JOHNSON & JOHNSON Form 10-Q May 03, 2013

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 March 31, 2013

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 b Accelerated filer o Non-accelerated filer o Smaller reporting company o

(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). o Yes b No

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

On April 26, 2013 2,808,886,962 shares of Common Stock, \$1.00 par value, were outstanding.

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## Part I — FINANCIAL INFORMATION

## Item 1 — FINANCIAL STATEMENTS

## JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	March 31, 2013	December 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$14,855	\$14,911
Marketable securities	6,813	6,178
Accounts receivable, trade, less allowances for doubtful accounts \$400 (2012, \$466)	11,515	11,309
Inventories (Note 2)	7,691	7,495
Deferred taxes on income	3,094	3,139
Prepaid expenses and other receivables	3,260	3,084
Total current assets	47,228	46,116
Property, plant and equipment at cost	34,695	34,654
Less: accumulated depreciation	(18,974)	(18,557)
Property, plant and equipment, net	15,721	16,097
Intangible assets, net (Note 3)	28,009	28,752
Goodwill (Note 3)	22,349	22,424
Deferred taxes on income	4,506	4,541
Other assets	3,723	3,417
Total assets	\$121,536	\$121,347
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Loans and notes payable	\$4,529	\$4,676
Accounts payable	5,372	5,831
Accrued liabilities	6,904	7,299
Accrued rebates, returns and promotions	2,910	2,969
Accrued compensation and employee related obligations	1,631	2,423
Accrued taxes on income	1,178	1,064
Total current liabilities	22,524	24,262
Long-term debt (Note 4)	11,363	11,489
Deferred taxes on income	3,619	3,136
Employee related obligations	8,978	9,082
Other liabilities	8,197	8,552
Total liabilities	54,681	56,521
Shareholders' equity:		
Common stock — par value \$1.00 per share (authorized 4,320,000,000 shares; issued	¢2.120	¢2.120
3,119,843,000 shares)	\$5,120	\$3,120
Accumulated other comprehensive income (loss) (Note 7)	(6,689)	(5,810)
Retained earnings	87,242	85,992
Less: common stock held in treasury, at cost (316,679,000 and 341,354,000 shares)	16,818	18,476
Total shareholders' equity	66,855	64,826
Total liabilities and shareholders' equity	\$121,536	\$121,347

See Notes to Consolidated Financial Statements

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## JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS

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

	Fiscal First Quarters Ended						
	March 31,	Percent		April 1,		Percent	
	2013	to Sales		2012		to Sales	
Sales to customers (Note 9)	\$17,505	100.0	%	\$16,139		100.0	%
Cost of products sold	5,554	31.7		4,915		30.4	
Gross profit	11,951	68.3		11,224		69.6	
Selling, marketing and administrative expenses	5,223	29.8		5,015		31.1	
Research and development expense	1,784	10.2		1,645		10.2	
In-process research and development	64	0.4		_		_	
Interest income	(21	(0.1	)	(17	)	(0.1	)
Interest expense, net of portion capitalized	125	0.7		147		0.9	
Other (income) expense, net	515	3.0		(611	)	(3.8	)
Earnings before provision for taxes on income	4,261	24.3		5,045		31.3	
Provision for taxes on income (Note 5)	764	4.3		1,135		7.1	
NET EARNINGS	\$3,497	20.0	%	\$3,910		24.2	%
NET EARNINGS PER SHARE (Note 8)							
Basic	\$1.25			\$1.43			
Diluted	\$1.22			\$1.41			
CASH DIVIDENDS PER SHARE	\$0.61			\$0.57			
AVG. SHARES OUTSTANDING							
Basic	2,790.2			2,736.9			
Diluted	2,858.8			2,774.9			
See Notes to Consolidated Financial Statements							

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

	Fiscal First Quarte March 31, 2013	rs Ended April 1, 2012
Net Earnings	\$3,497	3,910
Other Comprehensive Income (Loss), net of tax		
Foreign currency translation	(1,210	823
Securities:		
Unrealized holding gain arising during period	177	107
Reclassifications to earnings	_	(1)
Net change	177	106
Employee benefit plans:		
Prior service cost amortization during period	2	1
Gain amortization during period	129	93
Net change	131	94
Derivatives & hedges:		
Unrealized gain arising during period	5	26
Reclassifications to earnings	18	43
Net change	23	69
Other Comprehensive Income (Loss)	(879	1,092
Comprehensive Income	\$2,618	5,002

## See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal first quarters were as follows for 2013 and 2012, respectively: Securities: \$95 million and \$57 million; Employee Benefit Plans: \$69 million and \$49 million; Derivatives & Hedges: \$12 million and \$37 million.

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

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## JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; Dollars in Millions)

GAGNELONG EDOM ODER A TING A CTENUTIVES	Fiscal Three March 31, 2013	e Months En April 1, 2012	ded
CASH FLOWS FROM OPERATING ACTIVITIES Net earnings	\$3,497	\$3,910	
Adjustments to reconcile net earnings to cash flows from operating activities:  Depreciation and amortization of property and intangibles	1,036	773	
Stock based compensation	1,030	173	
Venezuela currency devaluation	108	_	
Asset write-downs	69	_	
Deferred tax provision	365	557	
Accounts receivable allowances	(11	) 42	
Changes in assets and liabilities, net of effects from acquisitions:	(42.4	\ (015	`
Increase in accounts receivable	•	) (215	)
Increase in inventories  Decrease in accounts payable and accrued liabilities	•	) (449	)
Increase in other current and non-current assets	(608	) (1,331 ) (754	)
(Decrease)/increase in other current and non-current liabilities	(192	) 89	,
(Decrease), increase in outer earrent and non-earrent machines	(1)2	) 0)	
NET CASH FLOWS FROM OPERATING ACTIVITIES	2,277	2,795	
CASH FLOWS FROM INVESTING ACTIVITIES			
Additions to property, plant and equipment	•	) (502	)
Proceeds from the disposal of assets	106	358	
Acquisitions, net of cash acquired	(168	) —	,
Purchases of investments	•	) (2,398	)
Sales of investments	2,800	6,600	`
Other	(4	) (2	)
NET CASH (USED BY)/FROM INVESTING ACTIVITIES	(1,403	) 4,056	
CASH FLOWS FROM FINANCING ACTIVITIES			
Dividends to shareholders	(1,706	) (1,565	)
Repurchase of common stock	<del></del>	(67	)
Proceeds from short-term debt	475	1,547	
Retirement of short-term debt	(704	) (1,790	)
Proceeds from long-term debt	6	2	`
Retirement of long-term debt Proceeds from the exercise of stock options/excess tax benefits	(1 1,123	) (30 880	)
Other	30	(160	)
Other	30	(100	,
NET CASH USED BY FINANCING ACTIVITIES	(777	) (1,183	)
Effect of exchange rate changes on cash and cash equivalents	(153	) 57	
(Decrease)/increase in cash and cash equivalents	(56	) 5,725	
Cash and Cash equivalents, beginning of period	14,911	24,542	

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$14,855	\$30,267
Acquisitions Fair value of assets acquired Fair value of liabilities assumed and noncontrolling interests Net fair value of acquisitions See Notes to Consolidated Financial Statements	\$186 (18 \$168	\$— > — \$—
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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 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 first quarter of 2013, the Company adopted the Financial Accounting Standards Board (FASB) 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 became effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. 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 2013, the Company adopted the FASB guidance related to additional reporting and disclosure of amounts reclassified out of accumulated other comprehensive income (AOCI). Under this new guidance, companies are required to disclose the effect of significant reclassifications out of AOCI on the respective line items on the income statement if the amount being reclassified is required under U.S. generally accepted accounting principles (GAAP) to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional details about those amounts. This update became effective for annual and interim reporting periods for fiscal years beginning after December 15, 2012. The Company has disclosed the reclassification details in Note 7 to the Consolidated Financial Statements.

During the fiscal first quarter of 2013, the FASB issued amended guidance clarifying the release of accumulated Foreign Currency Translation from OCI into current year Net Earnings. The amendment requires that when the parent company ceases to have a controlling interest in a subsidiary or a business within a foreign entity the parent is to release accumulated Foreign Currency Translation from OCI. This update is required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, with early adoption 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.

#### NOTE 2 — INVENTORIES

(Dollars in Millions)	March 31, 2013	December 30, 2012
Raw materials and supplies	\$1,250	1,416
Goods in process	2,368	2,262
Finished goods	4,073	3,817
Total inventories	\$7,691	7,495

## 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 2012. 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 the Acclarent IPR&D in the fiscal first quarter of 2013.

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(Dollars in Millions)	March 31, 2013	December 30, 2012
Intangible assets with definite lives:		
Patents and trademarks — gross	\$8,832	8,890
Less accumulated amortization	3,506	3,416
Patents and trademarks — net	5,326	5,474
Customer relationships and other intangibles — gross	18,509	18,755
Less accumulated amortization	4,211	4,030
Customer relationships and other intangibles — net	14,298	14,725
Intangible assets with indefinite lives:		
Trademarks	7,556	7,648
Purchased in-process research and development	829	905
Total intangible assets with indefinite lives	8,385	8,553
Total intangible assets — net	\$28,009	28,752

Goodwill as of March 31, 2013 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Dev & Diag	Total	
Goodwill, net at December 30, 2012	\$8,519	1,792	12,113	22,424	
Acquisitions	70	_	9	79	
Currency translation/Other	(112)	(30)	(12)	(154	)
Goodwill, net as of March 31, 2013	\$8,477	1,762	12,110	22,349	

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 \$335 million and \$205 million for the fiscal first quarter ended March 31, 2013 and April 1, 2012, respectively. The estimated amortization expense for the five succeeding years approximates \$1,350 million, before tax, per year. Amortization expense is included in cost of products sold.

#### 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 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 March 31, 2013, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of \$25.3 billion and \$2.4 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

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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 March 31, 2013, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was \$31 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 first quarters in 2013 and 2012:

	Gain/(Loss) Gain/(Loss)		Gain/ (Loss)				
	Recognized	d in	Reclassifie	d from	Recognized in		
	Accumulat	ed	Accumulate	ed OCI	Other		
	$OCI^{(1)}$		into Income	$e^{(1)}$	Income/Exp	ense <sup>(2)</sup>	
	Fiscal First	Quarters En	ded				
(Dollars in Millions)	March 31, 2013	April 1, 2012	March 31, 2013	April 1, 2012	March 31, 2013	April 1, 2012	
Cash Flow Hedges by Income Statement	2010	_01_	2010	_01_	2010	2012	
Caption							
Sales to customers <sup>(3)</sup>	\$(37	) 28	(3	(20)		1	
Cost of products sold <sup>(3)</sup>	5	58	(17	(21)	(2)	(1)	)
Research and development expense <sup>(3)</sup>	10	(19)	(3	2	(3)		
Interest (income)/Interest expense, net <sup>(4)</sup>	(10	) (1 )	(2	(3)	<del></del>	_	
Other (income)expense, net <sup>(3)</sup>	37	(40)	7	(1)		_	
Total	\$5	26	(18	(43)	(5)	_	

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 first quarters ended March 31, 2013 and April 1, 2012, a loss of \$44 million and a loss of \$9 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 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.

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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 March 31, 2013 and December 30, 2012 were as follows:

	March 31, 2013				December 30, 2012
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total <sup>(2)</sup>
Derivatives designated as hedging instruments:					
Assets:					
Foreign exchange contracts	<b>\$</b> —	480		480	423
Cross currency interest rate swaps <sup>(3)</sup>		12	_	12	98
Total		492	_	492	521
Liabilities:					
Foreign exchange contracts		198		198	252
Cross currency interest rate swaps <sup>(4)</sup>		32		32	10
Total		230		230	262
Derivatives not designated as hedging instruments:					
Assets:					
Foreign exchange contracts		26		26	75
Liabilities:					
Foreign exchange contracts		78		78	23
Other Investments <sup>(1)</sup>	\$1,515		_	1,515	1,247

- (1) Classified as non-current other assets. On April 25, 2013, the Company received proceeds of approximately \$0.9 billion from the sale of Elan securities. This will be recorded in the fiscal second quarter of 2013.
- (2) As of December 30, 2012, these assets and liabilities are classified as Level 2 with the exception of Other Investments of \$1,247 million which are classified as Level 1.
- (3) Includes \$10 million and \$96 million of non-current assets for March 31, 2013 and December 30, 2012, respectively.
- (4) Includes \$30 million and \$4 million of non-current liabilities for March 31, 2013 and December 30, 2012, respectively.

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Financial Instruments not measured at Fair Value:

The following financial assets and liabilities are held at carrying amount on the consolidated balance sheet as of March 31, 2013:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Assets		
Current Investments		
Cash	\$2,891	2,891
Government securities and obligations	16,184	16,184
Corporate debt securities	703	703
Money market funds	1,386	1,386
Time deposits	504	504
Total cash, cash equivalents and current marketable securities	\$21,668	21,668

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	\$4,529	4,529
Non-Current Debt	7.50	7.50
3 month LIBOR+0.09% FRN due 2014	750	750
1.20% Notes due 2014	999	1,010
2.15% Notes due 2016	898	944
5.55% Debentures due 2017	1,000	1,198
5.15% Debentures due 2018	898	1,081
4.75% Notes due 2019 (1B Euro 1.2772)	1,271	1,560
3% Zero Coupon Convertible Subordinated Debentures due in 2020	207	287
2.95% Debentures due 2020	542	586
3.55% Notes due 2021	446	497
6.73% Debentures due 2023	250	350
5.50% Notes due 2024 (500 GBP 1.5129)	751	960
6.95% Notes due 2029	296	418
4.95% Debentures due 2033	500	592
5.95% Notes due 2037	995	1,323
5.85% Debentures due 2038	700	926
4.50% Debentures due 2040	539	609
4.85% Notes due 2041	298	353
Other	23	21
Total Non-Current Debt	\$11,363	13,465

The weighted average effective interest rate on non-current debt is 4.45%.

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 first quarters of 2013 and 2012 were 17.9% and 22.5%, respectively. The lower effective tax rate in 2013 as compared to 2012 was primarily due to the inclusion of the benefit from the U.S. Research & Development (R&D) tax credit, the Controlled Foreign Corporation (CFC) look-through provisions from the 2012 fiscal year and increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions. The R&D tax credit and the CFC look-through provisions were enacted into law in January 2013 and were retroactive to January 1, 2012. The entire 2012 R&D tax credit and the CFC look-through provisions were reflected in the fiscal first quarter of 2013 and decreased the tax rate by 2.4 points. Additionally, the quarterly impact of the 2013 R&D tax credit and the CFC look-through provisions is reflected in the 2013 fiscal first quarter financial results.

As of March 31, 2013, the Company had approximately \$2.8 billion of liabilities from unrecognized tax benefits. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months, including the U.S. Internal Revenue Service audit related to tax years 2006-2009. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

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

#### Components of Net Periodic Benefit Cost

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal first quarters of 2013 and 2012 include the following components:

	Retirement Pl	ans	Other Benef	fit Plans
	Fiscal First Quarters Ended			
(Dollars in Millions)	March 31, 2013	April 1, 2012	March 31, 2013	April 1, 2012
Service cost	\$206	161	48	44
Interest cost	228	222	37	41
Expected return on plan assets	(363	(312)	(1	) (1
Amortization of prior service cost/(credit)	4	2	(1	) (1
Recognized actuarial losses	168	124	28	18
Curtailments and settlements		(1)		
Net periodic benefit cost	\$243	196	111	101

#### **Company Contributions**

For the fiscal three months ended March 31, 2013, the Company contributed \$13 million and \$9 million to its U.S. and international retirement plans, respectively. The Company plans to continue to fund its U.S. defined benefit plans to comply with the Pension Protection Act of 2006. International plans are funded in accordance with local regulations.

#### NOTE 7 — ACCUMULATED OTHER COMPREHENSIVE INCOME

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

	Eamaian	Gains /	Employee	Gains /	Total	
	Foreign	(Losses)	Employee	(Losses)	Accumulated	
	Currency	on	Benefit	on	Other	
	Currency	on	Delletti	Derivatives	Comprehensive	
(Dollars in Millions)	Translation	Securities (1)	Plans (2)	& Hedges (3)	Income/(Loss)	
(Dollars in Millions) December 30, 2012	Translation \$ (296)	Securities (1) 195		& Hedges (3) 8	Income/(Loss) (5,810	)
				_		)

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.

Details on reclassifications out of Accumulated Other Comprehensive Income:

- (1) Gains / (Losses) on Securities reclassifications released to other (income) expense, net.
- Employee Benefit Plans reclassifications are included in net periodic benefit cost. See note 6 for additional details.
- (3) Gains / (Losses) on Derivatives & Hedges reclassifications to earnings are recorded in the same account as the hedged transaction. See note 4 for additional details.

#### NOTE 8 — EARNINGS PER SHARE

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal first quarters ended March 31, 2013 and April 1, 2012:

	Fiscal First Quarters Ended	
(Shares in Millions)	March 31, 2013	April 1, 2012
Basic net earnings per share	\$1.25	\$1.43
Average shares outstanding — basic	2,790.2	2,736.9
Potential shares exercisable under stock option plans	175.8	152.2
Less: shares which could be repurchased under treasury stock method	(135.5	) (117.8
Convertible debt shares	3.6	3.6
Accelerated share repurchase program	24.7	
Average shares outstanding — diluted	2,858.8	2,774.9
Diluted earnings per share	\$1.22	\$1.41

The diluted earnings per share calculation for both fiscal first quarters ended March 31, 2013 and April 1, 2012 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 first quarter ended March 31, 2013 included the dilutive effect of 24.7 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 2.5 million shares.

The diluted earnings per share calculation for the fiscal first quarter ended March 31, 2013 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 first quarter ended April 1, 2012, excluded 50 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.

#### NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

#### SALES BY SEGMENT OF BUSINESS

STILLS DI SESTILITI SI DESTINES	Fiscal First Quarters Ended			
(Dollars in Millions)	March 31, 2013	April 1, 2012	Percent Change	
Consumer				
United States	\$1,348	1,316	2.4	%
International	2,327	2,279	2.1	
Total	3,675	3,595	2.2	
Pharmaceutical				
United States	3,471	3,026	14.7	
International	3,297	3,107	6.1	
Total	6,768	6,133	10.4	
Medical Devices & Diagnostics				
United States	3,206	2,877	11.4	
International	3,856	3,534	9.1	
Total	7,062	6,411	10.2	
Worldwide				
United States	8,025	7,219	11.2	
International	9,480	8,920	6.3	
Total	\$17,505	16,139	8.5	%
SEGMENT PRE-TAX PROFIT				
	Fiscal First Qu	arters Ended		

	Fiscal First Quarters Ended				
(Dollars in Millions)	March 31,	April 1,	Percent		
(Donars in Minions)	2013	2012 Change			
Consumer (1)	\$547	463	18.1	%	
Pharmaceutical (2)	2,417	2,586	(6.5	)	
Medical Devices & Diagnostics <sup>(3)</sup>	1,518	2,081	(27.1	)	
Segments operating profit	4,482	5,130	(12.6	)	
Less: Expense not allocated to segments <sup>(4)</sup>	221	85			
Worldwide income before taxes	\$4,261	5,045	(15.5	)%	

- (1) Includes a gain on the sale of intangible and other assets of \$55 million in the fiscal first quarter of 2013.
- (2) Includes litigation expense of \$178 million in the fiscal first quarter of 2013.
- (3) Includes Synthes integration/transaction costs of \$258 million and \$31 million recorded in the fiscal first quarter of 2013 and 2012, respectively. Includes litigation expense of \$345 million and an in-process research and development write-down of \$64 million recorded in the fiscal first quarter of 2013.
- (4) Amounts not allocated to segments include interest income/(expense), noncontrolling interests and general corporate income/expense. Includes litigation expense of \$6 million in the fiscal first quarter of 2013. Included in the fiscal first quarter of 2012, was a \$148 million positive currency adjustment associated with the acquisition of Synthes, Inc.

#### SALES BY GEOGRAPHIC AREA

	Fiscal First Qu	iarters Ended		
(Dollars in Millions)	March 31,	April 1, 2012	Percent	
(Dollars III Willions)	2013	April 1, 2012	Change	
United States	\$8,025	7,219	11.2	%
Europe	4,481	4,194	6.8	
Western Hemisphere, excluding U.S.	1,783	1,714	4.0	
Asia-Pacific, Africa	3,216	3,012	6.8	
Total	\$17,505	16,139	8.5	%

#### NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

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

During the fiscal second quarter of 2012, 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 was \$17.5 billion based on cash on hand at closing of \$2.7 billion.

Under the terms of the agreement, each share of Synthes, Inc. 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 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 either stock or cash in the third quarter of 2013. Based on the theoretical settlement of the ASR agreements, an additional 24.7 million shares would be issued to settle the ASR agreements as of March 31, 2013.

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.

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The following table summarizes the consideration transferred to acquire Synthes, Inc. 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) <sup>(B)</sup>	\$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 still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price is based on the best estimate of management. To assist management in the allocation, the Company engaged valuation specialists to prepare independent appraisals. Certain estimated values surrounding litigation loss contingencies are not yet finalized and are subject to change. The Company will finalize the amounts recognized as the information necessary to complete the analysis is obtained. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through March 31, 2013:

(D	oll	ars	in	Mi	illions	s)
$\sim$		_	$\sim$			

Cash & Cash equivalents	\$2,749
Inventory	1,194
Accounts Receivable, net	738
Other current assets	238
Property, plant and equipment	1,253
Goodwill	6,039
Intangible assets	12,861
Other non-current assets	46
Total Assets Acquired	25,118
Current liabilities	1,081
Deferred Taxes	3,471
Other non-current liabilities	329
Total Liabilities Assumed	4,881
Net Assets Acquired	\$20,237

The adjustments made since the date of acquisition were to account for changes to inventory, based on the results of the physical inventory counts and deferred taxes, to reflect the statutory tax rate that is being applied to the intangible assets. The revisions to the purchase price allocation were not material to the Statements of Consolidated Earnings or

the Consolidated Balance Sheet for the fiscal first quarter of 2013 and prior fiscal quarters.

The assets acquired are recorded in the Medical Devices and Diagnostics segment. The acquisition of Synthes, Inc. resulted in \$6.0 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition of Synthes, Inc. The goodwill is not expected to be deductible for tax purposes.

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

(Dollars in Millions)

Intangible assets with definite lives:

C	
Customer relationships	\$9,870
Patents and technology	1,508
Total amortizable intangibles	11,378
Trademark and Trade name	1,420
In-process research and development	63
Total intangible assets	\$12,861

The Customer relationships weighted average life of 22 years was determined using the projected customer retention period based on historical experience. The Patents and technology weighted average life of 18 years was derived based on technology obsolescence rates that are commensurate with the nature of the Synthes businesses. 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.

The operating results of Synthes were reported in the Company's financial statements beginning on June 14, 2012. The following table provides pro forma results of operations for the fiscal first quarter ended April 1, 2012, 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.

Unaudited Pro forma consolidated results

(Dollars in Millions Except Per Share Data)	April 1, 2012
Net Sales	17,071
Net Earnings attributable to Johnson & Johnson	4,010
Diluted Net Earnings per Common Share attributable to Johnson & Johnson	1.44

In the fiscal first quarter of 2013, the Company recorded acquisition related costs of \$258 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. As of December 30, 2012, the transaction had closed worldwide.

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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, Inc. Proceeds received from the divestiture were \$357 million.

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#### NOTE 11 — LEGAL PROCEEDINGS

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of March 31, 2013, 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 subsidiaries of Johnson & Johnson 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 subsidiaries are subject to product liability claims and lawsuits in which claimants seek substantial compensatory and, where available, punitive damages, including LEVAQUIN®, the ASR<sup>TM</sup> XL Acetabular System and DePuy ASR<sup>TM</sup> Hip Resurfacing System, the PINNACI®EAcetabular Cup System, RISPERDAL®, pelvic meshes, DURAGESIC®/fentanyl patches and TOPAMAX®. As of March 31, 2013, in the U.S. there were approximately 1,500 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to LEVAQUIN®, 11,100 with respect to the ASR<sup>TM</sup> XL Acetabular System and DePuy ASR<sup>TM</sup> Hip Resurfacing System, 4,000 with respect to the PINNACLE® Acetabular Cup System, 440 with respect to RISPERDAL®, 6,700 with respect to pelvic meshes, 30 with respect to DURAGESIC®/fentanyl patches and 100 with respect to TOPAMAX®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR<sup>TM</sup> XL Acetabular System and DePuy ASR<sup>TM</sup> 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 first quarter of 2013, the Company increased its accruals for the DePuy ASR<sup>TM</sup> Hip recall program and related product liability after the Company completed an analysis of additional information. 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

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

#### PATENT INFRINGEMENT

Certain subsidiaries of Johnson & Johnson 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 (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that several features of 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 in March 2013, the Court ruled that EES's HARMONIC Scalpel infringed on Tyco's patents and ordered EES to pay damages of approximately \$176 million. The Company believes EES has strong arguments supporting its appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the case.

In 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 appealed the judgment, and in April 2013, the United States Court of Appeals for the Federal Circuit reversed

the judgment and held that Cordis did not infringe Plaintiff's patent as a matter of law. Plaintiff has filed a petition with the Court of Appeals to reconsider the decision.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, 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. The parties are awaiting a ruling on claim construction. Roche is seeking monetary damages and injunctive relief.

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

In September 2011, LifeScan filed a lawsuit against Shasta Technologies, Instacare Corp and Conductive Technologies (collectively, Shasta) in the United States District Court for the Northern District of Northern California for patent infringement for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. In November, 2012, Shasta got a limited approval from the United States Food and Drug Administration for its strips. In December 2012, LifeScan filed an additional lawsuit alleging violation of the Lanham Act based on Shasta's packaging. LifeScan moved for, and the District Court granted, a preliminary injunction prohibiting Shasta from marketing their strips. Litigation regarding the preliminary injunction and the underlying merits of the claims is continuing.

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.

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 March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's past sales of the CYPHER® and CYPHER SELECT® Stents willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorney's fees.

#### Pharmaceutical

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor, Inc. (Centocor) (now Janssen Biotech, Inc. (JBI)) in the United States District Court for the District of Massachusetts alleging that SIMPONI® infringes Abbott's U.S. Patent Nos. 7,223,394 and 7,541,031 (the Salfeld patents). Abbott is seeking monetary damages and injunctive relief. 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. Discovery is ongoing. Oral argument on summary judgment motions is scheduled for July 2013.

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 JBI, invalidating Abbott's patent claims. In March 2013, the Court denied Abbott's post-trial motions challenging the outcome and granted JBI's motion on the appeal of the interference decision. Abbott filed its notice of appeal in April 2013. 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. A trial is scheduled for December 2013 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.

## ORTHO TRI-CYCLEN® LO

A number of generic companies have filed ANDAs seeking approval to market generic versions of ORTHO TRI-CYCLEN® LO. Janssen Pharmaceuticals, Inc. (JPI) filed patent infringement lawsuits against these generic companies seeking an Order enjoining them from marketing their generic versions of ORTHO TRI-CYCLEN® LO prior to the expiration of JPI's patent relating to ORTHO TRI-CYCLEN® LO (the OTCLO patent). In 2012, JPI entered into settlement agreements with certain of these generic companies. The two remaining cases were concluded in the fiscal first quarter of 2013, as described below.

In January 2010, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (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 upholding the validity of the patent. 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 appealed the decision to the Court of Appeals for the Federal Circuit. Oral argument was heard in February 2013. In March 2013, JPI and Lupin entered into a settlement agreement pursuant to which Lupin was granted a license under the OTCLO patent to market its generic version of ORTHO TRI-CYCLEN® LO starting December 31, 2015 (or earlier under certain circumstances).

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 February 2013, JPI and Sun entered into a settlement agreement pursuant to which Sun was granted a license under the OTCLO patent to market its generic version of ORTHO TRI-CYCLEN® LO starting December 31, 2015 (or earlier under certain circumstances), if and when they obtain FDA approval.

#### 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

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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. 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. These cases have 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 January 2013, the Court permitted these three additional patents to be added to the consolidated action. In March 2013, Janssen filed a patent infringement lawsuit against Hetero in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408.

In 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 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<sup>TM</sup> and EVICEL<sup>TM</sup> products, or alternatively, transfer of the patents to the State.

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 (SDNY) by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva) and Amneal Pharmaceuticals, LLC (Amneal). In February 2013, Noramco appeared on behalf of Noramco customers Watson Laboratories, Inc. - Florida and Andrx Labs, LLC (collectively, Watson/Andrx) in a similar lawsuit filed by Purdue in the SDNY. The lawsuits are in response to the defendants' respective 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, Amneal and Watson/Andrx. Although Noramco did not participate, in November 2012, a trial in a lawsuit brought by Purdue against another Noramco customer, Actavis Elizabeth, LLC (Actavis), took place. Because the active ingredient at issue in the Actavis lawsuit is the same as the active ingredient at issue in the above lawsuits, the District Court's decision in the Actavis case may affect those lawsuits. In April 2013, Actavis and Watson/Andrx entered into confidential settlements with Purdue.

In May 2012, Hospira UK Limited filed a revocation proceeding against The Kennedy Institute of Rheumatology (Kennedy) against European Patent (UK) Nos. 0914157, 1593393 and 1941904, which relate to REMICADE®. Janssen Biotech, Inc. licenses the patents from Kennedy. Hospira is also seeking a declaration of non-infringement of those patents. Trial is scheduled to begin in July 2013. In addition, in March 2013, Hospira Healthcare Corporation filed an impeachment lawsuit against Kennedy against Canadian Patent No. 2,261,630, which relates to REMICADE®. Janssen Inc. licenses the '630 patent from Kennedy.

In August 2012, Dr. James M. Swanson filed a lawsuit against ALZA Corporation (ALZA) in the Northern District of California seeking to be added as an inventor on three ALZA-owned patents relating to CONCERTA®. Alternatively, Dr. Swanson has alleged, among other things, that the patents-in-suit are invalid and/or unenforceable as a result of ALZA's alleged omission of Dr. Swanson as a named inventor on the patents. Dr. Swanson is seeking damages and an award of unjust enrichment. ALZA filed a motion to dismiss Dr. Swanson's claims. The Court granted the motion in part, and denied it in part. Discovery in the case is ongoing.

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## **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 AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts.

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

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including Kentucky, which had been set for trial in January 2012 and Kansas which had been set for trial in March 2013. Louisiana and Mississippi are set for trial in October 2013, Illinois is set for trial in May 2014, and Alaska is set for trial in July 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 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

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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.

In 2012, the Company also 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 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 not accrued an amount to cover the claimed amounts but rather an amount at least 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 (as discussed below).

In addition, the Attorneys General of multiple states, including Alaska, Arkansas, Louisiana, Massachusetts, Mississippi, Montana, New Mexico, 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. In January 2013, the same court awarded attorney fees of approximately \$180 million. This judgment will also be appealed.

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. In August 2012, an interlocutory appellate court affirmed the judgment. In January 2013, the Louisiana Supreme Court accepted Johnson & Johnson and JPI's request for appeal. Oral argument on the appeal took place in March 2013 and the parties are awaiting a decision.

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 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

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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. Oral argument on the appeal took place before the South Carolina Supreme Court in March 2013 and the parties are awaiting a decision.

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 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 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.

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

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to

an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In December 2012, Oregon filed a Notice of Appeal in the Court of Appeals of the State of Oregon.

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

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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 submitted a workplan to the FDA for remediation of the Lancaster and Las Piedras facilities, and that plan was approved by the FDA in October 2012. 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 declined to intervene. In January 2013, the Court granted Cordis's motion to dismiss the claims against Cordis, with prejudice. Plaintiff has appealed.

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 (EC) announced that it opened an investigation concerning an agreement between Janssen-Cilag B.V. (Janssen-Cilag) and Sandoz B.V. relating to the supply of fentanyl patches in The Netherlands and whether the agreement infringes European competition law. In January 2013, the EC issued a Statement of Objections setting out facts regarding a potential violation of EU antitrust laws. Janssen-Cilag has submitted its response to the Statement of Objections.

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

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

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc. (DePuy Synthes)), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice for the production of materials relating to the ASR<sup>TM</sup> XL Hip device. The government has since made additional informal requests for the production of documents as to the device. The government is investigating whether any person or entity submitted or caused to be submitted false claims or false statements affecting federal health care programs in connection with the marketing and use of the ASR<sup>TM</sup> XL Hip device. DePuy Orthopaedics, Inc., DePuy Synthes, and Johnson & Johnson Services, Inc. have voluntarily produced documents in response to the government's informal requests and are fully cooperating with the government's civil investigation. In addition, the Company has received Civil Investigative Demands from the Attorneys General of several states. These demands seek documents and information relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip replacement devices. The Company is responding to these demands.

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In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson subsidiaries. Johnson & Johnson and its subsidiaries have since entered into a tolling agreement with the 42 states participating in the multi-state investigation and are in the process of responding to Civil Investigative Demands served by certain of the participating states.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of UVADEX® (methoxsalen) and the UVAR XTS® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos, and have taken appropriate steps to retain potentially relevant documents and will cooperate with the United States Attorney's Office's investigation with respect to such activity.

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

## **GENERAL LITIGATION**

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as In re Blood Reagent Antitrust Litigation. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In October 2012, the United States Court of Appeals for the Third Circuit granted OCD's petition for interlocutory review of the class certification ruling. That appeal is pending.

In September 2010, a shareholder, Ronald Monk, filed a lawsuit in the United States District Court for the District of New Jersey seeking class certification and alleging that Johnson & Johnson and certain individuals, including executive officers and employees of Johnson & Johnson, failed to disclose that a number of manufacturing facilities failed to maintain current good manufacturing practices, and that as a result, the price of the Company's stock declined significantly. Plaintiff seeks to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In December 2011, a motion by Johnson & Johnson to dismiss was granted in part and denied in part. 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. Following mediation, the parties have reached an agreement in principle to settle the case.

In April 2011, OMJ Pharmaceuticals, Inc. (OMJ PR) filed a lawsuit against the United States in United States District Court for the District of Puerto Rico alleging overpayment of federal income taxes for the tax years ended November 30, 1999 and November 30, 2000. If OMJ PR loses this lawsuit, it may face liability for subsequent tax years. OMJ PR alleges that the Internal Revenue Service erroneously calculated OMJ PR's tax credits under Section 936 of the Tax Code. OMJ PR filed a motion for summary judgment, and the United States filed a cross motion for summary

judgment. In October 2012, the Court granted a motion by the United States for summary judgment and denied a motion by OMJ PR for summary judgment. OMJ PR has appealed 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. In February 2013, the arbitration panel determined that the Supply Price should be modified in favor of Tanabe. During the fiscal first quarter of 2013, the Company accrued an amount to cover the estimated impact of the arbitration decision.

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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 facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing is scheduled for October 2013.

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 is named as a nominal defendant. These actions were consolidated in August 2010 into 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.

Collectively, these shareholder derivative actions 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 the defendants 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. The Board of Directors of Johnson & Johnson 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.

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 current directors of Johnson & Johnson 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. The state lawsuits were consolidated in November 2011 into In re J&J Shareholder Derivative Litigation. In May 2012, the Court granted a motion by Johnson & Johnson to stay the state lawsuits pending resolution of In re J&J FCPA Derivative Shareholder Litigation.

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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 (the Settlement) to permanently resolve all of the actions in their entirety. In October 2012, the Settlement was approved by the United States District Court for the District of New Jersey. In November 2012, a notice of appeal was filed in the United States Court of Appeals for the Third Circuit by a shareholder who objected to the approval of the Settlement in the District Court on the grounds that the lawsuit and the Settlement did not provide any benefit to the Company, and that plaintiffs' counsel had requested an excessive fee award.

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 current directors and one former director of Johnson & Johnson as defendants and Johnson & Johnson as the nominal defendant. These lawsuits allege that the defendants breached their fiduciary duties in their decisions with respect to the compensation of the Chief Executive Officer during the period from 2008 through 2011, and that the defendants made misleading statements in the Company's annual proxy statements. Both of these lawsuits have been voluntarily dismissed without prejudice, but a similar lawsuit, The George Leon Family Trust v. Coleman, was refiled in July 2012. That lawsuit seeks a variety of relief, including monetary damages, injunctive relief, and corporate governance reforms. The Settlement does not resolve these potential claims. The Board of Directors' evaluation of these allegations is ongoing.

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

#### **RESULTS OF OPERATIONS**

#### **Analysis of Consolidated Sales**

For the fiscal first quarter of 2013, worldwide sales were \$17.5 billion, a total increase of 8.5%, including operational growth of 9.8% as compared to 2012 fiscal first quarter sales of \$16.1 billion. Currency fluctuations had a negative impact of 1.3% for the fiscal first quarter of 2013. The acquisition of Synthes, Inc., net of the related trauma business divestiture, increased both total sales growth and operational growth by 5.7%. Worldwide operational growth was impacted by 1.3% due to a positive adjustment to previous estimates for managed Medicaid rebates under the Affordable Care Act, primarily related to new data received from the states.

Sales by U.S. companies were \$8.0 billion in the fiscal first quarter of 2013, which represented an increase of 11.2% as compared to the prior year. Sales by international companies were \$9.5 billion, which represented a total increase of 6.3%, including an operational increase of 8.7%, and a negative currency impact of 2.4% as compared to the fiscal first quarter sales of 2012.

Sales by companies in Europe achieved growth of 6.8%, including operational growth of 6.2%, and a positive currency impact of 0.6%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 4.0%, including operational growth of 9.1%, and a negative currency impact of 5.1%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 6.8%, including operational growth of 11.8%, and a negative currency impact of 5.0%.

#### 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 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 full year impact of the excise tax is estimated to be between \$200 - \$300 million and will ultimately be recorded in cost of products sold within the statement of earnings.

#### ANALYSIS OF SALES BY BUSINESS SEGMENTS

## Consumer

Consumer segment sales in the fiscal first quarter of 2013 were \$3.7 billion, an increase of 2.2% as compared to the same period a year ago, including operational growth of 3.3% and a negative currency impact of 1.1%. U.S. Consumer segment sales increased by 2.4%. International Consumer segment sales increased by 2.1%, including operational growth of 3.8% and a negative currency impact of 1.7%.

## Major Consumer Franchise Sales — Fiscal First Quarters Ended

(Dollars in Millions)	March 31, April 1, 2012	Total		Operations		Currency		
	2013	April 1, 2012	Change		Change		Change	
OTC Pharm. & Nutritionals	\$1,183	\$1,104	7.2	%	7.6	%	(0.4)	)%
Skin Care	902	907	(0.6)	)	(0.2)	)	(0.4)	)

Baby Care	564	540	4.4	7.0	(2.6	)
Oral Care	403	387	4.1	5.1	(1.0	)
Women's Health	401	409	(2.0	) 0.8	(2.8	)
Wound Care/Other	222	248	(10.5	) (10.0	) (0.5	)
Total Consumer Sales	\$3,675	\$3,595	2.2	% 3.3	% (1.1	)%

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The OTC Pharmaceuticals and Nutritionals franchise achieved operational growth of 7.6% as compared to the prior year fiscal first quarter. The strong sales results in the U.S. were driven by analgesics and upper respiratory products, due to progress in returning a reliable supply of products to the marketplace and sales of cough and cold products. Strong growth of analgesics drove results outside the U.S.

The Skin Care franchise experienced an operational decline of 0.2% as compared to the prior year. Strong results for NEUTROGENA® were offset by the impact of divestitures, the initial stocking related to new product launches last year, and competitive pressures.

The Baby Care franchise achieved operational growth of 7.0% as compared to the prior year, primarily due to operational growth of 7.7% outside the U.S.

The Oral Care franchise achieved operational growth of 5.1% as compared to the prior year, primarily attributable to strong sales of LISTERINE®, due to the continued success of new product launches. This growth was partially offset by the impact of the divestiture of the manual toothbrush product line in the U.S.

The Women's Health franchise achieved operational growth of 0.8% as compared to the prior year. Strong growth in liners was partially offset by lower sales of KY products.

The Wound Care/Other franchise experienced an operational decline of 10.0% as compared to the prior year, due to competitive pressures and the impact of divestitures.

#### Pharmaceutical

Pharmaceutical segment sales in the fiscal first quarter of 2013 were \$6.8 billion, a total increase of 10.4% as compared to the same period a year ago with an operational increase of 11.4% and a negative currency impact of 1.0%. U.S. Pharmaceutical sales increased by 14.7% as compared to the same period a year ago. International Pharmaceutical sales increased by 6.1%, including operational growth of 8.1% and a negative currency impact of 2.0%. Pharmaceutical operational growth was impacted by 3.3% due to a positive adjustment to previous estimates for managed Medicaid rebates.

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Major Pharmaceutical Therapeutic Area Sales — Fiscal First Quarters Ende
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(D. 11 M.11)	March 31,	April 1,	Total		Operati	ons	Curre	ncy
(Dollars in Millions)	2013	2012	Change		Change	;	Chang	ge
Total Immunology	\$2,204	\$1,895	16.3		16.8	%	(0.5	)%
REMICADE®	1,600	1,521	5.2		5.5		(0.3)	)
SIMPONI®	237	116	**		**		(2.0	)
STELARA®	346	221	56.6		57.0		(0.4)	)
Other Immunology	21	37	(43.2	)	(42.9	)	(0.3)	)
Total Infectious Diseases	815	755	7.9		8.6		(0.7)	)
INCIVO®	162	132	22.7		24.9		(2.2	)
INTELENCE®	89	80	11.3		11.6		(0.3)	)
PREZISTA®	367	324	13.3		13.5		(0.2)	)
Other Infectious Diseases	197	219	(10.0	)	(9.3	)	(0.7)	)
Total Neuroscience	1,744	1,647	5.9		7.7		(1.8	)
CONCERTA®/methylphenidate	256	308	(16.9	)	(16.4	)	(0.5)	)
INVEGA®	132	121	9.1		11.1		(2.0)	)
INVEGA® SUSTENNA®/XEPLION®	284	161	76.4		76.1		0.3	
RISPERDAL® CONSTA®	335	361	(7.2	)	(6.0	)	(1.2	)
Other Neuroscience	737	696	5.9		8.9		(3.0)	)
Total Oncology	794	596	33.2		35.0		(1.8	)
VELCADE®	353	353	0.0		2.5		(2.5	)
ZYTIGA®	344	200	72.0		72.2		(0.2)	)
Other Oncology	97	43	**		**		(4.0)	)
Total Other	1,211	1,240	(2.3	)	(1.7	)	(0.6)	)
ACIPHEX®/PARIET®	152	222	(31.5	)	(31.2	)	(0.3)	)
PROCRIT®/EPREX®	378	376	0.5		0.5		0.0	
XARELTO®	158	27	**		**			
Other	523	615	(15.0	)	(13.9	)	(1.1)	)
Total Pharmaceutical Sales	\$6,768	\$6,133	10.4	%	11.4	%	(1.0	)%

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

Immunology products achieved operational sales growth of 16.8% as compared to the same period a year ago. The increased sales of STELARA® (ustekinumab), SIMPONI® (golimumab) and REMICADE® (infliximab) were primarily due to market growth. Immunology operational growth was impacted by approximately 5.0% due to a positive adjustment to previous estimates for managed Medicaid rebates partially offset by a decrease in U.S. export sales due to customer inventory planning.

Infectious disease products achieved operational sales growth of 8.6% as compared to the same period a year ago. Major contributors were INCIVO® (telaprevir), due to the success of the continued roll-out, primarily in Latin America,

the continued momentum and market share growth of PREZISTA® (darunavir) and sales of EDURANT® (rilpivirine).

Neuroscience products achieved operational sales growth of 7.7% as compared to the same period a year ago. Strong sales of INVEGA® SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA® (paliperidone palmitate) were partially offset by a decline in RISPERDAL® CONSTA®(risperidone) as well as lower sales of CONCERTA®/methylphenidate and DURAGESIC®/Fentanyl Transdermal (fentanyl transdermal system) due to

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

continued generic competition. Additionally, Other Neuroscience operational growth was impacted by a positive adjustment to previous estimates for managed Medicaid rebates. The Company's 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 received approval from the U.S. Food and Drug Administration (FDA) to manufacture and market a generic version of

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CONCERTA®. Another generic version of CONCERTA® was launched on December 31, 2012 resulting in a further reduction in CONCERTA® sales.

Oncology products achieved strong operational sales growth of 35.0% as compared to the same period a year ago. This growth was primarily due to sales of ZYTIGA®(abiraterone acetate) and VELCADE® (bortezomib) although timing of tender business negatively impacted the growth rate of VELCADE® in the first quarter of 2013. Additionally, Other Oncology increased, primarily due to DOXIL®(doxorubicin HCI liposome injection)/CAELYX®(pegylated liposomal doxorubicin hydrochloride). In the U.S., Janssen Products, LP is releasing additional DOXIL® produced by an alternate manufacturing approach under the regulatory discretion of the U.S. FDA. The longer term solution for DOXIL®/CAELYX® production, involving transitioning manufacturing to additional suppliers, continues to meet expected milestones.

In the fiscal first quarter of 2013, Other Pharmaceutical sales experienced an operational decline of 1.7% as compared to the prior year fiscal first quarter. Lower sales of EPREX® (Epoetin alfa) and PARIET® (rabeprazole sodium) were primarily due to generic competition. PROCRIT® (Epoetin alfa) sales were impacted by a positive adjustment to previous estimates for managed Medicaid rebates partially offset by a decline in the market. Additionally, strong sales of XARELTO® (rivaroxaban) partially offset the decline in Other Pharmaceuticals.

## Medical Devices and Diagnostics

Medical Devices and Diagnostics segment sales in the fiscal first quarter of 2013 were \$7.1 billion, an increase of 10.2% as compared to the same period a year ago, including operational growth of 11.9% and a negative currency impact of 1.7%. U.S. Medical Devices and Diagnostics sales increased 11.4%. The international Medical Devices and Diagnostics sales increase of 9.1% included operational growth of 12.2% and a negative currency impact of 3.1%. The acquisition of Synthes, Inc., net of the related trauma business divestiture, increased operational growth for the total Medical Devices and Diagnostics segment by 14.3%.

Major Medical Devices and Diagnostics Franchise Sales — Fiscal First Quarters Ended

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(Dellars in Millians)	March 31, April 1,		Total	Operations Currency			
(Dollars in Millions)	2013	3 2012		Change		Change	
Orthopaedics	\$2,385	\$1,493	59.7 %	60.7	%	(1.0)	)%
Surgical Care	1,508	1,625	(7.2)	(5.4	)	(1.8	)
Vision Care	740	757	(2.2)	1.6		(3.8)	)
Specialty Surgery	627	628	(0.2)	1.0		(1.2)	)
Diabetes Care	600	670	(10.4)	(9.8	)	(0.6)	)
Cardiovascular Care	513	482	6.4	8.5		(2.1	)
Diagnostics	477	512	(6.8)	(4.9	)	(1.9	)
Infection Prevention/Other	212	244	(13.1)	(10.5	)	(2.6	)
Total Medical Devices and Diagnostics Sales	\$7,062	\$6,411	10.2 %	11.9	%	(1.7	)%

The Orthopaedics franchise achieved operational sales growth of 60.7% as compared to the prior year fiscal first quarter. Growth was primarily due to sales of newly acquired products from Synthes, Inc. and Mitek sports medicine products. 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 61.4%.

The Surgical Care franchise experienced an operational sales decline of 5.4% as compared to the prior year fiscal first quarter. Competitive pressures and business exits negatively impacted growth.

The Vision Care franchise achieved operational sales growth of 1.6% as compared to the prior year fiscal first quarter. The growth was driven by ACUVUE® TruEye, ™1-DAY ACUVUE® MOIST® for Astigmatism and 1-DAY ACUVUE® MOIST®, partially offset by lower sales of reusable lenses.

The Specialty Surgery franchise achieved operational sales growth of 1.0% as compared to the prior year fiscal first quarter. Strong international sales of energy products and solid results for biosurgical products were substantially offset by lower sales of Mentor aesthetic products.

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The Diabetes Care franchise experienced an operational sales decline of 9.8% as compared to the prior year fiscal first quarter. Sales declined primarily due to the impact of the initial stocking related to new product launches last year, lower price and competitive pressures.

The Cardiovascular Care franchise achieved operational sales growth of 8.5% as compared to the prior year fiscal first quarter. Growth was primarily due to sales of Biosense Webster and endovascular products.

The Diagnostics franchise experienced an operational sales decline of 4.9% as compared to the prior year. The decline was primarily due to the divestitures of RhoGAM® and the Therakos business partially offset by U.S. growth in clinical labs and donor screening. In January 2013, the Company announced it is exploring strategic alternatives for the Ortho-Clinical Diagnostics business, including a possible divestiture.

The Infection Prevention/Other franchise experienced an operational sales decline of 10.5% as compared to the prior year fiscal first quarter was primarily due to competitive pressures.

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

Consolidated earnings before provision for taxes on income for the fiscal first quarter of 2013 decreased to \$4.3 billion as compared to \$5.0 billion in the fiscal first quarter of 2012, a decrease of 15.5%. The fiscal first quarter of 2013 was unfavorably impacted by \$0.7 billion versus the same period a year ago primarily due to higher litigation expenses of \$0.5 billion, higher costs of \$0.4 billion related to the acquisition of Synthes, Inc., a \$0.1 billion charge related to the devaluation of the Venezuelan currency and an in-process research and development charge of \$0.1 billion. This was partially offset by \$0.7 billion primarily due to increased sales and positive mix of \$0.4 billion and cost containment initiatives of \$0.3 billion. Additionally, the fiscal first quarter of 2012 included higher gains on divestitures of \$0.3 billion, recorded in other income, as compared to the fiscal first quarter of 2013.

#### Cost of Products Sold

Consolidated costs of products sold for the fiscal first quarter of 2013 increased to 31.7% from 30.4% of sales as compared to the same period a year ago. Increased costs of \$0.3 billion recorded in costs of products sold was primarily the result of an inventory step-up charge and incremental amortization expense related to Synthes. This was partially offset by positive mix and cost reduction efforts. Amortization expense for the fiscal first quarters of 2013 and 2012 was \$335 million and \$205 million, respectively. The increase in amortization expense was primarily related to Synthes.

## Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the fiscal first quarter of 2013 decreased to 29.8% from 31.1% of sales as compared to the same period a year ago. The decrease was primarily due to timing of expenditures and cost containment initiatives in the Pharmaceutical and Consumer segments.

## Research and Development Expense

Research and 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 and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities for the fiscal first quarter of 2013 were 10.2% of sales. This was flat compared to the fiscal first quarter of 2012.

In-Process Research and Development (IPR&D)

During the fiscal first quarter of 2013, the Company recorded a charge in the amount of \$0.1 billion for the write-down of the IPR&D for Acclarent related to the discontinuation of development projects.

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## Interest (Income) Expense

Interest income was relatively flat as compared to the same period a year ago. The ending balance of cash, cash equivalents and marketable securities, was \$21.7 billion at the end of the fiscal first quarter of 2013. This is a decrease of \$12.1 billion from the same period a year ago. The decline in the average cash balance was due to the Synthes acquisition partially offset by cash generated from operating activities.

Interest expense decreased in the fiscal first quarter of 2013 as compared to the same period a year ago due to a lower average debt balance. At the end of the fiscal first quarter of 2013, the Company's debt position was \$15.9 billion compared to \$19.4 billion from the same period a year ago. The decrease in debt was primarily due to a reduction in commercial paper.

## 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, acquisition related costs, litigation settlements, as well as royalty income. The change in other (income) expense, net for the fiscal first quarter of 2013, was unfavorable by \$1.1 billion as compared to the same period a year ago. The fiscal first quarter of 2013 included higher litigation expenses of \$0.5 billion, higher costs of \$0.2 billion related to the Synthes acquisition and a \$0.1 billion charge related to the devaluation of the Venezuelan currency. Additionally, the fiscal first quarter of 2012 included higher gains of \$0.3 billion related to divestitures.

#### SEGMENT PRE-TAX PROFIT

#### Consumer Segment

Pre-tax profit for the Consumer segment as a percent to sales in the fiscal first quarter of 2013 was 14.9% versus 12.9% for the same period a year ago. The favorable pre-tax profit was primarily due to a gain of \$55 million on the sale of intangible and other assets as well as cost containment initiatives realized in selling, marketing and administrative expenses partially offset by higher remediation costs in the McNeil OTC business.

## Pharmaceutical Segment

Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal first quarter of 2013 was 35.7% versus 42.2% for the same period a year ago. The unfavorable pre-tax profit was primarily due higher litigation expense of \$0.2 billion and a gain of \$0.3 billion related to the divestiture of BYSTOLIC® recorded in the fiscal first quarter of 2012. This was partially offset by a positive adjustment of approximately \$0.2 billion to previous estimates for managed Medicaid rebates and cost containment initiatives.

#### Medical Devices and Diagnostics Segment

Pre-tax profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal first quarter of 2013 was 21.5% versus 32.5% for the same period a year ago. Pre-tax profit was unfavorably impacted by higher costs of \$0.3 billion for litigation expense, \$0.2 billion for integration costs and amortization of the inventory step-up associated with the Synthes acquisition and \$0.1 billion attributed to the write-down of intangible assets and the medical device excise tax.

#### Provision for Taxes on Income

The worldwide effective income tax rates for the fiscal first quarter of 2013 and 2012 were 17.9% and 22.5%, respectively. The lower effective tax rate in 2013 as compared to 2012 was primarily due to the inclusion of the benefit from the U.S. Research & Development (R&D) tax credit, the Controlled Foreign Corporation (CFC) look-through provisions from the 2012 fiscal year and increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions. The R&D tax credit and the CFC look-through provisions were enacted into law in January 2013 and were retroactive to January 1, 2012. The entire 2012 R&D tax credit and the CFC look-through provisions were reflected in the fiscal first quarter of 2013 and decreased the tax rate by 2.4 points. Additionally, the quarterly impact of the 2013 R&D tax credit and the CFC look-through provisions is reflected in the 2013 fiscal first quarter financial results.

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As of March 31, 2013, the Company had approximately \$2.8 billion of liabilities from unrecognized tax benefits. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months, including the U.S. Internal Revenue Service audit related to tax years 2006-2009. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

See Note 8 to the Consolidated Financial Statements in the Annual Report on Form 10-K for the fiscal year ended December 30, 2012 for more detailed information regarding unrecognized tax benefits.

#### LIQUIDITY AND CAPITAL RESOURCES

#### Cash Flows

Cash and cash equivalents were \$14.9 billion at the end of both the fiscal first quarter of 2013 and the fiscal year end of 2012. The primary sources of cash were approximately \$2.3 billion net cash generated from operating activities offset by \$1.4 billion used by investing activities and \$0.8 billion used by financing activities.

Cash flow from operations of \$2.3 billion was the result of \$3.5 billion of net earnings and \$1.8 billion of non-cash charges primarily related to depreciation and amortization, stock-based compensation, the Venezuela currency devaluation, asset write-downs and deferred tax provision reduced by \$3.0 billion related to changes in assets and liabilities, net of effects from acquisitions.

Investing activities use of \$1.4 billion of cash was primarily for net purchases of investments in marketable securities of \$0.8 billion, additions to property, plant and equipment of \$0.6 billion and acquisitions, net of cash acquired, of \$0.2 billion partially offset by \$0.1 billion of proceeds from the disposal of assets.

Financing activities used \$0.8 billion of cash primarily for dividends to shareholders of \$1.7 billion and net retirement of short and long-term debt of \$0.2 billion partially offset by \$1.1 billion of net proceeds from stock options exercised/excess tax benefits.

In the fiscal first quarter of 2013, 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 January 2, 2013, the Board of Directors declared a regular quarterly cash dividend of \$0.61 per share, payable on March 12, 2013, to shareholders of record as of February 26, 2013.

On April 25, 2013, the Board of Directors declared a regular cash dividend of \$0.66 per share, payable on June 11, 2013 to shareholders of record as of May 28, 2013. The Company expects to continue the practice of paying regular quarterly cash dividends.

#### Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy,

Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately \$2.2 billion as of March 31, 2013 and approximately \$2.1 billion as of December 30, 2012. Approximately \$1.3 billion as of March 31, 2013 and approximately \$1.2 billion as of December 30, 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

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customers was approximately \$0.9 billion at March 31, 2013 and December 30, 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 Pronouncements** 

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

#### **Economic and Market Factors**

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concern about the rising cost of health care. The Company has a long-standing policy of pricing products responsibly. For the period 2002 through 2012 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.

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#### 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 adverse litigation or government action; 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; complex global supply chains with increasing regulatory requirements; and product efficacy or safety concerns resulting in product recalls or regulatory action.

The Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2012 contains, as Exhibit 99, a discussion of additional factors that could cause actual results to differ from expectations. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

## Item 3 — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in its Annual Report on Form 10-K for the fiscal year ended December 30, 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, Chairman, Board of Directors and Chief Executive Officer, and Dominic J. Caruso, Vice President, Finance and Chief Financial Officer, reviewed and

participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

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

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Part II — OTHER INFORMATION

## Item 1 — LEGAL PROCEEDINGS

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

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

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

The following table provides information with respect to Common Stock purchases by the Company during the fiscal first quarter of 2013. Pursuant to the accelerated stock repurchase agreements in connection with the acquisition of Synthes, Inc., the Company has not made any purchases of Common Stock on the open market during the fiscal first quarter. The repurchases below represent the stock-for-stock option exercises that settled in the fiscal first quarter.

Period	Total Number of Shares Purchased	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Naximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
December 31, 2012 through January 27, 2013	115,091	71.47	-	-
January 28, 2013 through February 24, 2013 February 25, 2013 through March 31, 2013	175,329	74.18	-	-
	114,916	76.31	-	-
Total	405,336			

## Item 6 — EXHIBITS

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

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

Exhibit 101 XBRL (Extensible Business Reporting Language) The following materials from Johnson & Johnson's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in Extensive Business Reporting Language (XBRL), (i) consolidated balance sheets, (ii) consolidated statements of earnings, (iii) consolidated statements of comprehensive income (iv) consolidated statements of cash flows, and (v) the notes to the consolidated financial statements.

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## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

JOHNSON & JOHNSON

(Registrant)

Date: May 3, 2013 By /s/ D. J. CARUSO

D. J. CARUSO

Vice President, Finance; Chief Financial Officer (Principal

Financial Officer)

Date: May 3, 2013 By /s/ S. J. COSGROVE

S. J. COSGROVE

Controller (Principal Accounting Officer)