

JOHNSON & JOHNSON  
Form 10-Q  
May 01, 2015

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 29, 2015  
or

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

Commission file number 1-3215

(Exact name of registrant as specified in its charter)

NEW JERSEY

22-1024240

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification No.)

One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933

(Address of principal executive offices)

Registrant's telephone number, including area code (732) 524-0400

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

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

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

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

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

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

On April 24, 2015, 2,773,045,351 shares of Common Stock, \$1.00 par value, were outstanding.

JOHNSON & JOHNSON AND SUBSIDIARIES  
TABLE OF CONTENTS

	Page No.
<u>Part I — Financial Information</u>	<u>3</u>
<u>Item 1. Financial Statements (unaudited)</u>	<u>3</u>
<u>Consolidated Balance Sheets — March 29, 2015 and December 28, 2014</u>	<u>3</u>
<u>Consolidated Statements of Earnings for the Fiscal First Quarters Ended March 29, 2015 and March 30, 2014</u>	<u>4</u>
<u>Consolidated Statements of Comprehensive Income for the Fiscal First Quarters Ended March 29, 2015 and March 30, 2014</u>	<u>5</u>
<u>Consolidated Statements of Cash Flows for the Fiscal Three Months Ended March 29, 2015 and March 30, 2014</u>	<u>6</u>
<u>Notes to Consolidated Financial Statements</u>	<u>7</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>28</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>35</u>
<u>Item 4. Controls and Procedures</u>	<u>35</u>
<u>Part II — Other Information</u>	<u>36</u>
<u>Item 1 - Legal Proceedings</u>	<u>36</u>
<u>Item 2 - Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>36</u>
<u>Item 6 - Exhibits</u>	<u>37</u>
<u>Signatures</u>	<u>38</u>
EX-10.1	
EX-31.1	
EX-32.1	
EX-101 INSTANCE DOCUMENT	
EX-101 SCHEMA DOCUMENT	
EX-101 CALCULATION LINKBASE DOCUMENT	
EX-101 LABELS LINKBASE DOCUMENT	
EX-101 PRESENTATION LINKBASE DOCUMENT	
EX-101 DEFINITION LINKBASE DOCUMENT	

Table of Contents

## Part I — FINANCIAL INFORMATION

## Item 1 — FINANCIAL STATEMENTS

## JOHNSON &amp; JOHNSON AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

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

	March 29, 2015	December 28, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$11,988	14,523
Marketable securities	19,331	18,566
Accounts receivable, trade, less allowances for doubtful accounts \$237 (2014, \$275)	11,533	10,985
Inventories (Note 2)	8,085	8,184
Deferred taxes on income	3,524	3,567
Prepaid expenses and other	3,731	3,486
Total current assets	58,192	59,311
Property, plant and equipment at cost	35,403	36,685
Less: accumulated depreciation	(20,039)	(20,559)
Property, plant and equipment, net	15,364	16,126
Intangible assets, net (Note 3)	27,025	27,222
Goodwill (Note 3)	21,345	21,832
Deferred taxes on income	3,059	3,396
Other assets	3,605	3,232
Total assets	\$128,590	131,119
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Loans and notes payable	\$4,045	3,638
Accounts payable	6,719	7,633
Accrued liabilities	5,575	6,553
Accrued rebates, returns and promotions	4,697	4,010
Accrued compensation and employee related obligations	1,557	2,751
Accrued taxes on income	1,243	500
Total current liabilities	23,836	25,085
Long-term debt (Note 4)	14,938	15,122
Deferred taxes on income	3,584	3,154
Employee related obligations	9,750	9,972
Other liabilities	8,604	8,034
Total liabilities	60,712	61,367
Shareholders' equity:		
Common stock — par value \$1.00 per share (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	\$3,120	3,120
Accumulated other comprehensive income (loss) (Note 7)	(13,300)	(10,722)
Retained earnings	98,656	97,245
Less: common stock held in treasury, at cost (343,969,000 and 336,620,000 shares)	20,598	19,891

Edgar Filing: JOHNSON & JOHNSON - Form 10-Q

Total shareholders' equity	67,878	69,752
Total liabilities and shareholders' equity	\$128,590	131,119
See Notes to Consolidated Financial Statements		

3

---

Table of ContentsJOHNSON & JOHNSON AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF EARNINGS

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

	Fiscal First Quarters Ended				Percent to Sales	Percent to Sales
	March 29, 2015	Percent to Sales		March 30, 2014		
Sales to customers (Note 9)	\$17,374	100.0	%	\$18,115	100.0	%
Cost of products sold	5,282	30.4		5,455	30.1	
Gross profit	12,092	69.6		12,660	69.9	
Selling, marketing and administrative expenses	4,847	27.9		5,183	28.6	
Research and development expense	1,899	10.9		1,831	10.1	
In-process research and development	—	—		18	0.1	
Interest income	(19	) (0.1	)	(18	) (0.1	)
Interest expense, net of portion capitalized	138	0.8		136	0.8	
Other (income) expense, net	(348	) (2.0	)	86	0.5	
Earnings before provision for taxes on income	5,575	32.1		5,424	29.9	
Provision for taxes on income (Note 5)	1,255	7.2		697	3.8	
NET EARNINGS	\$4,320	24.9	%	\$4,727	26.1	%
NET EARNINGS PER SHARE (Note 8)						
Basic	\$1.55			\$1.67		
Diluted	\$1.53			\$1.64		
CASH DIVIDENDS PER SHARE	\$0.70			\$0.66		
AVG. SHARES OUTSTANDING						
Basic	2,782.6			2,826.8		
Diluted	2,826.0			2,874.7		
See Notes to Consolidated Financial Statements						

Table of Contents

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

	Fiscal First Quarters Ended		
	March 29, 2015	March 30, 2014	
Net earnings	\$4,320	4,727	
Other comprehensive income (loss), net of tax			
Foreign currency translation	(2,563	) 137	
Securities:			
Unrealized holding gain (loss) arising during period	115	27	
Reclassifications to earnings	(57	) —	
Net change	58	27	
Employee benefit plans:			
Prior service cost amortization during period	(5	) (5	)
Gain (loss) amortization during period	159	99	
Net change	154	94	
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(195	) 10	
Reclassifications to earnings	(32	) (53	)
Net change	(227	) (43	)
Other comprehensive income (loss)	(2,578	) 215	
Comprehensive income	\$1,742	4,942	

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal first quarters were as follows for 2015 and 2014, respectively: Securities: \$32 million and \$15 million; Employee Benefit Plans: \$76 million and \$46 million; Derivatives & Hedges: \$122 million and \$23 million.

Table of Contents

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

	Fiscal Three Months Ended	
	March 29, 2015	March 30, 2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$4,320	4,727
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	895	1,013
Stock based compensation	204	198
Asset write-downs	—	37
Net gain on sale of assets/businesses	(38	) —
Deferred tax provision	545	495
Accounts receivable allowances	(21	) (25
Changes in assets and liabilities, net of effects from acquisitions:		
Increase in accounts receivable	(765	) (426
Increase in inventories	(276	) (512
Decrease in accounts payable and accrued liabilities	(2,451	) (1,004
Increase in other current and non-current assets	(562	) (152
Increase/(decrease) in other current and non-current liabilities	1,021	(428
<b>NET CASH FLOWS FROM OPERATING ACTIVITIES</b>	<b>2,872</b>	<b>3,923</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Additions to property, plant and equipment	(543	) (630
Proceeds from the disposal of assets/businesses, net	110	35
Acquisitions, net of cash acquired	(233	) —
Purchases of investments	(7,162	) (5,427
Sales of investments	6,050	4,077
Other	(11	) (81
<b>NET CASH USED BY INVESTING ACTIVITIES</b>	<b>(1,789</b>	<b>) (2,026</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends to shareholders	(1,946	) (1,867
Repurchase of common stock	(2,198	) (774
Proceeds from short-term debt	589	278
Retirement of short-term debt	(193	) (1,275
Proceeds from long-term debt	3	16
Retirement of long-term debt	(16	) (21
Proceeds from the exercise of stock options/excess tax benefits	584	586
Other	(50	) —
<b>NET CASH USED BY FINANCING ACTIVITIES</b>	<b>(3,227</b>	<b>) (3,057</b>
Effect of exchange rate changes on cash and cash equivalents	(391	) (45
Decrease in cash and cash equivalents	(2,535	) (1,205

Edgar Filing: JOHNSON & JOHNSON - Form 10-Q

Cash and Cash equivalents, beginning of period	14,523	20,927
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 11,988	19,722
Acquisitions		
Fair value of assets acquired	\$476	—
Fair value of liabilities assumed and noncontrolling interests	(243	) —
Net fair value of acquisitions	233	—
See Notes to Consolidated Financial Statements		

6

---



Table of Contents

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2014. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented.

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be adopted retroactively for all periods presented. This update will not have a material impact on the presentation of the Company's financial position.

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

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. This update is required to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2016. Early adoption of this standard is not permitted. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

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

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

NOTE 2 — INVENTORIES

(Dollars in Millions)	March 29, 2015	December 28, 2014
Raw materials and supplies	\$1,115	1,214
Goods in process	2,190	2,461
Finished goods	4,780	4,509
Total inventories	\$8,085	8,184

7

---

Table of Contents

## NOTE 3 — INTANGIBLE ASSETS AND GOODWILL

Intangible assets that have finite useful lives are amortized over their estimated useful lives. The latest annual impairment assessment of goodwill and indefinite lived intangible assets was completed in the fiscal fourth quarter of 2014. Future impairment tests for goodwill and indefinite lived intangible assets will be performed annually in the fiscal fourth quarter, or sooner, if warranted.

(Dollars in Millions)	March 29, 2015	December 28, 2014
Intangible assets with definite lives:		
Patents and trademarks — gross	\$8,400	9,074
Less accumulated amortization	4,201	4,700
Patents and trademarks — net	4,199	4,374
Customer relationships and other intangibles — gross	17,764	17,970
Less accumulated amortization	5,248	5,227
Customer relationships and other intangibles — net	12,516	12,743
Intangible assets with indefinite lives:		
Trademarks	7,115	7,263
Purchased in-process research and development	3,195	2,842
Total intangible assets with indefinite lives	10,310	10,105
Total intangible assets — net	\$27,025	27,222

Goodwill as of March 29, 2015 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer	Pharm	Med Devices	Total
Goodwill, net at December 28, 2014	\$7,675	2,626	11,531	21,832
Goodwill, related to acquisitions	—	64	22	86
Goodwill, related to divestitures	(8	) (1	) —	(9
Currency translation/Other	(393	) (77	) (94	) (1) (564
Goodwill, net as of March 29, 2015	\$7,274	2,612	11,459	21,345

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

<sup>(1)</sup>Includes \$98 million classified as held for sale, a component of other assets on the Consolidated Balance Sheet, related to the divestiture of Cordis which was pending as of March 29, 2015.

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 17 years and 24 years, respectively. The amortization expense of amortizable intangible assets included in cost of products sold was \$312 million and \$351 million for the fiscal three months ended March 29, 2015 and March 30, 2014, respectively. The estimated amortization expense for the five succeeding years approximates \$1,300 million, before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

## NOTE 4 — FAIR VALUE MEASUREMENTS

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company may use forward foreign exchange

contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in

8

---

Table of Contents

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 primarily enters into agreements with commercial institutions that have at least an "A" (or equivalent) credit rating. As of March 29, 2015, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of \$27.2 billion, \$2.4 billion and \$2.2 billion, respectively.

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

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts and cross currency interest rate swaps. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps were not material.

As of March 29, 2015, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was \$86 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 7. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

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

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI <sup>(1)</sup>		Gain/(Loss) Reclassified From Accumulated OCI Into Income <sup>(1)</sup>		Gain/(Loss) Recognized In Other Income/Expense <sup>(2)</sup>	
	Fiscal First Quarters Ended					
Cash Flow Hedges By Income Statement Caption	March 29, 2015	March 30, 2014	March 29, 2015	March 30, 2014	March 29, 2015	March 30, 2014
Sales to customers <sup>(3)</sup>	\$ (92 )	(34 )	(41 )	(13 )	(1 )	—
Cost of products sold <sup>(3)</sup>	(168 )	17	69	75	—	—

Edgar Filing: JOHNSON & JOHNSON - Form 10-Q

Research and development expense <sup>(3)</sup>	4	13	(16	) 5	—	(1	)
Interest (income)/Interest expense, net <sup>(4)</sup>	(36	) 12	(3	) (5	) —	—	
Other (income) expense, net <sup>(3)</sup>	97	2	23	(9	) —	(1	)
Total	\$(195	) 10	32	53	(1	) (2	)

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

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

Table of Contents

For the fiscal first quarters ended March 29, 2015 and March 30, 2014, a loss of \$84 million and a gain of \$9 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

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

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

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of March 29, 2015 and December 28, 2014 were as follows:

(Dollars in Millions)	March 29, 2015				December 28, 2014
	Level 1	Level 2	Level 3	Total	Total <sup>(1)</sup>
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts <sup>(7)</sup>	\$—	976	—	976	996
Interest rate contracts <sup>(2)(4)(7)</sup>	—	52	—	52	31
Total	—	1,028	—	1,028	1,027
Liabilities:					
Forward foreign exchange contracts <sup>(8)</sup>	—	1,068	—	1,068	751
Interest rate contracts <sup>(3)(4)(8)</sup>	—	202	—	202	8
Total	—	1,270	—	1,270	759
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts <sup>(7)</sup>	—	70	—	70	29
Liabilities:					
Forward foreign exchange contracts <sup>(8)</sup>	—	63	—	63	51
Available For Sale Other Investments:					
Equity Investments <sup>(5)</sup>	800	—	—	800	679
Debt Securities <sup>(6)</sup>	—	1,350	—	1,350	—

- (1) 2014 assets and liabilities are all classified as Level 2 with the exception of equity investments of \$679 million, which are classified as Level 1.
- (2) Includes \$49 million and \$29 million of non-current assets for March 29, 2015 and December 28, 2014, respectively.
- (3) Includes \$202 million and \$8 million of non-current liabilities for March 29, 2015 and December 28, 2014, respectively.
- (4) Includes cross currency interest rate swaps and interest rate swaps.



Table of Contents

Classified as non-current other assets. The carrying amount of the equity investments were \$314 million and \$284 million as of March 29, 2015 and December 28, 2014, respectively. The unrealized gains were \$491 million and \$406 million as of March 29, 2015 and December 28, 2014, respectively. The unrealized losses were \$5 million and \$11 million as of March 29, 2015 and December 28, 2014, respectively.

(6) Classified as current marketable securities.

(7) Classified as other current assets.

(8) Classified as accounts payables.

The Company's cash, cash equivalents and current marketable securities as of March 29, 2015 comprised:  
March 29, 2015

(Dollars in Millions)	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	1,739	—	—	1,739	1,739	
U.S. Gov't Securities <sup>(1)</sup>	15,114	1	—	15,115	750	14,364
Other Sovereign Securities <sup>(1)</sup>	3,762	—	—	3,762	1,199	2,563
U.S. Reverse repurchase agreements <sup>(1)</sup>	3,402	—	—	3,402	3,402	
Other Reverse repurchase agreements <sup>(1)</sup>	2,192	—	—	2,192	2,192	
Corporate debt securities <sup>(1)</sup>	1,410	—	—	1,410	356	1,054
Money market funds	1,396	—	—	1,396	1,396	
Time deposits <sup>(1)</sup>	954	—	—	954	954	
Subtotal	29,969	1	—	29,970	11,988	17,981
U.S. Gov't Securities	893	1	(2)	892	—	892
Corporate debt securities	457	1	—	458	—	458
Subtotal Available for Sale <sup>(2)</sup>	1,350	2	(2)	1,350	—	1,350
Total Cash, cash equivalents and current marketable securities	31,319	3	(2)	31,320	11,988	19,331

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

<sup>(2)</sup> Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

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

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. Available for sale securities with stated maturities of greater than one year from the date of purchase are available for current operations and are classified as current marketable securities.

The estimated fair value was the same as the amortized cost as of December 28, 2014.

The contractual maturities of the debt securities available for sale at March 29, 2015 are due from one year through five years.



Table of Contents

Financial Instruments not measured at Fair Value:

The following financial liabilities are held at carrying amount on the consolidated balance sheet as of March 29, 2015:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
<b>Financial Liabilities</b>		
Current Debt	\$4,045	4,045
<b>Non-Current Debt</b>		
2.15% Notes due 2016	898	913
3 month LIBOR+0.07% FRN due 2016	800	801
0.70% Notes due 2016	399	400
5.55% Debentures due 2017	1,000	1,107
1.125% Notes due 2017	704	707
5.15% Debentures due 2018	898	1,010
1.65% Notes due 2018	606	613
4.75% Notes due 2019 (1B Euro 1.0983)	1,094	1,318
1.875% Notes due 2019	507	512
3% Zero Coupon Convertible Subordinated Debentures due in 2020	145	234
2.95% Debentures due 2020	543	574
3.55% Notes due 2021	446	489
2.45% Notes due 2021	349	363
6.73% Debentures due 2023	250	330
3.375% Notes due 2023	812	872
5.50% Notes due 2024 (500 MM GBP 1.4901)	741	965
6.95% Notes due 2029	297	428
4.95% Debentures due 2033	500	596
4.375% Notes due 2033	864	985
5.95% Notes due 2037	995	1,357
5.85% Debentures due 2038	700	965
4.50% Debentures due 2040	539	628
4.85% Notes due 2041	298	367
4.50% Notes due 2043	499	596
Other	54	54
Total Non-Current Debt	\$ 14,938	17,184

The weighted average effective interest rate on non-current debt is 4.05%.

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

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

## NOTE 5 — INCOME TAXES

The worldwide effective income tax rates for the fiscal first quarters of 2015 and 2014 were 22.5% and 12.9%, respectively. The higher effective tax rate in 2015 as compared to 2014 was primarily due to a tax benefit in the fiscal first quarter of 2014 of \$398 million associated with the Conor Medsystems divestiture which reduced the 2014 first quarter tax rate by 7.3% and the

Table of Contents

U.S. Internal Revenue Service audit settlement partially offset by increased planned dividends. Additionally, 2015 taxable income increased in higher tax jurisdictions relative to lower tax jurisdictions.

As of March 29, 2015, the Company had approximately \$2.5 billion of liabilities from unrecognized tax benefits. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. The Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

## NOTE 6 — PENSIONS AND OTHER POSTRETIREMENT BENEFITS

## Components of Net Periodic Benefit Cost

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

(Dollars in Millions)	Fiscal First Quarters Ended			
	Retirement Plans		Other Benefit Plans	
	March 29, 2015	March 30, 2014	March 29, 2015	March 30, 2014
Service cost	\$248	197	64	53
Interest cost	249	257	47	50
Expected return on plan assets	(455	) (402	) (2	) (2
Amortization of prior service cost/(credit)	—	1	(8	) (9
Recognized actuarial losses	187	113	50	34
Curtailments and settlements	4	—	—	—
Net periodic benefit cost	\$233	166	151	126

## Company Contributions

For the fiscal three months ended March 29, 2015, the Company contributed \$82 million and \$8 million to its U.S. and international retirement plans, respectively. The Company plans to continue to fund its U.S. defined benefit plans to comply with the Pension Protection Act of 2006. International plans are funded in accordance with local regulations.

## NOTE 7 — ACCUMULATED OTHER COMPREHENSIVE INCOME

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

(Dollars in Millions)	Foreign	Gain/(Loss)	Employee	Gain/(Loss)	Total
	Currency	On	Benefit	On	Accumulated
	Translation	Securities	Plans	Derivatives	Other
December 28, 2014	\$ (4,803	) 257	(6,317	) 141	(10,722
Net change	(2,563	) 58	154	(227	) (2,578
March 29, 2015	\$ (7,366	) 315	(6,163	) (86	) (13,300

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

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 6 for additional details.

Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 4 for additional details.

13

---

Table of Contents

## 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 29, 2015 and March 30, 2014:

(Shares in Millions)	Fiscal First Quarters Ended	
	March 29, 2015	March 30, 2014
Basic net earnings per share	\$1.55	1.67
Average shares outstanding — basic	2,782.6	2,826.8
Potential shares exercisable under stock option plans	154.1	163.4
Less: shares which could be repurchased under treasury stock method	(113.0	) (118.5
Convertible debt shares	2.3	3.0
Average shares outstanding — diluted	2,826.0	2,874.7
Diluted earnings per share	\$1.53	1.64

The diluted earnings per share calculation for both the fiscal first quarters ended March 29, 2015 and March 30, 2014 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted earnings per share calculation for both the fiscal first quarters ended March 29, 2015 and March 30, 2014 included all shares related to stock options, as there were no options or other instruments which were anti-dilutive.

## NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

## SALES BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal First Quarters Ended		
	March 29, 2015	March 30, 2014	Percent Change
Consumer			
United States	\$1,359	1,309	3.8
International	2,031	2,248	(9.7
Total	3,390	3,557	(4.7
Pharmaceutical			
United States	4,371	3,740	16.9
International	3,355	3,758	(10.7
Total	7,726	7,498	3.0
Medical Devices			
United States	2,962	3,155	(6.1
International	3,296	3,905	(15.6
Total	6,258	7,060	(11.4
Worldwide			
United States	8,692	8,204	5.9
International	8,682	9,911	(12.4
Total	\$17,374	18,115	(4.1

Table of Contents

## SEGMENT PRE-TAX PROFIT

(Dollars in Millions)	Fiscal First Quarters Ended			Percent Change	
	March 29, 2015	March 30, 2014			
Consumer	\$644	479	34.4	%	
Pharmaceutical <sup>(1)</sup>	2,962	3,206	(7.6	)	
Medical Devices <sup>(2)</sup>	2,221	1,966	13.0		
Segments operating profit	5,827	5,651	3.1		
Less: Expense not allocated to segments <sup>(3)</sup>	252	227			
Worldwide income before taxes	\$5,575	5,424	2.8	%	

(1) Includes litigation expense of \$136 million in the fiscal first quarter of 2015.

(2) Includes a net litigation gain of \$538 million and \$139 million for costs associated with the DePuy ASR™ Hip program recorded in the fiscal first quarter of 2015. Includes Synthes integration costs of \$118 million recorded in the fiscal first quarter of 2014.

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

## SALES BY GEOGRAPHIC AREA

(Dollars in Millions)	Fiscal First Quarters Ended			Percent Change	
	March 29, 2015	March 30, 2014			
United States	\$8,692	8,204	5.9	%	
Europe	4,040	4,885	(17.3	)	
Western Hemisphere, excluding U.S.	1,639	1,695	(3.3	)	
Asia-Pacific, Africa	3,003	3,331	(9.8	)	
Total	\$17,374	18,115	(4.1	)%	

## NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

Subsequent to the quarter on April 2, 2015, the Company completed the divestiture of its U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution for approximately \$1.05 billion. Assets held for sale relating to the divestiture are immaterial.

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

During the fiscal first quarter of 2015, the Company announced a binding offer from Cardinal Health to acquire its Cordis business for an approximate value of \$2.0 billion. The proposed transaction is expected to close towards the end of 2015, subject to customary closing conditions and regulatory approvals. As of March 29, 2015, the assets classified as held for sale relating to the Cordis business were \$152 million of inventory classified as prepaid expenses and other on the Consolidated Balance Sheet. The non-current assets classified as held for sale relating to the Cordis business were \$105 million of property, plant and equipment, net, \$66 million of intangible assets and \$98 million of goodwill classified as other assets on the Consolidated Balance Sheet.

As of March 29, 2015, the assets classified as held for sale relating to the Ortho-Clinical Diagnostics companies in countries that have not completely closed due to local regulatory requirements were \$46 million of inventory, classified as prepaid expenses and other on the Consolidated Balance Sheet and \$107 million of property, plant and equipment, classified as other assets on the Consolidated Balance Sheet.





Table of Contents

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 29, 2015, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions.

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

PRODUCT LIABILITY

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

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, and RISPERDAL®. As of March 29, 2015, in the U.S. there were approximately 9,200 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 7,600 with respect to the PINNACLE® Acetabular Cup System, 38,500 with respect to pelvic meshes, and 2,400 with respect to RISPERDAL®.

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

Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement which would effectively extend the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,500 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the U.S. However, many lawsuits in the U.S. will remain, and the settlement program does not address litigation outside of the U.S. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Updates to these accruals may be required in the future as additional information becomes available.

## Table of Contents

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

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

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

## INTELLECTUAL PROPERTY

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

### Medical Devices

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

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

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, alleging LifeScan's OneTouch<sup>®</sup> Line of Blood Glucose Monitoring Systems infringe two patents related to the use of microelectrode sensors. Roche is seeking monetary

Table of Contents

damages and injunctive relief. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. Roche appealed and the Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. In December 2014, the District Court ruled in LifeScan's favor and reinstated the original claim construction. In February 2015, Roche appealed the ruling.

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

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

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

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

patents. In August 2014, the parties entered into a settlement of the portion of the lawsuit relating to suture anchors, and in March 2015, the parties entered into a settlement agreement relating to the remaining portion of the case.

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

In January 2014, Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare S.A. (collectively, Baxter) filed a lawsuit against Johnson & Johnson, Ethicon, Inc. (Ethicon), Ferrosan Medical Devices A/S and Packaging Coordinators

Table of Contents

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

In June 2014, My Health, Inc. (My Health) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the Eastern District of Texas, alleging LifeScan's OneTouch® Verio®IQ Blood Glucose Monitoring System infringes My Health's patent related to a method for monitoring and treating patients. My Health is seeking monetary damages and injunctive relief. In August 2014, LifeScan filed a motion to dismiss the lawsuit. In October 2014, Lifescan filed an Inter Partes review proceeding in the United States Patent and Trademark Office seeking to invalidate My Health's patent. In December 2014, LifeScan moved to stay the lawsuit pending a decision in the Inter Partes review proceeding. In March 2015, LifeScan's motion to dismiss was denied as premature.

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

Pharmaceutical

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

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 alleged that the patents-in-suit are invalid as a result of ALZA's alleged omission of Dr. Swanson as a named inventor. Dr. Swanson is seeking damages and an award of unjust enrichment. ALZA filed a motion for summary judgment and a hearing was held in February 2015. The Court granted ALZA's summary judgment motion and dismissed all of Dr. Swanson's claims against ALZA, concluding the matter.



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

Table of Contents

REMICADE® Related Cases

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

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

In September 2013, JBI and NYU Langone Medical Center (NYU Medical Center) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE® (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU Medical Center, and NYU Medical Center granted JBI an exclusive license to NYU Medical Center's rights under the patent. Currently, the '471 patent in the United States expires in September 2018. JBI responded to that rejection in December 2013 and in August 2014, JBI and NYU Medical Center received a further rejection. JBI responded to the rejection by filing a further amendment and in November 2014, JBI's petition to enter the amendment was granted. The application was returned to the examiner for issuance of a new Office Action, which occurred in February 2015, further rejecting the patent. JBI responded to that rejection and in April 2015, the USPTO issued a further action maintaining its rejection of the '471 patent. JBI will have until June 12, 2015 to file a notice of appeal to the USPTO's Patent Trial and Appeal Board and plans to do so. The '471 patent remains a valid and enforceable patent as it undergoes reexamination at the USPTO. JBI will continue to defend the patent and, if necessary, will pursue all available appeals.

In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®. In February 2015, JBI received a Notice of Commercial Marketing from Celltrion purportedly in accordance with the Biologics Price Competition and Innovation Act (the BPCIA), notifying JBI that Celltrion and/or Hospira intended to begin commercial marketing of a biosimilar product as early as 180 days from the date of the notice. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira seeking a declaratory judgment that their biosimilar product for which they are seeking FDA approval under the new BPCIA statute infringes or potentially infringes six JBI patents. JBI is also seeking a declaratory judgment that defendants have failed to comply with certain procedural requirements of the BPCIA. In addition, JBI moved for partial summary judgment holding that Celltrion and Hospira may not give JBI a Notice of Commercial Marketing before their biosimilar product is approved by the FDA. Subsequently in March 2015, JBI moved to stay all proceedings in the District Court with respect to the '471 patent, pending the USPTO re-examination proceeding.

If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. Biosimilar versions of REMICADE® have

been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States would be subject to approval by the FDA. Loss of exclusivity will likely result in a further reduction in sales as additional biosimilar versions of REMICADE® are introduced to the market.

#### Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering

Table of Contents

those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset.

PREZISTA®

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

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

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

Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. in March 2013 in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408. Discovery in this case is ongoing and a trial date is set for October 2015.

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

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

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

## Table of Contents

above-referenced actions. In January 2015, Janssen Inc. and Janssen Sciences Ireland UC filed a Notice of Application against Teva Canada Limited in response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent No. 2,485,834.

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

## CONCERTA®

In May 2014, ALZA and JPI filed a patent infringement lawsuit in the United States District Court for the District of West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (Mylan) in response to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of the '798 patent. Mylan filed counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit.

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

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

In each of the above lawsuits, ALZA and/or JPI are seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA® before the expiration of the '798 and/or '852 patents.

## NUCYNTA® AND NUCYNTA® ER

In July 2013, Janssen Pharmaceuticals, Inc. (JPI) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC, Actavis Inc. and Actavis LLC (collectively, Actavis), as well as Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively, Alkem). The patent infringement claims against Actavis and Alkem relate to their respective ANDAs seeking approval to market a generic version of NUCYNTA® ER before the expiration of United States Reissue Patent No. 39,593 (the '593 patent), United States Patent No. 7,994,364 (the '364 patent) and, as to Actavis only, United States Patent No. 8,309,060 (the '060 patent). The lawsuit also includes a patent infringement claim against Alkem in response to its ANDA seeking approval to market a generic version of NUCYNTA® before the expiration of the '593 and '364 patents. In December 2013, JPI filed an additional complaint in the District Court of New Jersey against Alkem asserting United States Patent No. 8,536,130 related to its ANDA seeking approval to market a generic version of NUCYNTA® ER. In August 2014, JPI amended the complaint against Alkem to add additional dosage strengths.

In October 2013, JPI received a Paragraph IV Notice from Sandoz, Inc. (Sandoz) with respect to NUCYNTA® related to the '364 patent, and a Paragraph IV Notice from Roxane Laboratories, Inc. (Roxane) with respect to NUCYNTA® related to the '364 and '593 patents. In response to those notices, JPI filed an additional complaint in the United States District Court for the District of New Jersey against Roxane and Sandoz asserting the '364 patent against Sandoz and the '364 and '593 patents against Roxane. In April 2014, JPI and Sandoz entered into a joint stipulation of dismissal of the case against Sandoz, based on Sandoz's agreement not to enter the market prior to the expiration of the asserted patents. In June 2014, in response to a Paragraph IV Notice from Roxane with respect to NUCYNTA® ER, JPI filed a complaint asserting the '364 and '593 patents against Roxane.

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

In April 2015, JPI completed the divestiture of its U.S. rights to NUCYNTA<sup>®</sup>, NUCYNTA<sup>®</sup> ER and NUCYNTA<sup>®</sup> oral solution and will thus seek removal from the above cases as plaintiff.

GOVERNMENT PROCEEDINGS

## Table of Contents

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

### Average Wholesale Price (AWP) Litigation

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

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

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

### RISPERDAL<sup>®</sup>

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL<sup>®</sup> from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL<sup>®</sup> with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL<sup>®</sup>, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL<sup>®</sup> prescriptions written for off-label use, compensation for treating their citizens for alleged adverse



reactions to RISPERDAL<sup>®</sup>, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL<sup>®</sup>. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above.

Four states have remaining claims in litigation related to RISPERDAL<sup>®</sup>: one claim is on remand in Arkansas; a Petition for Rehearing has been filed in South Carolina; in Kentucky, a trial has been set for April 2016; and in Mississippi, the case has not progressed to trial. State cases that went to judgment after trial are discussed below.

In 2004, the Attorney General of West Virginia commenced a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) based on claims of alleged consumer fraud as to DURAGESIC<sup>®</sup>, as well as RISPERDAL<sup>®</sup>. JPI was found liable and damages were

Table of Contents

assessed at \$4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court of Appeals reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

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

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

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

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

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc.

(McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. In March 2015, McNEIL-PPC entered a guilty plea in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL- PPC agreed to pay a \$20 million fine and a \$5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In

## Table of Contents

November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In December 2012, Oregon filed a Notice of Appeal in the Court of Appeals of the State of Oregon. Oral argument took place in July 2014 and the parties are awaiting a decision.

### Opioids Litigation

Along with other pharmaceutical companies, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI) have been named in two lawsuits alleging claims related to opioid marketing practices. In May 2014, Santa Clara and Orange Counties in California (the Counties) filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including J&J and JPI, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. The Counties seek injunctive and monetary relief. In February 2015, the defendants filed motions challenging the sufficiency of the complaint.

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

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

### Other

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

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

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

device investigation for a total payment of \$4 million to the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 45 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states.

## Table of Contents

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

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

## GENERAL LITIGATION

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

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

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing is scheduled for October 2015.

In August 2014, United States Customs and Border Protection issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (PREZISTA®) in

connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice.

In March 2015, Costco Wholesale Corporation (Costco) filed a complaint against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court of the Northern District of California, alleging antitrust claims of an unlawful vertical price fixing agreement between JJVCI, Costco and unnamed other distributors and retailers. Costco alleges that the alleged agreements harmed competition by causing increases in the price Costco customers pay for JJVCI contact lenses. Costco is seeking an injunction and monetary damages.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against JJVCI, other contact lens manufacturers, distributors and retailers, alleging vertical and

Table of Contents

horizontal conspiracies to fix the retail prices of contact lenses. The complaints alleged that the manufacturers reached agreements between each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages. Motions to consolidate the cases are pending.

In April 2015, Johnson & Johnson Vision Care, Inc. filed a complaint in the United States District Court for the District of Utah against the State of Utah seeking a declaratory judgment that a law passed by the state to ban unilateral pricing policies solely in the contact lens market violates the Commerce Clause of the United States Constitution. A hearing on JJVCI's motion for preliminary injunction is scheduled for May 2015.

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.



Table of Contents

## 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 2015, worldwide sales were \$17.4 billion, a total decrease of 4.1%, including operational growth of 3.1% as compared to 2014 fiscal first quarter sales of \$18.1 billion. Currency fluctuations had a negative impact of 7.2% for the fiscal first quarter of 2015. The introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 1.0% on the fiscal first quarter of 2015 worldwide operational sales growth. The divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 2.4% on the worldwide operational sales growth on the fiscal first quarter of 2015.

Sales by U.S. companies were \$8.7 billion in the fiscal first quarter of 2015, which represented an increase of 5.9% as compared to the prior year. Sales by international companies were \$8.7 billion, a decline of 12.4%, including operational growth of 0.8%, offset by a negative currency impact of 13.2% as compared to the fiscal first quarter sales of 2014.

Sales by companies in Europe experienced a decline of 17.3%, which included an operational increase of 0.3%, and a negative currency impact of 17.6%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 3.3%, including operational growth of 9.9%, offset by a negative currency impact of 13.2%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 9.8%, including an operational decrease of 3.0% and a negative currency impact of 6.8%.

## ANALYSIS OF SALES BY BUSINESS SEGMENTS

## Consumer

Consumer segment sales in the fiscal first quarter of 2015 were \$3.4 billion, a decrease of 4.7% as compared to the same period a year ago, including an operational increase of 3.4% offset by a negative currency impact of 8.1%. U.S. Consumer segment sales increased by 3.8%. International Consumer segment sales decreased by 9.7%, including operational growth of 3.1% offset by a negative currency impact of 12.8%.

## Major Consumer Franchise Sales — Fiscal First Quarters Ended

(Dollars in Millions)	March 29, 2015	March 30, 2014	Total Change	Operations Change	Currency Change
OTC	\$993	\$1,011	(1.8 )%	9.6 %	(11.4 )%
Skin Care	903	914	(1.2 )	4.6	(5.8 )
Baby Care	511	545	(6.2 )	1.0	(7.2 )
Oral Care	403	411	(1.9 )	5.0	(6.9 )
Wound Care/Other	293	349	(16.0 )	(12.1 )	(3.9 )
Women’s Health	287	327	(12.2 )	(0.4 )	(11.8 )
Total Consumer Sales	\$3,390	\$3,557	(4.7 )%	3.4 %	(8.1 )%

The OTC franchise achieved operational growth of 9.6% as compared to the prior year fiscal first quarter. The growth was driven by analgesics, upper respiratory products outside the U.S., as well as new products and relaunches in

digestive health, anti-smoking aids and ROGAINE®.

The Skin Care franchise achieved operational growth of 4.6% as compared to the prior year. The growth was primarily due to timing of shipments of seasonal products and market growth for NEUTROGENA® and AVEENO® products.

The Baby Care franchise achieved operational growth of 1.0% as compared to the prior year, primarily due to sales growth of U.S. cleansers and lotions.

Table of Contents

The Oral Care franchise achieved operational growth of 5.0% as compared to the prior year. The growth was driven by increased sales of LISTERINE®, as a result of new product launches and successful marketing campaigns outside the U.S.

The Wound Care/Other franchise experienced an operational decline of 12.1% as compared to the prior year, due to the BENECOL® divestiture outside the U.S. and lower sales of Nutritional products.

The Women's Health franchise experienced an operational decline of 0.4% as compared to the prior year primarily due to the divestiture of North American sanitary protection and intimate health business. This was partially offset by growth outside the U.S. due to new product launches and successful marketing campaigns.

## Pharmaceutical

Pharmaceutical segment sales in the fiscal first quarter of 2015 were \$7.7 billion, a total increase of 3.0% as compared to the same period a year ago, with an operational increase of 10.2% and a negative currency impact of 7.2%. U.S. Pharmaceutical sales increased by 16.9% as compared to the same period a year ago. International Pharmaceutical sales decreased by 10.7%, including operational growth of 3.7% offset by a negative currency impact of 14.4%. The introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.8% on the operational growth of the Pharmaceutical segment in the fiscal first quarter of 2015. The Pharmaceutical segment was impacted by a positive adjustment to previous reserve estimates including managed medicaid rebates, primarily in the Cardiovascular/Metabolism/Other therapeutic area and the Infectious Diseases therapeutic area.

## Major Pharmaceutical Therapeutic Area Sales — Fiscal First Quarters Ended\*

(Dollars in Millions)	March 29, 2015	March 30, 2014	Total Change	Operations Change	Currency Change
Total Immunology	\$2,463	\$2,343	5.1	% 9.9	% (4.8)
REMICADE®	1,600	1,610	(0.6)	) 2.8	(3.4)
SIMPONI®/ SIMPONI ARIA®	300	259	15.8	25.5	(9.7)
STELARA®	549	456	20.4	27.4	(7.0)
Other Immunology	14	18	(22.2)	) (13.7)	(8.5)
Total Infectious Diseases	975	1,200	(18.8)	) (10.2)	(8.6)
EDURANT®	91	81	12.3	33.6	(21.3)
OLYSIO®/ SOVRIAD®	234	354	(33.9)	) (26.2)	(7.7)
PREZISTA®/ PREZCOBIX™	427	445	(4.0)	) 3.7	(7.7)
Other Infectious Diseases	223	320	(30.3)	) (22.8)	(7.5)
Total Neuroscience	1,618	1,638	(1.2)	) 7.1	(8.3)
CONCERTA®/methylphenidate	224	150	49.3	58.0	(8.7)
INVEGA®	155	165	(6.1)	) 0.7	(6.8)
INVEGA® SUSTENNA®/ XEPLION®	411	373	10.2	18.7	(8.5)
RISPERDAL® CONSTA®	254	310	(18.1)	) (9.2)	(8.9)
Other Neuroscience	574	640	(10.3)	) (2.2)	(8.1)
Total Oncology	1,108	1,022	8.4	21.2	(12.8)
IMBRUVICA®	116	10	**	**	**
VELCADE®	339	408	(16.9)	) (4.0)	(12.9)
ZYTIGA®	556	512	8.6	19.2	(10.6)
Other Oncology	97	92	5.4	20.3	(14.9)
Cardiovascular / Metabolism / Other	1,562	1,295	20.6	25.1	(4.5)
XARELTO®	441	319	38.2	38.2	0.0

Edgar Filing: JOHNSON & JOHNSON - Form 10-Q

INVOKANA®/ INVOKAMET™	278	94	**	**	**
PROCRIT®/EPREX®	269	310	(13.2 )	(7.4 )	(5.8 )
Other	574	572	0.3	7.1	(6.8 )
Total Pharmaceutical Sales	\$7,726	\$7,498	3.0 %	10.2 %	(7.2 )%

29

---

Table of Contents

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

\*\* Percentage greater than 100% or not meaningful

Immunology products achieved operational sales growth of 9.9% as compared to the same period a year ago. Increased sales of STELARA® (ustekinumab) and SIMPONI®/SIMPONI® ARIA® (golimumab) were primarily due to market growth and market share gains. U.S. REMICADE® (infliximab) growth was primarily due to market growth. The patents for REMICADE® in certain countries in Europe (Germany, Spain, United Kingdom, Sweden, Austria, Belgium, Switzerland, Denmark, France, Greece, Italy, Luxembourg and the Netherlands) expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Loss of exclusivity will likely result in a further reduction in sales as additional biosimilar versions of REMICADE® are introduced to the market. See Note 11 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

Infectious disease products experienced an operational decline of 10.2% as compared to the same period a year ago. Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on U.S. sales and will continue to have a negative impact on future sales. The decline was partially offset by approximately 3.0% due to a positive adjustment to previous estimates for managed medicare rebates.

Neuroscience products achieved operational sales growth of 7.1% as compared to the same period a year ago. U.S. sales growth of CONCERTA®/methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors. Strong sales of INVEGA® SUSTENNA®/XEPLION® (paliperidone palmitate) were primarily due to increased market share.

Oncology products achieved strong operational sales growth of 21.2% as compared to the same period a year ago. Major contributors to the growth were strong sales of ZYTIGA®(abiraterone acetate) due to market growth and additional country launches and sales of IMBRUVICA® (ibrutinib) due to new indications and additional country launches.

Cardiovascular / Metabolism / Other products achieved operational sales growth of 25.1% as compared to the same period a year ago due to strong sales of XARELTO®(rivaroxaban) and INVOKANA®/INVOKAMET™ (canagliflozin) and was impacted by approximately 7.0% due to a positive adjustment to previous estimates for managed medicare rebates.

### Medical Devices

The Medical Devices segment sales in the fiscal first quarter of 2015 were \$6.3 billion, a decrease of 11.4% as compared to the same period a year ago, with an operational decrease of 4.6% and a negative currency impact of 6.8%. U.S. Medical Devices sales decreased 6.1%. International Medical Devices sales decreased by 15.6%, including an operational decrease of 3.3% and a negative currency impact of 12.3%. In the fiscal first quarter of 2015, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 5.9% on the operational growth of the Medical Devices segment.

### Major Medical Devices Franchise Sales — Fiscal First Quarters Ended

(Dollars in Millions)	March 29, 2015	March 30, 2014	Total Change	Operations Change	Currency Change
Orthopaedics	\$2,328	\$2,421	(3.8 )%	2.1 %	(5.9 )%
Surgical Care	1,423	1,508	(5.6 )	2.3	(7.9 )
Specialty Surgery/Other	833	874	(4.7 )	1.8	(6.5 )

Edgar Filing: JOHNSON & JOHNSON - Form 10-Q

Vision Care	631	761	(17.1 )	(9.0 )	(8.1 )
Cardiovascular Care	529	541	(2.2 )	6.4	(8.6 )
Diabetes Care	484	512	(5.5 )	4.2	(9.7 )
Diagnostics	30	443	(93.2 )	(91.8 )	(1.4 )
Total Medical Devices Sales	\$6,258	\$7,060	(11.4 )%	(4.6 )%	(6.8 )%

The Orthopaedics franchise achieved operational sales growth of 2.1% as compared to the prior year fiscal first quarter. Growth was primarily driven by sales of trauma, sports medicine, hip and knee products. Growth was negatively impacted by continued pricing pressures.

## Table of Contents

The Surgical Care franchise achieved operational sales growth of 2.3% as compared to the prior year fiscal first quarter. The success of new ECHELON FLEX™ products and growth in sutures was offset by lower sales of women's health and urology products primarily due to the Company's decision to exit from certain women's health products.

The Specialty Surgery/Other franchise achieved operational sales growth of 1.8% as compared to the prior year fiscal first quarter. Growth was primarily attributable to new product launches and market penetration for biosurgical and energy products.

The Vision Care franchise experienced an operational sales decline of 9.0% as compared to the prior year fiscal first quarter primarily due to competitive pricing actions taken in the U.S. and Asia Pacific region in mid-year 2014. In addition, the first quarter of 2014 was positively impacted from inventory builds due to customer buying patterns.

The Cardiovascular Care franchise, composed of the Cordis and Biosense Webster businesses, achieved operational sales growth of 6.4% as compared to the prior year fiscal first quarter due to strong sales growth in the electrophysiology business. In the fiscal first quarter of 2015, the Company received a binding offer from Cardinal Health to acquire the Cordis business. The transaction is expected to close towards the end of 2015. For additional details see Note 10 to the Consolidated Financial Statements.

The Diabetes Care franchise achieved operational sales growth of 4.2% as compared to the prior year fiscal first quarter primarily due to the success of the ANIMAS® VIBE™ products.

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

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

Consolidated earnings before provision for taxes on income for the fiscal first quarter of 2015 increased to \$5.6 billion as compared to \$5.4 billion in the fiscal first quarter of 2014, an increase of 2.8%. Contributors to the increase included operational sales growth and a net litigation gain of \$0.4 billion primarily due to a litigation settlement agreement of \$0.6 billion with Guidant Corporation (Guidant). This was partially offset by currency impacts and loss of sales of OLYSIO®(simeprevir), a higher margin product in the Pharmaceutical business.

### Cost of Products Sold

Consolidated costs of products sold for the fiscal first quarter of 2015 increased to 30.4% from 30.1% of sales as compared to the same period a year ago. The increase was primarily due to currency impacts and loss of sales of OLYSIO®(simeprevir), a higher margin product in the Pharmaceutical business. The intangible asset amortization expense for the fiscal first quarter of 2015 and 2014 was \$312 million and \$351 million, respectively.

### Selling, Marketing and Administrative Expenses

Consolidated selling, marketing and administrative expenses for the fiscal first quarter of 2015 decreased to 27.9% from 28.6% of sales as compared to the same period a year ago. The decrease was due to leveraged costs driven by mix and cost management as well as timing of certain expenses.

### Research and Development Expense

Worldwide costs of research and development activities for the fiscal first quarter of 2015 increased to 10.9% from 10.1% of sales as compared to the same period a year ago. The increase was primarily due to increased spending and timing of milestone payments in the Pharmaceutical segment.

In-Process Research and Development (IPR&D)

During the fiscal first quarter of 2014, the Company recorded a charge of \$18 million for the discontinuation of a development program related to MENTOR®.



## Table of Contents

### Interest (Income) Expense

Interest income in the fiscal first quarter of 2015 was comparable to the same period a year ago. A higher balance of cash, cash equivalents and marketable securities was offset by lower interest rates. The ending balance of cash, cash equivalents and marketable securities was \$31.3 billion at the end of the fiscal first quarter of 2015 which is an increase of \$1.9 billion as compared to the same period a year ago. The increase in the balance of cash, cash equivalents and marketable securities was due primarily to cash generated from operating activities.

Interest expense in fiscal first quarter of 2015 was slightly higher as compared to the same period a year ago. The higher average debt balance was primarily due to borrowings in November 2014 as the Company capitalized on favorable terms in the capital markets. At the end of the fiscal first quarter of 2015, the Company's debt position was \$19.0 billion as compared to \$17.3 billion the same period a year ago.

### Other (Income) Expense, Net

Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (formerly Johnson & Johnson Development Corporation), gains and losses on divestitures, currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal first quarter of 2015 was favorable by \$0.4 billion as compared to the same period a year ago due to higher net litigation gains of \$0.4 billion, primarily due to a litigation settlement agreement of \$0.6 billion with Guidant and lower Synthes integration costs of \$0.1 billion as compared to the fiscal first quarter of 2014. This was partially offset by higher costs of \$0.1 billion related to the DePuy ASR<sup>TM</sup>Hip program in the fiscal first quarter of 2015. Additionally, in 2015 higher gains on the sale of assets were primarily offset by a trade inventory reserve write-down.

## SEGMENT PRE-TAX PROFIT

### Consumer Segment

Pre-tax profit for the Consumer segment as a percent to sales in the fiscal first quarter of 2015 was 19.0% versus 13.5% for the same period a year ago. The favorable pre-tax profit was impacted by gross margin improvement due to favorable sales volume in the U.S. OTC business, lower selling and administrative expenses and timing of marketing expenses in the fiscal first quarter of 2015 versus the fiscal first quarter of 2014.

### Pharmaceutical Segment

Pre-tax profit for the Pharmaceutical segment as a percent to sales in the fiscal first quarter of 2015 was 38.3% versus 42.8% for the same period a year ago. The fiscal first quarter of 2015 was unfavorably impacted by sales declines of OLYSIO<sup>®</sup>(simeprevir), higher litigation expense of \$0.1 billion as compared to 2014 and currency impacts.

### Medical Devices Segment

Pre-tax profit for the Medical Devices segment as a percent to sales in the fiscal first quarter of 2015 was 35.5% versus 27.8% for the same period a year ago. The favorable pre-tax profit was primarily attributable to a net litigation gain of \$0.5 billion primarily related to a litigation settlement agreement of \$0.6 billion with Guidant and lower Synthes integration costs of \$0.1 billion as compared to the fiscal first quarter of 2014. This was partially offset by higher costs of \$0.1 billion related to the DePuy ASR<sup>TM</sup>Hip program.

Provision for Taxes on Income

The worldwide effective income tax rates for the fiscal first quarters of 2015 and 2014 were 22.5% and 12.9%, respectively. The higher effective tax rate in 2015 as compared to 2014 was primarily due to a tax benefit in the fiscal first quarter of 2014 of \$398 million associated with the Conor Medsystems divestiture which reduced the 2014 first quarter tax rate by 7.3% and the U.S. Internal Revenue Service audit settlement partially offset by increased planned dividends. Additionally, 2015 taxable income increased in higher tax jurisdictions relative to lower tax jurisdictions.

As of March 29, 2015, the Company had approximately \$2.5 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

Table of Contents

months. The Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

See Note 8 to the Consolidated Financial Statements in the Annual Report on Form 10-K for the fiscal year ended December 28, 2014 for more detailed information regarding unrecognized tax benefits.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

Cash and cash equivalents were \$12.0 billion at the end of the fiscal first quarter of 2015 as compared with \$14.5 billion at the fiscal year end of 2014. The primary sources of cash were approximately \$2.9 billion net cash generated from operating activities offset by \$1.8 billion used by investing activities and \$3.2 billion used by financing activities. In addition, the Company had \$19.3 billion in marketable securities at the end of the fiscal first quarter of 2015 and \$18.6 billion at the end of 2014.

Cash flow from operations of \$2.9 billion was the result of \$4.3 billion of net earnings and \$1.1 billion of non-cash charges and other adjustments for depreciation and amortization and stock-based compensation and \$1.6 billion related to deferred taxes and non-current liabilities. Cash flow from operations was reduced by \$4.1 billion related to accounts payable and accrued liabilities, inventories, account receivables, other current and non-current assets and net gains on sale of assets/businesses.

Investing activities use of \$1.8 billion of cash was primarily for net purchases of investments in marketable securities of \$1.1 billion, additions to property, plant and equipment of \$0.5 billion and acquisitions of \$0.2 billion partially offset by proceeds from the disposal of assets/businesses of \$0.1 billion.

Financing activities use of \$3.2 billion of cash was primarily for dividends to shareholders of \$1.9 billion and \$2.2 billion for the repurchase of common stock. Financing activities also included a source of \$0.6 billion of net proceeds from stock options exercised and associated tax benefits and net proceeds of short and long-term debt of \$0.4 billion.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2014, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 17, 2015, approximates \$10.0 billion. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

In the fiscal first quarter of 2015, the Company continued to have access to liquidity through the commercial paper market. The Company anticipates that operating cash flows, existing credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs. However, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's shares of common stock. As of March 29, 2015, \$4.6 billion has been repurchased under the program. Share repurchases will take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash.

Dividends

On January 5, 2015, the Board of Directors declared a regular quarterly cash dividend of \$0.70 per share, payable on March 10, 2015, to shareholders of record as of February 24, 2015.

On April 23, 2015, the Board of Directors declared a regular cash dividend of \$0.75 per share, payable on June 9, 2015 to shareholders of record as of May 26, 2015. The Company expects to continue the practice of paying regular quarterly cash dividends.

## Table of Contents

### Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately \$1.7 billion as of March 29, 2015 and approximately \$1.8 billion as of December 28, 2014. Approximately \$1.0 billion as of March 29, 2015 and approximately \$1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers, which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers was approximately \$0.7 billion at March 29, 2015 and December 28, 2014. The Company continues to receive payments from these customers and in some cases late payment premiums. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions, as necessary.

### OTHER INFORMATION

#### New Accounting Pronouncements

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

#### Economic and Market Factors

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates and currency exchange rates continue to have an effect on worldwide economies and, consequently, on the way the Company operates. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

The Venezuelan government has established or is in the process of establishing alternative systems and offerings of various foreign currency exchanges. In 2015, the Company continued to have access to an official government rate of 6.3 Bolivares Fuertes to one U.S. dollar to settle imports of various products into Venezuela. Through the first quarter of 2015, the Company has primarily utilized the official government rate of 6.3 Bolivares Fuertes to one U.S. dollar in preparing its consolidated financial statements. The Company continues to evaluate the appropriateness of the use of the official government rate for the translation of its financial statements. If the Company's ability to have consistent access to the official rate to exchange Bolivares Fuertes to U.S. dollars is impaired in the future, it would consider the use of one of the alternative rates in its preparing its consolidated financial statements. During 2014, the Company applied to settle an outstanding dividend payable at one of the alternative foreign exchange rates. As a result, the Company has applied this alternative exchange rate to translate certain transactions, as appropriate. As of March 29, 2015, the Company's Venezuelan subsidiaries represented less than 0.6% of the Company's consolidated assets, liabilities, revenues and profits; therefore, the effect of a possible change in the exchange rate is not expected to have a material adverse effect on the Company's 2015 full-year results.

As described above, while the Company continues to do business in Greece, the Company closely monitors the economic situation. As of March 29, 2015, the Company's Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and revenues, respectively.

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

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

Table of Contents

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

**CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS**

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

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

Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; the impact of patent expirations; uncertainty of commercial success of new and existing products; significant adverse litigation or government action, including related to product liability claims; impact of business combinations and divestitures; significant changes in customer relationships or changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to laws and regulations and global health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; financial instability of international economies and sovereign risk; manufacturing difficulties or delays; complex global supply chains with increasing regulatory requirements; product efficacy or safety concerns resulting in product recalls or regulatory action; disruptions due to natural disasters; and the potential failure to meet obligations in compliance agreements with government bodies.

The Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2014, including Exhibit 99 thereto, contains a discussion of additional factors that could cause actual results to differ from expectations. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

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

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in its Annual Report on Form 10-K

for the fiscal year ended December 28, 2014.

Item 4 — CONTROLS AND PROCEDURES

Disclosure controls and procedures. At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is 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

35

---



Table of Contents

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

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

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

## Part II — OTHER INFORMATION

## Item 1 — LEGAL PROCEEDINGS

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

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

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

The following table provides information with respect to Common Stock purchases by the Company during the fiscal first quarter of 2015. Common Stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's shares of common stock. Share repurchases will take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal first quarter.

Period	Total Number of Shares Purchased <sup>(1)</sup>	Avg. Price Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(2)</sup>	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(3)</sup>
December 29, 2014 through January 25, 2015	2,028,697	105.23	—	—
January 26, 2015 through February 22, 2015	13,728,174	100.77	4,847,200	—
February 23, 2015 through March 29, 2015	6,214,830	100.98	6,173,249	—
Total	21,971,701		11,020,449	3,936,678

(1) During the fiscal first quarter of 2015, the Company repurchased an aggregate of 21,971,701 shares of Johnson & Johnson Common Stock in open-market transactions, of which 11,020,449 shares were purchased pursuant to the repurchase program that was publicly announced on July 21, 2014, and of which 10,951,252 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of March 29, 2015, an aggregate of 44,703,507 shares were purchased for a total of \$4.6 billion since the inception of the repurchase program announced on July 21, 2014.

(3) As of March 29, 2015, the maximum number of shares that may yet be purchased under the plan is 3,936,678 based on the closing price of the Company's Common Stock on the New York Stock Exchange on March 27, 2015 of \$100.34 per share.

Table of Contents

Item 6 — EXHIBITS

Exhibit 10.1 Executive Life Insurance Program Closure Letter

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 29, 2015, formatted in Extensive Business Reporting Language (XBRL), (i) consolidated balance sheets, (ii) consolidated statements of earnings, (iii) consolidated statements of comprehensive income (iv) consolidated statements of cash flows, and (v) the notes to the consolidated financial statements.

Table of Contents

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 1, 2015

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

Date: May 1, 2015

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