

JOHNSON & JOHNSON  
Form 10-Q  
November 08, 2011

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**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 October 2, 2011  
or**

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the transition period from      to  
Commission file number 1-3215  
(Exact name of registrant as specified in its charter)**

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

22-1024240  
(I.R.S. Employer  
Identification No.)

One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933  
(Address of principal executive offices)

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

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

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

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

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

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

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

On October 28, 2011 2,730,849,018 shares of Common Stock, \$1.00 par value, were outstanding.

JOHNSON & JOHNSON AND SUBSIDIARIES

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## Part I FINANCIAL INFORMATION

## Item 1 FINANCIAL STATEMENTS

## JOHNSON &amp; JOHNSON AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

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

|   | October 2,<br>2011 | January 2,<br>2011 |
|---|--------------------|--------------------|
| <b>ASSETS</b>   |                    |                    |
| Current assets:   |                    |                    |
| Cash and cash equivalents   | \$ 15,617          | \$ 19,355          |
| Marketable securities   | 15,310             | 8,303              |
| Accounts receivable, trade, less allowances for doubtful accounts \$315<br>(2010, \$340)                    | 10,552             | 9,774              |
| Inventories (Note 2)  | 6,428              | 5,378              |
| Deferred taxes on income  | 2,480              | 2,224              |
| Prepaid expenses and other receivables  | 3,056              | 2,273              |
| Total current assets  | 53,443             | 47,307             |
| Property, plant and equipment at cost   | 31,736             | 30,426             |
| Less: accumulated depreciation  | (17,101)           | (15,873)           |
| Property, plant and equipment, net  | 14,635             | 14,553             |
| Intangible assets, net (Note 3)   | 18,225             | 16,716             |
| Goodwill, net (Note 3)  | 16,049             | 15,294             |
| Deferred taxes on income  | 5,564              | 5,096              |
| Other assets  | 3,905              | 3,942              |
| Total assets  | \$ 111,821         | \$ 102,908         |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>   |                    |                    |
| Current liabilities:  |                    |                    |
| Loans and notes payable   | \$ 5,326           | \$ 7,617           |
| Accounts payable  | 5,730              | 5,623              |
| Accrued liabilities   | 4,136              | 4,100              |
| Accrued rebates, returns and promotions   | 2,895              | 2,512              |
| Accrued compensation and employee related obligations   | 2,263              | 2,642              |
| Accrued taxes on income   | 1,336              | 578                |
| Total current liabilities   | 21,686             | 23,072             |
| Long-term debt (Note 4)   | 13,031             | 9,156              |
| Deferred taxes on income  | 1,889              | 1,447              |
| Employee related obligations  | 6,215              | 6,087              |
| Other liabilities   | 7,473              | 6,567              |
| Total liabilities   | 50,294             | 46,329             |
| Shareholders' equity:   |                    |                    |
| Common stock - par value \$1.00 per share (authorized 4,320,000,000<br>shares; issued 3,119,843,000 shares) | \$ 3,120           | \$ 3,120           |
| Accumulated other comprehensive income (Note 7)   | (3,068)            | (3,531)            |
| Retained earnings   | 82,634             | 77,773             |
| Less: common stock held in treasury, at cost (387,592,000 and 381,746,000<br>shares)                        | 21,159             | 20,783             |
| Total shareholders' equity  | 61,527             | 56,579             |
| Total liabilities and shareholders' equity  | \$ 111,821         | \$ 102,908         |



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

|  | Fiscal Third Quarters<br>Ended |                     |                    |                     |
|--|--------------------------------|---------------------|--------------------|---------------------|
|  | October 2,<br>2011             | Percent<br>to Sales | October 3,<br>2010 | Percent<br>to Sales |
| Sales to customers (Note 9)                    | \$ 16,005                      | 100.0%              | \$ 14,982          | 100.0%              |
| Cost of products sold                          | 5,072                          | 31.7                | 4,594              | 30.7                |
| Gross profit                                   | 10,933                         | 68.3                | 10,388             | 69.3                |
| Selling, marketing and administrative expenses | 5,240                          | 32.7                | 4,709              | 31.4                |
| Research and development expense               | 1,773                          | 11.1                | 1,657              | 11.1                |
| Interest income                                | (17)                           | (0.1)               | (13)               | (0.1)               |
| Interest expense, net of portion capitalized   | 134                            | 0.8                 | 108                | 0.7                 |
| Other (income) expense, net                    | (308)                          | (1.9)               | (292)              | (2.0)               |
| Earnings before provision for taxes on income  | 4,111                          | 25.7                | 4,219              | 28.2                |
| Provision for taxes on income (Note 5)         | 909                            | 5.7                 | 802                | 5.4                 |
| <b>NET EARNINGS</b>                            | <b>\$ 3,202</b>                | <b>20.0%</b>        | <b>\$ 3,417</b>    | <b>22.8%</b>        |
| <b>NET EARNINGS PER SHARE (Note 8)</b>         |                                |                     |                    |                     |
| Basic  | \$ 1.17                        |                     | \$ 1.24            |                     |
| Diluted  | \$ 1.15                        |                     | \$ 1.23            |                     |
| <b>CASH DIVIDENDS PER SHARE</b>                | <b>\$ 0.57</b>                 |                     | <b>\$ 0.54</b>     |                     |
| <b>AVG. SHARES OUTSTANDING</b>                 |                                |                     |                    |                     |
| Basic  | 2,737.0                        |                     | 2,751.6            |                     |
| Diluted  | 2,778.2                        |                     | 2,786.4            |                     |

See Notes to Consolidated Financial Statements

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

|  | Fiscal Nine Months<br>Ended |                     |                    |                     |
|--|-----------------------------|---------------------|--------------------|---------------------|
|  | October 2,<br>2011          | Percent<br>to Sales | October 3,<br>2010 | Percent<br>to Sales |
| Sales to customers (Note 9)                    | \$ 48,775                   | 100.0%              | \$ 45,943          | 100.0%              |
| Cost of products sold                          | 15,022                      | 30.8                | 13,752             | 29.9                |
| Gross profit                                   | 33,753                      | 69.2                | 32,191             | 70.1                |
| Selling, marketing and administrative expenses | 15,511                      | 31.8                | 14,244             | 31.0                |
| Research and development expense               | 5,393                       | 11.0                | 4,862              | 10.6                |
| Interest income                                | (56)                        | (0.1)               | (83)               | (0.2)               |
| Interest expense, net of portion capitalized   | 388                         | 0.8                 | 317                | 0.7                 |
| Other (income) expense, net                    | (115)                       | (0.2)               | (1,868)            | (4.0)               |
| Restructuring expense                          | 589                         | 1.2                 |                    |                     |
| Earnings before provision for taxes on income  | 12,043                      | 24.7                | 14,719             | 32.0                |
| Provision for taxes on income (Note 5)         | 2,589                       | 5.3                 | 3,327              | 7.2                 |
| NET EARNINGS                                   | \$ 9,454                    | 19.4%               | \$ 11,392          | 24.8%               |
| NET EARNINGS PER SHARE (Note 8)                |                             |                     |                    |                     |
| Basic  | \$ 3.45                     |                     | \$ 4.14            |                     |
| Diluted  | \$ 3.40                     |                     | \$ 4.08            |                     |
| CASH DIVIDENDS PER SHARE                       | \$ 1.68                     |                     | \$ 1.57            |                     |
| AVG. SHARES OUTSTANDING                        |                             |                     |                    |                     |
| Basic  | 2,738.5                     |                     | 2,754.2            |                     |
| Diluted  | 2,777.6                     |                     | 2,792.0            |                     |

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

|  | Fiscal Nine Months Ended |                    |
|--|--------------------------|--------------------|
|  | October<br>2,<br>2011    | October 3,<br>2010 |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>                                     |                          |                    |
| Net earnings   | \$ 9,454                 | \$ 11,392          |
| Adjustments to reconcile net earnings to cash flows from operating activities: |                          |                    |
| Depreciation and amortization of property and intangibles                      | 2,315                    | 2,170              |
| Stock based compensation   | 484                      | 474                |
| Deferred tax provision   | (849)                    | 644                |
| Accounts receivable allowances   | (21)                     | 30                 |
| Changes in assets and liabilities, net of effects from acquisitions:           |                          |                    |
| Increase in accounts receivable  | (489)                    | (585)              |
| Increase in inventories  | (787)                    | (197)              |
| Decrease in accounts payable and accrued liabilities                           | (100)                    | (1,552)            |
| Increase in other current and non-current assets                               | (906)                    | (310)              |
| Increase in other current and non-current liabilities                          | 1,746                    | 495                |
| <b>NET CASH FLOWS FROM OPERATING ACTIVITIES</b>                                | <b>10,847</b>            | <b>12,561</b>      |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                    |                          |                    |
| Additions to property, plant and equipment                                     | (1,765)                  | (1,425)            |
| Proceeds from the disposal of assets   | 721                      | 324                |
| Acquisitions, net of cash acquired   | (2,469)                  | (1,269)            |
| Purchases of investments   | (25,444)                 | (10,679)           |
| Sales of investments   | 18,438                   | 6,669              |
| Other  | (331)                    | (70)               |
| <b>NET CASH USED BY INVESTING ACTIVITIES</b>                                   | <b>(10,850)</b>          | <b>(6,450)</b>     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                                    |                          |                    |
| Dividends to shareholders  | (4,601)                  | (4,323)            |
| Repurchase of common stock   | (1,672)                  | (1,512)            |
| Proceeds from short-term debt  | 7,216                    | 1,896              |
| Retirement of short-term debt  | (10,044)                 | (5,390)            |
| Proceeds from long-term debt   | 4,471                    | 1,079              |
| Retirement of long-term debt   | (12)                     | (21)               |
| Proceeds from the exercise of stock options/excess tax benefits                | 946                      | 685                |
| <b>NET CASH USED BY FINANCING ACTIVITIES</b>                                   | <b>(3,696)</b>           | <b>(7,586)</b>     |
| Effect of exchange rate changes on cash and cash equivalents                   | (39)                     | 3                  |
| Decrease in cash and cash equivalents  | (3,738)                  | (1,472)            |
| Cash and Cash equivalents, beginning of period                                 | 19,355                   | 15,810             |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>                                | <b>\$ 15,617</b>         | <b>\$ 14,338</b>   |
| Acquisitions   |                          |                    |
| Fair value of assets acquired  | \$ 2,689                 | \$ 1,321           |
| Fair value of liabilities assumed and non-controlling interests                | (220)                    | (52)               |
| Net cash paid for acquisitions   | \$ 2,469                 | \$ 1,269           |

See Notes to Consolidated Financial Statements





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**NOTE 1** The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company ) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented.

During the fiscal third quarter of 2011, the Financial Accounting Standards Board (FASB) issued amendments to goodwill impairment testing. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. However, if an entity concludes otherwise, then it is required to perform the first step of the two-step impairment test. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal second quarter of 2011, the FASB issued an amendment to the disclosure requirements for presentation of comprehensive income. The amendment requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance is effective retrospectively for the interim periods and annual periods beginning after December 15, 2011. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

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

During the fiscal first quarter of 2011, the Company adopted the FASB guidance and amendments issued related to revenue recognition under the milestone method. The objective of the accounting standard update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. This update became effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2011, the Company adopted the FASB guidance on how pharmaceutical companies should recognize and classify in the Company's financial statements, the non-deductible annual fee paid to the Government in accordance with the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act. This fee is based on an allocation of a company's market share of total branded prescription drug sales from the prior year. The estimated fee was recorded as a selling, marketing and administrative expense in the Company's financial statement and will be amortized on a straight-line basis for the year as per the FASB guidance. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

**NOTE 2 INVENTORIES**

| (Dollars in Millions)      | October 2,<br>2011 | January 2,<br>2011 |
|----------------------------|--------------------|--------------------|
| Raw materials and supplies | \$ 1,348           | 1,073              |

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|                   |  |          |       |
|-------------------|--|----------|-------|
| Goods in process  |  | 1,853    | 1,460 |
| Finished goods    |  | 3,227    | 2,845 |
| Total inventories |  | \$ 6,428 | 5,378 |

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Intangible assets that have finite useful lives are amortized over their estimated useful lives. The latest impairment assessment of goodwill and indefinite lived intangible assets was completed in the fiscal fourth quarter of 2010. 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)                         | October 2,<br>2011 | January 2,<br>2011 |
|---|--------------------|--------------------|
| Intangible assets with definite lives:        |                    |                    |
| Patents and trademarks gross                  | \$ 7,789           | 6,660              |
| Less accumulated amortization                 | 2,883              | 2,629              |
| Patents and trademarks net                    | 4,906              | 4,031              |
| Other intangibles gross                       | 8,787              | 7,674              |
| Less accumulated amortization                 | 3,369              | 2,880              |
| Other intangibles net                         | 5,418              | 4,794              |
| Intangible assets with indefinite lives:      |                    |                    |
| Trademarks                                    | 5,951              | 5,954              |
| Purchased in-process research and development | 1,950              | 1,937              |
| Total intangible assets with indefinite lives | 7,901              | 7,891              |
| Total intangible assets net                   | \$ 18,225          | 16,716             |

The acquisition of Crucell N.V. during the fiscal first quarter of 2011, increased purchased in-process research and development by \$1.0 billion. During the fiscal second quarter of 2011, the Company reclassified \$971 million from purchased in-process research and development to amortizable other intangibles to reflect the commercialization of ZYTIGA®.

Goodwill as of October 2, 2011 was allocated by segment of business as follows:

| (Dollars in Millions)               | Consumer | Pharm | Med Dev<br>& Diag | Total  |
|-------------------------------------|----------|-------|-------------------|--------|
| Goodwill, net at January 2, 2011    | \$ 8,144 | 1,225 | 5,925             | 15,294 |
| Acquisitions                        | 251      | 538   |                   | 789    |
| Currency translation/Other          | (60)     | 5     | 21                | (34)   |
| Goodwill, net as of October 2, 2011 | \$ 8,335 | 1,768 | 5,946             | 16,049 |

The weighted average amortization periods for patents and trademarks and other intangible assets are 17 years and 27 years, respectively. The amortization expense of amortizable intangible assets for the fiscal nine months ended October 2, 2011 was \$611 million, and the estimated amortization expense for the five succeeding years approximates \$840 million, per year.

**NOTE 4 FAIR VALUE MEASUREMENTS**

The Company uses forward exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany product and third-party purchases of raw materials denominated in foreign currency. The Company also uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges. The Company also uses forward exchange contracts to manage its exposure to the variability of cash flows for repatriation of foreign dividends. These contracts are designated as net investment hedges. Additionally, the Company uses forward exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward exchange contracts are not designated as hedges, and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities. The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low,

because the Company enters into agreements with commercial institutions that have at least an A (or equivalent) credit rating. As of

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October 2, 2011, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of \$25 billion and \$3 billion, respectively.

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

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains/losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes in the cash flows of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in other (income)/expense, net, and was not material for the fiscal quarters ended October 2, 2011 and October 3, 2010. Refer to Note 7 for disclosures of movements in Accumulated Other Comprehensive Income.

As of October 2, 2011, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was \$180 million after-tax. For additional information, see Note 7. The Company expects that substantially all of the amounts related to foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months excluding interest rate swaps. The amount ultimately realized in earnings will differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as hedges for the fiscal third quarters in 2011 and 2010:

| (Dollars in Millions)                 | Gain/ (Loss)<br>recognized in<br>Accumulated<br>OCI <sup>(1)</sup> |      | Gain/(Loss)<br>reclassified from<br>Accumulated OCI<br>into income <sup>(1)</sup><br>Fiscal Third Quarters<br>Ended |           | Gain/ (Loss)<br>recognized in<br>other<br>income/expense <sup>(2)</sup> |      |
|---------------------------------------|--|------|---|-----------|---|------|
|                                       | 2011   | 2010 | 2011  | 2010      | 2011  | 2010 |
| <b>Cash Flow Hedges</b>               |  |      |   |           |   |      |
| Foreign exchange contracts            | \$ (57)  | 45   | 4   | (12) (A)  | 1   | 18   |
| Foreign exchange contracts            | (58)   | (7)  | (21)  | (106) (B) | (1)   | 121  |
| Foreign exchange contracts            | 6  | (46) | (40)  | 20 (C)    | 1   | (11) |
| Cross currency interest rate<br>swaps | (67)   | (24) | (6)   | (1) (D)   |   |      |
| Foreign exchange contracts            | 59   | (63) | (4)   | 9 (E)     | (1)   | (17) |
| Total                                 | \$ (117)   | (95) | (67)  | (90)      |   | 111  |

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

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The following table is a summary of the activity related to derivatives designated as hedges for the fiscal nine months in 2011 and 2010:

| (Dollars in Millions)              | <b>Gain/ (Loss)<br/>recognized in<br/>Accumulated<br/>OCI<sup>(1)</sup></b> |       | <b>Gain/ (Loss)<br/>reclassified from<br/>Accumulated OCI<br/>into income<sup>(1)</sup></b><br>Fiscal Nine Months<br>Ended |           | <b>Gain/ (Loss)<br/>recognized in<br/>other<br/>income/expense<sup>(2)</sup></b> |      |
|------------------------------------|---|-------|--|-----------|--|------|
|                                    | 2011  | 2010  | 2011   | 2010      | 2011   | 2010 |
| <b>Cash Flow Hedges</b>            |   |       |  |           |  |      |
| Foreign exchange contracts         | \$ (30)   | (39)  | (6)  | (41) (A)  | (1)  | (3)  |
| Foreign exchange contracts         | 34  | (213) | (127)  | (204) (B) | 2  | (33) |
| Foreign exchange contracts         | (2)   | 27    | (21)   | 41 (C)    | (1)  | 5    |
| Cross currency interest rate swaps | (107)   | (73)  | (24)   | 10 (D)    |  |      |
| Foreign exchange contracts         |   | 18    | (7)  | 8 (E)     | 1  | 3    |
| Total                              | \$ (105)  | (280) | (185)  | (186)     | 1  | (28) |

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

(1) Effective portion

(2) Ineffective portion

(A) Included in Sales to customers

(B) Included in Cost of products sold

(C) Included in Research and development expense

(D) Included in Interest (income)/Interest expense, net

(E) Included in Other (income)/expense, net

For the fiscal third quarters ended October 2, 2011 and October 3, 2010, a loss of \$10 million and a gain of \$119 million, respectively, were recognized in Other (income)/expense, net, relating to foreign exchange contracts not designated as hedging instruments.

For the fiscal nine months ended October 2, 2011 and October 3, 2010, a loss of \$2 million and a gain of \$50 million, respectively, were recognized in Other (income)/expense, net, relating to foreign exchange contracts not designated as hedging instruments.

In addition, during the fiscal second quarter of 2011, the Company entered into an option to hedge the currency risk associated with the cash portion of the payment for the planned acquisition of Synthes, Inc. The option was not designated as a hedge, and therefore, changes in the fair value of the option are recognized as other (income)/expense, net. During the fiscal third quarter and the fiscal nine months ended October 2, 2011, the mark to market adjustment to reduce the value of the currency option was \$304 million and \$202 million, respectively.

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

The fair value of a derivative financial instrument (i.e., forward exchange contract or currency swap) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differs 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.



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The Company's significant financial assets and liabilities measured at fair value as of October 2, 2011 and January 2, 2011 were as follows:

| (Dollars in Millions)                                     | October 2, 2011 |         |         | January 2, 2011 |                      |
|---|-----------------|---------|---------|-----------------|----------------------|
|   | Level 1         | Level 2 | Level 3 | Total           | Total <sup>(1)</sup> |
| <b>Derivatives designated as hedging instruments:</b>     |                 |         |         |                 |                      |
| <b>Assets:</b>  |                 |         |         |                 |                      |
| Foreign exchange contracts                                | \$              | \$ 604  | \$      | \$ 604          | \$ 321               |
| Cross currency interest rate swaps <sup>(2)</sup>         |                 | 7       |         | 7               | 17                   |
| <b>Total</b>  |                 | 611     |         | 611             | 338                  |
| <b>Liabilities:</b>                                       |                 |         |         |                 |                      |
| Foreign exchange contracts                                |                 | 425     |         | 425             | 586                  |
| Cross currency interest rate swaps <sup>(3)</sup>         |                 | 599     |         | 599             | 502                  |
| <b>Total</b>  |                 | 1,024   |         | 1,024           | 1,088                |
| <b>Derivatives not designated as hedging instruments:</b> |                 |         |         |                 |                      |
| <b>Assets:</b>  |                 |         |         |                 |                      |
| Foreign exchange contracts                                |                 | 20      |         | 20              | 19                   |
| Swiss Franc Option*                                       |                 | 265     |         | 265             |                      |
| <b>Total</b>  |                 | 285     |         | 285             | 19                   |
| <b>Liabilities:</b>                                       |                 |         |         |                 |                      |
| Foreign exchange contracts                                |                 | 14      |         | 14              | 39                   |
| <b>Other Investments<sup>(4)</sup></b>                    | \$ 1,211        | \$      | \$      | \$ 1,211        | \$ 1,165             |

\* Currency option related to the planned acquisition of Synthes, Inc.

(1) As of January 2, 2011, these assets and liabilities are classified as Level 2 with the exception of Other Investments of \$1,165 which are classified as Level 1.

(2) Includes \$7 million and \$14 million of non-current assets for October 2, 2011 and January 2, 2011, respectively.

(3) Includes \$598 million and \$502 million of non-current liabilities for October 2, 2011 and January 2, 2011, respectively.

(4) Classified as non-current other assets.

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Financial Instruments not measured at Fair Value:

The following financial assets and liabilities are held at carrying amount on the consolidated balance sheet as of October 2, 2011:

| (Dollars in Millions)   | Carrying<br>Amount | Estimated<br>Fair Value |
|---|--------------------|-------------------------|
| <b>Financial Assets</b>   |                    |                         |
| <b>Current Investments</b>  |                    |                         |
| Cash  | \$ 2,314           | 2,314                   |
| Government securities and obligations   | 25,380             | 25,381                  |
| Corporate debt securities   | 612                | 612                     |
| Money market funds  | 1,550              | 1,550                   |
| Time deposits   | 1,071              | 1,071                   |
| Total cash, cash equivalents and current marketable securities  | \$ 30,927          | 30,928                  |
| Fair value of government securities and obligations and corporate debt securities was estimated using quoted broker prices in active markets. |                    |                         |
| <b>Financial Liabilities</b>  |                    |                         |
| <b>Current Debt</b>   |                    |                         |
|   | \$ 5,326           | 5,326                   |
| <b>Non-Current Debt</b>   |                    |                         |
| 0.70% Notes due 2013  | 500                | 502                     |
| 3.80% Debentures due 2013   | 500                | 526                     |
| 3 month LIBOR+0% FRN due 2013   | 500                | 500                     |
| 3 month LIBOR+0.09% FRN due 2014  | 750                | 750                     |
| 1.20% Notes due 2014  | 999                | 1,015                   |
| 2.15% Notes due 2016  | 898                | 933                     |
| 5.55% Debentures due 2017   | 1,000              | 1,214                   |
| 5.15% Debentures due 2018   | 898                | 1,081                   |
| 4.75% Notes due 2019 (1B Euro 1.3634)   | 1,356              | 1,560                   |
| 3% Zero Coupon Convertible Subordinated Debentures due in 2020  | 199                | 232                     |
| 2.95% Debentures due 2020   | 541                | 567                     |
| 3.55% Notes due 2021  | 446                | 496                     |
| 6.73% Debentures due 2023   | 250                | 358                     |
| 5.50% Notes due 2024 (500 GBP1.5672)  | 778                | 927                     |
| 6.95% Notes due 2029  | 294                | 426                     |
| 4.95% Debentures due 2033   | 500                | 582                     |
| 5.95% Notes due 2037  | 995                | 1,318                   |
| 5.86% Debentures due 2038   | 700                | 925                     |
| 4.50% Debentures due 2040   | 539                | 601                     |
| 4.85% Notes due 2041  | 298                | 351                     |
| Other   | 90                 | 90                      |
| Total Non-Current Debt  | \$ 13,031          | 14,954                  |

The weighted average effective rate on non-current debt is 4.02%.

Fair value of the non-current debt was estimated using market prices, which were corroborated by quoted broker prices in active markets.

**Table of Contents****NOTE 5 INCOME TAXES**

The worldwide effective income tax rates for the fiscal nine months of 2011 and 2010 were 21.5% and 22.6%, respectively. The lower effective tax rate was due to higher income in lower tax jurisdictions and the U.S. Research and Development tax credit, which was not in effect for the fiscal nine months of 2010. Additionally, in 2010 the Company had litigation gains in high tax jurisdictions.

**NOTE 6 PENSIONS AND OTHER POSTRETIREMENT BENEFITS****Components of Net Periodic Benefit Cost**

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal third quarters of 2011 and 2010 include the following components:

|   | Retirement Plans            |                 |                 | Other Benefit Plans |
|---|-----------------------------|-----------------|-----------------|---------------------|
|   | Fiscal Third Quarters Ended |                 |                 |                     |
|   | October 2, 2011             | October 3, 2010 | October 2, 2011 | October 3, 2010     |
| (Dollars in Millions)                       |                             |                 |                 |                     |
| Service cost                                | \$ 146                      | 125             | 38              | 33                  |
| Interest cost                               | 214                         | 198             | 47              | 52                  |
| Expected return on plan assets              | (279)                       | (251)           |                 |                     |
| Amortization of prior service cost/(credit) | 3                           | 1               | (1)             | (2)                 |
| Amortization of net transition obligation   |                             |                 |                 |                     |
| Recognized actuarial losses                 | 97                          | 59              | 11              | 12                  |
| Net periodic benefit cost                   | \$ 181                      | 132             | 95              | 95                  |

Net periodic benefit cost for the Company's defined benefit retirement plans and other benefit plans for the fiscal nine months of 2011 and 2010 include the following components:

|   | Retirement Plans         |                 |                 | Other Benefit Plans |
|---|--------------------------|-----------------|-----------------|---------------------|
|   | Fiscal Nine Months Ended |                 |                 |                     |
|   | October 2, 2011          | October 3, 2010 | October 2, 2011 | October 3, 2010     |
| (Dollars in Millions)                       |                          |                 |                 |                     |
| Service cost                                | \$ 433                   | 372             | 112             | 100                 |
| Interest cost                               | 641                      | 592             | 141             | 152                 |
| Expected return on plan assets              | (834)                    | (751)           | (1)             | (1)                 |
| Amortization of prior service cost/(credit) | 7                        | 7               | (2)             | (4)                 |
| Amortization of net transition obligation   | 1                        | 1               |                 |                     |
| Recognized actuarial losses                 | 291                      | 176             | 34              | 37                  |
| Net periodic benefit cost                   | \$ 539                   | 397             | 284             | 284                 |

**Company Contributions**

For the fiscal nine months ended October 2, 2011, the Company contributed \$129 million and \$24 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.

**Table of Contents****NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME**

Total comprehensive income for the fiscal nine months ended October 2, 2011 was \$9.9 billion, compared with \$11.5 billion for the same period a year ago. Total comprehensive income for the fiscal third quarter ended October 2, 2011 was \$1.3 billion, compared with \$6.2 billion for the same period a year ago. Total comprehensive income included net earnings, net unrealized currency gains and losses on translation, net unrealized gains and losses on securities available for sale, adjustments related to employee benefit plans, and net gains and losses on derivative instruments qualifying and designated as cash flow hedges.

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

|   | Foreign<br>Currency<br>Translation | Securities<br>Available<br>for sale | Employee<br>Benefit<br>Plans | Deriv.<br>&<br>Hedges | Total<br>Accum<br>Other<br>Comp.<br>Income/<br>(Loss) |
|---|------------------------------------|-------------------------------------|------------------------------|-----------------------|---|
| Gains/(Losses)<br>(Dollars in Millions) |                                    |                                     |                              |                       |   |
| January 2, 2011                         | \$ (969)                           | 24                                  | (2,686)                      | 100                   | (3,531)   |
| 2011 nine months change                 |                                    |                                     |                              |                       |   |
| Unrealized gain (loss)                  |                                    | 327                                 |                              | (105)                 |   |
| Net amount reclassified to net earnings |                                    | (142)                               |                              | 185*                  |   |
| Net nine months change                  | (3)                                | 185                                 | 201                          | 80                    | 463   |
| October 2, 2011                         | \$ (972)                           | 209                                 | (2,485)                      | 180                   | (3,068)   |

\* Substantially offset in net earnings by changes in value of the underlying transactions.

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation adjustments are not currently adjusted for income taxes as they relate to permanent investments in international subsidiaries.

**NOTE 8 EARNINGS PER SHARE**

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal third quarters ended October 2, 2011 and October 3, 2010:

|   | Fiscal Third Quarters Ended |                    |
|---|-----------------------------|--------------------|
|   | October<br>2,<br>2011       | October 3,<br>2010 |
| (Shares in Millions)  |                             |                    |
| Basic net earnings per share  | \$ 1.17                     | \$ 1.24            |
| Average shares outstanding basic                                    | 2,737.0                     | 2,751.6            |
| Potential shares exercisable under stock option plans               | 165.0                       | 149.6              |
| Less: shares which could be repurchased under treasury stock method | (127.4)                     | (118.4)            |
| Convertible debt shares   | 3.6                         | 3.6                |
| Average shares outstanding diluted                                  | 2,778.2                     | 2,786.4            |
| Diluted earnings per share  | \$ 1.15                     | \$ 1.23            |

The diluted earnings per share calculation for both fiscal third quarters ended October 2, 2011 and October 3, 2010 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted earnings per share calculation for the fiscal third quarters ended October 2, 2011 and October 3, 2010, excluded 51 million and 86 million shares, respectively, related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share.

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The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal nine months ended October 2, 2011 and October 3, 2010:

| (Shares in Millions)  | Fiscal Nine Months Ended |                 |
|---|--------------------------|-----------------|
|   | October 2, 2011          | October 3, 2010 |
| Basic net earnings per share  | \$ 3.45                  | \$ 4.14         |
| Average shares outstanding basic                                    | 2,738.5                  | 2,754.2         |
| Potential shares exercisable under stock option plans               | 164.7                    | 149.9           |
| Less: shares which could be repurchased under treasury stock method | (129.2)                  | (115.7)         |
| Convertible debt shares   | 3.6                      | 3.6             |
| Average shares outstanding diluted                                  | 2,777.6                  | 2,792.0         |
| Diluted earnings per share  | \$ 3.40                  | \$ 4.08         |

The diluted earnings per share calculation for both the fiscal nine months ended October 2, 2011 and October 3, 2010 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense.

The diluted earnings per share calculation for the fiscal nine months ended October 2, 2011 and October 3, 2010 excluded 51 million and 85 million shares related to stock options, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share.

**NOTE 9 SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS****SALES BY SEGMENT OF BUSINESS**

| (Dollars in Millions)                    | Fiscal Third Quarters Ended |                 |                |
|--|-----------------------------|-----------------|----------------|
|  | October 2, 2011             | October 3, 2010 | Percent Change |
| <b>Consumer</b>                          |                             |                 |                |
| United States                            | \$ 1,219                    | \$ 1,277        | (4.5)%         |
| International                            | 2,521                       | 2,290           | 10.1           |
| Total                                    | 3,740                       | 3,567           | 4.9            |
| <b>Pharmaceutical</b>                    |                             |                 |                |
| United States                            | 2,869                       | 3,054           | (6.1)          |
| International                            | 3,113                       | 2,441           | 27.5           |
| Total                                    | 5,982                       | 5,495           | 8.9            |
| <b>Medical Devices &amp; Diagnostics</b> |                             |                 |                |
| United States                            | 2,780                       | 2,800           | (0.7)          |
| International                            | 3,503                       | 3,120           | 12.3           |
| Total                                    | 6,283                       | 5,920           | 6.1            |
| <b>Worldwide</b>                         |                             |                 |                |
| United States                            | 6,868                       | 7,131           | (3.7)          |
| International                            | 9,137                       | 7,851           | 16.4           |
| Total                                    | \$ 16,005                   | \$ 14,982       | 6.8%           |

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| (Dollars in Millions)         | Fiscal Nine Months Ended |                    |                   |
|-------------------------------|--------------------------|--------------------|-------------------|
|                               | October<br>2,<br>2011    | October 3,<br>2010 | Percent<br>Change |
| Consumer                      |                          |                    |                   |
| United States                 | \$ 3,903                 | \$ 4,300           | (9.2)%            |
| International                 | 7,312                    | 6,680              | 9.5               |
| Total                         | 11,215                   | 10,980             | 2.1               |
| Pharmaceutical                |                          |                    |                   |
| United States                 | 9,499                    | 9,370              | 1.4               |
| International                 | 8,775                    | 7,316              | 19.9              |
| Total                         | 18,274                   | 16,686             | 9.5               |
| Medical Devices & Diagnostics |                          |                    |                   |
| United States                 | 8,521                    | 8,551              | (0.4)             |
| International                 | 10,765                   | 9,726              | 10.7              |
| Total                         | 19,286                   | 18,277             | 5.5               |
| Worldwide                     |                          |                    |                   |
| United States                 | 21,923                   | 22,221             | (1.3)             |
| International                 | 26,852                   | 23,722             | 13.2              |
| Total                         | \$ 48,775                | \$ 45,943          | 6.2%              |

**OPERATING PROFIT BY SEGMENT OF BUSINESS**

| (Dollars in Millions)                 | Fiscal Third Quarters Ended |                    |                   |
|---------------------------------------|-----------------------------|--------------------|-------------------|
|                                       | October<br>2,<br>2011       | October 3,<br>2010 | Percent<br>Change |
| Consumer                              | \$ 644                      | \$ 501             | 28.5%             |
| Pharmaceutical                        | 2,078                       | 1,858              | 11.8              |
| Medical Devices & Diagnostics         | 1,927                       | 2,002              | (3.7)             |
| Segments operating profit             | 4,649                       | 4,361              | 6.6               |
| Expense not allocated to segments (3) | (538)                       | (142)              |                   |
| Worldwide income before taxes         | \$ 4,111                    | \$ 4,219           | (2.6)%            |

| (Dollars in Millions)                 | Fiscal Nine Months Ended |                    |                   |
|---------------------------------------|--------------------------|--------------------|-------------------|
|                                       | October<br>2,<br>2011    | October 3,<br>2010 | Percent<br>Change |
| Consumer                              | \$ 1,766                 | \$ 1,955           | (9.7)%            |
| Pharmaceutical (1)                    | 6,001                    | 5,661              | 6.0               |
| Medical Devices & Diagnostics (2)     | 5,146                    | 7,580              | (32.1)            |
| Segments operating profit             | 12,913                   | 15,196             | (15.0)            |
| Expense not allocated to segments (3) | (870)                    | (477)              |                   |
| Worldwide income before taxes         | \$ 12,043                | \$ 14,719          | (18.2)%           |

(1) Includes litigation expense of \$540 million and a gain related to the Company's earlier investment in Crucell recorded in the fiscal nine months of 2011. The fiscal nine months of 2010 includes net litigation expense of \$202 million.

- (2) Includes restructuring expense of \$676 million recorded in the fiscal nine months of 2011. Includes litigation expense and additional DePuy ASR Hip recall costs of \$223 million recorded in the fiscal nine months of 2011. Includes net litigation income of \$1,542 million recorded in the fiscal nine months of 2010.

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(3) Amounts not allocated to segments include interest income/(expense), non-controlling interests and general corporate income/(expense).

**SALES BY GEOGRAPHIC AREA**

| (Dollars in Millions)              | Fiscal Third Quarters Ended |                    |                   |
|------------------------------------|-----------------------------|--------------------|-------------------|
|                                    | October<br>2,<br>2011       | October 3,<br>2010 | Percent<br>Change |
| United States                      | \$ 6,868                    | \$ 7,131           | (3.7)%            |
| Europe                             | 4,124                       | 3,629              | 13.6              |
| Western Hemisphere, excluding U.S. | 1,751                       | 1,424              | 23.0              |
| Asia-Pacific, Africa               | 3,262                       | 2,798              | 16.6              |
| Total                              | \$ 16,005                   | \$ 14,982          | 6.8%              |

| (Dollars in Millions)              | Fiscal Nine Months Ended |                    |                   |
|------------------------------------|--------------------------|--------------------|-------------------|
|                                    | October<br>2,<br>2011    | October 3,<br>2010 | Percent<br>Change |
| United States                      | \$ 21,923                | \$ 22,221          | (1.3)%            |
| Europe                             | 12,850                   | 11,563             | 11.1              |
| Western Hemisphere, excluding U.S. | 4,730                    | 4,079              | 16.0              |
| Asia-Pacific, Africa               | 9,272                    | 8,080              | 14.8              |
| Total                              | \$ 48,775                | \$ 45,943          | 6.2%              |

**NOTE 10 BUSINESS COMBINATIONS AND DIVESTITURES**

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

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

During the fiscal third quarter of 2011, the Company completed the divestiture of the Animal Health business to Elanco, a Division of Eli Lilly. During the fiscal third quarter of 2011, the Company completed the divestiture of MONISTAT<sup>®</sup> in Canada, the U.S. and its territories (including Puerto Rico). Proceeds from the aforementioned divestitures were \$578 million. The gains on the divestitures were recognized in Other (income)/expense, net.

On November 4, 2011, the Company announced the closing of the transaction to acquire SterilMed, Inc., a leader in the reprocessing and remanufacturing of medical devices in the U.S.

During the fiscal second quarter of 2011, the Company entered into a definitive agreement to acquire Synthes, Inc. for approximately \$21.3 billion, approximately \$19.3 billion net of cash acquired, subject to the terms of the merger agreement and currency values at the time of closing. Under the terms of the agreement, each share of Synthes common stock, subject to certain conditions, would be exchanged for approximately 35% in cash and 65% in Johnson & Johnson common stock. Synthes, Inc. is a premier global developer and manufacturer of orthopaedics devices. The acquisition is expected to close in the first half of 2012.

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





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During the fiscal third quarter of 2010, the Company acquired Micrus Endovascular Corporation, a global developer and manufacturer of minimally invasive devices to address hemorrhagic and ischemic stroke for a net purchase price of approximately \$0.4 billion. The purchase price for the acquisition was primarily recorded as amortizable intangible assets for \$0.3 billion.

During the fiscal third quarter of 2010, the Company completed the divestiture of the Breast Care business of Ethicon Endo-Surgery, Inc. to Devicor Medical Products, Inc.

During the fiscal second quarter of 2010, the Company acquired RespiVert Ltd., a privately held drug discovery company focused on developing small-molecule, inhaled therapies for the treatment of pulmonary diseases.

During the fiscal first quarter of 2010, the Company acquired Acclarent, Inc., a medical technology company dedicated to designing, developing and commercializing devices that address conditions affecting the ear, nose and throat, for a net purchase price of \$0.8 billion. The purchase price for the acquisition was primarily recorded as amortizable intangible assets for \$0.7 billion.

**NOTE 11 LEGAL PROCEEDINGS**

Johnson & Johnson (the Company) 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. Through the period ended October 2, 2011, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals for new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; there are numerous parties involved.

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

**PRODUCT LIABILITY**

The Company's subsidiaries are involved in numerous product liability cases. The damages claimed are substantial, and while the Company's subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

Multiple products of the Company's subsidiaries are subject to product liability claims and lawsuits in which claimants seek substantial compensatory and, where available, punitive damages, including LEVAQUIN<sup>®</sup>, the ASR XL Acetabular System and DePuy ASR Hip Resurfacing System, the PINNACLE<sup>®</sup> Acetabular Cup System, RISPERDAL<sup>®</sup>, pelvic meshes, the CYPHER<sup>®</sup> Stent and DURAGESIC<sup>®</sup>/fentanyl patches. As of October 2, 2011, there were approximately 3,500 claimants who have pending lawsuits regarding injuries allegedly due to LEVAQUIN<sup>®</sup>, 3,500 with respect to the ASR XL Acetabular System and DePuy ASR Hip Resurfacing System, 560 with respect to the PINNACLE<sup>®</sup> Acetabular Cup System, 500 with respect to RISPERDAL<sup>®</sup>, 350 with respect to pelvic meshes, 90 with respect to the CYPHER<sup>®</sup> Stent, and 80 with respect to DURAGESIC<sup>®</sup>/fentanyl patches.

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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 the Company, and the number of pending lawsuits continues to increase. The Company continues to receive information with respect to potential costs associated with this recall. The Company has established a product liability accrual in anticipation of product liability litigation settlements and costs associated with the DePuy ASR Hip recall program. Changes to the accrual may be required in the future as additional information becomes available.

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

**INTELLECTUAL PROPERTY**

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

**PATENT INFRINGEMENT**

Certain of the Company's subsidiaries are involved in lawsuits challenging the coverage and/or validity of the patents on their products. Although the Company's 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 the Company's subsidiaries to sell their products, or require the payment of past damages and future royalties.

**Medical Devices & Diagnostics**

In October 2004, Tyco Healthcare Group, LP, (Tyco) and U.S. Surgical Corporation filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that several features of EES's HARMONI® scalpel infringed four Tyco patents. In October 2007, on motions for summary judgment prior to the initial trial, a number of claims were found invalid and a number were found infringed.

However, no claim was found both valid and infringed. Trial commenced in December 2007, and the court dismissed the case without prejudice on grounds that Tyco did not own the patents in suit. The dismissal without prejudice was affirmed on appeal. In January 2010, Tyco filed another complaint in the United States District Court for the District of Connecticut asserting infringement of three of the four patents from the previous lawsuit and adding new products. Tyco is seeking monetary damages and injunctive relief. This case is scheduled to be tried in November 2011.

Starting in March 2006, Cordis Corporation (Cordis) filed patent infringement lawsuits in the United States District Courts for the Districts of New Jersey and Delaware, against Guidant Corporation (Guidant), Abbott Laboratories, Inc. (Abbott), Boston Scientific Corporation (Boston Scientific) and Medtronic Ave, Inc. (Medtronic) alleging that the Xience V (Abbott), Promus (Boston Scientific) and Endeavor (Medtronic) drug eluting stents infringe several of Cordis's Wright/Falotico patents. Cordis is seeking monetary relief. In January 2010, in one of the cases against Boston Scientific, the United States District Court for the District of Delaware found the Wright/Falotico patents invalid for lack of written description and/or lack of enablement. In June 2011, the Court of Appeals for the Federal Circuit affirmed the ruling, and in September 2011, it denied Cordis's motion for a re-hearing.

In October 2007, Bruce Saffran (Saffran) filed a patent infringement lawsuit against the Company and Cordis in the United States District Court for the Eastern District of Texas alleging infringement on U.S. Patent No. 5,653,760. In January 2011, a jury returned a verdict finding that Cordis's sales of its CYPHER® stent willfully infringed a patent issued to Saffran. The jury awarded Saffran \$482 million. In March 2011, the Court entered judgment against Cordis in the amount of \$593 million, representing the jury verdict, plus \$111 million in pre-judgment interest. The District Court has denied Cordis's motion to overturn the jury verdict and to vacate the judgment. Cordis will appeal the judgment. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established a reserve with respect to the case.

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In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, accusing LifeScan's entire OneTouch® line of blood glucose monitoring systems of infringement of two patents related to the use of microelectrode sensors. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. The Court entered judgment against Roche in July 2010 and Roche appealed. Briefing on appeal issues has been completed. Oral argument will be held in November 2011. Roche is seeking monetary damages and injunctive relief.

Starting in February 2008, Cordis filed patent infringement lawsuits in the United States District Court for the District of New Jersey against Guidant, Abbott, Boston Scientific and Medtronic alleging that the Xience V (Abbott), Promus (Boston Scientific) and Endeavor® (Medtronic) drug eluting stents infringe several of Wyeth's (now Pfizer Inc.) Morris patents, which have been licensed to Cordis. Cordis is seeking monetary relief. In September 2011, the Court ruled that it would grant defendants' motion to invalidate the Morris patents for lack of enablement and failure to adequately describe the full scope of the invention.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE ADVANCE® and ACUVUE® OASYS HYDROGEL contact lenses infringe their U.S. Patent No. 5,712,327 (the Chang patent). Rembrandt is seeking monetary relief. The case is scheduled for trial in April 2012.

**Pharmaceutical**

In April 2007, Centocor, Inc. (Centocor) (now Janssen Biotech, Inc. (JBI)) filed a patent infringement lawsuit against Abbott Laboratories, Inc. (Abbott) in the United States District Court for the Eastern District of Texas alleging that Abbott's HUMIRA® anti-TNF alpha product infringes Centocor's U.S. Patent 7,070,775. In June 2009, a jury returned a verdict finding the patent valid and infringed, and awarded JBI damages of approximately \$1.7 billion. In February 2011, the Court of Appeals reversed the June 2009 decision and the judgment of the District Court. JBI will file a petition for review of the decision in the United States Supreme Court.

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor (now JBI) in the United States District Court for the District of Massachusetts alleging that SIMPONI® infringes Abbott's U.S. Patent Nos. 7,223,394 and 7,451,031 (the Salfeld patents). Abbott is seeking monetary damages and injunctive relief. No trial date has been set.

In August 2009, Abbott GmbH & Co. (Abbott GmbH) and Abbott Bioresearch Center filed a patent infringement lawsuit against Centocor (now JBI) in the United States District Court for the District of Massachusetts alleging that STELARA® infringes two United States patents assigned to Abbott GmbH. JBI filed a complaint in the United States District Court for the District of Columbia for a declaratory judgment of non-infringement and invalidity of the Abbott GmbH patents, as well as a Complaint for Review of a Patent Interference Decision that granted priority of invention on one of the two asserted patents to Abbott GmbH. The cases have been transferred from the District of Columbia to the District of Massachusetts. No trial date has been set. Also in August 2009, Abbott GmbH and Abbott Laboratories Limited brought a patent infringement lawsuit in The Federal Court of Canada alleging that STELARA® infringes Abbott GmbH's Canadian patent. The Canadian case is scheduled to be tried in October 2012. In each of these cases, Abbott is seeking monetary damages and injunctive relief.

In August 2009, Bayer HealthCare LLC (Bayer) filed a patent infringement lawsuit against Centocor Ortho Biotech Inc. (now JBI) in United States District Court for the District of Massachusetts alleging that the manufacture and sale by JBI of SIMPONI® infringes a Bayer patent relating to human anti-TNF antibodies. In January 2011, the court issued judgment dismissing Bayer's infringement claims. Bayer appealed this ruling. In addition, in November 2009, Bayer filed a lawsuit under its European counterpart to these patents in Germany and the Netherlands. The court in the Netherlands held the Dutch patent invalid and entered judgment in favor of JBI's European affiliate, Janssen Biologics B.V. Bayer appealed that judgment in the Netherlands. In addition, in March 2010, Janssen-Cilag NV filed a revocation action in the High Court in London seeking to invalidate Bayer's UK patent relating to human anti-TNF antibodies. In May 2011, JBI settled all of these cases and received a paid-up, royalty-free license to the family of patents in suit.

LITIGATION AGAINST FILERS OF ABBREVIATED NEW DRUG APPLICATIONS (ANDAs)

The following summarizes lawsuits pending against generic companies that filed Abbreviated New Drug Applications (ANDAs) seeking to market generic forms of products sold by various subsidiaries of the Company prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of these patents. In the event the Company's subsidiaries are not successful in these actions, or the statutory 30-month stays expire before the United States District Court rulings are obtained, the third-party companies involved will have the

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ability, upon approval of the United States Food and Drug Administration (FDA), to introduce generic versions of the products at issue resulting in very substantial market share and revenue losses for those products.

**CONCERTA®**

In January 2010, ALZA Corporation (ALZA) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) (now Janssen Pharmaceuticals, Inc. (JPI)) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Kremers-Urban, LLC and KUDCO Ireland, Ltd. (collectively, KUDCO) in response to KUDCO's ANDA seeking approval to market a generic version of CONCERTA® before the expiration of two of ALZA and JPI's patents relating to CONCERTA®. KUDCO filed counterclaims alleging non-infringement and invalidity. ALZA and JPI subsequently removed one of the patents from the lawsuit. In September 2011, the parties entered into a settlement agreement pursuant to which KUDCO was granted a license to market its generic version of CONCERTA® starting on July 1, 2012, assuming KUDCO obtains FDA approval.

In November 2010, ALZA and OMJPI (now JPI) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively, Teva) in response to Impax and Teva's filing of a major amendment to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of ALZA and JPI's patent relating to CONCERTA®. Impax and Teva filed counterclaims alleging non-infringement and invalidity. In May 2011, ALZA and JPI filed a second lawsuit against Teva in response to Teva's filing of a second major amendment to its ANDA seeking approval to market additional dosage strengths of its generic CONCERTA® product before the expiration of ALZA and JPI's patent relating to CONCERTA®. In each of the above cases, ALZA and JPI are seeking an Order enjoining the defendants from marketing its generic version of CONCERTA® prior to the expiration of ALZA and JPI's CONCERTA® patent.

**ORTHO TRI-CYLEN® LO**

In October 2008, OMJPI (now JPI) and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (JJPRD) filed a patent infringement lawsuit against Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. (collectively, Watson) in the United States District Court for the District of New Jersey in response to Watson's ANDA seeking approval to market a generic version of JPI's product prior to the expiration of JPI's patent relating to ORTHO TRI-CYCLEN® LO (the OTCLO patent). Watson filed a counterclaim alleging invalidity of the patent. In addition, in January 2010, JPI filed a patent infringement lawsuit against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) in the United States District Court for the District of New Jersey in response to Lupin's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. Lupin filed a counterclaim alleging invalidity of the patent. The Lupin and Watson cases have been consolidated.

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

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

In each of the above cases, JJPRD and/or JPI are seeking an Order enjoining the defendants from marketing their generic versions of ORTHO TRI-CYLCEN® LO before the expiration of the OTCLO patent.

**PREZISTA®**

In November 2010, Tibotec, Inc. and Tibotec Pharmaceuticals, Inc. (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

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of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of two patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle.

In March 2011, Tibotec and G.D. Searle filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd. (collectively, Teva) in the United States District Court for the District of New Jersey in response to Teva's ANDA seeking approval to market a generic version of PREZISTA® before the expiration of certain patents relating to PREZISTA® that Tibotec either owns or exclusively licenses from G.D. Searle.

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

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

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

**OTHER INTELLECTUAL PROPERTY MATTERS**

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

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against various affiliates of Omrix Biopharmaceuticals, Inc. (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 or, alternatively, transfer of the patents to the State.

In January 2011, Genentech, Inc. (Genentech) initiated an arbitration against UCB Celltech (Celltech) seeking damages for allegedly cooperating with Centocor (now JBI) to improperly terminate a prior agreement in which JBI was sublicensed under Genentech's Cabilly patents. JBI has an indemnity agreement with Celltech, and Celltech has asserted that JBI is liable for any damages Celltech may be required to pay Genentech in that arbitration. Trial is scheduled for June 2012.

**GOVERNMENT PROCEEDINGS**

Like other companies in the pharmaceutical and medical devices and diagnostics industries, the Company 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.

**Table of Contents****AVERAGE WHOLESALE PRICE (AWP) LITIGATION**

The Company and several of its pharmaceutical subsidiaries (the J&J AWP defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWP's in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain of the Company's subsidiaries have been settled and two are set for trial: Kentucky in January 2012 and Kansas in March 2013. Other state cases are likely to be set for trial. In addition, an AWP case against the J&J AWP defendants brought by the Commonwealth of Pennsylvania was tried in Commonwealth Court in October and November 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPL), entered an injunction, and awarded \$45 million in restitution and \$6.5 million in civil penalties. The Court found in the J&J AWP defendants favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP defendants have appealed the Commonwealth Court's UTPL ruling to the Pennsylvania Supreme Court. The Company believes that it has strong arguments supporting its appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established a reserve with respect to the verdict.

**RISPERDAL®**

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

Discussions have been ongoing in an effort to resolve criminal penalties under the Food Drug and Cosmetic Act related to the promotion of RISPERDAL®. An agreement in principal on key issues relevant to a disposition of criminal charges pursuant to a single misdemeanor violation of the Food Drug and Cosmetic Act has been reached, but certain issues remain open before a settlement can be finalized. The Company adjusted the accrued amount in the second quarter of 2011 to cover the financial component of the proposed criminal settlement.

In addition, discussions with state and federal government representatives to resolve the separate civil claims related to the marketing of RISPERDAL® and INVEGA®, including those under the False Claims Act (the qui tam actions), have been ongoing. The Company believes there are meritorious defenses to these claims, and it remains unclear

whether a settlement can be reached as discovery is not complete, there are significant facts in dispute, the damages sought in the claims are unsubstantiated and indeterminate, there are numerous parties involved, and possible outcomes are uncertain. For these reasons,

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the Company is unable to estimate a range of loss. However, future negotiations may lead to a narrowing of the areas of disagreement and the liability may then become reasonably estimable in accordance with applicable accounting principles. If a negotiated resolution cannot be reached, civil litigation relating to the allegations of off-label promotion of RISPERDAL® and/or INVEGA® is likely. In the Company's opinion, the ultimate resolution of the above criminal and these civil matters is not expected to have a material adverse effect on the Company's financial position, although the resolution in any reporting period could have a material impact on the Company's results of operations and cash flows for that period.

The Attorneys General of multiple states, including Alaska, Arkansas, Louisiana, Massachusetts, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Texas and Utah, have pending actions against Janssen (now JPI) seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties, damages for overpayments by the state and others, violations of state consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also seek injunctive relief relating to the promotion of RISPERDAL®. In the Texas matter, the Attorney General of Texas has joined a qui tam action in that state seeking similar relief, and the trial is scheduled to commence in late November 2011.

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

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen (now JPI). The Company was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether the Company or JPI had violated the State's Medicaid Fraud Act (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Provider letter. The jury returned a verdict that JPI and the Company 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. The Company's and JPI's motion for a new trial was denied. The Company and JPI have filed an appeal and believe that they have strong arguments supporting the appeal. The Company believes that the potential for an unfavorable outcome is not probable, and therefore, the Company has not established a reserve with respect to the verdict.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen (now JPI) on a multi-Count Complaint related to Janssen'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's post-trial motions were denied. The Commonwealth filed an appeal in April 2011.

In 2007, the Attorney General of South Carolina filed a lawsuit against the Company and Janssen (now JPI) on several counts. In March 2011, the matter was tried on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practice Act, including, among others, questions of whether the Company 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 Provider letter or in their use of the FDA-approved label. The jury found in favor of the Company and against JPI. In June 2011, the Court awarded civil penalties of approximately \$327.1 million. JPI intends to appeal this judgment. The Company and JPI believe that JPI has strong arguments supporting an appeal and that the potential for an unfavorable outcome is not probable. Therefore, the Company has not established a reserve with respect to the verdict.

The Attorneys General of approximately 40 other states have indicated a potential interest in pursuing similar litigation against JPI, and have obtained a tolling agreement staying the running of the statute of limitations while they pursue a coordinated civil investigation of JPI regarding potential consumer fraud actions in connection with the marketing of RISPERDAL®.

**MCNEIL CONSUMER HEALTHCARE**

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (McNeil Consumer Healthcare), and certain affiliates, including the Company (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recent 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 recent recalls of a small number of products of other Company subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil

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Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. The Companies are cooperating with the United States Attorney's Office in responding to these subpoenas.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries. In January 2011, the Oregon Attorney General filed a civil complaint against the Company, 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. The Companies removed this case to federal court and sought transfer of the case to the United States District Court for the Eastern District of Pennsylvania. The Judicial Panel on Multidistrict Litigation denied the transfer request. Currently, the case is before the United States District Court for the District of Oregon pending its decision on a motion for remand filed by the Oregon Attorney General.

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

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

**OMNICARE**

In September 2005, the Company received a subpoena from the United States Attorney's Office, District of Massachusetts, seeking documents related to the sales and marketing of eight drugs to Omnicare, Inc. (Omnicare), a manager of pharmaceutical benefits for long-term care facilities. In April 2009, the Company and certain of its pharmaceutical subsidiaries were served in two civil qui tam cases asserting claims under the Federal False Claims Act and related state law claims alleging that the defendants provided Omnicare with rebates and other alleged kickbacks, causing Omnicare to file false claims with Medicaid and other government programs. In January 2010, the government intervened in both of these cases, naming the Company, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (now Janssen Pharmaceuticals, Inc. (JPI)), and Johnson & Johnson Health Care Systems Inc. as defendants. Subsequently, the Commonwealth of Massachusetts, Virginia, and Kentucky, and the States of California and Indiana intervened in the action. The defendants moved to dismiss the complaints, and in February 2011, the United States District Court for the District of Massachusetts dismissed one qui tam case entirely and dismissed the other case in part, rejecting allegations that the defendants had violated their obligation to report its best price to health care program officials. The defendants subsequently moved the Court to reconsider its decision not to dismiss the second case in its entirety, which the Court denied in May 2011. The claims of the United States and individual states remain pending.

In November 2005, a lawsuit was filed under seal by Scott Bartz, a former employee, in the United States District Court for the Eastern District of Pennsylvania against the Company and certain of its pharmaceutical subsidiaries (the J&J Defendants), along with co-defendants McKesson Corporation and Omnicare, Inc. The Bartz complaint raises many issues in common with the Omnicare-related litigation discussed above already pending before the United States District Court for the District of Massachusetts, such as best price and a number of kickback allegations. After

investigation, the United States declined to intervene. The case was subsequently unsealed in January 2011. In February 2011, the plaintiff filed an amended complaint, which was placed under seal. Thereafter, on the J&J Defendants' motion, the case was transferred to the United States District Court for the District of Massachusetts, where it is currently pending. In April 2011, the amended complaint was ordered unsealed and alleges a variety of causes of action under the Federal False Claims Act and corresponding state and local statutes, including that the J&J Defendants engaged in various improper transactions that were allegedly designed to report false prescription drug prices to the federal government in order to reduce the J&J Defendants' Medicaid rebate obligations. The complaint further alleges that the J&J Defendants improperly retaliated against the plaintiff for having raised these allegations internally. Bartz seeks multiple forms of relief, including damages and reinstatement to a position with the same seniority status.

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The J&J Defendants subsequently moved to dismiss the complaint in May 2011, and oral argument was held in August 2011. In June 2011, Bartz filed a notice of intent to voluntarily dismiss McKesson and Omnicare from the case and added McKesson Specialty Pharmaceuticals, LLC, as a co-defendant.

**OTHER**

In July 2003, Centocor, Inc. (now Janssen Biotech, Inc. (JBI)), received a request that it voluntarily provide documents and information to the criminal division of the United States Attorney's Office, District of New Jersey, in connection with its investigation into various JBI marketing practices. Subsequent requests for documents have been received from the United States Attorney's Office. Both the Company and JBI have responded to these requests for documents and information.

In July 2005, Scios Inc. (Scios) received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the sales and marketing of NATRECOR®. In August 2005, Scios was advised that the investigation would be handled by the United States Attorney's Office for the Northern District of California in San Francisco. In February 2009, two qui tam complaints were unsealed in the United States District Court for the Northern District of California, alleging, among other things, improper activities in the promotion of NATRECOR®. In June 2009, the United States government intervened in one of the qui tam actions, and filed a complaint against Scios and the Company seeking relief under the Federal False Claims Act and asserting a claim of unjust enrichment. The civil case is proceeding and discovery is ongoing. In October 2011, the Court approved a settlement of the criminal case in which Scios pled guilty to a single misdemeanor violation of the Food, Drug & Cosmetic Act and paid a fine of \$85 million.

In February 2007, the Company voluntarily disclosed to the United States Department of Justice (DOJ) and the United States Securities & Exchange Commission (SEC) that subsidiaries outside the United States are believed to have made improper payments in connection with the sale of medical devices in two small-market countries, which payments may fall within the jurisdiction of the Foreign Corrupt Practices Act (FCPA). In the course of continuing dialogues with the agencies, other issues potentially rising to the level of FCPA violations in additional markets were brought to the attention of the agencies by the Company. In addition, in February 2006, the Company received a subpoena from the SEC requesting documents relating to the participation by several Company subsidiaries in the United Nations Iraq Oil for Food Program. In April 2011, the Company resolved the FCPA and Oil for Food matters through settlements with the DOJ, SEC and United Kingdom Serious Fraud Office. These settlements required payments of approximately \$78 million in financial penalties. As part of the settlement with the DOJ, the Company entered into a Deferred Prosecution Agreement that requires the Company to complete a three-year term of enhanced compliance practices.

In April 2007, the Company received two subpoenas from the Office of the Attorney General of the State of Delaware. The subpoenas seek documents and information relating to nominal pricing agreements. For purposes of the subpoenas, nominal pricing agreements are defined as agreements under which the Company agreed to provide a pharmaceutical product for less than ten percent of the Average Manufacturer Price for the product. The Company responded to these requests.

In May 2007, the New York State Attorney General issued a subpoena to the Company seeking information relating to the marketing, sale, reimbursement and safety of PROCRI®. The Company has responded to the subpoena.

In June 2008, the Company received a subpoena from the United States Attorney's Office for the District of Massachusetts relating to the marketing of biliary stents by Cordis Corporation (Cordis). Cordis is currently cooperating in responding to the subpoena. In addition, in January 2010, a complaint was unsealed in the United States District Court for the Northern District of Texas seeking damages against Cordis for alleged violations of the Federal False Claims Act and several similar state laws in connection with the marketing of biliary stents. The United States Department of Justice and several states have declined to intervene at this time. In April 2011, the United States District Court for the Northern District of Texas dismissed the complaint without prejudice.

In May 2009, the New Jersey Attorney General issued a subpoena to DePuy Orthopaedics, Inc., seeking information regarding the financial interest of clinical investigators who performed clinical studies for DePuy Orthopaedics, Inc. and DePuy Spine, Inc. DePuy Orthopaedics, Inc. has responded to these requests.



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

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

**GENERAL LITIGATION**

In September 2004, Plaintiffs in an employment discrimination litigation initiated against the Company in 2001 in the United States District Court for the District of New Jersey moved to certify a class of all African American and Hispanic salaried employees of the Company and its affiliates in the United States, who were employed at any time from November 1997 to the present. Plaintiffs sought monetary damages for the period 1997 through the present (including punitive damages) and equitable relief. The Court denied Plaintiffs' class certification motion in December 2006 and their motion for reconsideration in April 2007. Plaintiffs sought to appeal these decisions and, in April 2008, the Court of Appeals ruled that Plaintiffs' appeal of the denial of class certification was untimely. In July 2009, Plaintiffs filed a motion for certification of a modified class, which the Company opposed. The District Court denied Plaintiffs' motion in July 2010, and the Court of Appeals denied Plaintiffs' request for leave to appeal the denial of certification of the modified class. In May 2011, the case was dismissed with prejudice.

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

In April 2009, Ortho-Clinical Diagnostics, Inc. (OCD) received a grand jury subpoena from the United States Department of Justice, Antitrust Division, requesting documents and information for the period beginning September 1, 2000 through the present, pertaining to an investigation of alleged violations of the antitrust laws in the blood reagents industry. OCD complied with the subpoena. In February 2011, OCD received a letter from the Antitrust Division indicating that it had closed its investigation in November 2010. In June 2009, following the public announcement that OCD had received a grand jury subpoena, multiple class action complaints seeking damages for alleged price fixing were filed against OCD. The various cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania. Discovery is ongoing.

In May 2009, Centocor Ortho Biotech Inc. (now Janssen Biotech, Inc. (JBI)) commenced an arbitration proceeding before the American Arbitration Association against Schering-Plough Corporation and its subsidiary Schering-Plough (Ireland) Company (collectively, Schering-Plough). JBI and Schering-Plough are parties to a series of agreements (Distribution Agreements) that grant Schering-Plough the exclusive right to distribute the drugs REMICADE<sup>®</sup> and SIMPONI<sup>®</sup> worldwide, except within the United States, Japan, Taiwan, Indonesia, and the People's Republic of China (including Hong Kong). JBI distributes REMICADE<sup>®</sup> and SIMPONI<sup>®</sup>, the next generation treatment, within the United States. In the arbitration, JBI sought a declaration that the agreement and merger between Merck & Co., Inc. (Merck) and Schering-Plough constituted a change of control under the terms of the Distribution Agreements that permitted JBI to terminate the Agreements. In April 2011, the Company, JBI and Merck announced an agreement to amend the Distribution Agreements. This agreement concluded the arbitration proceeding.

Pursuant to the terms of the amended Distribution Agreements, on July 1, 2011, Merck's subsidiary, Schering-Plough (Ireland) relinquished exclusive marketing rights for REMICADE<sup>®</sup> and SIMPONI<sup>®</sup> to the Company's Janssen pharmaceutical companies in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific (relinquished territories). Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (retained territories). The retained territories represent approximately 70 percent of Merck's 2010 revenue of approximately \$2.8 billion from REMICADE<sup>®</sup> and SIMPONI<sup>®</sup>, while the relinquished territories represent approximately 30 percent. In addition, as of July 1, 2011, all profit derived from Merck's exclusive distribution of the two products in the retained territories is being equally divided between Merck and JBI. Under the prior terms of the

Distribution Agreements, the contribution income (profit) split, which was at 58 percent to Merck and 42 percent to JBI, would have declined for Merck and increased for JBI each year until 2014, when it would have been equally divided. JBI also received a one-time payment of \$500 million in April 2011, which is being amortized over the period of the agreement.

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In April 2010, a putative class action lawsuit was filed in the United States District Court for the Northern District of California by representatives of nursing home residents or their estates against the Company, Omnicare, Inc. (Omnicare), and other unidentified companies or individuals. In February 2011, plaintiffs filed a second amended complaint asserting that certain rebate agreements between the Company and Omnicare increased the amount of money spent on pharmaceuticals by the nursing home residents and violated the Sherman Act and the California Business & Professions Code. The second amended complaint also asserts a claim of unjust enrichment. Plaintiffs seek multiple forms of monetary and injunctive relief. The Company moved to dismiss the second amended complaint in March 2011. The Court granted the motion in its entirety in August 2011, dismissing all claims asserted by Plaintiffs.

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

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

The Company filed a report in the *In re Johnson & Johnson Derivative Litigation* matter in July 2011, prepared by a Special Committee of the Board of Directors, which investigated the allegations contained in the derivative actions and in a number of shareholder demand letters that the Board received in 2010 raising similar issues. The Special Committee was assisted in its investigation by independent counsel. The Special Committee's report recommended: i) that the Company reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation and ii) that the Board of Directors create a new Regulatory and Compliance Committee charged with responsibility for monitoring and oversight of the Company's Health Care Compliance and Quality & Compliance systems and issues. The Company's Board of Directors unanimously adopted the Special Committee's recommendations. In August 2011, two shareholders who had submitted shareholder demand letters in 2010 filed shareholder derivative lawsuits in the United States District Court for the District of New Jersey naming various current and former officers and directors as defendants and challenging the Board's rejection of their demands. The Company intends to move to terminate these lawsuits on the basis of the Board's decision to adopt the Special Committee's recommendations.

Two additional shareholder derivative lawsuits were filed in May 2011 in the United States District Court for the District of New Jersey, and two other shareholder derivative lawsuits were filed in New Jersey Superior Court in May 2011 and August 2011, all naming the Company's current directors as defendants and the Company as the nominal defendant. The complaints allege breaches of fiduciary duties related to the Company's compliance with the Foreign Corrupt Practices Act and participation in the United Nations Iraq Oil For Food Program, that the Company has suffered damages as a result of those alleged breaches, and that the defendants failed to disclose the alleged misconduct in the Company's filings under the Securities Exchange Act of 1934. Plaintiffs seek monetary damages, and one plaintiff also seeks corporate governance reforms. The federal lawsuits were consolidated in July 2011, and an amended consolidated complaint was filed in August 2011. The Company intends to move to dismiss the consolidated federal lawsuit on the grounds, *inter alia*, that the plaintiffs failed to make a demand upon the Board of

Directors. The Company intends to move to dismiss or stay the state lawsuits pending resolution of the federal lawsuit.

In September 2011, two additional shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey naming the Company's current directors and one former director as defendants and the Company as the nominal defendant. These lawsuits allege that the defendants breached their fiduciary duties in their decisions with respect to the compensation of the Chief Executive Officer during the period from 2008 through the present, and that the defendants made misleading statements in the Company's annual proxy statements. One of these suits has been voluntarily dismissed. An

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amended complaint has been filed in the other. The Company intends to move to dismiss the remaining suit on the grounds, *inter alia*, that the plaintiff failed to make a demand upon the Board of Directors. Starting in May 2010, multiple complaints seeking class action certification related to the McNeil recalls have been filed against McNeil Consumer Healthcare and certain affiliates, including the Company, in the United States District Court for the Eastern District of Pennsylvania, the Northern District of Illinois, the Central District of California, the Southern District of Ohio and the Eastern District of Missouri. These consumer complaints allege generally that purchasers of various McNeil medicines are owed monetary damages and penalties because they paid premium prices for defective medications rather than less expensive alternative medications. All but one complaint seeks certification of a nation-wide class of purchasers of these medicines, whereas one complaint, the Harvey case, seeks certification of a class of Motrin® IB purchasers in Missouri. In October 2010, the Judicial Panel on Multidistrict Litigation (JPML) consolidated all of the consumer complaints, except for the Harvey case, which was consolidated in March 2011, for pretrial proceedings in the United States District Court for the Eastern District of Pennsylvania. In January 2011, the plaintiffs in all of the cases except the Harvey case filed a Consolidated Amended Civil Consumer Class Action Complaint (CAC) naming additional parties and claims. In July 2011, the Court granted the Company's motion to dismiss the CAC without prejudice, but permitted the plaintiffs to file an amended complaint within thirty days of the dismissal order. In August 2011, the plaintiffs filed a Second Amended Civil Consumer Class Action Complaint (SAC). The Company moved to dismiss the SAC in September 2011. This second motion to dismiss is pending.

Separately, in September 2011, the Company, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed in the Supreme Court of British Columbia, Canada (the Canadian Civil Claim). The Canadian Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased various McNeil children's over-the-counter medicines during the period between September 20, 2001 and the present. The Canadian Civil Claim alleges that the defendants violated the Canadian Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that did not comply with Canadian Good Manufacturing Practices.

In September 2010, a shareholder, Ronald Monk, filed a lawsuit in the United States District Court for the District of New Jersey seeking class certification and alleging that the Company and certain individuals, including executive officers and employees of the Company, failed to disclose that a number of manufacturing facilities were failing to maintain current good manufacturing practices, and that as a result, the price of the Company's stock has declined significantly. Plaintiff seeks to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In May 2011, the Company filed a motion to dismiss, which is pending before the Court.

In April 2011, OMJ Pharmaceuticals, Inc. (OMJ PR) filed a lawsuit against the United States in United States District Court for the District of Puerto Rico alleging overpayment of federal income taxes for the tax years ended November 30, 1999 and November 30, 2000. OMJ PR alleges that the Internal Revenue Service erroneously calculated OMJ PR's tax credits under Section 936 of the Tax Code. Discovery is ongoing.

In August 2011, an arbitration panel ruled that Mitsubishi Tanabe Pharma Corporation (Tanabe), JBI's distributor of REMICADE® in Japan, could seek to modify the proportion of net sales revenue that Tanabe must remit to JBI in exchange for distribution rights and commercial supply of REMICADE® (the Supply Price). Tanabe commenced the arbitration against JBI in 2009 pursuant to the parties' distribution agreement, which grants Tanabe the right to distribute REMICADE® in Japan and certain other parts of Asia. JBI has counterclaimed for an increase in the Supply Price. The arbitration hearing to determine the appropriate split of revenue is scheduled for November 2011, and a decision is anticipated in 2012.

The Company 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.

**NOTE 12 RESTRUCTURING**

In the fiscal second quarter of 2011, Cordis Corporation, a subsidiary of Johnson & Johnson, announced the discontinuation of its clinical development program for the NEVO® Sirolimus-Eluting Coronary Stent and cessation of the manufacture and marketing of CYPHER® and CYPHER SELECT® Plus Sirolimus-Eluting Coronary Stents by the

end of 2011. This will allow the Company to focus on other cardiovascular therapies where significant patient needs exist.

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As a result of the above mentioned restructuring plan announced by Cordis Corporation, the Company recorded \$676 million in related pre-tax charges, of which approximately \$164 million of the pre-tax restructuring charges require cash payments. The \$676 million of restructuring charges consists of asset write-offs of \$512 million and \$164 million related to leasehold and contract obligations and other expenses. The \$512 million of asset write-offs relate to property, plant and equipment of \$265 million, intangible assets of \$160 million and inventory of \$87 million (recorded in cost of products sold). The Cordis restructuring program has been substantially completed as of October 2, 2011.

The Company recorded an accrual for restructuring in the fourth quarter of 2009.

The following table summarizes the remaining severance reserves associated with the restructuring plan recorded in the fourth quarter of 2009.

| (Dollars in Millions)  | Severance |
|------------------------|-----------|
| Reserve balance as of: |           |
| January 2, 2011        | \$ 345    |
| Cash outlays           | (87)      |
| October 2, 2011*       | \$ 258    |

\* Remaining cash outlays for severance are expected to be paid out in accordance with the Company's plans and local laws.

Of the 7,500 positions the Company planned to eliminate in the 2009 restructuring plan, approximately 5,800 positions have been eliminated as of October 2, 2011.

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

### RESULTS OF OPERATIONS

#### Analysis of Consolidated Sales

For the fiscal nine months of 2011, worldwide sales were \$48.8 billion, an increase of 6.2%, including an operational increase of 2.3% as compared to 2010 fiscal nine months sales of \$45.9 billion. Currency fluctuations had a positive impact of 3.9% for the fiscal nine months of 2011.

Sales by U.S. companies were \$21.9 billion in the fiscal nine months of 2011, which represented a decrease of 1.3% as compared to the same period last year. Sales by international companies were \$26.9 billion, which represented a total increase of 13.2% including an operational increase of 5.8%, and a positive impact from currency of 7.4% as compared to the fiscal nine months sales of 2010.

Sales by companies in Europe achieved growth of 11.1%, including operational growth of 4.0% and a positive impact from currency of 7.1%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 16.0% including operational growth of 10.1% and a positive impact from currency of 5.9%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 14.8%, including operational growth of 6.3% and an increase of 8.5% related to the positive impact of currency.

For the fiscal third quarter of 2011, worldwide sales were \$16.0 billion, an increase of 6.8%, including an operational increase of 2.6% as compared to 2010 fiscal third quarter sales of \$15.0 billion. Currency fluctuations had a positive impact of 4.2% for the fiscal third quarter of 2011.

Sales by U.S. companies were \$6.9 billion in the fiscal third quarter of 2011, which represented a decrease of 3.7% as compared to the same period last year. Sales by international companies were \$9.1 billion, which represented a total increase of 16.4%, including an operational increase of 8.3%, and a positive impact from currency of 8.1% as compared to the fiscal third quarter sales of 2010.



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Sales by companies in Europe achieved growth of 13.6%, including operational growth of 4.9% and a positive impact from currency of 8.7%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 23.0%, including operational growth of 17.1%, and a positive impact from currency of 5.9%. Sales by companies in the Asia-Pacific, Africa region achieved sales growth of 16.6%, including operational growth of 8.1%, and an increase of 8.5% related to the positive impact of currency.

**U.S. Health Care Reform**

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law during March 2010. The health care reform legislation included an increase in the minimum Medicaid rebate rate from 15.1% to 23.1% and also extended the rebate to drugs provided through Medicaid managed care organizations. The 2011 full year impact to sales rebates, thereby reducing sales revenue, is estimated to be between \$400 - \$500 million of which approximately \$330 million and \$100 million impacted the Company's fiscal nine months and third quarter of 2011, respectively. The impact to the Company's fiscal nine months and fiscal third quarter of 2010 were approximately \$260 million and \$110 million, respectively.

Beginning in 2011, companies that sell branded prescription drugs to specified U.S. Government programs pay an annual non-tax deductible fee based on an allocation of the company's market share of total branded prescription drug sales from the prior year. The 2011 full year impact to selling, marketing and administrative expenses is estimated to be between \$140 - \$150 million. Additionally, in 2011, discounts are provided on the Company's brand-name drugs to patients who fall within the Medicare Part D coverage gap - donut hole. Beginning in 2013, the Company will be required to pay a tax deductible 2.3% excise tax imposed on the sale of certain medical devices.

**ANALYSIS OF SALES BY BUSINESS SEGMENTS****Consumer**

Consumer segment sales in the fiscal nine months of 2011 were \$11.2 billion, an increase of 2.1% as compared to the same period a year ago, including an operational decline of 1.9% and a positive currency impact of 4.0%. U.S.

Consumer segment sales declined by 9.2% while international sales growth of 9.5%, included operational growth of 2.9% and a positive currency impact of 6.6%.

**Major Consumer Franchise Sales - Fiscal Nine Months Ended**

|                       | October<br>2,<br>2011 | October<br>3,<br>2010 | Total<br>Change | Operations<br>Change | Currency<br>Change |
|-----------------------|-----------------------|-----------------------|-----------------|----------------------|--------------------|
| (Dollars in Millions) |                       |                       |                 |                      |                    |
| OTC Pharm & Nutr      | \$ 3,266              | \$ 3,457              | (5.5)%          | (9.7)%               | 4.2%               |
| Skin Care             | 2,771                 | 2,563                 | 8.1             | 4.5                  | 3.6                |
| Baby Care             | 1,772                 | 1,632                 | 8.6             | 4.1                  | 4.5                |
| Women's Health        | 1,394                 | 1,394                 |                 | (4.3)                | 4.3                |
| Oral Care             | 1,212                 | 1,137                 | 6.6             | 2.5                  | 4.1                |
| Wound Care/Other      | 800                   | 797                   | 0.4             | (2.7)                | 3.1                |
| Total                 | \$ 11,215             | \$ 10,980             | 2.1%            | (1.9)%               | 4.0%               |

Consumer segment sales in the fiscal third quarter of 2011 were \$3.7 billion, an increase of 4.9% as compared to the same period a year ago, including an operational increase of 0.5%, and a positive currency impact of 4.4%. U.S.

Consumer segment sales declined by 4.5% while international sales achieved sales growth of 10.1%, including operational growth of 3.3%, and a positive currency impact of 6.8%.

**Major Consumer Franchise Sales - Fiscal Third Quarters Ended**

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| (Dollars in Millions) | October<br>2,<br>2011 | October<br>3,<br>2010 | Total<br>Change | Operations<br>Change | Currency<br>Change |
|-----------------------|-----------------------|-----------------------|-----------------|----------------------|--------------------|
| OTC Pharm & Nutr      | \$ 1,054              | \$ 1,109              | (5.0)%          | (9.4)%               | 4.4%               |
| Skin Care             | 943                   | 800                   | 17.9            | 13.2                 | 4.7                |
| Baby Care             | 613                   | 566                   | 8.3             | 4.1                  | 4.2                |
| Women's Health        | 458                   | 459                   | (0.2)           | (4.8)                | 4.6                |
| Oral Care             | 422                   | 384                   | 9.9             | 5.8                  | 4.1                |
| Wound Care/Other      | 250                   | 249                   | 0.4             | (2.8)                | 3.2                |
| Total                 | \$ 3,740              | \$ 3,567              | 4.9%            | 0.5%                 | 4.4%               |

The OTC Pharmaceuticals and Nutritionals franchise experienced an operational decline of 9.4% as compared to the prior year fiscal third quarter. Sales in the U.S. were negatively impacted by the suspension of production at McNeil Consumer Healthcare's Fort Washington, Pennsylvania facility as well as the impact on production volumes related to ongoing efforts to enhance quality and manufacturing systems.

During the fiscal first quarter of 2011, a consent decree was signed with the U.S. Food and Drug Administration (FDA), which will govern certain McNeil Consumer Healthcare manufacturing operations. The consent decree identifies procedures that will help provide additional assurance of product quality to the FDA. The consent decree recognizes the work already initiated by McNeil under the Comprehensive Action Plan (CAP).

Production volumes from the Las Piedras and Lancaster facilities have been impacted due to the additional review and approval processes. However, many of the key selected products are returning to the market, and volumes will continue to ramp up throughout the remainder of the year and into 2012. Products previously produced at the Fort Washington facility are being re-sited to other facilities and a modest amount of certain products are expected to ship in late 2011. The balance of the portfolio of key selected products will continue to be reintroduced throughout 2012. The Skin Care franchise achieved operational growth of 13.2% as compared to the prior year primarily due to the success of new product launches including the NEUTROGENA® and Dabao product lines.

The Baby Care franchise achieved operational growth of 4.1% as compared to the prior year primarily due to growth in lotions, creams and wipes outside the U.S.

The Women's Health Franchise experienced an operational decline of 4.8% as compared to the prior year primarily impacted by the divestiture of certain brands.

The Oral Care franchise achieved operational growth of 5.8% as compared to the prior year primarily due to increased sales of LISTERINE® outside the U.S.

**Pharmaceutical**

Pharmaceutical segment sales in the fiscal nine months of 2011 were \$18.3 billion, a total increase of 9.5% as compared to the same period a year ago with an operational increase of 6.1% and an increase of 3.4% related to the positive impact of currency. U.S. Pharmaceutical sales increased by 1.4% as compared to the same period a year ago and international Pharmaceutical sales achieved growth of 19.9%, including operational growth of 12.1%, and an increase of 7.8% related to the positive impact of currency.

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## Major Pharmaceutical Product Revenues Fiscal Nine Months Ended\*

|                           | October<br>2,<br>2011 | October<br>3,<br>2010 | Total<br>Change | Operations<br>Change | Currency<br>Change |
|---------------------------|-----------------------|-----------------------|-----------------|----------------------|--------------------|
| (Dollars in Millions)     |                       |                       |                 |                      |                    |
| REMICADE®                 | \$ 4,064              | \$ 3,545              | 14.6%           | 14.2%                | 0.4%               |
| PROCRIPT®/EPREX®          | 1,255                 | 1,455                 | (13.7)          | (16.5)               | 2.8                |
| RISPERDAL® CONSTA®        | 1,198                 | 1,112                 | 7.7             | 2.4                  | 5.3                |
| CONCERTA®/methylphenidate | 994                   | 951                   | 4.5             | 2.1                  | 2.4                |
| VELCADE®                  | 922                   | 793                   | 16.3            | 9.1                  | 7.2                |
| ACIPHEX®/PARIET®          | 721                   | 754                   | (4.4)           | (8.4)                | 4.0                |
| LEVAQUIN®/FLOXIN®         | 618                   | 957                   | (35.4)          | (35.5)               | 0.1                |
| Other Pharmaceuticals     | 8,502                 | 7,119                 | 19.4            | 14.5                 | 4.9                |
| Total                     | \$ 18,274             | \$ 16,686             | 9.5%            | 6.1%                 | 3.4%               |

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

Pharmaceutical segment sales in the fiscal third quarter of 2011 were \$6.0 billion, a total increase of 8.9% as compared to the same period a year ago with an operational increase of 4.9% and an increase of 4.0% related to the positive impact of currency. U.S. Pharmaceutical sales decreased by 6.1% as compared to the same period a year ago and international Pharmaceutical sales achieved growth of 27.5%, including operational growth of 18.5%, and an increase of 9.0% related to the positive impact of currency.

## Major Pharmaceutical Product Revenues Fiscal Third Quarters Ended\*

|                           | October<br>2,<br>2011 | October<br>3,<br>2010 | Total<br>Change | Operations<br>Change | Currency<br>Change |
|---------------------------|-----------------------|-----------------------|-----------------|----------------------|--------------------|
| (Dollars in Millions)     |                       |                       |                 |                      |                    |
| REMICADE®                 | \$ 1,408              | \$ 1,229              | 14.6%           | 13.6%                | 1.0%               |
| RISPERDAL® CONSTA®        | 390                   | 378                   | 3.2             | (2.6)                | 5.8                |
| PROCRIPT®/EPREX®          | 383                   | 406                   | (5.7)           | (9.6)                | 3.9                |
| VELCADE®                  | 295                   | 246                   | 19.9            | 11.5                 | 8.4                |
| CONCERTA®/methylphenidate | 283                   | 299                   | (5.4)           | (7.9)                | 2.5                |
| ACIPHEX®/PARIET®          | 235                   | 240                   | (2.1)           | (7.2)                | 5.1                |
| LEVAQUIN®/FLOXIN®         | 25                    | 286                   | (91.3)          | (91.4)               | 0.1                |
| Other Pharmaceuticals     | 2,963                 | 2,411                 | 22.9            | 17.5                 | 5.4                |
| Total                     | \$ 5,982              | \$ 5,495              | 8.9%            | 4.9%                 | 4.0%               |

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

REMICADE® (infliximab), a biologic approved for the treatment of a number of immune-mediated inflammatory diseases, achieved operational growth of 13.6% as compared to the prior year fiscal third quarter. A significant increase in sales outside the U.S. was driven by the impact of the agreement with Merck & Co., Inc. (Merck). On April 15, 2011, the Company announced it reached an agreement with Merck which includes distribution rights to REMICADE® and SIMPONI® whereby, effective July 1, 2011, certain territories were relinquished to the Company. On July 1, 2011, the Company began to record sales of product from certain territories, including Canada, Brazil, Australia and Mexico, which were previously supplied by Merck.

RISPERDAL® CONSTA® (risperidone), a long-acting injectable antipsychotic, experienced an operational sales decline of 2.6% as compared to the prior year fiscal third quarter. Sales of RISPERDAL® CONSTA® outside the U.S. decreased reflecting the launch of INVEGA® SUSTENNA®, known as XEPLION® in Europe, as well as pricing pressures. Total U.S. sales of the Company's long-acting injectables, including RISPERDAL® CONSTA® and INVEGA® SUSTENNA® (paliperidone palmitate), increased by double digits versus a year ago due to an increase in

combined market share.

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PROCRIT® (Epoetin alfa)/EPREX® (Epoetin alfa), experienced an operational sales decline of 9.6%, as compared to the prior year fiscal third quarter. The decline was primarily due to softening of the market for Erythropoiesis Stimulating Agents (ESAs) and increased competition.

VELCADE® (bortezomib), a product for the treatment for multiple myeloma, for which the Company has commercial rights in Europe and the rest of the world outside the U.S., achieved operational sales growth of 11.5% as compared to the prior year fiscal third quarter primarily due to strong growth in Asia and Latin America.

CONCERTA®/methylphenidate, a product for the treatment of attention deficit hyperactivity disorder, experienced an operational sales decline of 7.9% as compared to the prior year fiscal third quarter. On November 1, 2010, the Company entered into a U.S. Supply and Distribution Agreement with Watson Laboratories, Inc. to distribute an authorized generic version of CONCERTA® beginning May 1, 2011. Lower sales of the branded product were partially offset by shipments to Watson Laboratories, Inc.

ACIPHEX®/PARIET® experienced an operational decline of 7.2% as compared to the prior year fiscal third quarter primarily due to increased generic competition in the category.

LEVAQUIN® (levofloxacin)/FLOXIN®(ofloxacin), an anti-infective, experienced an operational decline of 91.4% as compared to the prior year fiscal third quarter due to the loss of market exclusivity in the U.S. in June 2011. In 2010, full year U.S. sales of LEVAQUIN® were \$1.3 billion. U.S. sales of LEVAQUIN® in the fiscal third quarter and the fiscal nine months of 2010 were \$0.3 billion and \$0.9 billion, respectively. U.S. sales of LEVAQUIN® in the fiscal third quarter and the fiscal nine months of 2011 were \$25.0 million and \$0.6 billion, respectively. Due to the loss of market exclusivity in the U.S., year over year sales of LEVAQUIN® will continue to decline in 2011 and the first half of 2012.

In the fiscal third quarter of 2011, Other Pharmaceutical sales achieved operational growth of 17.5% as compared to the prior year fiscal third quarter. Contributors to the increase were sales of ZYTIGA®(abiraterone acetate), STELARA® (ustekinumab), PREZISTA® (darunavir), SIMPONI® (golimumab), INVEGA® SUSTENNA (paliperidone palmitate), NUCYNTA® (tapentadol), INTELENCE® (etravirine), and newly acquired products from Crucell. This growth was partially offset by lower sales of DURAGESIC®/Fentanyl Transdermal (fentanyl transdermal system), and TOPAMAX® (topiramate) due to continued generic competition.

**Medical Devices and Diagnostics**

Medical Devices and Diagnostics segment sales in the fiscal nine months of 2011 were \$19.3 billion, an increase of 5.5% as compared to the same period a year ago, with 1.4% of this change due to an operational increase and an increase of 4.1% related to the positive impact of currency. U.S. Medical Devices and Diagnostics sales decreased 0.4% as compared to the prior year. The international Medical Devices and Diagnostics sales increase of 10.7% included an operational increase of 3.0% and an increase of 7.7% related to the positive impact of currency.

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

|                             | October<br>2,<br>2011 | October<br>3,<br>2010 | Total<br>Change | Operations<br>Change | Currency<br>Change |
|-----------------------------|-----------------------|-----------------------|-----------------|----------------------|--------------------|
| (Dollars in Millions)       |                       |                       |                 |                      |                    |
| DEPUY®                      | \$ 4,356              | \$ 4,138              | 5.3%            | 1.6%                 | 3.7%               |
| ETHICON ENDO-SURGERY®       | 3,747                 | 3,501                 | 7.0             | 2.5                  | 4.5                |
| ETHICON®                    | 3,637                 | 3,351                 | 8.5             | 4.5                  | 4.0                |
| Vision Care                 | 2,206                 | 2,021                 | 9.2             | 3.6                  | 5.6                |
| Diabetes Care               | 1,982                 | 1,826                 | 8.5             | 5.2                  | 3.3                |
| Cardiovascular Care*        | 1,748                 | 1,923                 | (9.1)           | (13.1)               | 4.0                |
| ORTHO-CLINICAL DIAGNOSTICS® | 1,610                 | 1,517                 | 6.1             | 2.7                  | 3.4                |
| Total                       | \$ 19,286             | \$ 18,277             | 5.5%            | 1.4%                 | 4.1%               |

\* Previously referred to as CORDIS®

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Medical Devices and Diagnostics segment sales in the fiscal third quarter of 2011 were \$6.3 billion, an increase of 6.1% as compared to the same period a year ago, including an operational increase of 1.7% and a positive currency impact of 4.4%. U.S. Medical Devices and Diagnostics sales decreased 0.7%. The international Medical Devices and Diagnostics sales increase of 12.3% included an operational increase of 3.9% and an increase of 8.4% related to the positive impact of currency.

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

| (Dollars in Millions)       | October    | October    | Total<br>Change | Operations<br>Change | Currency<br>Change |
|-----------------------------|------------|------------|-----------------|----------------------|--------------------|
|                             | 2,<br>2011 | 3,<br>2010 |                 |                      |                    |
| DEPUY®                      | \$ 1,384   | \$ 1,309   | 5.7%            | 1.7%                 | 4.0%               |
| ETHICON ENDO-SURGERY®       | 1,231      | 1,137      | 8.3             | 3.4                  | 4.9                |
| ETHICON®                    | 1,187      | 1,072      | 10.7            | 6.4                  | 4.3                |
| Vision Care                 | 752        | 695        | 8.2             | 2.5                  | 5.7                |
| Diabetes Care               | 664        | 613        | 8.3             | 4.4                  | 3.9                |
| ORTHO-CLINICAL DIAGNOSTICS® | 539        | 498        | 8.2             | 4.5                  | 3.7                |
| Cardiovascular Care*        | 526        | 596        | (11.7)          | (15.9)               | 4.2                |
| Total                       | \$ 6,283   | \$ 5,920   | 6.1%            | 1.7%                 | 4.4%               |

\* Previously referred to as CORDIS®

The DePuy franchise achieved operational growth of 1.7% as compared to the same period a year ago. This growth was primarily due to sales of newly acquired products from Micrus Endovascular. The growth was partially offset by lower sales of knees and hips in the U.S. due in part to increased competition, continued pricing pressure and the impact of the DePuy ASR Hip recall.

The Ethicon Endo-Surgery franchise achieved operational growth of 3.4% as compared to the prior year fiscal third quarter. Growth was attributable to increased sales of Advanced Sterilization products and outside the U.S., the HARMONIC® and Endo mechanical product lines were contributors to the growth.

The Ethicon franchise achieved operational growth of 6.4% as compared to the prior year fiscal third quarter. Drivers of the growth include the emerging market growth in sutures, newly launched products, PHYSIOMESH and SECURESTRAP, and growth in the Acclarent product line.

The Vision Care franchise achieved operational sales growth of 2.5% as compared to the prior year fiscal third quarter. ACUVUE® MOIST® and astigmatism lenses were strong contributors to the growth in the quarter partially offset by lower sales of reusable lenses.

The Diabetes Care franchise achieved operational sales growth of 4.4% as compared to the prior year fiscal third quarter. The growth was primarily due to sales in the OneTouch® product line.

The Ortho-Clinical Diagnostics franchise achieved operational sales growth of 4.5% as compared to the prior year fiscal third quarter. The growth was primarily attributable to the continued growth in clinical labs due to the strength of the VITROS® 5600 and 3600 analyzers.

The Cardiovascular Care franchise experienced an operational sales decline of 15.9% as compared to the prior year fiscal third quarter. Sales were impacted by the Company's decision to exit the drug-eluting stent market and lower sales of endovascular products due to increased competition. Sales for drug-eluting stents were approximately 7% and 23% of the total Cardiovascular Care franchise sales in the fiscal third quarters of 2011 and 2010, respectively. The decline in sales was partially offset by strong growth in Biosense Webster, the Company's electrophysiology business.

**Cost of Products Sold and Selling, Marketing and Administrative Expenses**

Consolidated costs of products sold for the fiscal nine months of 2011 increased to 30.8% from 29.9% of sales compared to the same period a year ago. Consolidated costs of products sold for the fiscal third quarter of 2011 increased to 31.7% from 30.7% of sales as compared to the same period a year ago. The increase in the fiscal nine months was primarily attributable to inventory write-offs due to the restructuring charges related to the Cardiovascular Care business and ongoing remediation costs



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in the Consumer OTC business. In addition, lower margins and integration costs including an inventory step-up charge associated with the acquisition of Crucell negatively impacted cost of products sold. The increase in the fiscal third quarter was primarily due to ongoing remediation costs in the Consumer OTC business and lower margins and integration costs including an inventory step-up charge associated with the acquisition of Crucell.

Consolidated selling, marketing and administrative expenses for the fiscal nine months of 2011 increased to 31.8% from 31.0% of sales as compared to the same period a year ago. Consolidated selling, marketing and administrative expenses for the fiscal third quarter of 2011 increased to 32.7% from 31.4% of sales as compared to the same period a year ago. The increase in both periods was primarily due to investment spending, as well as the fee on branded pharmaceutical products incurred due to the U.S. health care reform legislation.

**Research & Development Expense**

Research & development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research & development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities for the fiscal nine months of 2011 were \$5.4 billion, an increase of 10.9% compared to the prior fiscal period. The increase was primarily due to higher levels of spending to advance the Company's Pharmaceutical pipeline. Worldwide costs of research and development activities for the fiscal third quarter of 2011 were \$1.8 billion or 11.1% of sales which was consistent with the prior year fiscal period.

**Restructuring Expense**

During the fiscal second quarter of 2011, Cordis Corporation, a subsidiary of Johnson & Johnson, announced the discontinuation of its clinical development program for the NEVO Sirolimus-Eluting Coronary Stent and cessation of the manufacture and marketing of CYPHER® and CYPHER SELECT® Plus Sirolimus-Eluting Coronary Stents by the end of 2011. This will allow the Company to focus on other cardiovascular therapies where significant patient needs exist.

During the fiscal second quarter of 2011, the Company recorded a pre-tax charge of \$676 million, of which \$87 million is included in cost of products sold. See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

**Other (Income) Expense, Net**

Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain equity securities of the Johnson & Johnson Development Corporation, gains and losses on the disposal of assets, currency gains and losses, gains and losses relating to non-controlling interests, litigation settlements, as well as royalty income. The change in other (income) expense, net for the fiscal nine months of 2011 was unfavorable by \$1.8 billion as compared to the same period a year ago. The fiscal nine months of 2011 included \$0.8 billion of litigation expense and DePuy ASR Hip recall costs and a mark-to-market adjustment to reduce the value of the currency option and deal costs related to the planned acquisition of Synthes, Inc. versus a net gain of \$1.3 billion from litigation matters recorded in the fiscal nine months of 2010. The fiscal nine months of 2011 also included gains related to the Company's earlier investment in Crucell and various divestitures. The change in other (income) expense, net for the fiscal third quarter of 2011, was slightly favorable as compared to the same period a year ago. The fiscal third quarter of 2011 included gains related to the divestitures of MONISTAT® and the Animal Health business offset by a mark-to-market adjustment to reduce the value of the currency option and deal costs related to the planned acquisition of Synthes, Inc.

**OPERATING PROFIT BY SEGMENT****Consumer Segment**

Operating profit for the Consumer segment as a percent to sales in the fiscal nine months of 2011 was 15.7% versus 17.8% for the same period a year ago. The primary drivers of the decline in operating profit for the fiscal nine months were unfavorable product mix and remediation costs associated with the recall of certain OTC products partially offset by the gain on the divestiture of MONISTAT®. Operating profit for the Consumer segment as a percent to sales in the fiscal third quarter of 2011 was 17.2% versus 14.0% for the same period a year ago. The primary driver of the increase in operating profit for the fiscal third quarter was the gain on the divestiture of MONISTAT®. This was partially offset



by ongoing remediation costs associated with the recall of certain OTC products.

**Table of Contents****Pharmaceutical Segment**

Operating profit for the Pharmaceutical segment as a percent to sales in the fiscal nine months of 2011 was 32.8% versus 33.9% for the same period a year ago. The primary drivers of the decrease in the operating profit margin were higher litigation expense recorded in 2011, the impact of the health care reform fee and integration costs including an inventory step-up charge associated with the Crucell acquisition. This was partially offset by the gain related to the Company's earlier investment in Crucell, the gain on the divestiture of the Animal Health business and lower manufacturing costs. Operating profit for the Pharmaceutical segment as a percent to sales in the fiscal third quarter of 2011 was 34.7% versus 33.8% for the same period a year ago. The primary drivers of the increase in the operating profit were a gain on the divestiture of the Animal Health business, higher sales and lower manufacturing costs partially offset by the impact of the U.S. health care reform legislation fee and integration costs including an inventory step-up charge associated with the Crucell acquisition.

**Medical Devices and Diagnostics Segment**

Operating profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal nine months of 2011 was 26.7% versus 41.5% for the same period a year ago. The primary drivers of the decline in the operating profit margin in the Medical Devices and Diagnostics segment for the fiscal nine months were restructuring expense of \$676 million, litigation expense and additional DePuy ASR Hip recall costs and increased investment spending. The fiscal nine months of 2010 included a \$1.5 billion gain from net litigation matters and the gain on the divestiture of the breast care business of Ethicon Endo-Surgery recorded in the fiscal third quarter of 2010. Operating profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal third quarter of 2011 was 30.7% versus 33.8% for the same period a year ago. The primary drivers of the decline in the operating profit margin in the Medical Devices and Diagnostics segment for the fiscal third quarter versus the prior year was the inclusion of the gain on the divestiture of the breast care business of Ethicon Endo-Surgery in the fiscal third quarter of 2010. The decline was partially offset by cost improvement initiatives and favorable mix in 2011.

**Interest (Income) Expense**

Interest income decreased in the fiscal nine months of 2011 and was relatively flat in the fiscal third quarter of 2011 as compared to the same periods a year ago, due to lower rates of interest earned despite higher average cash balances. The ending balance of cash, cash equivalents and marketable securities, was \$30.9 billion at the end of the fiscal third quarter of 2011. This is an increase of \$8.8 billion from the same period a year ago. The increase was primarily due to cash generated from operating activities.

Interest expense increased in both the fiscal nine months and the fiscal third quarter of 2011 as compared to the same periods a year ago due to a higher average debt balance. At the end of the fiscal third quarter of 2011, the Company's debt position was \$18.4 billion compared to \$12.0 billion from the same period a year ago. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the debt were used for general corporate purposes.

**Provision for Taxes on Income**

The worldwide effective income tax rates for the fiscal nine months of 2011 and 2010 were 21.5% and 22.6%, respectively. The lower effective tax rate was due to higher income in lower tax jurisdictions and the U.S. Research and Development tax credit, which was not in effect for the fiscal nine months of 2010. Additionally, in 2010 the Company had litigation gains in high tax jurisdictions.

As of October 2, 2011, the Company had approximately \$2.5 billion of liabilities from unrecognized tax benefits. The Company does not expect that the total amount of unrecognized tax benefits will change significantly during the next twelve months.

See Note 8 to the Consolidated Financial Statements in the Annual Report on Form 10-K for the fiscal year ended January 2, 2011 for more detailed information regarding unrecognized tax benefits.

**LIQUIDITY AND CAPITAL RESOURCES****Cash Flows**

Cash and cash equivalents were \$15.6 billion at the end of the fiscal third quarter of 2011 as compared with \$19.4 billion at the fiscal year end of 2010. The primary uses of cash that contributed to the \$3.8 billion decrease were approximately \$10.9 billion



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net cash used by investing activities and \$3.7 billion used by financing activities partially offset by approximately \$10.8 billion generated from operating activities.

Cash flow from operations of \$10.8 billion was the result of \$9.5 billion of net earnings and \$1.9 billion of non cash charges primarily related to depreciation and amortization, stock based compensation, and deferred tax provision reduced by \$0.5 billion related to changes in assets and liabilities, net of effects from acquisitions.

Cash used by investing activities of \$10.9 billion was primarily due to net purchases of investments in marketable securities of \$7.0 billion, acquisitions of \$2.5 billion, \$1.8 billion used for additions to property, plant and equipment and other of \$0.3 billion primarily related to intangible assets partially offset by proceeds of \$0.7 billion from the disposal of assets.

Financing activities use of \$3.7 billion was primarily for dividends to shareholders of \$4.6 billion and \$0.7 billion for repurchase of common stock net of proceeds from stock options exercised partially offset by \$1.6 billion net proceeds from short and long-term debt.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2011, the Company secured a new 364-day Credit Facility. Total credit available to the Company under the facility, which expires September 20, 2012, approximates \$10 billion. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

In the fiscal third quarter of 2011, the Company continued to have access to liquidity through the commercial paper market. The Company anticipates that operating cash flows, existing credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs. However, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable.

**Dividends**

On July 18, 2011, the Board of Directors declared a regular cash dividend of \$0.570 per share, payable on September 13, 2011 to shareholders of record as of August 30, 2011.

On October 21, 2011, the Board of Directors declared a regular cash dividend of \$0.570 per share, payable on December 13, 2011 to shareholders of record as of November 29, 2011. The Company expects to continue the practice of paying regular quarterly cash dividends.

**OTHER INFORMATION**

**New Accounting Standards**

During the fiscal third quarter of 2011, the Financial Accounting Standards Board (FASB) issued amendments to goodwill impairment testing. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. However, if an entity concludes otherwise, then it is required to perform the first step of the two-step impairment test. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal second quarter of 2011, the FASB issued an amendment to the disclosure requirements for presentation of comprehensive income. The amendment requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance is effective retrospectively for the interim periods and annual periods beginning after December 15, 2011. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal second quarter of 2011, the FASB issued amendments to disclosure requirements for common fair value measurement. These amendments result in convergence of fair value measurement and disclosure requirements between U.S. GAAP and IFRS. This guidance is effective prospectively for the interim periods and annual periods

beginning after December 15, 2011. Early adoption is prohibited. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

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During the fiscal first quarter of 2011, the Company adopted the FASB guidance and amendments issued related to revenue recognition under the milestone method. The objective of the accounting standard update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. This update became effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2011, the Company adopted the FASB guidance on how pharmaceutical companies should recognize and classify in the Company's financial statements, the non-deductible annual fee paid to the Government in accordance with the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act. This fee is based on an allocation of a company's market share of total branded prescription drug sales from the prior year. The estimated fee was recorded as a selling, marketing and administrative expense in the Company's financial statement and will be amortized on a straight-line basis for the year as per the FASB guidance. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

**Economic and Market Factors**

Johnson & Johnson is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concern about the rising cost of health care. Johnson & Johnson has a long-standing policy of pricing products responsibly. For the period 2000 through 2010 in the United States, the weighted average compound annual growth rate of Johnson & Johnson price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases. The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement.

Changes in the behavior and spending patterns of consumers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of a prolonged global economic downturn will continue to impact the Company's businesses. The Company also operates in an environment increasingly hostile to intellectual property rights. Generic drug firms have filed Abbreviated New Drug Applications seeking to market generic forms of most of the Company's key pharmaceutical products, prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending a lawsuit resulting from an Abbreviated New Drug Application filing, the generic firms will then introduce generic versions of the product at issue, resulting in very substantial market share and revenue losses. For further information see the discussion on Litigation Against Filers of Abbreviated New Drug Applications included in Item 1. Financial Statements (unaudited)- Notes to Consolidated Financial Statements, Note 11.

**CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS**

This Form 10-Q contains forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. Forward-looking statements may be identified by the use of words like plans, expects, will, anticipates, estimates and other words similar meaning in conjunction with, among other things, discussions of future operations, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures. Forward-looking statements are based on current expectations of future events. The Company cannot guarantee that any forward-looking statement will be accurate, although the Company believes that it has been reasonable in its expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or that

unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Investors are therefore cautioned not to place undue reliance on any forward-looking statements. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.

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Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; significant litigation adverse to the Company; impact of business combinations; financial distress and bankruptcies experienced by significant customers and suppliers; changes to governmental laws and regulations and U.S. and foreign health care reforms; trends toward healthcare cost containment; increased scrutiny of the health care industry by government agencies; changes in behavior and spending patterns of healthcare products and services; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action.

The Company's Annual Report on Form 10-K for the fiscal year ended January 2, 2011 contains, as an Exhibit, a discussion of additional factors that could cause actual results to differ from expectations. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

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

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in its Annual Report on Form 10-K for the fiscal year ended January 2, 2011.

**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. William C. Weldon, Chairman and Chief Executive Officer, and Dominic J. Caruso, Vice President, Finance and Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Weldon and Caruso concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

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

**Part II OTHER INFORMATION**

**Item 1 LEGAL PROCEEDINGS**

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

**Item 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

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

The following table provides information with respect to Common Stock purchases by the Company during the fiscal third quarter of 2011. 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.



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| Fiscal Month                            | Total Number<br>of Shares<br>Purchased | Average<br>Price Paid<br>per Share |
|---|--|------------------------------------|
| July 4, 2011 through July 31, 2011      | 2,381,603                              | \$ 67.03                           |
| August 1, 2011 through August 28, 2011  | 5,821,549                              | \$ 62.76                           |
| August 29, 2011 through October 2, 2011 | 3,408,950                              | \$ 63.75                           |
| Total                                   | 11,612,102                             |                                    |

## Item 6 EXHIBITS

Exhibit 10.1 Compensation Arrangements for Non-Employee Directors

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 October 2, 2011, formatted in Extensive Business Reporting Language (XBRL), (i) consolidated balance sheets, (ii) consolidated statements of earnings, (iii) consolidated statements of cash flows, and (iv) the notes to the consolidated financial statements.

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SIGNATURES

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

|                  |   |
|------------------|---|
|                  | JOHNSON & JOHNSON<br>(Registrant)   |
| November 8, 2011 | By /s/ D. J. CARUSO<br>D. J. CARUSO<br>Vice President, Finance; Chief Financial<br>Officer<br>(Principal Financial Officer) |
| November 8, 2011 | By /s/ S. J. COSGROVE<br>S. J. COSGROVE<br>Controller (Principal Accounting Officer)  |