

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 30, 2012

or

☐

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

Commission file number 1-3215



(Exact name of registrant as specified in its charter)

NEW JERSEY
(State or other jurisdiction of
incorporation or organization)

22-1024240
(I.R.S. Employer
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 26, 2012 2,771,261,581 shares of Common Stock, \$1.00 par value, were outstanding.

TABLE OF CONTENTS

	Page No.
Part I—Financial Information	3
Item 1. Financial Statements (unaudited)	3
Consolidated Balance Sheets — September 30, 2012 and January 1, 2012	3
Consolidated Statements of Earnings for the Fiscal Third Quarters Ended September 30, 2012 and October 2, 2011	4
Consolidated Statements of Earnings for the Fiscal Nine Months Ended September 30, 2012 and October 2, 2011	5
Consolidated Statements of Comprehensive Income for the Fiscal Third Quarters and Fiscal Nine Months Ended September 30, 2012 and October 2, 2011	6
Consolidated Statements of Cash Flows for the Fiscal Nine Months Ended September 30, 2012 and October 2, 2011	7
Notes to Consolidated Financial Statements	9
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	36
Item 3. Quantitative and Qualitative Disclosures About Market Risk	47
Item 4. Controls and Procedures	47
Part II—Other Information	48
Item 1 - Legal Proceedings	48
Item 2—Unregistered Sales of Equity Securities and Use of Proceeds	48
Item 6 - Exhibits	48
Signatures	49
EX-10.1	
EX-10.2	
EX-31.1	
EX-32.1	
EX-101 INSTANCE DOCUMENT	
EX-101 SCHEMA DOCUMENT	
EX-101 CALCULATION LINKBASE DOCUMENT	
EX-101 LABELS LINKBASE DOCUMENT	
EX-101 PRESENTATION LINKBASE DOCUMENT	
EX-101 DEFINITION LINKBASE DOCUMENT	

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 30, 2012	January 1, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,486	\$ 24,542
Marketable securities	4,285	7,719
Accounts receivable, trade, less allowances for doubtful accounts \$451 (2011, \$361)	11,175	10,581
Inventories (Note 2)	7,809	6,285
Deferred taxes on income	3,247	2,556
Prepaid expenses and other receivables	2,789	2,633
Total current assets	44,791	54,316
Property, plant and equipment at cost	34,082	31,829
Less: accumulated depreciation	(18,237)	(17,090)
Property, plant and equipment, net	15,845	14,739
Intangible assets, net (Note 3)	28,790	18,138
Goodwill, net (Note 3)	21,777	16,138
Deferred taxes on income	4,227	6,540
Other assets	3,521	3,773
Total assets	\$ 118,951	\$ 113,644
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Loans and notes payable	\$ 5,423	\$ 6,658
Accounts payable	5,344	5,725
Accrued liabilities	6,498	4,608
Accrued rebates, returns and promotions	3,040	2,637
Accrued compensation and employee related obligations	2,128	2,329
Accrued taxes on income	1,502	854
Total current liabilities	23,935	22,811
Long-term debt (Note 4)	11,428	12,969
Deferred taxes on income	2,716	1,800
Employee related obligations	7,904	8,353
Other liabilities	9,207	10,631
Total liabilities	55,190	56,564
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)	(4,925)	(5,632)
Retained earnings	84,880	81,251
Less: common stock held in treasury, at cost (357,285,000 and 395,480,000 shares)	19,314	21,659
Total shareholders' equity	63,761	57,080
Total liabilities and shareholders' equity	\$ 118,951	\$ 113,644

See Notes to Consolidated Financial Statements

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

	September 30, 2012	Fiscal Third Quarters Ended Percent to Sales	October 2, 2011	Percent to Sales
Sales to customers (Note 9)	\$ 17,052	100.0 %	\$ 16,005	100.0 %
Cost of products sold	5,597	32.8	5,072	31.7
Gross profit	11,455	67.2	10,933	68.3
Selling, marketing and administrative expenses	5,228	30.6	5,240	32.7
Research and development expense	1,923	11.3	1,773	11.1
In-process research and development	679	4.0	—	—
Interest income	(15)	(0.1)	(17)	(0.1)
Interest expense, net of portion capitalized	135	0.8	134	0.8
Other (income) expense, net	(90)	(0.5)	(308)	(1.9)
Earnings before provision for taxes on income	3,595	21.1	4,111	25.7
Provision for taxes on income (Note 5)	966	5.7	909	5.7
NET EARNINGS	2,629	15.4	3,202	20.0
Add: Net loss attributable to noncontrolling interest, net of tax	339	2.0	—	—
NET EARNINGS ATTRIBUTABLE TO JOHNSON & JOHNSON	\$ 2,968	17.4 %	\$ 3,202	20.0 %
NET EARNINGS PER SHARE ATTRIBUTABLE TO JOHNSON & JOHNSON (Note 8)				
Basic	\$ 1.08		\$ 1.17	
Diluted	\$ 1.05		\$ 1.15	
CASH DIVIDENDS PER SHARE	\$ 0.61		\$ 0.57	
AVG. SHARES OUTSTANDING				
Basic	2,757.4		2,737.0	
Diluted	2,818.1		2,778.2	

See Notes to Consolidated Financial Statements

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

	September 30, 2012	Fiscal Nine Months Ended Percent to Sales	October 2, 2011	Percent to Sales
Sales to customers (Note 9)	\$ 49,666	100.0 %	\$ 48,775	100.0 %
Cost of products sold	15,655	31.5	15,022	30.8
Gross profit	34,011	68.5	33,753	69.2
Selling, marketing and administrative expenses	15,208	30.6	15,511	31.8
Research and development expense	5,334	10.7	5,393	11.0
In-process research and development	1,108	2.2	—	—
Interest income	(46)	(0.1)	(56)	(0.1)
Interest expense, net of portion capitalized	425	0.9	388	0.8
Other (income) expense, net	1,307	2.7	(115)	(0.2)
Restructuring expense	—	—	589	1.2
Earnings before provision for taxes on income	10,675	21.5	12,043	24.7
Provision for taxes on income (Note 5)	2,728	5.5	2,589	5.3
NET EARNINGS	7,947	16.0	9,454	19.4
Add: Net loss attributable to noncontrolling interest, net of tax	339	0.7	—	—
NET EARNINGS ATTRIBUTABLE TO JOHNSON & JOHNSON	\$ 8,286	16.7 %	\$ 9,454	19.4 %
NET EARNINGS PER SHARE ATTRIBUTABLE TO JOHNSON & JOHNSON (Note 8)				
Basic	\$ 3.02		\$ 3.45	
Diluted	\$ 2.96		\$ 3.40	
CASH DIVIDENDS PER SHARE	\$ 1.79		\$ 1.68	
AVG. SHARES OUTSTANDING				
Basic	2,747.1		2,738.5	
Diluted	2,805.0		2,777.6	

See Notes to Consolidated Financial Statements

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

	Fiscal Third Quarters Ended		Fiscal Nine Months Ended	
	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
Net Earnings	\$ 2,629	3,202	7,947	9,454
Other Comprehensive Income (Loss), net of tax				
Foreign currency translation	1,485	(1,790)	689	(3)
Securities:				
Unrealized holding gain (loss) arising during period	(263)	(108)	(194)	327
Reclassifications to earnings	(3)	(3)	(4)	(142)
Net change	(266)	(111)	(198)	185
Employee benefit plans:				
Prior service cost amortization during period	—	1	1	3
Gain (loss) amortization during period	94	72	282	198
Net change	94	73	283	201
Derivatives & hedges:				
Unrealized gain (loss) arising during period	(5)	(117)	(90)	(105)
Reclassifications to earnings	(29)	67	23	185
Net change	(34)	(50)	(67)	80
Other Comprehensive Income (Loss)	1,279	(1,878)	707	463
Comprehensive Income	3,908	1,324	\$ 8,654	9,917
Comprehensive Loss Attributable To Noncontrolling Interest, net of tax	339	—	339	—
Comprehensive Income Attributable To Johnson & Johnson	\$ 4,247	1,324	8,993	9,917

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal third quarters were as follows for 2012 and 2011 respectively: Securities; \$144 million and \$59 million, Employee Benefits; \$49 million and \$39 million, Derivatives & Hedges; \$18 million and \$26 million.

The tax effects in other comprehensive income for the fiscal nine months were as follows for 2012 and 2011 respectively: Securities; \$107 million and \$100 million, Employee Benefits; \$147 million and \$108 million, Derivatives & Hedges; \$36 million and \$44 million.

Foreign currency translation is not adjusted for income taxes as it relates to permanent investments in international subsidiaries.

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

	Fiscal Nine Months Ended	
	September 30, 2012	October 2, 2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 7,947	\$ 9,454
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	2,630	2,315
Stock based compensation	515	484
Noncontrolling interest	339	—
Intangible asset write-downs	2,047	160
Deferred tax provision	(324)	(849)
Accounts receivable allowances	86	(21)
Changes in assets and liabilities, net of effects from acquisitions:		
Decrease/(Increase) in accounts receivable	94	(489)
Increase in inventories	(593)	(787)
Increase/(Decrease) in accounts payable and accrued liabilities	1,220	(100)
Increase in other current and non-current assets	(790)	(1,066)
(Decrease)/Increase in other current and non-current liabilities	(1,151)	1,746
NET CASH FLOWS FROM OPERATING ACTIVITIES	12,020	10,847
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(1,782)	(1,765)
Proceeds from the disposal of assets	905	721
Acquisitions, net of cash acquired	(4,423)	(2,469)
Purchases of investments	(8,837)	(25,444)
Sales of investments	12,134	18,438
Other	(4)	(331)
NET CASH USED BY INVESTING ACTIVITIES	(2,007)	(10,850)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(4,924)	(4,601)
Repurchase of common stock	(12,919)	(1,672)
Proceeds from short-term debt	3,606	7,216
Retirement of short-term debt	(5,780)	(10,044)
Proceeds from long-term debt	16	4,471
Retirement of long-term debt	(796)	(12)
Proceeds from the exercise of stock options/excess tax benefits	1,817	946
Other	(111)	—
NET CASH USED BY FINANCING ACTIVITIES	(19,091)	(3,696)
Effect of exchange rate changes on cash and cash equivalents	22	(39)
Decrease in cash and cash equivalents	(9,056)	(3,738)
Cash and Cash equivalents, beginning of period	24,542	19,355
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 15,486	\$ 15,617

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

	Fiscal Nine Months Ended	
	September 30, 2012	October 2, 2011
Supplemental schedule of non-cash investing and financing activities		
Issuance of common stock associated with the acquisition of Synthes, Inc.	13,335	—
Acquisitions		
Fair value of assets acquired	\$ 18,984	\$ 2,689
Fair value of liabilities assumed and noncontrolling interests	(1,226)	(220)
Net fair value of acquisitions	\$ 17,758	\$ 2,469
Less: Issuance of common stock associated with the acquisition of Synthes, Inc.	\$ 13,335	\$ —
Net cash paid for acquisitions	\$ (4,423)	\$ (2,469)

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented.

During the fiscal third quarter of 2012, the Financial Accounting Standards Board (FASB) issued guidance and amendments related to testing indefinite lived intangible assets for impairment. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to determine the fair value. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. This update will become effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. However, early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2012, the Company adopted the FASB guidance and amendments issued related to goodwill impairment testing. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. However, if an entity concludes otherwise, then it is required to perform the first step of the two-step impairment test. This update became effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. 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 2012, the Company adopted the FASB amendment to the disclosure requirements for presentation of comprehensive income. The amendment requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance became effective retrospectively for the interim periods and annual periods beginning after December 15, 2011; however, the FASB agreed to an indefinite deferral of the reclassification requirement. For the Consolidated Statements of Comprehensive Income see page 6.

During the fiscal first quarter of 2012, the FASB issued amendments to disclosure requirements for common fair value measurement. These amendments result in convergence of fair value measurement and disclosure requirements between U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). This guidance became effective prospectively for the interim periods and annual periods beginning after December 15, 2011. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

Revision to previously issued financial statements

In connection with the preparation of the consolidated financial statements for the third quarter of 2012, a misclassification was identified with respect to the manner in which the Company presented the shares of common stock issued in connection with the acquisition of Synthes, Inc. in the Consolidated Statement of Cash Flow for the six months ended July 1, 2012. The Company has now determined that the issuance of these shares, including appreciation between June 13, 2012 and June 14, 2012, should have been reported as supplemental non-cash information. The effect of the misclassification in the Statement of Cash Flows for the six months ended July 1, 2012 resulted in net cash used by investing activities to be overstated by \$13.3 billion, net cash used by financing activities to be understated by \$12.8 billion and net cash flows from operating activities to be overstated by \$0.5 billion. The Company assessed this misclassification and concluded that it was not material to the Company's previously issued financial statements. The Company has properly presented the issuance of these shares in the Consolidated Statement of Cash Flows for the nine months ended September 30, 2012. The revision of the six month period ended July 1, 2012 will be reflected in the Company's second quarter filing of fiscal 2013. The Company's Consolidated Statements of Earnings for the fiscal second quarter and fiscal six months ended July 1, 2012 and the Consolidated Balance Sheet as of July 1, 2012 remain unchanged.

NOTE 2 — INVENTORIES

(Dollars in Millions)	September 30, 2012	January 1, 2012
Raw materials and supplies	\$ 1,408	1,206
Goods in process	2,480	1,637
Finished goods	3,921	3,442
Total inventories	\$ 7,809	6,285

As of September 30, 2012 the remaining inventory step-up related to the Synthes acquisition is approximately \$0.2 billion.

NOTE 3 — INTANGIBLE ASSETS AND GOODWILL

Intangible assets that have finite useful lives are amortized over their estimated useful lives. The latest impairment assessment of goodwill and indefinite lived intangible assets was completed in the fiscal fourth quarter of 2011. Future impairment tests for goodwill and indefinite lived intangible assets will be performed annually in the fiscal fourth quarter, or sooner if warranted, as was the case for certain indefinite lived intangible assets in 2012.

(Dollars in Millions)	September 30, 2012	January 1, 2012
Intangible assets with definite lives:		
Patents and trademarks — gross	\$ 8,874	7,947
Less accumulated amortization	3,317	2,976
Patents and trademarks — net	5,557	4,971
Customer relationships and other intangibles — gross	18,646	8,716
Less accumulated amortization	3,891	3,432
Customer relationships and other intangibles — net	14,755	5,284
Intangible assets with indefinite lives:		
Trademarks	7,521	6,034
Purchased in-process research and development	957	1,849
Total intangible assets with indefinite lives	8,478	7,883
Total intangible assets — net	\$ 28,790	18,138

Goodwill as of September 30, 2012 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Dev & Diag	Total
Goodwill, net at January 1, 2012	\$ 8,298	1,721	6,119	16,138
Acquisitions	—	48	5,451	5,499
Currency translation/Other	161	(1)	(20)	140
Goodwill, net as of September 30, 2012	\$ 8,459	1,768	11,550	21,777

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 \$866 million and \$611 million for the fiscal nine months ended September 30, 2012 and October 2, 2011, respectively, and the estimated amortization expense for the five succeeding years approximates \$1,340 million, before tax, per year. Amortization expense is included in cost of products sold.

Intangible assets and goodwill increased by \$12.9 billion and \$5.4 billion respectively, related to the Synthes acquisition. The Intangible assets and goodwill related to the Synthes acquisition were based on the preliminary purchase price allocation. See Note 10 to the Consolidated Financial Statements for additional details on Synthes. The increase in intangible assets was partially offset by \$0.9 billion in intangible asset write-downs and a \$1.1 billion impairment of purchased in-process research

and development, primarily related to the discontinuation of the Phase III clinical development of bapineuzumab IV and the partial impairment related to the Crucell vaccine business.

NOTE 4 — FAIR VALUE MEASUREMENTS

The Company uses forward 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 raw materials denominated in foreign currency. The Company also uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges. The Company also uses forward 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 exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward 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 30, 2012, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of \$24.9 billion and \$2.7 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/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 in the cash flows 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.

As of September 30, 2012, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was \$235 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 foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months excluding interest rate swaps. The amount ultimately realized in earnings will 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 hedges for the fiscal third quarters in 2012 and 2011:

	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		Fiscal Third Quarters Ended		Fiscal Third Quarters Ended	
(Dollars in Millions)	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
Cash Flow Hedges by Income Statement Caption						
Sales to customers ⁽³⁾	\$ 30	(57)	(12)	4	(1)	1
Cost of products sold ⁽³⁾	(61)	(58)	(19)	(21)	(1)	(1)
Research and development expense ⁽³⁾	22	6	43	(40)	—	1
Interest (income)/Interest expense, net ⁽⁴⁾	28	(67)	(2)	(6)	—	—
Other (income)expense, net ⁽³⁾	(24)	59	19	(4)	1	(1)
Total	\$ (5)	(117)	29	(67)	(1)	—

The following table is a summary of the activity related to derivatives designated as hedges for the fiscal nine months in 2012 and 2011:

	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		Fiscal Nine Months Ended		Fiscal Nine Months Ended	
(Dollars in Millions)	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
Cash Flow Hedges by Income Statement Caption						
Sales to customers ⁽³⁾	\$ 16	(30)	(42)	(6)	(1)	(1)
Cost of products sold ⁽³⁾	(100)	34	(53)	(127)	(1)	2
Research and development expense ⁽³⁾	33	(2)	56	(21)	—	(1)
Interest (income)/Interest expense, net ⁽⁴⁾	(14)	(107)	(11)	(24)	—	—
Other (income)expense, net ⁽³⁾	(25)	—	27	(7)	—	1
Total	\$ (90)	(105)	(23)	(185)	(2)	1

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

(1) Effective portion

(2) Ineffective portion

(3) Foreign exchange contracts

(4) Cross currency interest rate swaps

For the fiscal third quarters ended September 30, 2012 and October 2, 2011, a gain of \$35 million and a loss of \$10 million, respectively, were recognized in Other (income)expense, net, relating to foreign exchange contracts not designated as hedging instruments.

For the fiscal nine months ended September 30, 2012 and October 2, 2011, a gain of \$9 million and a loss of \$2 million, respectively, were recognized in Other (income)expense, net, relating to 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 that is determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., foreign exchange contract or cross currency interest rate swap) is the

[Table of Contents](#)

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 30, 2012 and January 1, 2012 were as follows:

(Dollars in Millions)	September 30, 2012				January 1, 2012
	Level 1	Level 2	Level 3	Total	Total ⁽²⁾
Derivatives designated as hedging instruments:					
Assets:					
Foreign exchange contracts	\$ —	213	—	213	442
Cross currency interest rate swaps ⁽³⁾	—	9	—	9	15
Total	—	222	—	222	457
Liabilities:					
Foreign exchange contracts	—	315	—	315	452
Cross currency interest rate swaps ⁽⁴⁾	—	583	—	583	594
Total	—	898	—	898	1,046
Derivatives not designated as hedging instruments:					
Assets:					
Foreign exchange contracts	—	18	—	18	29
Swiss Franc Option ⁽⁵⁾	—	—	—	—	17
Total	—	18	—	18	46
Liabilities:					
Foreign exchange contracts	—	27	—	27	34
Other Investments⁽¹⁾	\$ 1,258	—	—	1,258	1,563

(1) Classified as non-current other assets.

(2) As of January 1, 2012, these assets and liabilities are classified as Level 2 with the exception of Other Investments of \$1,563 million which are classified as Level 1.

(3) Includes \$6 million and \$15 million of non-current assets for September 30, 2012 and January 1, 2012, respectively.

(4) Includes \$576 million and \$594 million of non-current liabilities for September 30, 2012 and January 1, 2012, respectively.

(5) Currency option related to the acquisition of Synthes, Inc., which expired in January 2012.

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 30, 2012:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Assets		
Current Investments		
Cash	\$ 3,204	3,204
Government securities and obligations	13,906	13,906
Corporate debt securities	617	617
Money market funds	1,554	1,554
Time deposits	490	490
Total cash, cash equivalents and current marketable securities	\$ 19,771	19,771

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

Financial Liabilities

Current Debt	\$ 5,423	5,423
Non-Current Debt		
3 month LIBOR+0.09% FRN due 2014	750	750
1.20% Notes due 2014	999	1,015
2.15% Notes due 2016	898	950
5.55% Debentures due 2017	1,000	1,217
5.15% Debentures due 2018	898	1,099
4.75% Notes due 2019 (1B Euro 1.2874)	1,281	1,562
3% Zero Coupon Convertible Subordinated Debentures due in 2020	205	193
2.95% Debentures due 2020	542	591
3.55% Notes due 2021	446	508
6.73% Debentures due 2023	250	363
5.50% Notes due 2024 (500 GBP 1.6227)	806	1,056
6.95% Notes due 2029	296	429
4.95% Debentures due 2033	500	638
5.95% Notes due 2037	995	1,409
5.85% Debentures due 2038	700	987
4.50% Debentures due 2040	539	669
4.85% Notes due 2041	298	388
Other	25	22
Total Non-Current Debt	\$ 11,428	13,846

The weighted average effective rate on non-current debt is 4.34%.

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 2012 and 2011 were 25.6% and 21.5%, respectively. The higher effective tax rate in 2012 as compared to 2011 was primarily due to lower tax rates associated with in-process research and development write downs; integration, transaction and currency related costs associated with the Synthes acquisition and litigation accruals which added 3.4 points to the effective tax rate. These items are located in low tax jurisdictions which reduced the tax benefit associated with the expense therefore increasing the worldwide effective tax rate. The expiration of the Research and Development tax credit at year end 2011 increased the 2012 tax rate by 0.6 points.

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 2012 and 2011 include the following components:

	Retirement Plans		Other Benefit Plans	
	Fiscal Third Quarters Ended			
(Dollars in Millions)	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
Service cost	\$ 163	146	42	38
Interest cost	218	214	41	47
Expected return on plan assets	(307)	(279)	(1)	—
Amortization of prior service cost/(credit)	2	3	(1)	(1)
Amortization of net transition obligation	1	—	—	—
Recognized actuarial losses	123	97	21	11
Curtailments and settlements	—	—	—	—
Net periodic benefit cost	\$ 200	181	102	95

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal nine months of 2012 and 2011 include the following components:

	Retirement Plans		Other Benefit Plans	
	Fiscal Nine Months Ended			
(Dollars in Millions)	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
Service cost	\$ 492	433	131	112
Interest cost	659	641	123	141
Expected return on plan assets	(927)	(834)	(3)	(1)
Amortization of prior service cost/(credit)	4	7	(3)	(2)
Amortization of net transition obligation	1	1	—	—
Recognized actuarial losses	371	291	59	34
Curtailments and settlements	(1)	—	—	—
Net periodic benefit cost	\$ 599	539	307	284

Company Contributions

For the fiscal nine months ended September 30, 2012, the Company contributed \$388 million and \$26 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

The following table sets forth the components of accumulated other comprehensive income:

Gains/(Losses) (Dollars in Millions)	Foreign Currency Translation	Securities Available For Sale	Employee Benefit Plans	Derivatives & Hedges	Total Accumulated Other Comprehensive Income/(Loss)
January 1, 2012	\$ (1,526)	448	(4,386)	(168)	(5,632)
Net change	689	(198)	283	(67)	707
September 30, 2012	\$ (837)	250	(4,103)	(235)	(4,925)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes as it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

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 30, 2012 and October 2, 2011:

(Shares in Millions)	Fiscal Third Quarters Ended	
	September 30, 2012	October 2, 2011
Basic net earnings per share attributable to Johnson & Johnson	\$ 1.08	\$ 1.17
Average shares outstanding — basic	2,757.4	2,737.0
Potential shares exercisable under stock option plans	181.6	165.0
Less: shares which could be repurchased under treasury stock method	(141.5)	(127.4)
Convertible debt shares	3.6	3.6
Accelerated share repurchase program	17.0	—
Average shares outstanding — diluted	2,818.1	2,778.2
Diluted earnings per share attributable to Johnson & Johnson	\$ 1.05	\$ 1.15

The diluted earnings per share calculation for both fiscal third quarters ended September 30, 2012 and October 2, 2011 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 30, 2012 included the dilutive effect of 17.0 million shares related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. See Note 10 to the Consolidated Financial Statements for additional details. A \$1 increase/decrease in the volume weighted average share price would impact this estimate by approximately 2.7 million shares.

The diluted earnings per share calculation for the fiscal third quarter ended September 30, 2012 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock during the quarter. The diluted earnings per share calculation for the fiscal third quarter ended October 2, 2011, excluded 51 million shares related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share.

[Table of Contents](#)

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal nine months ended September 30, 2012 and October 2, 2011:

(Shares in Millions)	Fiscal Nine Months Ended	
	September 30, 2012	October 2, 2011
Basic net earnings per share attributable to Johnson & Johnson	\$ 3.02	\$ 3.45
Average shares outstanding — basic	2,747.1	2,738.5
Potential shares exercisable under stock option plans	181.5	164.7
Less: shares which could be repurchased under treasury stock method	(144.2)	(129.2)
Convertible debt shares	3.6	3.6
Accelerated share repurchase program	17.0	—
Average shares outstanding — diluted	2,805.0	2,777.6
Diluted earnings per share attributable to Johnson & Johnson	\$ 2.96	\$ 3.40

The diluted earnings per share calculation for both the fiscal nine months ended September 30, 2012 and October 2, 2011 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 30, 2012 included the dilutive effect of 17.0 million shares related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. See Note 10 to the Consolidated Financial Statements for additional details. A \$1 increase/decrease in the volume weighted average share price would impact this estimate by approximately 2.7 million shares.

The diluted earnings per share calculation for the fiscal nine months ended September 30, 2012 and October 2, 2011, excluded 1 million and 51 million shares, respectively, related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share.

NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

SALES BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Third Quarters Ended		
	September 30, 2012	October 2, 2011	Percent Change
Consumer			
United States	\$ 1,214	\$ 1,219	(0.4)%
International	2,367	2,521	(6.1)
Total	3,581	3,740	(4.3)
Pharmaceutical			
United States	3,288	2,869	14.6
International	3,114	3,113	0.0
Total	6,402	5,982	7.0
Medical Devices & Diagnostics			
United States	3,289	2,780	18.3
International	3,780	3,503	7.9
Total	7,069	6,283	12.5
Worldwide			
United States	7,791	6,868	13.4
International	9,261	9,137	1.4
Total	\$ 17,052	\$ 16,005	6.5 %

(Dollars in Millions)	Fiscal Nine Months Ended		
	September 30, 2012	October 2, 2011	Percent Change
Consumer			
United States	\$ 3,843	\$ 3,903	(1.5)%
International	6,952	7,312	(4.9)
Total	10,795	11,215	(3.7)
Pharmaceutical			
United States	9,408	9,499	(1.0)
International	9,418	8,775	7.3
Total	18,826	18,274	3.0
Medical Devices & Diagnostics			
United States	9,119	8,521	7.0
International	10,926	10,765	1.5
Total	20,045	19,286	3.9
Worldwide			
United States	22,370	21,923	2.0
International	27,296	26,852	1.7
Total	\$ 49,666	\$ 48,775	1.8 %

OPERATING PROFIT BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Third Quarters Ended		
	September 30, 2012	October 2, 2011	Percent Change
Consumer	\$ 510	\$ 644	(20.8)%
Pharmaceutical ⁽²⁾	1,388	2,078	(33.2)
Medical Devices & Diagnostics ⁽³⁾	1,927	1,927	—
Segments operating profit	3,825	4,649	(17.7)
Expense not allocated to segments ⁽⁴⁾	(230)	(538)	
Worldwide income before taxes	\$ 3,595	\$ 4,111	(12.6)%

(Dollars in Millions)	Fiscal Nine Months Ended		
	September 30, 2012	October 2, 2011	Percent Change
Consumer ⁽¹⁾	\$ 1,239	\$ 1,766	(29.8)%
Pharmaceutical ⁽²⁾	4,494	6,001	(25.1)
Medical Devices & Diagnostics ⁽³⁾	5,880	5,146	14.3
Segments operating profit	11,613	12,913	(10.1)
Expense not allocated to segments ⁽⁴⁾	(938)	(870)	
Worldwide income before taxes	\$ 10,675	\$ 12,043	(11.4)%

(1) Includes intangible asset write-downs of \$294 million recorded in the fiscal nine months of 2012.

(2) Includes in-process research and development charges of \$679 million and \$1,108 million recorded in the fiscal third quarter and fiscal nine months of 2012, respectively. Includes litigation expense of \$658 million and intangible asset write-

[Table of Contents](#)

downs of \$499 million included in the fiscal nine months of 2012. Includes litigation expense of \$540 million recorded in the fiscal nine months of 2011.

(3) Includes Synthes integration/transaction costs of \$165 million and \$388 million recorded in the fiscal third quarter and the fiscal nine months of 2012, respectively. Includes intangible asset write-downs of \$146 million recorded in the fiscal nine months of 2012. Includes ASR™ Hip related costs of \$116 million recorded in the fiscal third quarter and the fiscal nine months of 2012. Includes restructuring expense of \$676 million, ASR™ Hip related costs of \$187 million and litigation expense of \$36 million recorded in the fiscal nine months of 2011.

(4) Amounts not allocated to segments include interest income/(expense), noncontrolling interests and general corporate income/expense. Includes currency losses related to the Synthes acquisition of \$234 million and litigation expense of \$11 million recorded in the fiscal nine months of 2012. Includes a currency loss of \$316 million and \$214 million related to the Synthes acquisition recorded in the fiscal third quarter and fiscal nine months of 2011, respectively.

SALES BY GEOGRAPHIC AREA

(Dollars in Millions)	Fiscal Third Quarters Ended		Percent Change
	September 30, 2012	October 2, 2011	
United States	\$ 7,791	\$ 6,868	13.4 %
Europe	3,983	4,124	(3.4)
Western Hemisphere, excluding U.S.	1,824	1,751	4.2
Asia-Pacific, Africa	3,454	3,262	5.9
Total	\$ 17,052	\$ 16,005	6.5 %

(Dollars in Millions)	Fiscal Nine Months Ended		Percent Change
	September 30, 2012	October 2, 2011	
United States	\$ 22,370	\$ 21,923	2.0 %
Europe	12,342	12,850	(4.0)
Western Hemisphere, excluding U.S.	5,266	4,730	11.3
Asia-Pacific, Africa	9,688	9,272	4.5
Total	\$ 49,666	\$ 48,775	1.8 %

NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

On October 11, 2012, the Company announced that Ortho-Clinical Diagnostics (OCD) has received a binding offer from The Gores Group, an investment firm, to acquire the Therakos business. The transaction is expected to close at the end of 2012, subject to satisfaction of customary closing conditions.

During the fiscal second quarter, the Company completed the acquisition of Synthes, Inc., a global developer and manufacturer of orthopaedics devices, for a purchase price of \$20.2 billion in cash and stock. The net acquisition cost of the transaction is \$17.5 billion based on cash on hand at closing of \$2.7 billion.

Under the terms of the agreement, each share of Synthes common stock was exchanged for CHF 55.65 in cash and 1.717 shares of Johnson & Johnson common stock, based on the calculated exchange ratio. The exchange ratio was calculated on June 12, 2012 and based on the relevant exchange rate and closing price of Johnson & Johnson common stock on that date, the total fair value of consideration transferred was \$19.7 billion. When the acquisition was completed on June 14, 2012, based on the relevant exchange rate and closing price of Johnson & Johnson common stock on that date, the total fair value of the consideration transferred was \$20.2 billion. Janssen Pharmaceutical, a company organized under the laws of Ireland and a wholly owned subsidiary of Johnson & Johnson, used cash on hand to satisfy the cash portion of the merger consideration.

The stock portion of the merger consideration consisted of shares of Johnson & Johnson common stock purchased by Janssen Pharmaceutical, from two banks, pursuant to two accelerated share repurchase (ASR) agreements dated June 12, 2012. On

[Table of Contents](#)

June 13, 2012, Janssen Pharmaceutical purchased an aggregate of approximately 203.7 million shares of Johnson & Johnson common stock at an initial purchase price of \$12.9 billion under the ASR agreements, with all of the shares delivered to Janssen Pharmaceutical on June 13, 2012. Final settlement of the transactions under each ASR agreement is expected to occur in the first half of 2013, and may occur earlier at the option of the two banks, as applicable, or later under certain circumstances. Based on the theoretical settlement of the ASR agreements an additional 17.0 million shares would be issued to settle the ASR agreements as of September 30, 2012.

In addition, while the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

The following table summarizes the consideration transferred to acquire Synthes, valued on the acquisition date of June 14th, 2012:

(Dollars in Millions)		
Cash (multiply 55.65CHF by shares of Synthes common stock outstanding by the exchange rate) ^(A)	\$	6,902
Common Stock (multiply 1.717 by shares of Synthes common stock outstanding by J&J stock price) ^(B)	\$	13,335
Total fair value of consideration transferred	\$	20,237

(A) Synthes common stock outstanding of 118.7 million shares as of the acquisition date and CHF/USD exchange rate of .95674

(B) Johnson & Johnson closing stock price on the New York Stock Exchange as of acquisition date of \$65.45 per share.

The Company is in the process of finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The preliminary allocation of the purchase price included in the current period balance sheet is based on the best estimates of management and is preliminary and subject to change. To assist management in the allocation, the Company engaged valuation specialists to prepare independent appraisals. The completion of the purchase price allocation may result in adjustments to the carrying value of Synthes, Inc.'s recorded assets and liabilities, revisions of the useful lives of intangible assets, the determination of any residual amount that will be allocated to goodwill and related tax effects. The related depreciation and amortization from the acquired assets are also subject to revision based on the final allocation.

The following table presents the preliminary allocation of the purchase price related to Synthes, Inc. as of the date of acquisition:

(Dollars in Millions)		
Cash & Cash equivalents	\$	2,749
Inventory ⁽¹⁾		889
Accounts Receivable, net		738
Other current assets		249
Property, plant and equipment		1,253
Goodwill		5,371
Intangible assets		12,929
Other non-current assets		46
Total Assets Acquired		24,224
Current liabilities		825
Deferred Taxes		2,731
Other non-current liabilities		431
Total Liabilities Assumed		3,987
Net Assets Acquired	\$	20,237

(1) Includes \$0.4 billion related to inventory step-up.

The assets acquired are recorded in the Medical Devices and Diagnostics segment. The acquisition of Synthes, Inc. resulted in \$5.4 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the business acquisition of Synthes, Inc. The goodwill is not expected to be deductible for tax purposes.

The preliminary purchase price allocation to the identifiable intangible assets included in the current period balance sheet is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Customer relationships	\$	9,950
Patents and technology		1,495
Total amortizable intangibles		11,445
Trademark and Trade name		1,420
In-process research and development		64
Total intangible assets	\$	12,929

The weighted average life for the \$11.4 billion of total amortizable intangibles is approximately 21 years.

The trade name asset values were determined to have an indefinite life based on a number of factors, including trade name history, the competitive environment, market share and future operating plans. The intangible assets with definite lives were assigned asset lives ranging from 7 to 22 years.

The majority of the intangible asset valuation relates to customer relationships, patents and technology and trade name intangible assets in the Company's trauma, cranio maxillofacial, spine and power tools business lines. Additionally, in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 14%.

The Company is in the process of executing the integration plans to combine businesses, sales organizations, systems and locations as a result of which the Company has and will continue to incur integration costs.

[Table of Contents](#)

The operating results of Synthes, Inc. were reported in the Company's financial statements beginning on June 14, 2012. Total sales and net earnings for Synthes, Inc. for the fiscal nine months ended September 30, 2012 were \$1,182 million and \$177 million, respectively. Total sales and net earnings for Synthes, Inc. for the third quarter ended September 30, 2012 were \$989 million and \$149 million, respectively.

The following table provides pro forma results of operations for the fiscal third quarters and the fiscal nine months ended September 30, 2012 and October 2, 2011, as if Synthes, Inc. had been acquired as of January 3, 2011. The pro forma results include the effect of divestitures and certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Synthes, Inc. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

(Dollars in Millions Except Per Share Data)	Unaudited Pro forma consolidated results		
	Fiscal Nine Months Ended		Fiscal Third Quarter Ended
	September 30, 2012	October 2, 2011	October 2, 2011
Net Sales	\$ 51,336	51,558	16,949
Net Earnings attributable to Johnson & Johnson	\$ 8,734	9,346	3,207
Diluted Net Earnings per Common Share attributable to Johnson & Johnson	\$ 3.11	3.37	1.15

In 2012, the Company recorded acquisition related costs of \$622 million before tax, which were recorded in Cost of products sold and Other(income)expense.

In connection with the Synthes acquisition, DePuy Orthopaedics, Inc. agreed to divest certain rights and assets related to its trauma business, to Biomet, Inc. and completed the initial closing for this transaction in the fiscal second quarter of 2012, including those countries that represented the majority of sales. By the end of the fiscal third quarter of 2012, closing in countries representing nearly all sales had been completed.

During the fiscal third quarter, the Company acquired Calibra Medical, developer of a unique, wearable three-day insulin patch for convenient and discreet mealtime dosing for people with diabetes who take multiple daily injections of insulin and Spectrum Vision LLC, a full service distributor of contact lenses serving Russia and with facilities in the Ukraine and Kazakhstan.

During the fiscal third quarter, the Company completed the initial closing related to the divestiture of the RhoGAM® business. The Company also completed the sale of certain consumer brands in the United States and Canada to Valeant Pharmaceuticals.

During the fiscal second quarter of 2012, the Company acquired Guangzhou Bioseal Biotech Co., Ltd., a privately held biopharmaceutical company specializing in the design, development and commercialization of a porcine plasma-derived biologic product for controlling bleeding during surgery; CorImmun GmbH, a privately held drug development company in Germany, whose lead compound, COR-1, is a small cyclic peptide currently in early clinical development for the treatment of heart failure; and certain assets of the Angiotech Pharmaceuticals, Inc. barbed suture business.

During the fiscal first quarter of 2012, the Company completed the divestiture of its U.S. patents and other U.S. and Canadian intellectual property for BYSTOLIC® (nebivolol), which is currently approved in the U.S. for the treatment of hypertension, to Forest Laboratories Holdings Limited. Proceeds received from the divestiture were \$357 million.

During the fiscal third quarter of 2011, the Company completed the acquisition of several over-the-counter cough and cold brands in Russia from J.B. Chemicals and Pharmaceuticals Ltd.

During the fiscal third quarter of 2011, the Company acquired full ownership of the Johnson & Johnson Merck Consumer Pharmaceuticals Co. joint venture in the United States. The joint venture has been renamed McNeil Consumer Pharmaceuticals Co. and continues to market products under the PEPCID®, MYLANTA®, and MYLICON® brands. In addition, the Company acquired from Merck Canada Inc. its partnership interest in the Canadian joint venture. The McNeil Consumer Healthcare Division of Johnson & Johnson Inc. will continue to market and sell PEPCID®, 222® and FLEET ENEMA® in Canada.

[Table of Contents](#)

During the fiscal third quarter of 2011, the Company completed the divestiture of the Animal Health business to Elanco, a Division of Eli Lilly. During the fiscal third quarter of 2011, the Company completed the divestiture of MONISTAT® in Canada, the U.S. and its territories (including Puerto Rico). Proceeds from the aforementioned divestitures were \$578 million.

During the fiscal first quarter of 2011, the Company acquired substantially all of the outstanding equity of Crucell N.V. that it did not already own. Crucell is a global biopharmaceutical company focused on the research and development, production and marketing of vaccines and antibodies against infectious disease worldwide. The net purchase price of \$2.0 billion was primarily recorded as non-amortizable intangible assets for \$1.0 billion, amortizable intangible assets for \$0.7 billion and goodwill for \$0.5 billion. During the fiscal second quarter of 2012, the Company recorded a charge of \$0.5 billion for the intangible asset write-down and \$0.4 billion for the impairment of the in-process research and development related to the Crucell business.

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 30, 2012, 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 for new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to 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.

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 of Johnson & Johnson's subsidiaries are involved in numerous product liability cases. The damages claimed are substantial, and while these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue, 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.

Multiple products of Johnson & Johnson's subsidiaries are subject to product liability claims and lawsuits in which claimants seek substantial compensatory and, where available, punitive damages, including LEVAQUIN®, the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, RISPERDAL®, pelvic meshes, DURAGESIC®/fentanyl patches and TOPAMAX®. As of September 30, 2012, in the U.S. there were approximately 3,400 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to LEVAQUIN®, 10,100 with respect to the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 2,500 with respect to the PINNACLE® Acetabular Cup System, 420 with respect to RISPERDAL®, 3,100 with respect to pelvic meshes, 30 with respect to DURAGESIC®/fentanyl patches and 65 with respect to TOPAMAX®.

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, and the number of pending lawsuits continues to increase. 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. The Company continues to receive information with respect to potential costs associated with this recall. During the fiscal third quarter of 2012, the Company's product liability accrual was increased in part due to anticipated product liability litigation and costs associated with the DePuy ASR™ Hip Recall program. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. The Company has established a product liability accrual in anticipation of 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, a class action and several individual personal injury cases have been commenced in Canada and Australia seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established a product liability accrual in anticipation of 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.

The Company believes that the ultimate resolution of these matters based on historical and reasonably likely future trends is not expected to have a material adverse effect on the Company's financial position, annual results of operations and cash flows. The resolution in any interim reporting period could have a material impact on the Company's results of operations and cash flows for that period.

INTELLECTUAL PROPERTY

Certain of Johnson & Johnson's subsidiaries are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their business. The most significant of these matters are described below.

PATENT INFRINGEMENT

Certain of Johnson & Johnson's subsidiaries are involved in lawsuits challenging the coverage and/or validity of the patents on their 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.

Medical Devices and Diagnostics

In October 2004, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation 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 EES's HARMONIC® Scalpel infringed four Tyco patents. In October 2007, on motions for summary judgment prior to the initial trial, a number of claims were found invalid and a number were found infringed. However, no claim was found both valid and infringed. Trial commenced in December 2007, and the Court dismissed the case without prejudice on grounds that Tyco did not own the patents in suit. The dismissal without prejudice was affirmed on appeal. In January 2010, Tyco filed another complaint in the United States District Court for the District of Connecticut asserting infringement of three of the four patents from the previous lawsuit and adding new products. Tyco is seeking monetary damages and injunctive relief. The case was tried in July 2012, and the parties are awaiting a decision from the Court.

In October 2007, Bruce Saffran (Saffran) filed a patent infringement lawsuit against Johnson & Johnson and Cordis Corporation (Cordis) in the United States District Court for the Eastern District of Texas alleging infringement on U.S. Patent No. 5,653,760. In January 2011, a jury returned a verdict finding that Cordis's sales of its CYPHER® Stent willfully infringed the '760 patent. The jury awarded Saffran \$482 million. In March 2011, the Court entered judgment against Cordis in the amount of \$593 million, representing the jury verdict, plus \$111 million in pre-judgment interest. Cordis has appealed the judgment. 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 November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc.

[Table of Contents](#)

(LifeScan) in the United States District Court for the District of Delaware, accusing LifeScan's entire OneTouch® line of blood glucose monitoring systems of infringement of 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. Roche is seeking monetary damages and injunctive relief.

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 infringe the '327 patent. Rembrandt has filed an appeal with the United States Court of Appeals for the Federal Circuit.

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 are seeking monetary damages and injunctive relief. DePuy filed its answer in February 2012 and filed a counterclaim asserting that Stryker's Trident Acetabular Hip System infringes DePuy's U.S. Patent No. 6,610,097. DePuy is seeking damages and injunctive relief from Howmedica and Stryker. No trial date has been set.

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 in the United States District Court for the Central District of California alleging that Animas' OneTouch® Ping® Glucose Management System infringes nine of their patents. Medtronic Minimed is seeking monetary damages and injunctive relief.

In June 2012, DePuy filed a declaratory judgment action against Orthopaedic Hospital (OH) in the United States District Court for the Northern District of Indiana seeking a declaration of the parties' rights and obligations under a Patent Rights and License Agreement between the parties related to development of a polyethylene material. OH has claimed that DePuy owes royalties on products made with anti-oxidant polyethylene. DePuy disputes that it owes such royalties to OH and is thus seeking a declaration from the Court on disputed contractual provisions. No trial date has been set.

Pharmaceutical

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor (now 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. In April 2012, the parties participated in an arbitration on the issue of JBI's defense that Abbott is equitably estopped from asserting the patents. In May 2012, the arbitrator rejected JBI's defense. The case has been reinstated in the District Court and fact discovery is ongoing. No trial date has been set.

In August 2009, Abbott GmbH & Co. (Abbott GmbH) and Abbott Bioresearch Center 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 have been transferred from the District of Columbia to the District of Massachusetts. Trial was held in September 2012 with a jury verdict in favor of Centocor, invalidating Abbott's patent claims. Post-trial briefing will commence soon. Also in August 2009, Abbott GmbH and Abbott Laboratories Limited brought a patent infringement lawsuit in The Federal Court of Canada alleging that STELARA® infringes Abbott GmbH's Canadian patent. No trial date has been set in the Canadian Case. In addition to the U.S. and Canadian litigations, in August 2012, Abbott filed patent infringement lawsuits in the Netherlands, Switzerland and Germany. In each of the above cases, Abbott is seeking monetary damages and injunctive relief.

LITIGATION AGAINST FILERS OF ABBREVIATED NEW DRUG APPLICATIONS (ANDAs)

The following summarizes lawsuits pending against generic companies that filed Abbreviated New Drug Applications

(ANDAs) 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 these patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the United States Food and Drug Administration (FDA), to introduce generic versions of the products at issue, resulting in very substantial market share and revenue losses for those products.

CONCERTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of CONCERTA®. In September 2011, a settlement agreement was entered into with Kremers-Urban, LLC and KUDCO Ireland, Ltd. (collectively, KUDCO) pursuant to which KUDCO was granted a license under the patent-in-suit to market its generic version of CONCERTA® starting on July 1, 2012, when and if KUDCO obtains FDA approval.

In November 2010, ALZA Corporation (ALZA) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) (now Janssen Pharmaceuticals, Inc. (JPI)) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively, Teva) in response to Impax and Teva's filing of a major amendment to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of ALZA and JPI's patent relating to CONCERTA®. Impax and Teva filed counterclaims alleging non-infringement and invalidity. In May 2011, ALZA and JPI filed a second lawsuit against Teva in response to Teva's filing of a second major amendment to its ANDA seeking approval to market additional dosage strengths of its generic CONCERTA® product before the expiration of ALZA and JPI's patent relating to CONCERTA®. In each of the above cases, ALZA and JPI are seeking an Order enjoining the defendants from marketing its generic version of CONCERTA® prior to the expiration of ALZA and JPI's CONCERTA® patent. In September 2012, a settlement agreement was entered into with Impax and Teva pursuant to which those parties were granted a license under the patent-in-suit to market their generic version of CONCERTA® starting July 14, 2013 (or earlier under certain circumstances), if and when they obtain FDA approval.

In August 2012, Dr. James M. Swanson (Swanson) filed a lawsuit against ALZA Corporation (ALZA) in the Northern District of California seeking to be added as an inventor on two ALZA-owned patents relating to CONCERTA®. Alternatively, Dr. Swanson has alleged 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. Dr. Swanson is seeking damages and an award of unjust enrichment.

ORTHO TRI-CYCLEN® LO

A number of generic companies have filed ANDAs seeking approval to market generic versions of ORTHO TRI-CYCLEN® LO. In February 2012, JPI and Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. (collectively, Watson) entered into a settlement agreement. Pursuant to the settlement agreement, the parties entered into a supply agreement whereby JPI will supply to Watson a combinational oral contraceptive containing certain specified compounds from December 31, 2015 (or earlier under certain circumstances) through the expiration of the '815 patent on December 6, 2019. In addition, in the event Watson does not wish to exercise its rights under the supply agreement, JPI has granted Watson a license to market Watson's ANDA product from December 31, 2015 (or earlier under certain circumstances) through December 6, 2019.

In January 2010, OMJPI (now JPI) filed a patent infringement lawsuit against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) in the United States District Court for the District of New Jersey in response to Lupin's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. Lupin filed a counterclaim alleging invalidity of the patent. Trial concluded in June 2012, and in September 2012, the Court issued a decision in favor of JPI. In particular, the Court ordered that the effective date of the approval of Lupin's ANDA (which had previously been approved) be not earlier than the expiration of the OTCLO patent. Lupin has appealed the decision.

In November 2010, OMJPI (now JPI) filed a patent infringement lawsuit against Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan), and Famy Care, Ltd. (Famy Care) in the United States District Court for the District of New Jersey in response to Famy Care's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. Mylan and Famy Care filed counterclaims alleging invalidity of the patent.

In October 2011, JPI filed a patent infringement lawsuit against Sun Pharma Global FZE and Sun Pharmaceutical Industries (collectively, Sun) in the United States District Court for the District of New Jersey in response to Sun's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent.

In May 2012, JPI filed a patent infringement lawsuit against Haupt Pharma, Inc., Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively, Haupt) in the United States District Court for the District of New Jersey in response to Haupt's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent.

In August 2012, JPI filed a patent infringement lawsuit against Glenmark Generics Ltd. and Glenmark Generics Inc., USA (collectively, Glenmark) in the United States District Court for the District of New Jersey in response to Glenmark's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. In November 2012, a settlement agreement was entered into with Glenmark pursuant to which Glenmark was granted a license under the OTCLO patent to market its generic version of OTCLO starting December 31, 2015 (or earlier under certain circumstances), if and when they obtain FDA approval.

In each of the above cases, JPI is seeking an Order enjoining the defendants from marketing their generic versions of ORTHO TRI-CYCLEN® LO before the expiration of the OTCLO patent.

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 patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle.

In March 2011, Tibotec and G.D. Searle filed a patent infringement lawsuit 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 Tibotec either owns or exclusively licenses from G.D. Searle.

In March 2011, Tibotec filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. (collectively, Hetero) in the United States District Court for the District of New Jersey in response to Hetero's ANDA seeking approval to market a generic version of PREZISTA® before the expiration of certain patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle. In July 2011, upon agreement by the parties, the Court entered a stay of the lawsuit pending a final decision in the lawsuit against Teva with respect to the validity and/or enforceability of the patents that Tibotec licenses from G.D. Searle, with Hetero agreeing to be bound by such final decision.

In September 2011, the Court consolidated the above lawsuits, as well as lawsuits brought by the United States Government against each of the defendants for infringement of a United States Government-owned patent relating to PREZISTA®, for purposes of pre-trial discovery and trial, with the proviso that after discovery is completed, any party can move to have the cases de-consolidated for trial.

In May and June 2012, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) and G.D. Searle filed a patent infringement lawsuit against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of newly issued United States Reissue Patent No. Re42,889, which Janssen exclusively licenses from G.D. Searle. This case has been consolidated with the above lawsuits.

In August 2012, Janssen and G.D. Searle filed a patent infringement lawsuit against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of newly issued United States Reissue Patent No. Re43,596, which Janssen exclusively licenses from G.D. Searle. This case also has been consolidated with the above lawsuits.

In October 2012, Janssen filed a motion to file a Supplemental Complaint against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,772,411 (Mylan only), 7,126,015 (Lupin and Teva only) and 7,595,408 (Lupin and Teva only).

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

OTHER INTELLECTUAL PROPERTY MATTERS

In September 2009, Centocor Ortho Biotech Products, L.P. (now Janssen Products, LP (JPLP)) intervened in an inventorship lawsuit filed by the University of Kansas Center for Research, Inc. (KUCR) against the United States of America (USA) in the United States District Court for the District of Kansas. KUCR alleges that two KUCR scientists should be added as inventors on two USA-owned patents relating to VELCADE®. The USA licensed the patents (and their foreign counterparts) to Millennium Pharmaceuticals, Inc. (MPI), who in turn sublicensed the patents (and their foreign counterparts) to JPLP for commercial marketing outside the United States. In July 2010, the parties reached a settlement agreement to resolve the disputes in this case and submitted the inventorship issue to arbitration. The arbitration took place in December 2011 and a decision in favor of KUCR was issued in March 2012. As a result, JPLP will be required to make the aforementioned pre-specified payments to KUCR. As a result of the settlement agreement, the outcome of the arbitration regarding inventorship will determine whether pre-specified payments will be made to KUCR, but will not affect JPLP's right to market VELCADE®.

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.

In January 2011, Genentech, Inc. (Genentech) initiated an arbitration against UCB Celltech (Celltech) seeking damages for allegedly cooperating with Centocor (now JBI) to improperly terminate a prior agreement in which JBI was sublicensed under Genentech's Cabilly patents to sell REMICADE®. JBI has an indemnity agreement with Celltech, and Celltech has asserted that JBI is liable for any damages Celltech may be required to pay Genentech in that arbitration. Following an arbitration hearing in June 2012, the arbitrators issued a decision finding no liability for Celltech, and therefore, JBI is not liable for any potential indemnity claim.

In March 2012, Noramco, Inc. (Noramco) moved to intervene in three patent infringement lawsuits filed in the United States District Court for the Southern District of New York by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva) and Amneal Pharmaceuticals, LLC (Amneal). The lawsuits are in response to the defendants' respective ANDAs 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 and Amneal.

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 of Johnson & Johnson's subsidiaries have been settled, including Kentucky, which had been set for trial in January 2012. Kansas is set for trial in March 2013, Louisiana and Mississippi are set for trial in June 2013 and Illinois is set for trial in May 2014. Other state cases are likely to be set for trial in due course. In addition, an AWP case against the J&J AWP Defendants brought by 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 have appealed the Commonwealth Court's UTPL ruling to the Pennsylvania Supreme Court. The Company believes that the J&J AWP Defendants have strong arguments supporting their 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 verdict.

RISPERDAL®

In January 2004, Janssen Pharmaceutica Inc. (Janssen Pharmaceutica) (now Janssen Pharmaceuticals, Inc. (JPI)) received a subpoena from the Office of the Inspector General of the United States Office of Personnel Management seeking documents concerning sales and marketing of, any and all payments to physicians in connection with sales and marketing of, and clinical trials for, RISPERDAL® from 1997 to 2002. Documents subsequent to 2002 have also been requested by the Department of Justice. An additional subpoena seeking information about marketing of, and adverse reactions to, RISPERDAL® was received from the United States Attorney's Office for the Eastern District of Pennsylvania in November 2005. Numerous subpoenas seeking testimony from various witnesses before a grand jury were also received. JPI cooperated in responding to these requests for documents and witnesses. The United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania (the Government) are continuing to actively pursue both criminal and civil actions. In February 2010, the Government served Civil Investigative Demands seeking additional information relating to sales and marketing of RISPERDAL® and sales and marketing of INVEGA®. The focus of these matters is the alleged promotion of RISPERDAL® and INVEGA® for off-label uses. The Government has notified JPI that there are also pending qui tam actions alleging off-label promotion of RISPERDAL®. The Government informed JPI that it will intervene in these qui tam actions and file a superseding complaint.

In addition, the Attorneys General of multiple states, including Alaska, Arkansas, Louisiana, Massachusetts, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, and Utah, have pending actions against Janssen Pharmaceutica (now JPI) seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties, damages for "overpayments" by the state and others, violations of state consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also seek injunctive relief relating to the promotion of RISPERDAL®. In January 2012, JPI settled a lawsuit filed by the Attorney General of Texas. 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. JPI and Johnson & Johnson have filed an appeal and believe that they have strong arguments supporting the appeal.

The Attorney General of West Virginia commenced suit in 2004 against Janssen Pharmaceutica (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 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 (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 Medicaid Fraud Act (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. Johnson & Johnson and JPI filed an appeal, which was denied in August 2012. Johnson & Johnson and JPI will seek review in the Louisiana Supreme Court.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's

[Table of Contents](#)

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 in April 2011, 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 (now JPI) on several counts. In March 2011, the matter was tried on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practice 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. JPI has appealed this judgment and the Company believes it has strong arguments supporting the appeal.

The Attorneys General of approximately 40 other states and the District of Columbia indicated an interest in pursuing similar litigation against JPI, and obtained a tolling agreement staying the running of the statute of limitations while they pursued an investigation of JPI regarding potential consumer fraud actions in connection with the marketing of RISPERDAL®. In September 2012, JPI settled with 36 of the states and the District of Columbia non-Medicaid claims in connection with the sales and marketing of RISPERDAL® and INVEGA® for a total of approximately \$181 million, an amount which had been previously accrued.

In 2011, discussions to resolve criminal penalties under the Food Drug and Cosmetic Act related to the promotion of RISPERDAL® resulted in an agreement in principle with the United States Attorney's Office for the Eastern District of Pennsylvania on key issues relevant to a disposition of criminal charges pursuant to a single misdemeanor violation of the Food Drug and Cosmetic Act, but certain issues remain open before a settlement can be finalized. During 2011, the Company accrued amounts to cover the financial component of the proposed criminal settlement.

The Company has also now reached an agreement in principle with the United States Department of Justice to settle three pending civil False Claims Act matters that are pending in (1) the Eastern District of Pennsylvania concerning sales and marketing of RISPERDAL® and INVEGA®, (2) the Northern District of California regarding the sales and marketing of NATRECOR®, discussed separately below; and (3) the District of Massachusetts alleging that the defendants provided the Omnicare, Inc. (Omnicare) long-term care pharmacy with rebates and other payments regarding RISPERDAL® and other products, discussed separately below. Assuming these agreements are finalized, they will resolve the federal government's claims under the federal False Claims Act, resolve all pending state and federal government litigation regarding Omnicare and NATRECOR®, and settle the RISPERDAL® Medicaid-related claims for those states that opt into the settlement. With the tentative settlement agreements described above, issues remain open that must be resolved before the settlements can be finalized.

The Company has accrued amounts, including an additional accrual made in the second quarter of 2012, to cover these tentative settlement agreements. However, the settlements will not resolve all pending state litigation matters regarding RISPERDAL®, and some states may elect to opt out of the settlements. To the extent any state has a claim and has or will elect to opt out of these settlements, the Company has accrued an amount equal to what that state would receive if it was participating in the settlements. Among other states, Arkansas, Louisiana and South Carolina are not expected to participate in the settlements. Because the Company believes there are strong arguments on appeal in those cases, the Company has only accrued an amount equal to what these states would receive if they participated in the settlements.

In the Company's opinion, the ultimate resolution of any of the above RISPERDAL® matters is not expected to have a material adverse effect on the Company's financial position, although the resolution in any reporting period could have a material impact on the Company's results of operations and cash flows for that period.

OMNICARE

In September 2005, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the sales and marketing of eight drugs to Omnicare, Inc. (Omnicare), a manager of pharmaceutical benefits for long-term care facilities. In April 2009, Johnson & Johnson and certain of its pharmaceutical subsidiaries were served in two civil qui tam cases asserting claims under the Federal False Claims Act and related state law claims alleging that the defendants provided Omnicare with rebates and other alleged kickbacks, causing Omnicare to file false claims with Medicaid and other government programs. In January 2010, the government intervened in both of these cases, naming Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (now Janssen Pharmaceuticals, Inc. (JPI)), and Johnson & Johnson Health Care Systems Inc. as defendants. Subsequently, the Commonwealth of Massachusetts, Virginia, and Kentucky, and the States of California and Indiana intervened in the action. In February 2011, the United States District Court

[Table of Contents](#)

for the District of Massachusetts dismissed one qui tam case entirely and dismissed the other case in part, rejecting allegations that the defendants had violated their obligation to report its “best price” to health care program officials. The claims of the United States and individual states remain pending. In June 2012, the parties were granted their joint motion to stay the case pending resolution of the potential settlement discussed in the RISPERDAL® section above.

In November 2005, a lawsuit was filed by Scott Bartz, a former employee, in the United States District Court for the Eastern District of Pennsylvania against Johnson & Johnson and certain of its pharmaceutical subsidiaries (the J&J Defendants), along with co-defendants McKesson Corporation (McKesson) and Omnicare, Inc. In February 2011, the plaintiff filed an amended complaint. Thereafter, on the J&J Defendants' motion, the case was transferred to the United States District Court for the District of Massachusetts, where it is currently pending. The amended complaint alleges a variety of causes of action under the Federal False Claims Act and corresponding state and local statutes, including that the J&J Defendants engaged in various improper transactions that were allegedly designed to report false prescription drug prices to the federal government in order to reduce the J&J Defendants' Medicaid rebate obligations. The complaint further alleges that the J&J Defendants improperly retaliated against the plaintiff for having raised these allegations internally. Bartz seeks multiple forms of relief, including damages and reinstatement to a position with the same seniority status. The J&J Defendants subsequently moved to dismiss the complaint in May 2011. In March 2012, the District Court dismissed Bartz's claims under the Federal False Claims Act, and declined to exercise supplemental jurisdiction over numerous related claims under state false claims act statutes. The District Court, however, denied the dismissal motion with regard to Bartz's claims that he was retaliated against in violation of the Federal False Claims Act and in violation of New Jersey's Conscientious Employee Protection Act. Discovery is proceeding on those two claims.

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 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 Companies are cooperating with the United States Attorney's Office in responding to these subpoenas.

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. 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. After a removal to federal court, the case was remanded back to state court in Oregon. The Companies filed a motion to dismiss in February 2012. In June 2012, the state court granted the Companies' motion to dismiss in its entirety, but granted Oregon leave to amend. In July 2012, Oregon filed an amended complaint. In August 2012, the Companies filed a motion to dismiss the amended complaint. Oregon opposed, and the Companies filed a reply in October 2012.

In March 2011, the United States filed a complaint for injunctive relief in the United States District Court for the Eastern District of Pennsylvania against McNEIL-PPC and two of its employees, alleging that McNEIL-PPC is in violation of FDA regulations regarding the manufacture of drugs at the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico. On the same day, the parties filed a consent decree of permanent injunction resolving the claims set forth in the complaint. The Court approved and entered the consent decree on March 16, 2011.

The consent decree, which is subject to ongoing enforcement by the Court, requires McNEIL-PPC to take enhanced measures to remediate the three facilities. The Fort Washington facility, which was voluntarily shut down in April 2010, will remain shut down until a third-party consultant certifies that its operations will be in compliance with applicable law, and the FDA concurs with the third-party certification. The Lancaster and Las Piedras facilities may continue to manufacture and distribute drugs, provided that a third party reviews manufacturing records for selected batches of drugs released from the facilities, and certifies that any deviations reviewed do not adversely affect the quality of the selected batches. McNEIL-PPC has submitted a workplan to the FDA for remediation of the Lancaster and Las Piedras facilities; that plan is subject to FDA approval. Third-party batch record review may cease if the FDA has stated that the facilities appear to be in compliance with applicable law. Each facility is subject to a five-year audit period by a third party after the facility has been deemed by the FDA to be in apparent compliance with applicable law.

OTHER

In July 2005, Scios Inc. (Scios) received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the sales and marketing of NATRECOR®. In August 2005, Scios was advised that the investigation would be handled by the United States Attorney's Office for the Northern District of California in San Francisco. In February 2009, two qui tam complaints were unsealed in the United States District Court for the Northern District of California, alleging, among other things, improper activities in the promotion of NATRECOR®. In June 2009, the United States government intervened in one of the qui tam actions, and filed a complaint against Scios and Johnson & Johnson seeking relief under the Federal False Claims Act and asserting a claim of unjust enrichment. In October 2011, the criminal matter was resolved. The civil case has been stayed pending resolution of the potential settlement discussed in the RISPERDAL® section above.

In June 2008, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts relating to the marketing of biliary stents by Cordis Corporation (Cordis). In February 2012, the government informed Cordis that it was closing its investigation. In addition, in January 2010, a complaint was unsealed in the United States District Court for the Northern District of Texas, filed by Kevin Colquitt, seeking damages against Cordis and other parties for alleged violations of the Federal False Claims Act and several similar state laws in connection with the marketing of biliary stents. The United States Department of Justice and several states have declined to intervene at this time. In March 2012, the Court issued an opinion dismissing one part of the complaint with prejudice and other parts of the complaint without prejudice. A motion filed by Plaintiff for partial reconsideration of the dismissal with prejudice was denied. In September 2012, Plaintiff filed an amended complaint, and in October 2012, Cordis filed a motion to dismiss the amended complaint.

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 October 2011, the European Commission announced that it opened an investigation concerning an agreement between Janssen-Cilag B.V. and Sandoz B.V. relating to the supply of fentanyl patches in The Netherlands. The investigation seeks to determine whether the agreement infringes European competition law.

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®. JPI has provided documents and continues to cooperate with this government inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and promotion by Acclarent of RELIEVA STRATUS™ MicroFlow Spacer products. Acclarent is cooperating with the United States Attorney's Office in responding to the subpoena.

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 Johnson & Johnson's policy to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

Starting in July 2006, five lawsuits were filed in United States District Court for the District of New Jersey by various employers and employee benefit plans and funds seeking to recover amounts they paid for RISPERDAL® for plan participants. In general, Plaintiffs allege that Johnson & Johnson and certain of its pharmaceutical subsidiaries engaged in off-label marketing of RISPERDAL® in violation of the federal and New Jersey RICO statutes. In addition, Plaintiffs asserted various state law claims. All of the cases were consolidated into one case seeking class action status, but shortly thereafter, one action was voluntarily dismissed. In December 2008, the Court dismissed the actions of the four remaining plaintiffs. In April 2010, those plaintiffs filed a new consolidated class action against Johnson & Johnson and Janssen, L.P. (now Janssen Pharmaceuticals, Inc. (JPI)); and in March 2011, that action was dismissed. In April 2011, one of those plaintiffs filed a notice of appeal with the United States Court of Appeals for the Third Circuit. That appeal was dismissed in July 2011.

In April 2009, Ortho-Clinical Diagnostics, Inc. (OCD) received a grand jury subpoena from the United States Department of Justice, Antitrust Division, requesting documents and information for the period beginning September 1, 2000 through the present, pertaining to an investigation of alleged violations of the antitrust laws in the blood reagents industry. OCD complied with the subpoena. In February 2011, OCD received a letter from the Antitrust Division indicating that it had closed its

investigation in November 2010. In June 2009, following the public announcement that OCD had received a grand jury subpoena, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. The various 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*. Discovery is ongoing. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. OCD requested interlocutory review of the class certification decision, and in October 2012, the Appellate Court granted OCD's petition for interlocutory review.

In April 2010, a putative class action lawsuit was filed in the United States District Court for the Northern District of California by representatives of nursing home residents or their estates against Johnson & Johnson, Omnicare, Inc. (Omnicare), and other unidentified companies or individuals. In February 2011, Plaintiffs filed a second amended complaint asserting that certain rebate agreements between Johnson & Johnson and Omnicare increased the amount of money spent on pharmaceuticals by the nursing home residents and violated the Sherman Act and the California Business & Professions Code. The second amended complaint also asserted a claim of unjust enrichment. Plaintiffs sought multiple forms of monetary and injunctive relief. Johnson & Johnson moved to dismiss the second amended complaint in March 2011. The Court granted the motion in its entirety in August 2011, dismissing all claims asserted by Plaintiffs. In October 2011, the Court dismissed the action with prejudice. The plaintiffs filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit in November 2011. In February 2012, Plaintiffs stipulated to a voluntary dismissal of the matter, with prejudice. Pursuant to the terms of the stipulation, the Ninth Circuit dismissed the case in its entirety in March 2012.

Starting in May 2010, multiple complaints seeking class action certification related to the McNeil recalls have been filed against McNeil Consumer Healthcare and certain affiliates, including Johnson & Johnson, in the United States District Court for the Eastern District of Pennsylvania, the Northern District of Illinois, the Central District of California, the Southern District of Ohio and the Eastern District of Missouri. These consumer complaints allege generally that purchasers of various McNeil medicines are owed monetary damages and penalties because they paid premium prices for defective medications rather than less expensive alternative medications. All but one complaint seeks certification of a nation-wide class of purchasers of these medicines, whereas one complaint, the Harvey case, seeks certification of a class of MOTRIN® IB purchasers in Missouri. In October 2010, the Judicial Panel on Multidistrict Litigation consolidated all of the consumer complaints, except for the Harvey case, which was consolidated in March 2011, into one lawsuit: *In re: McNeil Consumer Healthcare, et al., Marketing and Sales Practices Litigation*, for pretrial proceedings in the United States District Court for the Eastern District of Pennsylvania. In January 2011, the plaintiffs in all of the cases except the Harvey case filed a Consolidated Amended Civil Consumer Class Action Complaint (CAC) naming additional parties and claims. In July 2011, the Court granted Johnson & Johnson's motion to dismiss the CAC without prejudice, but permitted the plaintiffs to file an amended complaint within thirty days of the dismissal order. In August 2011, the plaintiffs filed a Second Amended Civil Consumer Class Action Complaint (SAC). In July 2012, the Court granted Johnson & Johnson's motion to dismiss the SAC with prejudice.

Separately, 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 the present one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington, PA facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The BC plaintiff served their affidavits in support of class certification in April 2012. The defendants responding affidavits were served in June 2012. The date for hearing of the certification application has not yet been scheduled.

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 Johnson & Johnson's stock declined significantly. Plaintiff seeks to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In December 2011, Johnson & Johnson's motion to dismiss was granted in part and denied in part. Plaintiff moved the Court to reconsider part of the December 2011 ruling. Defendants filed answers to the remaining claims of the Amended Complaint in February 2012 and the case is proceeding to discovery. In May 2012, the Court denied Plaintiff's motion for reconsideration. In September 2012, Plaintiff filed a Second Amended Complaint and Johnson & Johnson has moved to dismiss Plaintiff's Second Amended Complaint in part.

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 taxyears ended November 30, 1999 and November 30, 2000. OMJ PR alleges that the Internal Revenue Service erroneously calculated OMJ PR's tax credits under

[Table of Contents](#)

Section 936 of the Tax Code. OMJ filed a motion for summary judgment, and the United States filed a cross motion for summary judgment. In October 2012, the Court granted the United States' motion for summary judgment and denied OMJ PR's motion for summary judgment. OMJ PR intends to appeal this decision.

In August 2011, an arbitration panel ruled that Mitsubishi Tanabe Pharma Corporation (Tanabe), Janssen Biotech, Inc.'s (JBI's) distributor of REMICADE® in Japan, could seek to modify the proportion of net sales revenue that Tanabe must remit to JBI in exchange for distribution rights and commercial supply of REMICADE® (the Supply Price). Tanabe commenced the arbitration against Centocor Ortho Biotech, Inc. (now JBI) in 2009 pursuant to the parties' distribution agreement, which grants Tanabe the right to distribute REMICADE® in Japan and certain other parts of Asia. JBI has counterclaimed for an increase in the Supply Price. A hearing was held in November 2011 to determine the appropriate split of revenue and the parties are awaiting a decision.

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 ACTIONS

Starting in April 2010, a number of shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey against certain current and former directors and officers of Johnson & Johnson. Johnson & Johnson is named as a nominal defendant. These actions were consolidated in August 2010 into one lawsuit: *In re Johnson & Johnson Derivative Litigation*. Additionally, in September 2010, another shareholder derivative lawsuit was filed by Michael Wolin in New Jersey Superior Court against certain current and former directors and officers of Johnson & Johnson. Johnson & Johnson is named as a nominal defendant in this action as well. The parties to this action have stipulated that it shall be stayed until the *In re Johnson & Johnson Derivative Litigation* is completely resolved.

These shareholder derivative actions are similar in their claims and collectively they assert a variety of alleged breaches of fiduciary duties, including, among other things, that the defendants allegedly engaged in, approved of, or failed to remedy or prevent defective medical devices, improper pharmaceutical rebates, improper off-label marketing of pharmaceutical and medical device products, violations of current good manufacturing practice regulations that resulted in product recalls, and that they failed to disclose the aforementioned alleged misconduct in the Company's filings under the Securities Exchange Act of 1934. Each complaint seeks a variety of relief, including monetary damages and corporate governance reforms. Johnson & Johnson moved to dismiss these actions on the grounds, *inter alia*, that the plaintiffs failed to make a demand upon the Board of Directors. In September 2011, *In re Johnson & Johnson Derivative Litigation* was dismissed without prejudice and with leave to file an amended complaint.

Johnson & Johnson filed a report in the *In re Johnson & Johnson Derivative Litigation* matter in July 2011, prepared by a Special Committee of the Board of Directors, which investigated the allegations contained in the derivative actions and in a number of shareholder demand letters that the Board received in 2010 raising similar issues. The Special Committee was assisted in its investigation by independent counsel. The Special Committee's report recommended: i) that Johnson & Johnson reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation and ii) that the Board of Directors create a new Regulatory and Compliance Committee charged with responsibility for monitoring and oversight of the Company's Health Care Compliance and Quality & Compliance systems and issues. Johnson & Johnson's Board of Directors unanimously adopted the Special Committee's recommendations, and in April 2012, the Board of Directors created the Regulatory, Compliance & Government Affairs Committee.

In August 2011, two shareholders who had submitted shareholder demand letters in 2010 filed shareholder derivative lawsuits in the United States District Court for the District of New Jersey naming various current and former officers and directors as defendants and challenging the Board's rejection of their demands. In November 2011, the Court consolidated these two cases into *Copeland v. Prince*. Johnson & Johnson secured an extension of time to respond to the complaint.

Two additional shareholder derivative lawsuits were filed in May 2011 in the United States District Court for the District of New Jersey, and two other shareholder derivative lawsuits were filed in New Jersey Superior Court in May 2011 and August 2011, all naming Johnson & Johnson's current directors as defendants and Johnson & Johnson as the nominal defendant. The complaints allege breaches of fiduciary duties related to the Company's compliance with the Foreign Corrupt Practices Act and participation in the United Nations Iraq Oil For Food Program, that the Company has suffered damages as a result of those alleged breaches, and that the defendants failed to disclose the alleged misconduct in the Company's filings under the Securities Exchange Act of 1934. Plaintiffs seek monetary damages, and the state court plaintiffs also seek corporate governance reforms. The federal lawsuits were consolidated in July 2011 into *In re J&J FCPA Derivative Shareholder Litigation*, and an amended

[Table of Contents](#)

consolidated complaint was filed in August 2011. In October 2011, Johnson & Johnson moved to dismiss the consolidated federal lawsuit on the grounds that the plaintiffs failed to make a demand upon the Board of Directors. The plaintiffs secured an extension of time to respond to the motion. The state lawsuits were consolidated in November 2011 into *In re J&J Shareholder Derivative Litigation*, and a consolidated complaint was filed in December 2011. In January 2012, Johnson & Johnson moved to dismiss or stay the state lawsuits pending resolution of the federal lawsuit and moved to dismiss on the ground that the plaintiffs failed to make a demand on the Board of Directors. In May 2012, the Court granted Johnson & Johnson's motion to stay the state lawsuits pending resolution of *In re J&J FCPA Derivative Shareholder Litigation*.

In July 2012, the parties in each of the shareholder derivative cases pending in federal court discussed above (specifically, *In re Johnson & Johnson Derivative Litigation*, *Copeland v. Prince*, and *In re J&J FCPA Derivative Shareholder Litigation*) filed a Stipulation of Settlement to permanently resolve all of the actions in their entirety. In October 2012, the settlement was approved by the Court.

In June 2012, two other shareholders who had submitted a shareholder demand letter in March 2010, the New Jersey Building Laborers Annuity and the New Jersey Building Laborers Pension Funds, filed an additional shareholder derivative lawsuit in New Jersey Superior Court naming various current and former officers and directors as defendants and also challenging the Board's rejection of their demands. This shareholder derivative lawsuit purports to allege the same claims that are the subject of the settlement described above. The parties to this action had entered into a consent order staying the action pending final approval of the settlement discussed above. In November 2012, the plaintiffs agreed to voluntarily dismiss the action.

In September 2011, two additional 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 Johnson & Johnson's current directors and one former director 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 Johnson & Johnson's annual proxy statements. Both of these lawsuits have been voluntarily dismissed without prejudice, but a similar lawsuit on behalf of The George Leon Family Trust was refiled in July 2012. That lawsuit seeks a variety of relief, including monetary damages, injunctive relief, and corporate governance reforms. The above settlement does not resolve these potential claims. The Board of Directors' evaluation of these allegations is ongoing.

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 2012, worldwide sales were \$49.7 billion, a total increase of 1.8%, including operational growth of 5.0% as compared to 2011 fiscal nine months sales of \$48.8 billion. Currency fluctuations had a negative impact of 3.2% for the fiscal nine months of 2012. The acquisition of Synthes, Inc., net of the related trauma business divestiture, increased both total sales growth and operational growth by 2.2%.

Sales by U.S. companies were \$22.4 billion in the fiscal nine months of 2012, which represented an increase of 2.0% as compared to the prior year. Sales by international companies were \$27.3 billion, which represented a total increase of 1.7%, including an operational increase of 7.5%, and a negative currency impact of 5.8% as compared to the fiscal nine months sales of 2011.

Sales by companies in Europe experienced a decline of 4.0%, including operational growth of 4.2%, and a negative currency impact of 8.2%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 11.3%, including operational growth of 19.1%, and a negative currency impact of 7.8%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 4.5%, including operational growth of 6.1%, and a negative currency impact of 1.6%.

For the fiscal third quarter of 2012, worldwide sales were \$17.1 billion, a total increase of 6.5%, including operational growth of 10.8% as compared to 2011 fiscal third quarter sales of \$16.0 billion. Currency fluctuations had a negative impact of 4.3% for the fiscal third quarter of 2012. The acquisition of Synthes, Inc., net of the related trauma business divestiture, increased both total sales growth and operational growth by 5.8%.

Sales by U.S. companies were \$7.8 billion in the fiscal third quarter of 2012, which represented an increase of 13.4% as compared to the prior year. Sales by international companies were \$9.3 billion, which represented a total increase of 1.4%, including an operational increase of 8.9%, and a negative currency impact of 7.5% as compared to the fiscal third quarter sales of 2011.

Sales by companies in Europe experienced a decline of 3.4%, including operational growth of 7.1%, and a negative currency impact of 10.5%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 4.2%, including operational growth of 12.8%, and a negative currency impact of 8.6%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 5.9%, including operational growth of 9.0%, and a negative currency impact of 3.1%.

U.S. Health Care Reform

Under the provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, beginning in 2011, companies that sold branded prescription drugs to specified U.S. Government programs paid an annual non-tax deductible fee based on an allocation of each company’s market share of total branded prescription drug sales from the prior year. The 2012 full year impact to selling, marketing and administrative expenses is approximately \$125 million. The 2011 full year impact to selling, marketing and administrative expenses was approximately \$140 million. Under the current law, beginning in 2013, the Company will be required to pay a tax deductible 2.3% excise tax imposed on the sale of certain medical devices. The 2013 excise tax is estimated to be between \$200 - \$300 million and depending on the final implementation of guidance, the Company will record the excise tax either in cost of products sold or selling, marketing and administrative expenses.

ANALYSIS OF SALES BY BUSINESS SEGMENTS

Consumer

Consumer segment sales in the fiscal nine months of 2012 were \$10.8 billion, a decrease of 3.7% as compared to the same period a year ago, including operational growth of 0.4% and a negative currency impact of 4.1%. U.S. Consumer segment sales declined by 1.5%. International Consumer segment sales declined by 4.9%, including operational growth of 1.4% and a negative currency impact of 6.3%.

Major Consumer Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
OTC Pharm. & Nutritionals	\$ 3,196	\$ 3,266	(2.1)%	2.0%	(4.1)%
Skin Care	2,724	2,771	(1.7)	1.5	(3.2)
Baby Care	1,682	1,772	(5.1)	(0.1)	(5.0)
Women's Health	1,218	1,394	(12.6)	(6.7)	(5.9)
Oral Care	1,208	1,212	(0.3)	3.7	(4.0)
Wound Care/Other	767	800	(4.1)	(1.5)	(2.6)
Total Consumer Sales	\$ 10,795	\$ 11,215	(3.7)%	0.4%	(4.1)%

Consumer segment sales in the fiscal third quarter of 2012 were \$3.6 billion, a decrease of 4.3% as compared to the same period a year ago, including operational growth of 1.0% and a negative currency impact of 5.3%. U.S. Consumer segment sales declined by 0.4%. International Consumer segment sales declined by 6.1%, including operational growth of 1.8% and a negative currency impact of 7.9%.

Major Consumer Franchise Sales — Fiscal Third Quarters Ended

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
OTC Pharm. & Nutritionals	\$ 1,060	\$ 1,054	0.6 %	5.9%	(5.3)%
Skin Care	904	943	(4.1)	0.2	(4.3)
Baby Care	564	613	(8.0)	(1.9)	(6.1)
Oral Care	413	422	(2.1)	3.0	(5.1)
Women's Health	407	458	(11.1)	(3.2)	(7.9)
Wound Care/Other	233	250	(6.8)	(3.6)	(3.2)
Total Consumer Sales	\$ 3,581	\$ 3,740	(4.3)%	1.0%	(5.3)%

The OTC Pharmaceuticals and Nutritionals franchise achieved operational growth of 5.9% as compared to the prior year fiscal third quarter. Sales in the U.S. increased due to the relaunch of selected key products and the impact of the acquisition of full ownership rights of PEPCID® products partially offset by supply constraints on other products. McNEIL-PPC, Inc. continues to operate under a consent decree signed with the U.S. Food and Drug Administration (FDA), which governs certain McNeil Consumer Healthcare manufacturing operations. McNeil continues to operate the manufacturing facilities in Las Piedras, Puerto Rico and Lancaster, Pennsylvania; however, production volumes from these facilities continue to be impacted by additional review and approval processes required under the consent decree. The Company expects this to continue throughout 2012 and most of 2013. Plants operating under the consent decree will produce a simplified portfolio focused on key brands. The Fort Washington, Pennsylvania manufacturing site is not in operation at this time. McNeil continues to work on the re-siting of the products previously produced at the Fort Washington facility to other facilities.

The Skin Care franchise achieved operational growth of 0.2% as compared to the prior year, attributable to increased sales of NEUTROGENA® in the U.S. partially offset by competition and economic conditions outside the U.S.

[Table of Contents](#)

The Baby Care franchise experienced an operational decline of 1.9% as compared to the prior year, primarily due to competitive pressures.

The Oral Care franchise achieved operational growth of 3.0% as compared to the prior year, primarily due to increased sales outside the U.S. from newly launched LISTERINE® products.

The Women's Health Franchise experienced an operational decline of 3.2% as compared to the prior year, primarily due to the impact of the divestiture of MONISTAT® in the fiscal third quarter of 2011.

The Wound Care/Other franchise experienced an operational decline of 3.6% as compared to the prior year, due to competitive pressures.

Pharmaceutical

Pharmaceutical segment sales in the fiscal nine months of 2012 were \$18.8 billion, a total increase of 3.0% as compared to the same period a year ago with an operational increase of 6.3% and a negative currency impact of 3.3%. U.S. Pharmaceutical sales decreased by 1.0% as compared to the same period a year ago while international Pharmaceutical sales achieved growth of 7.3%, including operational growth of 14.1%, and a negative currency impact of 6.8%.

Major Pharmaceutical Therapeutic Area Sales — Fiscal Nine Months Ended*

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
Total Immunology	\$ 5,898	\$ 5,002	17.9%	19.2%	(1.3)%
REMICADE®	4,635	4,064	14.1	15.1	(1.0)
SIMPONI®	426	291	46.4	49.8	(3.4)
STELARA®	756	531	42.4	46.1	(3.7)
Other Immunology	81	116	(30.2)	(27.2)	(3.0)
Total Infectious Diseases	2,338	2,473	(5.5)	(0.7)	(4.8)
INTELENCE®	265	231	14.7	19.4	(4.7)
LEVAQUIN®/FLOXIN®	65	618	(89.5)	(89.2)	(0.3)
PREZISTA®	1,061	895	18.5	23.5	(5.0)
Other Infectious Diseases	947	729	29.9	38.4	(8.5)
Total Neuroscience	5,029	5,209	(3.5)	(0.2)	(3.3)
CONCERTA®/methylphenidate	830	994	(16.5)	(14.5)	(2.0)
INVEGA®	403	374	7.8	10.0	(2.2)
INVEGA® SUSTENNA®/XEPLION®	568	243	**	**	(2.7)
RISPERDAL® CONSTA®	1,067	1,198	(10.9)	(6.7)	(4.2)
Other Neuroscience	2,161	2,400	(10.0)	(6.9)	(3.1)
Total Oncology	1,810	1,485	21.9	29.0	(7.1)
DOXIL®/CAELYX®	53	363	(85.4)	(84.6)	(0.8)
VELCADE®	998	922	8.2	15.7	(7.5)
ZYTIGA®	697	149	**	**	(4.2)
Other Oncology	62	51	21.6	28.1	(6.5)
Total Other	3,751	4,105	(8.6)	(5.5)	(3.1)
ACIPHEX®/PARIET®	649	721	(10.0)	(5.7)	(4.3)
PROCRIT®/EPREX®	1,136	1,255	(9.5)	(6.4)	(3.1)
Other	1,966	2,129	(7.7)	(5.0)	(2.7)
Total Pharmaceutical Sales	\$ 18,826	\$ 18,274	3.0%	6.3%	(3.3)%

* Prior year amounts have been reclassified to conform to current year presentation.

** Percentage greater than 100%

[Table of Contents](#)

Pharmaceutical segment sales in the fiscal third quarter of 2012 were \$6.4 billion, a total increase of 7.0% as compared to the same period a year ago with an operational increase of 11.3% and a negative currency impact of 4.3%. U.S. Pharmaceutical sales increased by 14.6% as compared to the same period a year ago. International Pharmaceutical sales were flat and reflected an operational increase of 8.2% offset by a negative currency impact of 8.2%.

Major Pharmaceutical Therapeutic Area Sales — Fiscal Third Quarters Ended*

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
Total Immunology	\$ 2,084	\$ 1,767	17.9%	19.8%	(1.9)%
REMICADE®	1,591	1,408	13.0	14.3	(1.3)
SIMPONI®	185	129	43.4	47.9	(4.5)
STELARA®	287	189	51.9	56.4	(4.5)
Other Immunology	21	41	(48.8)	(46.6)	(2.2)
Total Infectious Diseases	795	714	11.3	18.6	(7.3)
INTELENCE®	94	83	13.3	19.5	(6.2)
LEVAQUIN®/FLOXIN®	20	25	(20.0)	(18.1)	(1.9)
PREZISTA®	364	316	15.2	21.3	(6.1)
Other Infectious Diseases	317	290	9.3	18.7	(9.4)
Total Neuroscience	1,668	1,684	(1.0)	3.3	(4.3)
CONCERTA®/methylphenidate	254	283	(10.2)	(7.7)	(2.5)
INVEGA®	140	126	11.1	14.3	(3.2)
INVEGA® SUSTENNA®/XEPLION®	212	101	**	**	(3.4)
RISPERDAL® CONSTA®	351	390	(10.0)	(4.6)	(5.4)
Other Neuroscience	711	784	(9.3)	(5.0)	(4.3)
Total Oncology	628	494	27.1	36.2	(9.1)
DOXIL®/CAELYX®	16	86	(81.4)	(80.4)	(1.0)
VELCADE®	327	295	10.8	20.7	(9.9)
ZYTIGA®	265	95	**	**	(5.2)
Other Oncology	20	18	11.1	18.8	(7.7)
Total Other	1,227	1,323	(7.3)	(3.3)	(4.0)
ACIPHEX®/PARIET®	195	235	(17.0)	(11.5)	(5.5)
PROCRIT®/EPREX®	359	383	(6.3)	(2.2)	(4.1)
Other	673	705	(4.5)	(1.1)	(3.4)
Total Pharmaceutical Sales	\$ 6,402	\$ 5,982	7.0%	11.3%	(4.3)%

* Prior year amounts have been reclassified to conform to current year presentation.

** Percentage greater than 100%

Immunology products achieved strong operational sales growth of 19.8% as compared to the same period a year ago. The increased sales of STELARA® (ustekinumab) and SIMPONI® (golimumab) were primarily due to market growth. The increased sales of REMICADE® (infliximab) were primarily due to market growth and customer inventory planning.

Infectious disease products achieved operational sales growth of 18.6% as compared to the same period a year ago. Major contributors were INCIVO® (telaprevir), the continued momentum in market share growth of PREZISTA® (darunavir) and INTELENCE® (etravirine), partially offset by lower sales of vaccines.

Neuroscience products achieved operational sales growth of 3.3% as compared to the same period a year ago. Contributors to the growth were the long acting injectable anti-psychotics INVEGA® SUSTENNA® (paliperidone palmitate) in the U.S., INVEGA® SUSTENNA®, known as XEPLION®, sales in Europe and INVEGA® (paliperidone palmitate) sales in Japan. This growth was partially offset by lower sales of CONCERTA®/methylphenidate, RAZADYNE® (galantamine), RISPERDAL® (risperidone) and DURAGESIC®/Fentanyl Transdermal (fentanyl transdermal system) due to continued generic competition.

[Table of Contents](#)

The U.S. Supply and Distribution Agreement with Watson Laboratories, Inc. to distribute an authorized generic version of CONCERTA® became effective May 1, 2011. The original CONCERTA® patent expired in 2004 and parties have filed Abbreviated New Drug Applications (ANDAs) for generic versions of CONCERTA®, which are pending and may be approved at any time. An approval of another generic version of CONCERTA® is likely to result in a further reduction in CONCERTA® sales.

Oncology products achieved strong operational sales growth of 36.2% as compared to the same period a year ago. This growth was primarily due to sales of ZYTIGA® (abiraterone acetate) and VELCADE® (bortezomib). This growth was partially offset by lower sales of DOXIL® (doxorubicin HCl liposome injection)/CAELYX® (pegylated liposomal doxorubicin hydrochloride), due to supply restraints from the Company's third-party manufacturer. The Company has been working to restore a reliable supply of DOXIL®. Full access in the U.S. has commenced. In the European Union (EU), the Company expects CAELYX® to be available in the fourth quarter of 2012, and in non-EU countries the timing is projected to be the first quarter of 2013.

In the fiscal second quarter of 2012, Other Pharmaceutical sales experienced an operational decline of 3.3% as compared to the prior year fiscal third quarter primarily due to divestitures and lower sales of EPREX® (Epoetin alfa) and ACIPHEX®/PARIET® (rabeprazole sodium), primarily due to the impact of generic competition. These results were partially offset by sales growth of XARELTO® (rivaroxaban).

Medical Devices and Diagnostics

Medical Devices and Diagnostics segment sales in the fiscal nine months of 2012 were \$20.0 billion, an increase of 3.9% as compared to the same period a year ago, including operational growth of 6.5% and a negative currency impact of 2.6%. U.S. Medical Devices and Diagnostics sales increased 7.0%. The international Medical Devices and Diagnostics sales increase of 1.5% included operational growth of 6.2% and a negative currency impact of 4.7%. The acquisition of Synthes, Inc., net of the related divestiture, increased operational growth for the total Medical Devices and Diagnostics segment by 5.7%.

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

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
Orthopaedics	5,411	4,356	24.2 %	26.5%	(2.3)%
Surgical Care**	4,816	4,943	(2.6)	0.8	(3.4)
Vision Care	2,251	2,206	2.0	3.6	(1.6)
Diabetes Care	1,972	1,982	(0.5)	2.8	(3.3)
Specialty Surgery	1,871	1,773	5.5	8.3	(2.8)
Diagnostics	1,539	1,610	(4.4)	(2.3)	(2.1)
Cardiovascular Care	1,479	1,748	(15.4)	(13.0)	(2.4)
Infection Prevention/Other	706	668	5.7	8.1	(2.4)
Total Medical Devices and Diagnostics Sales	\$ 20,045	\$ 19,286	3.9 %	6.5%	(2.6)%

* Prior year amounts have been reclassified to conform to current year presentation.

** Previously referred to as General Surgery

Medical Devices and Diagnostics segment sales in the fiscal third quarter of 2012 were \$7.1 billion, an increase of 12.5% as compared to the same period a year ago, including operational growth of 16.1% and a negative currency impact of 3.6%. U.S. Medical Devices and Diagnostics sales increased 18.3%. The international Medical Devices and Diagnostics sales increase of 7.9% included operational growth of 14.4% and a negative currency impact of 6.5%. The acquisition of Synthes, Inc., net of the related trauma business divestiture, increased operational growth for the total Medical Devices and Diagnostics segment by 14.7%.

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

(Dollars in Millions)	September 30, 2012	October 2, 2011	Total Change	Operations Change	Currency Change
Orthopaedics	2,290	1,384	65.5 %	68.6%	(3.1)%
Surgical Care**	1,551	1,622	(4.4)	0.1	(4.5)
Vision Care	764	752	1.6	4.4	(2.8)
Diabetes Care	629	664	(5.3)	(1.1)	(4.2)
Specialty Surgery	597	576	3.6	7.2	(3.6)
Diagnostics	513	539	(4.8)	(1.9)	(2.9)
Cardiovascular Care	493	526	(6.3)	(2.7)	(3.6)
Infection Prevention/Other	232	220	5.5	9.0	(3.5)
Total Medical Devices and Diagnostics Sales	\$ 7,069	\$ 6,283	12.5 %	16.1%	(3.6)%

* Prior year amounts have been reclassified to conform to current year presentation.

** Previously referred to as General Surgery

The Orthopaedics franchise achieved operational growth of 68.6% as compared to the prior year fiscal third quarter. Growth was primarily due to sales of newly acquired products from Synthes, Inc. and sales of joint reconstruction and Mitek sports medicine products. Sales were impacted by the divestitures of the surgical instruments business of Codman & Shurtleff, Inc. in the fiscal fourth quarter of 2011 and the divestiture of certain rights and assets related to the DePuy trauma business. The positive impact on the Orthopaedics franchise operational sales growth due to the newly acquired products from Synthes, Inc. net of the related trauma business divestiture was 67.2%.

The Surgical Care franchise achieved operational growth of 0.1% as compared to the prior year fiscal third quarter. Sales of new products, including SECURESTRAP™, PHYSIOMESH® and ECHELON FLEX™ powered ENDOPATH® Stapler, were offset by lower sales of mechanical products and pelvic floor products.

The Vision Care franchise achieved operational sales growth of 4.4% as compared to the prior year fiscal third quarter. The growth was driven by ACUVUE® TruEye™, 1-DAY ACUVUE® MOIST® for Astigmatism and 1-DAY ACUVUE® MOIST®.

The Diabetes Care franchise experienced an operational sales decline 1.1% as compared to the prior year fiscal third quarter. Sales growth in Asia and Latin America was offset by sales declines in the U.S.

The Specialty Surgery franchise achieved operational growth of 7.2% as compared to the prior year fiscal third quarter. Incremental sales from the acquisition of SterilMed Inc., sales of biosurgery products and international sales of energy products were the major contributors to the growth.

The Diagnostics franchise experienced an operational sales decline of 1.9% as compared to the prior year. The decline was primarily due to lower sales in donor screening due to competitive pressures and the divestiture of the RhoGAM® business during the third quarter of 2012.

The Cardiovascular Care franchise experienced an operational sales decline of 2.7% as compared to the prior year fiscal third quarter. Sales were impacted by the Company's decision to exit the drug-eluting stent market in the second quarter of 2011 and lower sales of endovascular products, impacted by competitive launches and a disruption in supply that was resolved late in the third quarter. The decline in sales was partially offset by strong growth in Biosense Webster's electrophysiology business primarily due to the success of the new THERMOCOOL® catheter launches.

The Infection Prevention/Other franchise achieved operational sales growth of 9.0% as compared to the prior year fiscal third quarter primarily due to strong consumables sales growth.

ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income fiscal nine months of 2012 decreased to \$10.7 billion as compared to \$12.0 billion in the fiscal nine months of 2011, a decrease of 11.4%. The fiscal nine months of 2012 was unfavorably impacted by \$2.0 billion attributed to intangible asset write-downs and in-process research and development, primarily related to the discontinuation of the Phase III clinical development of bapineuzumab IV and the Crucell vaccine business. In addition, the fiscal nine months of 2012 included higher costs related to the Synthes acquisition of \$0.4 billion, including an inventory step-up recorded in cost of products sold. The fiscal nine months of 2011 included a \$0.7 billion restructuring expense related to the Cardiovascular Care business partially offset by higher gains of \$0.4 billion, recorded in other income as compared to the fiscal nine months of 2012. Consolidated earnings before provision for taxes on income was favorably impacted by lower operating expenses of approximately \$0.4 billion in the fiscal nine months of 2012 primarily due to cost containment initiatives in selling, marketing and administrative expenses and the discontinuation of clinical development for the NEVO™ Sirolimus-Eluting Coronary Stent in research and development expense offset by ongoing remediation in the Consumer OTC business. Consolidated earnings before provision for taxes on income for the fiscal third quarter of 2012 decreased to \$3.6 billion as compared to \$4.1 billion in the fiscal third quarter of 2011, a decrease of 12.6%. The fiscal third quarter of 2012 was unfavorably impacted by \$0.7 billion attributed to an in-process research and development charge related to the discontinuation of the Phase III clinical development of bapineuzumab IV. Additionally, the fiscal third quarter of 2012 included costs of \$0.1 billion related to the DePuy ASR™ Hip recalls and higher research and development costs of \$0.2 billion due to the timing of milestone payments in the Pharmaceutical business partially offset by cost containment initiatives. The fiscal third quarter of 2011 included higher costs of approximately \$0.2 billion related to a mark-to-market adjustment to reduce the value of the currency option and deal costs related to the acquisition of Synthes, Inc. The fiscal third quarter of 2011 included higher gains of \$0.5 billion, recorded in other income, as compared to the fiscal third quarter of 2012.

Cost of Products Sold

Consolidated costs of products sold for the fiscal nine months of 2012 increased to 31.5% from 30.8% of sales as compared to the same period a year ago. The increase of costs of products sold was primarily the result of ongoing remediation in the Consumer OTC business and an inventory step-up charge of \$0.2 billion related to the Synthes acquisition. Included in the fiscal nine months of 2011 was \$0.1 billion of inventory write-offs due to the restructuring charges related to the Cardiovascular Care business and an inventory step-up charge associated with the acquisition of Crucell. The consolidated costs of products sold for the fiscal third quarter of 2012 increased to 32.8% from 31.7% of sales as compared to the same period a year ago primarily due to an inventory step-up charge of \$0.2 billion related to the Synthes acquisition and ongoing remediation in the Consumer OTC business. The fiscal third quarter of 2011 included an inventory step-up charge associated with the acquisition of Crucell.

Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the fiscal nine months of 2012 decreased to 30.6% from 31.8% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal third quarter of 2012 decreased to 30.6% from 32.7% of sales as compared to the same period a year ago. The decreases in both periods were primarily due to cost containment initiatives across many of the businesses. The prior year periods included higher investment spending in the Pharmaceutical business for new products.

Research & Development Expense

Research & development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research & development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities for the fiscal nine months of 2012 were \$5.3 billion, which was a decrease of 1.1% in spending as compared to the same period a year ago. The decrease of approximately \$0.1 billion in the fiscal nine months of 2012, was primarily due to the discontinuation of the clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent and timing of expenditures. Worldwide costs of research and development activities for the fiscal third quarter of 2012 were \$1.9 billion which was an increase of 8.5% in spending as compared to the same period a year ago was primarily due to the timing of milestone payments in the Pharmaceutical business.

In-Process Research and Development

Beginning in 2009, in accordance with U.S. GAAP for business combinations, purchased in-process research and development (IPR&D) is no longer expensed at the time of acquisition but capitalized as an asset and tested for impairment. During the fiscal third quarter of 2012, the Company recorded a charge in the amount of \$0.7 billion for the impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV. Of the \$0.7 billion impairment, \$0.3 billion is attributable to noncontrolling interest. During the fiscal nine months of 2012, the Company recorded a charge of \$1.1 billion which included \$0.7 billion for the impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV and the partial impairment of the IPR&D related to the Crucell vaccine business in the amount of \$0.4 billion. These charges relate to development projects which have been recently discontinued or delayed.

Other (Income) Expense, Net

Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain equity securities of the Johnson & Johnson Development Corporation, gains and losses on the disposal of assets, currency gains and losses, gains and losses relating to noncontrolling interests, acquisition related costs, litigation settlements, as well as royalty income. The change in other (income) expense, net for the fiscal nine months of 2012, was unfavorable by \$1.4 billion as compared to the same period a year ago. The fiscal nine months of 2012 were unfavorably impacted by \$0.9 billion attributed to write-downs of intangible assets, primarily related to the Crucell vaccine business and higher net litigation expense of \$0.1 billion versus the prior year. In addition, the fiscal nine months of 2012 included higher costs of \$0.2 billion related to the Synthes acquisition as compared to the prior year. The fiscal nine months of 2011 included higher gains of \$0.4 billion primarily related to divestitures. The change in other (income) expense, net for the fiscal third quarter of 2012, was unfavorable by \$0.2 billion as compared to the same period a year ago. The fiscal third quarter of 2012 included \$0.1 billion related to the DePuy ASR™ Hip recalls. The fiscal third quarter of 2011 included higher gains of \$0.5 billion primarily related to divestitures as compared to the same period a year ago. This was partially offset by a \$0.3 billion mark-to-market adjustment to reduce the value of the currency option and deal costs related to the acquisition of Synthes, Inc.

Restructuring Expense

During the fiscal second quarter of 2011, Cordis Corporation, a subsidiary of Johnson & Johnson, announced the discontinuation of its clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent and cessation of the manufacture and marketing of CYPHER® and CYPHER SELECT® Plus Sirolimus-Eluting Coronary Stents by the end of 2011. The Company recorded a pre-tax charge of \$0.7 billion, of which \$0.1 billion is included in cost of products sold.

OPERATING PROFIT BY SEGMENT

Consumer Segment

Operating profit for the Consumer segment as a percent to sales in the fiscal nine months of 2012 was 11.5% versus 15.7% for the same period a year ago. Operating profit for the Consumer segment as a percent to sales in the fiscal third quarter of 2012 was 14.2% versus 17.2% for the same period a year ago. The fiscal nine months of 2012 were unfavorably impacted by \$0.3 billion attributed to intangible asset write-downs and approximately \$0.2 billion due to unfavorable product mix and remediation costs associated with the McNEIL-PPC consent decree. This was partially offset by cost containment initiatives realized in selling, marketing and administrative expenses in both periods of 2012. In addition, the fiscal third quarter of 2011 included the gain on the divestiture of MONISTAT®.

Pharmaceutical Segment

Operating profit for the Pharmaceutical segment as a percent to sales in the fiscal nine months of 2012 was 23.9% versus 32.8% for the same period a year ago. The fiscal nine months of 2012 were unfavorably impacted by \$1.6 billion attributed to the write-down of intangible assets and in-process research and development, primarily related to the Crucell vaccine business and to the discontinuation of the Phase III clinical development of bapineuzumab IV. Additionally, the fiscal nine months included higher net litigation expense of \$0.1 billion versus the prior year. This was partially offset by favorable operating expenses of \$0.2 billion. Operating profit for the Pharmaceutical segment as a percent to sales in the fiscal third quarter of 2012 was 21.7% versus 34.7% for the same period a year ago. The fiscal third quarter of 2012 was unfavorably impacted by \$0.7 billion attributable to an in-process research and development charge related to the discontinuation of the Phase III clinical development of bapineuzumab IV.

Medical Devices and Diagnostics Segment

Operating profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal nine months of 2012 was 29.3% versus 26.7% for the same period a year ago. The fiscal nine months of 2012 included integration costs and inventory step-up of \$0.4 billion associated with the acquisition of Synthes, Inc. and \$0.1 billion attributed to the write-down of intangible assets. Additionally, operating expenses were favorably impacted by cost containment initiatives of approximately \$0.1 billion. The fiscal nine months 2011 included a \$0.7 billion restructuring expense related to the Cardiovascular Care business and higher cost of \$0.1 billion related to DePuy ASR™ Hip recall costs versus 2012. Operating profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal third quarter of 2012 was 27.3% versus 30.7% for the same period a year ago. The fiscal third quarter of 2012 was unfavorably impacted by the inventory step-up charge of \$0.2 billion related to the Synthes acquisition and \$0.1 billion related to DePuy ASR™ Hip recall costs.

Interest (Income) Expense

Interest income decreased in both the fiscal nine months and the fiscal third quarter of 2012 as compared to the same period a year ago, due to lower rates of interest earned and lower average cash balances. The ending balance of cash, cash equivalents and marketable securities, was \$19.8 billion at the end of the fiscal third quarter of 2012. This is a decrease of \$11.1 billion from the same period a year ago. The decline in the average cash balance was due to the acquisition of Synthes, Inc. partially offset by cash generated from operating activities.

Interest expense increased in both the fiscal nine months and the fiscal third quarter of 2012 as compared to the same period a year ago due to a higher average debt balance. At the end of the fiscal third quarter of 2012, the Company's debt position was \$16.9 billion compared to \$18.4 billion from the same period a year ago. The reduction in debt in the first fiscal nine months of 2012 of approximately \$1.5 billion was primarily due to a reduction in commercial paper.

Provision for Taxes on Income

The worldwide effective income tax rates for the fiscal nine months of 2012 and 2011 were 25.6% and 21.5%, respectively. The higher effective tax rate in 2012 as compared to 2011 was primarily due to lower tax rates associated with in-process research and development write downs; integration, transaction and currency related costs associated with the Synthes acquisition and litigation accruals which added 3.4 points to the effective tax rate. These items are located in low tax jurisdictions which reduced the tax benefit associated with the expense therefore increasing the worldwide effective tax rate. The expiration of the Research and Development tax credit at year end 2011 increased the 2012 tax rate by 0.6 points.

As of September 30, 2012, the Company had approximately \$3.0 billion of liabilities from unrecognized tax benefits. The Company does not expect that the total amount of unrecognized tax benefits will change significantly during the next twelve months.

See Note 8 to the Consolidated Financial Statements in the Annual Report on Form 10-K for the fiscal year ended January 1, 2012 for more detailed information regarding unrecognized tax benefits.

Noncontrolling Interest

A charge of \$0.7 billion for the impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV was recorded in the fiscal third quarter of 2012. Of the \$0.7 billion impairment, \$0.3 billion is attributable to noncontrolling interest.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

Cash and cash equivalents were \$15.5 billion at the end of the fiscal third quarter of 2012 as compared with \$24.5 billion at the fiscal year end of 2011. The primary uses of cash that contributed to the \$9.0 billion decrease were approximately \$2.0 billion net cash used by investing activities and \$19.1 billion used by financing activities partially offset by \$12.0 billion generated from operating activities.

[Table of Contents](#)

Cash flow from operations of \$12.0 billion was the result of \$7.9 billion of net earnings and \$5.3 billion of non-cash charges primarily related to depreciation and amortization, intangible asset write-downs (primarily in-process research and development), stock-based compensation, noncontrolling interest and deferred tax provision reduced by \$1.2 billion related to changes in assets and liabilities, net of effects from acquisitions.

Investing activities use of \$2.0 billion was primarily for acquisitions, net of cash acquired of \$4.4 billion and \$1.8 billion for additions to property, plant and equipment partially offset by net sales of investments in marketable securities of \$3.3 billion and \$0.9 billion of proceeds from the disposal of assets.

Financing activities use of \$19.1 billion was for the repurchase of common stock of \$12.9 billion primarily for the acquisition of Synthes, Inc., dividends to shareholders of \$4.9 billion and net retirement of short and long-term debt of \$3.0 billion partially offset by \$1.8 billion of net proceeds from stock options exercised/excess tax benefits.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2012, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 19, 2013, 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 2012, 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.

Dividends

On July 16, 2012, the Board of Directors declared a regular cash dividend of \$0.61 per share, which was paid on September 11, 2012 to shareholders of record as of August 28, 2012.

On October 17, 2012, the Board of Directors declared a regular cash dividend of \$0.61 per share payable on December 11, 2012 to shareholders of record as of November 27, 2012. 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. Recent 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 \$2.0 billion as of September 30, 2012 and approximately \$2.4 billion as of January 1, 2012. Approximately \$1.2 billion as of September 30, 2012 and approximately \$1.4 billion as of January 1, 2012 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 \$0.8 billion at September 30, 2012 and \$1.0 billion at January 1, 2012. 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 Standards

[Table of Contents](#)

During the fiscal third quarter of 2012, the Financial Accounting Standards Board (FASB) issued guidance and amendments related to testing indefinite lived intangible assets for impairment. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to determine the fair value. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. This update will become effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. However, early adoption is permitted. This adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2012, the Company adopted the FASB guidance and amendments issued related to goodwill impairment testing. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. However, if an entity concludes otherwise, then it is required to perform the first step of the two-step impairment test. This update became effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. 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 2012, the Company adopted the FASB amendment to the disclosure requirements for presentation of comprehensive income. The amendment requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance became effective retrospectively for the interim periods and annual periods beginning after December 15, 2011; however, the FASB agreed to an indefinite deferral of the reclassification requirement. For the Consolidated Statements of Comprehensive Income see page 6.

During the fiscal first quarter of 2012, the FASB issued amendments to disclosure requirements for common fair value measurement. These amendments result in convergence of fair value measurement and disclosure requirements between U.S. GAAP and IFRS. This guidance became effective prospectively for the interim periods and annual periods beginning after December 15, 2011. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

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 2001 through 2011 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.

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 drug firms have filed Abbreviated New Drug Applications seeking to market generic forms of most 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 an Abbreviated New Drug Application filing, the generic firms will then introduce generic versions of the product at issue, resulting in very substantial market share and revenue losses. For further information see the discussion on

“Litigation Against Filers of Abbreviated New Drug Applications” included in Item 1. Financial Statements (unaudited)- Notes to Consolidated Financial Statements, Note 11.

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 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, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; significant litigation or government action adverse to the Company; impact of business combinations; financial distress and bankruptcies experienced by significant customers and suppliers; changes to governmental laws and regulations and U.S. and foreign health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and sovereign risk; disruptions due to natural disasters; manufacturing difficulties or delays; 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 January 1, 2012 contains, as an Exhibit, 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 January 1, 2012.

Item 4 — CONTROLS AND PROCEDURES

Disclosure controls and procedures. At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company’s disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Alex Gorsky, 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. The Company acquired Synthes, Inc. and its consolidated subsidiaries (Synthes) in June 2012. Synthes total assets and total revenues represented approximately 20% and 6%, respectively, of the related consolidated financial statements as of and for the period ended September 30, 2012. As the acquisition occurred in June 2012 and Synthes was previously not subject to SOX 404 requirements, the scope of the Company’s assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2012 will exclude Synthes. This exclusion is in accordance with the SEC’s general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

[Table of Contents](#)

During the period covered by this report, except as stated above for Synthes, 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 Company did not purchase any shares of its Common Stock during the fiscal third quarter of 2012.

Item 6 — EXHIBITS

Exhibit 10.1 The Johnson & Johnson Executive Income Deferral Plan.

Exhibit 10.2 Offer Letter for Paul Stoffels

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 30, 2012, formatted in Extensible 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.

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)

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

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