either owns or exclusively licenses from G.D. Searle. In March 2014, the parties entered into a settlement agreement and the lawsuits against Teva were dismissed.

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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 is ongoing.

Also in July 2014, Janssen Inc. and Janssen R&D Ireland filed a Notice of Application against Mylan Pharmaceuticals ULC 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.

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 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 June 2013, ALZA Corporation (ALZA) and Janssen Pharmaceuticals, Inc. (JPI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against Par Pharmaceuticals, Inc. (Par), Osmotica Kereskedelmies Szolgaltato Kft (Osmotica), and Norwich Pharmaceuticals, Inc. (Norwich) in response to those parties' ANDAs seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent No. 8,163,798 (the '798 patent). In addition, in September 2013, Par and Osmotica filed counterclaims against ALZA and JPI seeking declarations of invalidity and noninfringement of the patent-in-suit, and Norwich filed a motion to dismiss. Norwich was dismissed from the case in October 2013 based on its agreement to be bound by the outcome of the case with Osmotica. In March 2014, ALZA and JPI amended its complaint against Par and Osmotica to assert infringement of newly issued United States Patent No. 8,629,179 (the '179 patent). In June 2014, ALZA, JPI and Osmotica entered into a settlement of the action, and in September 2014, ALZA, JPI and Par entered into a settlement.

In May 2014, ALZA and 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 the '798 patent. Mylan filed counterclaims seeking declarations of invalidity and noninfringement of the patents-in-suit.

In June 2014, ALZA and JPI filed a patent infringement lawsuit in the District of Delaware against Sandoz, Inc. in response to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of the '798 and '179 patents. Sandoz filed counterclaims seeking declarations of invalidity, unenforceability, and noninfringement of the patents-in-suit.

In each of the above lawsuits, ALZA and/or JPI are seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA® before the expiration of the '798 and/or '179 patents.

NUCYNTA® AND NUCYNTA® ER

In July 2013, Janssen Pharmaceuticals, Inc. (JPI) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC, Actavis Inc. and Actavis LLC (collectively, Actavis), as well as Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively, Alkem). The patent infringement claims against Actavis and Alkem relate to their respective ANDAs seeking approval to market a generic version of

NUCYNTA[®] ER before the expiration of United States Reissue Patent No. 39,593 (the '593 patent), United States Patent No. 7,994,364 (the '364 patent) and, as to Actavis only, United States Patent No. 8,309,060 (the '060 patent). The lawsuit also includes a patent infringement claim against Alkem in response to its ANDA seeking approval to market a generic version of NUCYNTA[®] before the expiration of the '593 and '364 patents. In December 2013, JPI filed an additional complaint in the District Court of New Jersey against Alkem asserting United States Patent No. 8,536,130 related to its ANDA seeking approval to market a generic version of NUCYNTA[®] ER. In August 2014, JPI amended the complaint against Alkem to add additional dosage strengths.

In October 2013, JPI received a Paragraph IV Notice from Sandoz, Inc. (Sandoz) with respect to NUCYNTA[®] related to the '364 patent, and a Paragraph IV Notice from Roxane Laboratories, Inc. (Roxane) with respect to NUCYNTA[®] related to the '364 and '593 patents. In response to those notices, JPI filed an additional complaint in the United States District Court for the District of New Jersey against Roxane and Sandoz asserting the '364 patent against Sandoz and the '364 and '593 patents against Roxane. In April 2014, JPI and Sandoz entered into a joint stipulation of dismissal of the case against Sandoz, based on

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Sandoz's agreement not to enter the market prior to the expiration of the asserted patents. In June 2014, in response to a Paragraph IV Notice from Roxane with respect to NUCYNTA® ER, JPI filed a complaint asserting the '364 and '593 patents against Roxane.

In July 2014, in response to a Paragraph IV Notice from Watson Laboratories, Inc. (Watson) with respect to the NUCYNTA® oral solution product and the '364 and '593 patents, JPI filed a lawsuit in the United States District Court for the District of New Jersey asserting the '364 and '593 patents against Watson.

In each of the above lawsuits, JPI is seeking an Order enjoining the defendants from marketing their generic versions of NUCYNTA® ER and NUCYNTA® before the expiration of the asserted patents.

GOVERNMENT PROCEEDINGS

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

Average Wholesale Price (AWP) Litigation

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

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

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and a few state cases are still pending. The case filed by the Attorney General of Illinois had been set for trial in September 2014, but that trial has been adjourned and no new trial date has been set. In addition, an AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in October and November 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. Because the Company believes

that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the verdict.

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

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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.

Four states have remaining claims in litigation related to RISPERDAL[®]: one claim is on remand in Arkansas, the case in South Carolina is on appeal, and the cases in Kentucky and Mississippi have not progressed to trial. The Company has not accrued an amount equal to the judgment obtained in South Carolina. To the extent any state has an outstanding Medicaid-related claim not resolved by the settlements referenced above, the Company has accrued an amount approximately equal to what that state would have received if it had participated in the relevant federal settlement. 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.

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

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica, Inc. (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL[®] or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately \$327.1 million against JPI. JPI has appealed this judgment and the Company believes it has strong arguments supporting the appeal. Oral argument on the appeal took place before the South Carolina Supreme Court in March 2013, and the parties are awaiting a decision.

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. Trial on the remand of the case is scheduled for June 2015.

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (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

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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. The grand jury and False Claims investigations are continuing. The Companies are cooperating with the United States Attorney's Office in responding to these investigations.

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.

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 April 2012, Janssen Pharmaceuticals, Inc. (JPI) received a letter requesting certain documents from the United States Department of Justice relating to the marketing and promotion of DORIBAX[®]. In 2012, JPI provided documents and will continue to cooperate with any further inquiries if and when they are received.

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 RELIEVA STRATUS[®] MicroFlow Spacer products. The investigation is continuing and Acclarent is cooperating with the United States Attorney's Office in responding to the subpoena.

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 45 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 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.

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In May 2013, Janssen Pharmaceuticals, Inc. (JPI) received a subpoena from the Atlanta Regional Office of the Department of Health and Human Services, Office of Inspector General, seeking production of documents and information regarding: (1) the sales, marketing and promotional practices, including the remuneration of healthcare providers, related to NUCYNTA® IR and NUCYNTA® ER; and (2) any studies, reports and/or complaints regarding the safety and/or actual or potential side effects of NUCYNTA® IR and NUCYNTA® ER. In October 2014, the United States Department of Justice (DOJ) informed JPI that the government's investigation stemmed from the filing of a qui tam complaint, that the DOJ had formally declined to intervene in the qui tam action, and that the DOJ was closing its investigation related to NUCYNTA® IR and NUCYNTA® ER.

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. Johnson & Johnson is seeking to recover substantial damages for the breach. In June 2011, Guidant filed a motion for summary judgment, and in July 2014, the judge denied Guidant's motion. The trial is scheduled to begin in November 2014.

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*. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In October 2012, the United States Court of Appeals for the Third Circuit granted OCD's petition for interlocutory review of the class certification ruling. Oral argument on the appeal was held in February 2014 and the parties are awaiting a decision. Following the divestiture of OCD, Johnson & Johnson retains any liability that may result from these cases.

In September 2010, a shareholder, Ronald Monk, filed a lawsuit in the United States District Court for the District of New Jersey seeking class certification and alleging that Johnson & Johnson and certain individuals, including executive officers and employees of Johnson & Johnson, failed to disclose that a number of manufacturing facilities failed to maintain current good manufacturing practices, and that as a result, the price of the Company's stock declined significantly. Plaintiff sought to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In December 2011, a motion by Johnson & Johnson to dismiss was granted in part and denied in part. In September 2012, Plaintiff filed a Second Amended Complaint and Johnson & Johnson and the individual defendants moved to dismiss Plaintiff's Second Amended Complaint in part. Following mediation, the parties reached an agreement in principle to settle the case, and in July 2013, filed for preliminary approval of the proposed settlement. In November 2013, the Court approved the settlement. Three parties that had objected to the settlement appealed the Court's approval orders. Prior to the mediation for the appeal, the parties agreed to dismiss the appeal with prejudice and without costs against any party. The United States Court of Appeals for the Third Circuit dismissed the case in April 2014.

In April 2011, OMJ Pharmaceuticals, Inc. (OMJ PR) filed a lawsuit against the United States in United States District Court for the District of Puerto Rico alleging overpayment of federal income taxes for the tax years ended November 30, 1999 and November 30, 2000. OMJ PR alleged that the Internal Revenue Service erroneously calculated OMJ

PR's tax credits under Section 936 of the Tax Code. OMJ PR filed a motion for summary judgment, and the United States filed a cross motion for summary judgment. In October 2012, the Court granted a motion by the United States for summary judgment and denied a motion by OMJ PR for summary judgment. OMJ PR appealed this decision. In June 2014, the appellate court reversed the trial court's decision and instructed the trial court to enter summary judgment in favor of OMJ PR.

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

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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 is scheduled for October 2015.

In August 2014, United States Customs and Border Protection 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.

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.

Shareholder Derivative Action

In September 2011, two shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey by Donovan Spamer and The George Leon Family Trust naming current and former directors of Johnson & Johnson as defendants and Johnson & Johnson as the nominal defendant. These lawsuits allege that the defendants breached their fiduciary duties in their decisions with respect to the compensation of the Chief Executive Officer during the period from 2008 through 2011, and that the defendants made misleading statements in the Company's annual proxy statements. Both of these lawsuits were voluntarily dismissed without prejudice, but a similar lawsuit, *The George Leon Family Trust v. Coleman*, was refiled in July 2012. That lawsuit sought a variety of relief, including monetary damages, injunctive relief, and corporate governance reforms. In June 2013, the Board of Directors of Johnson & Johnson (the Board) received a report prepared by special, independent counsel to the Board, which investigated the allegations contained in the derivative actions filed by Donovan Spamer and by The George Leon Family Trust, and in several shareholder demand letters that the Board received in 2011 and 2012 raising similar issues. The report recommended that Johnson & Johnson reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation. The Board unanimously adopted the report's recommendations.

In September 2013, Johnson & Johnson moved to dismiss or, in the alternative, for summary judgment in *The George Leon Family Trust v. Coleman*, based upon the Board's determination. In October 2013, the plaintiff in the Leon litigation filed an amended complaint and Johnson & Johnson moved to dismiss the amended complaint or, in the alternative, for summary judgment, based upon the Board's determination. In June 2014, the Court granted summary judgment in favor of Johnson & Johnson.

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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 2014, worldwide sales were \$56.1 billion, a total increase of 5.9%, including operational growth of 6.8% as compared to 2013 fiscal nine months sales of \$53.0 billion. Currency fluctuations had a negative impact of 0.9% for the fiscal nine months of 2014. Worldwide sales for the fiscal nine months of 2013 were positively impacted by an adjustment to previous estimates for Managed Medicaid rebates under the Affordable Care Act, primarily related to new data received from the states in the fiscal first quarter of 2013. This negatively impacted the worldwide sales growth for the fiscal nine months of 2014 by 0.4% as compared to 2013. In the fiscal nine months of 2014, sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 3.4% and the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 1.1% on the worldwide operational growth.

Sales by U.S. companies were \$26.2 billion in the fiscal nine months of 2014, which represented an increase of 9.5% as compared to the prior year. Sales by international companies were \$29.9 billion, which represented a total increase of 2.9%, including an operational increase of 4.6%, and a negative currency impact of 1.7% as compared to the fiscal nine months sales of 2013.

Sales by companies in Europe achieved growth of 5.5%, including operational growth of 3.3%, and a positive currency impact of 2.2%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 2.7%, including operational growth of 5.7%, offset by a negative currency impact of 8.4%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 2.4%, including operational growth of 5.8%, and a negative currency impact of 3.4%.

For the fiscal third quarter of 2014, worldwide sales were \$18.5 billion, a total increase of 5.1%, including operational growth of 5.8% as compared to 2013 fiscal third quarter sales of \$17.6 billion. Currency fluctuations had a negative impact of 0.7% for the fiscal third quarter of 2014. In the fiscal third quarter of 2014 sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 4.3% and the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 2.6% on the worldwide operational growth.

Sales by U.S. companies were \$8.8 billion in the fiscal third quarter of 2014, which represented an increase of 11.6% as compared to the prior year. Sales by international companies were \$9.6 billion, a decline of 0.3%, including operational growth of 1.0%, offset by a negative currency impact of 1.3% as compared to the fiscal third quarter sales of 2013.

Sales by companies in Europe experienced a decline of 0.7%, which included an operational decrease of 0.8%, and a positive currency impact of 0.1%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 1.2%, including operational growth of 3.5%, offset by a negative currency impact of 4.7%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 0.9%, including operational growth of 2.0% partially offset by a negative currency impact of 1.1%.

U.S. Health Care Reform

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

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ANALYSIS OF SALES BY BUSINESS SEGMENTS

Consumer

Consumer segment sales in the fiscal nine months of 2014 were \$10.9 billion, a decrease of 0.5% as compared to the same period a year ago, including an operational increase of 1.1% offset by a negative currency impact of 1.6%. U.S. Consumer segment sales decreased by 2.5%. International Consumer segment sales increased by 0.6%, including operational growth of 3.0% and a negative currency impact of 2.4%.

Major Consumer Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	September 28, September 29, Total			Operations		Currency	
	2014	2013	Change	Change	Change		
OTC	\$3,033	\$2,949	2.8	% 3.9	% (1.1))%	
Skin Care	2,802	2,734	2.5	3.2	(0.7))	
Baby Care	1,715	1,710	0.3	3.6	(3.3))	
Oral Care	1,233	1,204	2.4	3.8	(1.4))	
Wound Care/Other	1,113	1,127	(1.2)) (0.8)) (0.4))	
Women's Health	994	1,220	(18.5)) (15.0)) (3.5))	
Total Consumer Sales	\$10,890	\$10,944	(0.5))% 1.1	% (1.6))%	

Consumer segment sales in the fiscal third quarter of 2014 were \$3.6 billion, a decrease of 0.6% as compared to the same period a year ago, including an operational increase of 0.3% offset by a negative currency impact of 0.9%. U.S. Consumer segment sales decreased by 4.2%. International Consumer segment sales increased by 1.3%, including operational growth of 2.6% and a negative currency impact of 1.3%.

Major Consumer Franchise Sales — Fiscal Third Quarters Ended

(Dollars in Millions)	September 28, September 29, Total			Operations		Currency	
	2014	2013	Change	Change	Change		
OTC	\$1,019	\$975	4.5	% 5.7	% (1.2))%	
Skin Care	920	924	(0.4)) 0.0	(0.4))	
Baby Care	563	560	0.5	1.6	(1.1))	
Oral Care	409	395	3.5	3.7	(0.2))	
Wound Care/Other	353	349	1.1	1.1	0.0)	
Women's Health	325	408	(20.3)) (18.3)) (2.0))	
Total Consumer Sales	\$3,589	\$3,611	(0.6))% 0.3	% (0.9))%	

The OTC franchise achieved operational growth of 5.7% as compared to the prior year fiscal third quarter driven by upper respiratory and analgesics products.

The Skin Care franchise operational growth was flat as compared to the prior year. Sales growth of NEUTROGENA® and DABAO® products were partially offset by lower sales of CLEAN & CLEAR® and RoC® products.

The Baby Care franchise achieved operational growth of 1.6% as compared to the prior year, primarily due to sales growth of haircare and wipes.

The Oral Care franchise achieved operational growth of 3.7% 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 achieved operational growth of 1.1% as compared to the prior year, due to increased sales of NEOSPORIN®.

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The Women's Health franchise experienced an operational decline of 18.3% as compared to the prior year, primarily due to the divestiture of women's sanitary protection products in the U.S., Canada and Caribbean, which was completed in the fiscal fourth quarter of 2013. This was partially offset by growth in emerging markets.

Pharmaceutical

Pharmaceutical segment sales in the fiscal nine months of 2014 were \$24.3 billion, a total increase of 16.7% as compared to the same period a year ago, with an operational increase of 17.4% and a negative currency impact of 0.7%. U.S. Pharmaceutical sales increased by 25.8% as compared to the same period a year ago. International Pharmaceutical sales increased by 7.7%, including operational growth of 9.1% and a negative currency impact of 1.4%. In the fiscal nine months of 2013, Pharmaceutical segment sales included a positive adjustment to previous estimates for Managed Medicaid rebates. This negatively impacted 2014 fiscal nine months Pharmaceutical operational sales growth by 1.1%. In the fiscal nine months of 2014 sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 8.4% on the operational growth of the Pharmaceutical segment.

Major Pharmaceutical Therapeutic Area Sales — Fiscal Nine Months Ended*

(Dollars in Millions)	September 28,	September 29,	Total	Operations		Currency	
	2014	2013	Change	Change	Change		
Total Immunology	\$7,615	\$ 6,788	12.2	% 13.1	% (0.9))%	
REMICADE®	5,196	4,961	4.7	5.7	(1.0))	
SIMPONI®/SIMPONI® ARIA™	841	678	24.0	25.3	(1.3))	
STELARA®	1,527	1,087	40.5	40.3	0.2)	
Other Immunology	51	62	(17.7)	(13.8)	(3.9))	
Total Infectious Diseases	4,523	2,606	73.6	73.7	(0.1))	
EDURANT®	275	163	68.7	66.1	2.6)	
INCIVO®	221	410	(46.1)	(45.6)	(0.5))	
OLYSIO®/SOVRIAD®	1,981	—	**	**	0.0)	
PREZISTA®	1,383	1,212	14.1	13.9	0.2)	
Other Infectious Diseases	663	821	(19.2)	(18.7)	(0.5))	
Total Neuroscience	4,836	5,016	(3.6)	(2.6)	(1.0))	
CONCERTA®/methylphenidate	430	613	(29.9)	(28.3)	(1.6))	
INVEGA®	479	429	11.7	12.5	(0.8))	
INVEGA® SUSTENNA®/XEPLION®	1,170	898	30.3	30.1	0.2)	
RISPERDAL® CONSTA®	896	997	(10.1)	(9.9)	(0.2))	
Other Neuroscience	1,861	2,079	(10.5)	(8.6)	(1.9))	
Total Oncology	3,245	2,660	22.0	22.5	(0.5))	
VELCADE®	1,200	1,136	5.6	7.1	(1.5))	
ZYTIGA®	1,642	1,203	36.5	36.1	0.4)	
Other Oncology	403	321	25.5	25.9	(0.4))	
Total Other	4,095	3,759	8.9	9.3	(0.4))	
PROCRIT®/EPREX®	936	1,057	(11.4)	(11.3)	(0.1))	
XARELTO®	1,094	593	84.5	84.5	0.0)	
Other	2,065	2,109	(2.1)	(1.5)	(0.6))	
Total Pharmaceutical Sales	\$24,314	\$ 20,829	16.7	% 17.4	% (0.7))%	

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

** Percentage greater than 100%

Pharmaceutical segment sales in the fiscal third quarter of 2014 were \$8.3 billion, a total increase of 18.1% as compared to the same period a year ago, with an operational increase of 18.7% and a negative currency impact of 0.6%. U.S. Pharmaceutical sales increased by 33.1% as compared to the same period a year ago. International Pharmaceutical sales increased by 2.8%, including operational growth of 4.1% and a negative currency impact of 1.3%. In the fiscal third quarter of 2014

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sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 10.7% on the operational growth of the Pharmaceutical segment.

Major Pharmaceutical Therapeutic Area Sales — Fiscal Third Quarters Ended*

(Dollars in Millions)	September 28, September 29, Total			Operations		Currency	
	2014	2013	Change	Change	Change		
Total Immunology	\$2,641	\$2,343	12.7	% 13.3	% (0.6))%	
REMICADE®	1,782	1,689	5.5	6.1	(0.6))	
SIMPONI®/SIMPONI® ARIA™	300	266	12.8	13.8	(1.0))	
STELARA®	543	370	46.8	47.0	(0.2))	
Other Immunology	16	18	(11.1)	(11.8)	0.7)	
Total Infectious Diseases	1,561	821	90.1	90.3	(0.2))	
EDURANT®	102	64	59.4	58.8	0.6)	
INCIVO®	38	76	(50.0)	(49.1)	(0.9))	
OLYSIO®/SOVRIAD®	796	—	**	**	0.0)	
PREZISTA®	446	410	8.8	8.9	(0.1))	
Other Infectious Diseases	179	271	(33.9)	(32.6)	(1.3))	
Total Neuroscience	1,571	1,592	(1.3)	(0.5)	(0.8))	
CONCERTA®/methylphenidate	135	142	(4.9)	(3.3)	(1.6))	
INVEGA®	156	147	6.1	6.8	(0.7))	
INVEGA® SUSTENNA®/XEPLION®	403	324	24.4	24.7	(0.3))	
RISPERDAL® CONSTA®	284	326	(12.9)	(12.3)	(0.6))	
Other Neuroscience	593	653	(9.2)	(8.1)	(1.1))	
Total Oncology	1,112	981	13.4	14.4	(1.0))	
VELCADE®	389	404	(3.7)	(2.0)	(1.7))	
ZYTIGA®	568	464	22.4	22.8	(0.4))	
Other Oncology	155	113	37.2	38.3	(1.1))	
Total Other	1,422	1,299	9.5	9.9	(0.4))	
PROCRIT®/EPREX®	307	344	(10.8)	(10.5)	(0.3))	
XARELTO®	414	246	68.3	68.3	0.0)	
Other	701	709	(1.1)	(0.5)	(0.6))	
Total Pharmaceutical Sales	\$8,307	\$7,036	18.1	% 18.7	% (0.6))%	

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

** Percentage greater than 100%

Immunology products achieved operational sales growth of 13.3% as compared to the same period a year ago. Increased sales of STELARA® (ustekinumab) and SIMPONI®/SIMPONI® ARIA™ (golimumab) were primarily due to market growth and market share gains. REMICADE® (infliximab) growth was primarily due to market growth. The patents for REMICADE® in certain countries in Europe (Germany, Spain, United Kingdom, Sweden, Austria, Belgium, Switzerland, Denmark, France, Greece, Italy, Luxembourg and the Netherlands) expire in February 2015. If a biosimilar version of REMICADE® were to be introduced to the market, loss of exclusivity would likely result in a reduction in sales. See Note 11 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

Infectious disease products achieved operational sales growth of 90.3% as compared to the same period a year ago. Major contributors to the growth were the recent launch of OLYSIO®/SOVRIAD® (simeprevir); PREZISTA® (darunavir), due to market growth and increased script share; and sales of EDURANT® (rilpivirine). This was partially offset by lower sales of INCIVO® (telaprevir), due to competitive pressures, and lower sales of vaccine products. The

recent approval of a competitive product for OLYSIO®/SOVRIAD® (simeprevir) is expected to have a significant negative impact on future sales of OLYSIO®/SOVRIAD® (simeprevir).

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Neuroscience products experienced an operational decline of 0.5% as compared to the same period a year ago. Strong sales of INVEGA® SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA® (paliperidone palmitate) were partially offset by lower sales of RISPERDAL® CONSTA® (risperidone). Additionally, a decline in CONCERTA®/methylphenidate sales was due to continued generic competition.

Oncology products achieved strong operational sales growth of 14.4% as compared to the same period a year ago. Major contributors to the growth were strong sales of ZYTIGA®(abiraterone acetate), as well as the recent launch of IMBRUVICA® (ibrutinib). Sales of VELCADE® (bortezomib) were negatively impacted by the timing of tenders.

In the fiscal third quarter of 2014, Other Pharmaceutical sales achieved operational sales growth of 9.9% as compared to the same period a year ago. Strong sales of XARELTO®(rivaroxaban) and INVOKANA®(canagliflozin) were partially offset by lower sales of ACIPHEX®(rabeprazole sodium) due to the expiration of the U.S. patent exclusivity period and the termination of the co-promotion agreement with Eisai Inc.

Medical Devices and Diagnostics

Medical Devices and Diagnostics segment sales in the fiscal nine months of 2014 were \$20.9 billion, a decrease of 1.5% as compared to the same period a year ago, including an operational decline of 0.6% and a negative currency impact of 0.9%. U.S. Medical Devices and Diagnostics sales decreased 3.1%. International Medical Devices and Diagnostics sales decreased by 0.1%, including operational growth of 1.5% offset by a negative currency impact of 1.6%. In the fiscal nine months of 2014, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 2.3% on the operational growth of the Medical Devices and Diagnostics segment.

Major Medical Devices and Diagnostics Franchise Sales — Fiscal Nine Months Ended*

(Dollars in Millions)	September 28, September 29, Total			Operations		Currency	
	2014	2013	Change	Change	Change	Change	Change
Orthopaedics	\$ 7,234	\$ 7,053	2.6 %	3.0 %	(0.4)%		
Surgical Care	4,604	4,630	(0.6)	0.4	(1.0)		
Specialty Surgery/Other	2,637	2,575	2.4	3.6	(1.2)		
Vision Care	2,172	2,218	(2.1)	(0.1)	(2.0)		
Cardiovascular Care	1,650	1,543	6.9	7.8	(0.9)		
Diabetes Care	1,628	1,746	(6.8)	(6.1)	(0.7)		
Diagnostics	948	1,419	(33.2)	(32.4)	(0.8)		
Total Medical Devices and Diagnostics Sales	\$ 20,873	\$ 21,184	(1.5)%	(0.6)%	(0.9)%		

* Prior year amounts have been reclassified to conform to current year presentation. Infection Prevention is included in Specialty Surgery/Other.

Medical Devices and Diagnostics segment sales in the fiscal third quarter of 2014 were \$6.6 billion, a decrease of 5.2% as compared to the same period a year ago, with an operational decrease of 4.6% and a negative currency impact of 0.6%. U.S. Medical Devices and Diagnostics sales decreased 6.5%. International Medical Devices and Diagnostics sales decreased by 4.0%, including an operational decrease of 2.8% and a negative currency impact of 1.2%. In the fiscal third quarter of 2014, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 6.2% on the operational growth of the Medical Devices and Diagnostics segment.

Major Medical Devices and Diagnostics Franchise Sales — Fiscal Third Quarters Ended*

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(Dollars in Millions)	September 28,	September 29,	Total	Operations	Currency
	2014	2013	Change	Change	Change
Orthopaedics	\$ 2,344	\$ 2,283	2.7 %	2.9 %	(0.2)%
Surgical Care	1,521	1,534	(0.8)	0.0	(0.8)
Specialty Surgery/Other	858	846	1.4	2.2	(0.8)
Vision Care	704	748	(5.9)	(4.5)	(1.4)
Diabetes Care	558	557	0.2	1.3	(1.1)
Cardiovascular Care	542	501	8.2	9.0	(0.8)
Diagnostics	44	459	(90.4)	(90.1)	(0.3)
Total Medical Devices and Diagnostics Sales	\$ 6,571	\$ 6,928	(5.2)%	(4.6)%	(0.6)%

* Prior year amounts have been reclassified to conform to current year presentation. Infection Prevention is included in Specialty Surgery/Other.

The Orthopaedics franchise achieved operational sales growth of 2.9% as compared to the prior year fiscal third quarter. Growth was primarily driven by sales of trauma, sports medicine, knee and hip products. Growth was negatively impacted by continued pricing pressures.

The Surgical Care franchise was flat operationally as compared to the prior year fiscal third quarter. The success of the ECHELON FLEX™ powered ENDOPATH® Stapler outside the U.S. was offset by lower sales of women's health and urology products, due to the Company's decision to exit from certain women's health products and U.S. pricing pressure.

The Specialty Surgery/Other franchise achieved operational sales growth of 2.2% as compared to the prior year fiscal third quarter. Growth was primarily attributable to new product launches and market growth for biosurgical and energy products partially offset by competitive pressures for ACCLARENT®, MENTOR® and STERILMED® products in the U.S.

The Vision Care franchise experienced an operational sales decline of 4.5% as compared to the prior year fiscal third quarter primarily due to increased competition and pricing pressures in the U.S. and Asia Pacific region.

The Diabetes Care franchise achieved operational sales growth of 1.3% as compared to the prior year fiscal third quarter. The U.S. benefited from a favorable pricing adjustment within the managed care channel in the fiscal third quarter of 2014. Additionally, volume growth was partially offset by lower prices primarily related to competitive bidding.

The Cardiovascular Care franchise achieved operational sales growth of 9.0% as compared to the prior year fiscal third quarter due to strong sales growth of Biosense Webster products in all major regions.

The Diagnostics franchise experienced an operational sales decline of 90.1% as compared to the prior year fiscal third quarter. The decline was due to the divestiture of the Ortho-Clinical Diagnostics business (the Diagnostics franchise) to The Carlyle Group on June 30, 2014.

ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income for the fiscal nine months of 2014 increased to \$17.9 billion as compared to \$12.7 billion in the fiscal nine months of 2013, an increase of 40.4%. The increase in earnings before provision for taxes of \$5.2 billion was primarily due to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost reduction efforts across many of the businesses.

Additionally, the fiscal nine months of 2014 included higher net gains on divestitures of \$2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of \$1.2 billion, lower in-process research and development costs of \$0.2 billion and lower Synthes integration/transaction costs of \$0.1 billion as compared to the fiscal nine months of 2013. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of \$0.2 billion in 2014. The fiscal nine months of 2013 included a net gain of \$0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares, and a gain of \$0.1 billion on the sale of intangible and other assets.

Consolidated earnings before provision for taxes on income for the fiscal third quarter of 2014 increased to \$6.8 billion as compared to \$3.7 billion in the fiscal third quarter of 2013, an increase of 85.7%. The increase in earnings before provision for taxes of \$3.1 billion was primarily due to strong sales volume growth, particularly sales of OLYSIO[®]/SOVRIAD[®] (simeprevir), positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower

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margin businesses and cost reduction efforts across many of the businesses. Additionally, the fiscal third quarter of 2014 included higher net gains on divestitures of \$2.0 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of \$0.6 billion and lower in-process research and development costs of \$0.2 billion as compared to the fiscal third quarter of 2013. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of \$0.2 billion in 2014 and higher costs of \$0.1 billion related to the DePuy ASR[®] Hip program and Synthes integration/transaction costs.

Cost of Products Sold

Consolidated costs of products sold for the fiscal nine months of 2014 decreased to 30.1% from 30.9% of sales as compared to the same period a year ago. Consolidated costs of products sold for the fiscal third quarter of 2014 decreased to 29.2% from 30.4% of sales as compared to the same period a year ago. The decrease in both periods was primarily due to positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost improvements across many of the businesses. This was partially offset by pricing and the impact of the weakening of the Japanese yen as compared to the currencies where products are sourced. In addition, the fiscal nine months of 2013 included an inventory step-up charge of \$0.1 billion related to the Synthes acquisition. The amortization expense for the fiscal nine months of 2014 and 2013 was \$1,033 million and \$980 million, respectively.

Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the fiscal nine months of 2014 decreased to 28.8% from 30.0% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal third quarter of 2014 decreased to 29.6% from 30.2% of sales as compared to the same period a year ago. The decrease in both periods was due to leveraged costs resulting from growth in the Pharmaceutical business, particularly sales of OLYSIO[®]/SOVRIAD[®] (simeprevir), and cost containment initiatives across many of the businesses. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of \$220 million in the fiscal third quarter of 2014.

Research and Development Expense

Worldwide costs of research and development activities for the fiscal nine months of 2014 decreased to 10.5% from 10.9% of sales as compared to the same period a year ago. However research spending increased in absolute dollars to \$5.9 billion as compared to \$5.8 billion in the prior year. Worldwide costs of research and development activities for the fiscal third quarter of 2014 decreased to 11.0% from 11.6% of sales as compared to the same period a year ago. The reduction as a percent to sales in both periods was primarily due to timing of project spend as well as strong sales growth in the Pharmaceutical business.

In-Process Research and Development (IPR&D)

During the fiscal nine months of 2014, the Company recorded a charge of \$22 million for the discontinuation of a development program related to Mentor and an impairment related to Synthes. During the fiscal nine months of 2013, the Company recorded a charge in the amount of \$242 million primarily for the impairment of IPR&D related to CorImmune and Acclarent for the delay or discontinuation of certain development projects.

Interest (Income) Expense

Interest income was comparable in both the fiscal nine months and the fiscal third quarter of 2014 as compared to the same periods a year ago. A higher balance in cash, cash equivalents and marketable securities was offset by lower

interest rates. The ending balance of cash, cash equivalents and marketable securities was \$33.0 billion at the end of the fiscal third quarter of 2014 which is an increase of \$7.8 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 increased in both the fiscal nine months and the fiscal third quarter of 2014 as compared to the same periods a year ago due to a higher average debt balance. The higher average debt balance was primarily due to borrowings in December 2013 as the Company increased borrowings, capitalizing on favorable terms in the capital markets. This was partially offset by the maturity and retirement of short and long term debt. At the end of the fiscal third quarter of 2014, the Company's debt position was \$15.3 billion as compared to \$15.1 billion the same period a year ago.

Other (Income) Expense, Net

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Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain equity securities of the Johnson & Johnson Development Corporation, gains and losses on the disposal of assets, currency gains and losses, acquisition-related costs, litigation settlements, as well as royalty income. The change in other (income) expense, net for the fiscal nine months of 2014 was favorable by \$2.7 billion as compared to the same period a year ago. The fiscal nine months of 2014 was favorable as compared to the fiscal nine months of 2013 due to higher net gains on divestitures of \$2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, and lower litigation expense of \$1.2 billion. This was partially offset by higher Synthes integration/transaction costs of \$0.1 billion as compared to the fiscal nine months of 2013 and a \$0.1 billion intangible asset write-down related to INCIVO® (telaprevir) in 2014. Additionally, the fiscal nine months of 2013 included a net gain of \$0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares and a gain of \$55 million on the sale of intangible and other assets.

The change in other (income) expense, net for the fiscal third quarter of 2014 was favorable by \$2.3 billion as compared to the same period a year ago. The fiscal third quarter of 2014 was favorable as compared to the fiscal third quarter of 2013 due to higher net gains of \$2.0 billion, primarily on the divestiture of the Ortho-Clinical Diagnostics business, and lower litigation expense of \$0.6 billion. This was partially offset by higher costs of \$0.2 billion related to the DePuy ASR™ Hip program and Synthes integration/transaction costs as compared to the fiscal third quarter of 2013.

SEGMENT PRE-TAX PROFIT

Consumer Segment

Pre-tax profit for the Consumer segment as a percent to sales in the fiscal nine months of 2014 was 14.6% versus 13.9% for the same period a year ago. The fiscal nine months of 2014 included a gain of \$0.4 billion on the divestiture of the K-Y® brand as compared to the fiscal nine months of 2013, which included a gain of \$0.1 billion on the sale of intangible and other assets. The increase was partially offset by higher selling, marketing and administrative expenses and \$0.1 billion for litigation expense in 2014. Pre-tax profit for the Consumer segment as a percent to sales in the fiscal third quarter of 2014 was 11.3% versus 12.9% for the same period a year ago. The lower pre-tax profit was impacted by \$0.1 billion for litigation expense and higher selling, marketing and administrative expenses in the fiscal third quarter of 2014 versus the fiscal third quarter of 2013.

Pharmaceutical Segment

Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal nine months of 2014 was 40.8% versus 37.7% for the same period a year ago. The increase in the pre-tax profit was attributable to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive sales mix of higher margin products and cost containment initiatives realized in selling, marketing and administrative expenses. This was partially offset by \$0.2 billion for an additional year of the Branded Prescription Drug Fee and a \$0.1 billion intangible asset write-down related to INCIVO® (telaprevir). Additionally, the fiscal nine months of 2013 included a net gain of \$0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares, and a positive adjustment of \$0.2 billion to previous estimates for Managed Medicaid rebates partially offset by litigation expense of \$0.2 billion and \$0.2 billion for the impairment of IPR&D. Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal third quarter of 2014 was 39.1% versus 34.8% 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. Additionally, the fiscal third quarter of 2013 included \$0.2 billion for the impairment of IPR&D.

Medical Devices and Diagnostics Segment

Pre-tax profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal nine months of 2014 was 33.9% versus 18.8% for the same period a year ago. The favorable pre-tax profit was primarily attributable to the net gain of \$1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business in 2014 and lower litigation expense of \$1.1 billion as compared to 2013. Pre-tax profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal third quarter of 2014 was 51.7% versus 13.8% for the same period a year ago. The favorable pre-tax profit was primarily attributable to the net gain of \$1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business in 2014 and lower litigation expense of \$0.6 billion as compared to 2013.

Provision for Taxes on Income

The worldwide effective income tax rates for the fiscal nine months of 2014 and 2013 were 22.7% and 18.9%, respectively. The higher effective tax rate in 2014 as compared to 2013 was primarily due to the divestiture of the Ortho-Clinical

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Diagnostics business at an approximate 41% effective tax rate, litigation accruals at low tax rates, the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. Also, the mix of earnings into higher tax jurisdictions, primarily the United States, increased the tax rate. Additionally, the 2014 tax rate was adversely impacted by the expiration, at year end 2013, of the U.S. Research & Development (R&D) tax credit and the Controlled Foreign Corporation (CFC) look-through provision as compared to 2013. The 2013 fiscal nine months tax rate included both the 2012 benefit and the 2013 benefit from the R&D tax credit and the CFC look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

These increases to the year to date 2014 tax rate were partially offset by a tax benefit of \$398 million associated with the Conor Medsystems divestiture. The tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 11 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009.

As of September 28, 2014, the Company had approximately \$2.3 billion of liabilities from unrecognized tax benefits, which reflects the adjustments described above. 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 29, 2013 for more detailed information regarding unrecognized tax benefits.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

Cash and cash equivalents were \$13.8 billion at the end of the fiscal third quarter of 2014 as compared with \$20.9 billion at the fiscal year end of 2013. The primary sources of cash were approximately \$14.1 billion net cash generated from operating activities offset by \$9.4 billion used by investing activities and \$11.6 billion used by financing activities.

Cash flow from operations of \$14.1 billion was the result of \$13.8 billion of net earnings and \$3.9 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation, asset write-downs and \$1.1 billion related to deferred taxes and current and non-current assets and liabilities. Cash flow from operations was reduced by \$4.7 billion related to accounts payable and accrued liabilities, inventories, account receivables and net gains on sale of assets/businesses.

Investing activities use of \$9.4 billion of cash was primarily for net purchases of investments in marketable securities of \$11.2 billion, additions to property, plant and equipment of \$2.2 billion and acquisitions of \$0.3 million partially offset by proceeds from the disposal of assets of \$4.5 billion.

Financing activities use of \$11.6 billion of cash was primarily for dividends to shareholders of \$5.8 billion, net retirement of short and long-term debt of \$2.9 billion and \$4.4 billion for the repurchase of common stock. Financing activities also included a source of \$1.4 billion of net proceeds from stock options exercised and associated tax benefits.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2014, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 17, 2015, 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 2014, 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.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's shares of common stock. Share repurchases will take place on the

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open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash.

Dividends

On July 21, 2014, the Board of Directors declared a regular quarterly cash dividend of \$0.70 per share, payable on September 9, 2014, to shareholders of record as of August 26, 2014.

On October 16, 2014, the Board of Directors declared a regular cash dividend of \$0.70 per share, payable on December 9, 2014 to shareholders of record as of November 25, 2014. 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 \$1.9 billion as of September 28, 2014 and approximately \$2.3 billion as of December 29, 2013. Approximately \$1.2 billion as of September 28, 2014 and approximately \$1.3 billion as of December 29, 2013 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 and Diagnostics 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 and Diagnostics local affiliates. The total net trade accounts receivable balance for these customers was approximately \$0.7 billion at September 28, 2014 and \$1.0 billion at December 29, 2013. 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 is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concern about the rising cost of health care. The Company has a long-standing policy of pricing products responsibly. For the period 2003 through 2013 in the United States, the weighted average compound annual growth rate of the Company's price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. 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 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.

The Venezuelan government has established or is in the process of establishing alternative systems and offerings of various foreign currency exchanges. Currently, 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. Through the third quarter of 2014, the

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Company has primarily utilized the official government rate of 6.3 Bolivares Fuertes to one U.S. dollar in preparing its financial statements. During the second fiscal quarter, 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. As of September 28, 2014, the Company's Venezuelan subsidiaries represented less than 0.5% of the Company's consolidated assets, liabilities, revenues and profits; therefore, the effect of a change in the exchange rate is not expected to have a material adverse effect on the Company's 2014 full-year results.

Changes in the behavior and spending patterns of consumers 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 a prolonged global economic downturn, will continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Generic medication firms have filed Abbreviated New Drug Applications 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 a lawsuit resulting from such an Abbreviated New Drug Application filing or patent challenge, the generic firms will then introduce generic or biosimilar versions of the product at issue, which will likely result in substantial market share and revenue losses. For further information see the discussion in the "Intellectual Property" section of Note 11 included in Item 1. Financial Statements (unaudited) - Notes to 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; uncertainty of commercial success of new and existing products; challenges to patents; the impact of patent expirations; significant adverse litigation or government action including related to product liability claims; the impact of business combinations and divestitures; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; financial instability of international economies and sovereign risk; disruptions due to natural disasters; manufacturing difficulties or delays, internally or within the supply chain; complex global supply chains with increasing regulatory requirements; and product efficacy or safety concerns resulting in product recalls or regulatory

action.

The Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, 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 29, 2013.

Item 4 — CONTROLS AND PROCEDURES

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

Internal control. During the period covered by this report, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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.

The following table provides information with respect to Common Stock purchases by the Company during the fiscal third quarter of 2014. Common Stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal 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 ⁽³⁾
June 30, 2014 through July 27, 2014	3,892,054	103.69	—	—
July 28, 2014 through August 24, 2014	10,392,381	101.07	7,855,767	—
August 25, 2014 through September 28, 2014				
	9,254,424	104.54	9,226,419	—
Total	23,538,859		17,082,186	30,283,418

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's shares of common stock. Share repurchases

will take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

(1) During the fiscal third quarter of 2014, the Company repurchased an aggregate of 23,538,859 shares of Johnson & Johnson Common Stock in open-market transactions, of which 17,082,186 shares were purchased pursuant to the repurchase program that was publicly announced on July 21, 2014, and of which 6,456,673 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of September 28, 2014, an aggregate of 17,082,186 shares were purchased for a total of \$1.8 billion since the inception of the repurchase program announced on July 21, 2014.

(3) As of September 28, 2014, the maximum number of shares that may yet be purchased under the plan is 30,283,418 based on the closing price of the Company's Common Stock on the New York Stock Exchange on September 26, 2014 of \$107.10 per share.

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Item 6 — EXHIBITS

Exhibit 10.1 Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies

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 28, 2014, 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, 2014

By /s/ D. J. CARUSO
D. J. CARUSO
Vice President, Finance; Chief Financial Officer (Principal
Financial Officer)

Date: October 30, 2014

By /s/ S. J. COSGROVE
S. J. COSGROVE
Controller (Principal Accounting Officer)