10-Q 1 firstquartertenq.txt UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q (X) Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 28, 2004 or ( ) Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the for the transition period from to Commission file number 1-3215 JOHNSON & JOHNSON (Exact name of registrant as specified in its charter) NEW JERSEY 22-1024240 (State or other jurisdiction of (I.R.S. Employer Incorporation or organization) 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 (X) No Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. On April 25, 2004, 2,968,603,275 shares of Common Stock, $1.00 par value, were outstanding. 1 JOHNSON & JOHNSON AND SUBSIDIARIES TABLE OF CONTENTS Part I - Financial Information Page No. Item 1. 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Controls and Procedures 24 Part II - Other Information Item 1 - Legal Proceedings 24 Item 5 - Exhibits and Reports on Form 8-K 34 Signatures 35 2 Part I - FINANCIAL INFORMATION Item 1 - Financial Statements JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (Unaudited; Dollars in Millions) ASSETS March 28, December 28, 2004 2003 Current Assets: Cash and cash equivalents $ 5,637 5,377 Marketable securities 4,724 4,146 Accounts receivable, trade, less allowances for doubtful accounts $188(2003, $192) 6,772 6,574 Inventories (Note 4) 3,522 3,588 Deferred taxes on income 1,558 1,526 Prepaid expenses and other receivables 2,151 1,784 Total current assets 24,364 22,995 Marketable securities, non-current 70 84 Property, plant and equipment, at cost 17,104 17,052 Less accumulated depreciation 7,435 7,206 Property, plant and equipment, net 9,669 9,846 Intangible assets (Note 5) 14,191 14,168 Less accumulated amortization 2,749 2,629 Intangible assets, net 11,442 11,539 Deferred taxes on income 822 692 Other assets 2,501 3,107 Total assets $48,868 48,263 See Notes to Consolidated Financial Statements 3 JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (Unaudited; Dollars in Millions) LIABILITIES AND SHAREHOLDERS' EQUITY March 28, December 28, 2004 2003 Current Liabilities: Loans and notes payable $ 594 1,139 Accounts payable 3,782 4,966 Accrued liabilities 2,729 2,639 Accrued rebates, returns and promotions 2,671 2,308 Accrued salaries, wages and commissions 813 1,452 Taxes on income 1,860 944 Total current liabilities 12,449 13,448 Long-term debt 2,961 2,955 Deferred tax liability 741 780 Employee related obligations 2,282 2,262 Other liabilities 1,941 1,949 Shareholders' equity: Preferred stock - without par value (authorized and unissued 2,000,000 shares) - - Common stock - par value $1.00 per share (authorized 4,320,000,000 shares; issued 3,119,842,000 shares) 3,120 3,120 Note receivable from employee stock ownership plan (11) (18) Accumulated other comprehensive income (Note 8) (598) (590) Retained earnings 32,153 30,503 4 Less common stock held in treasury, at cost (152,286,000 & 151,869,000 shares) 6,170 6,146 Total shareholders' equity 28,494 26,869 Total liabilities and shareholders' equity $48,868 48,263 See Notes to Consolidated Financial Statements 5 JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS (Unaudited; dollars & shares in millions except per share figures) Fiscal Quarters Ended March 28, Percent March 30, Percent 2004 to Sales 2003 to Sales Sales to customers (Note 6) $11,559 100.0 9,821 100.0 Cost of products sold 3,367 29.1 2,722 27.7 Gross Profit 8,192 70.9 7,099 72.3 Selling, marketing and administrative expenses 3,640 31.5 3,253 33.1 Research expense 1,095 9.5 936 9.5 Purchased in-process research and development - - 18 .2 Interest income (39) (.3) (38) (.4) Interest expense, net of portion capitalized 45 .4 38 .4 Other (income)expense, net (53) (.5) (37) (.3) Earnings before provision for taxes on income 3,504 30.3 2,929 29.8 Provision for taxes on income (Note 3) 1,011 8.7 859 8.7 NET EARNINGS $2,493 21.6 2,070 21.1 NET EARNINGS PER SHARE (Note 7) Basic $ .84 .70 Diluted $ .83 .69 CASH DIVIDENDS PER SHARE $ .24 .205 AVG. SHARES OUTSTANDING Basic 2,967.8 2,968.4 Diluted 3,004.6 3,018.5 See Notes to Consolidated Financial Statements 6 JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited; Dollars in Millions) Fiscal Quarters Ended March 28, March 30, 2004 2003 CASH FLOWS FROM OPERATIONS Net earnings $ 2,493 2,070 Adj. to reconcile net earnings to cash flows: Depreciation and amortization of property and intangibles 502 446 Purchased in-process research and development - 18 Increase in deferred taxes (191) (47) Accounts receivable provisions 20 (5) Changes in assets and liabilities, net of effects from acquisition of businesses: Increase in accounts receivable (271) (366) Decrease (increase) in inventories 38 (181) Decrease in accounts payable and accrued liabilities (1,350) (594) Decrease (increase) in other current and non-current assets 368 (172) Increase in other current and non-current liabilities 1,046 867 NET CASH FLOWS FROM OPERATING ACTIVITIES 2,655 2,036 CASH FLOWS FROM INVESTING ACTIVITIES Additions to property, plant and equipment (292) (408) Proceeds from the disposal of assets 49 3 Acquisition of businesses, net of cash acquired - (258) Purchases of investments (3,103) (1,634) Sales of investments 2,512 1,417 Other (16) (17) NET CASH USED BY INVESTING ACTIVITIES (850) (897) CASH FLOWS FROM FINANCING ACTIVITIES Dividends to shareholders (713) (609) Repurchase of common stock (407) (339) Proceeds from short-term debt 147 221 Retirement of short-term debt (675) (354) Proceeds from long-term debt 19 2 Retirement of long-term debt 1 (20) Proceeds from the exercise of stock options 125 90 NET CASH USED BY FINANCING ACTIVITIES (1,503) (1,009) 7 EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS (42) 37 INCREASE(DECREASE) IN CASH AND CASH EQUIVALENTS 260 167 CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD 5,377 2,894 CASH AND CASH EQUIVALENTS, END OF PERIOD $ 5,637 3,061 ACQUISITION OF BUSINESSES Fair value of assets acquired - 285 Fair value of liabilities assumed - (27) Net cash paid for acquisitions $ - 258 See Notes to Consolidated Financial Statements 8 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS NOTE 1 - The accompanying unaudited interim financial statements and related notes should be read in conjunction with the Consolidated Financial Statements of Johnson & Johnson and Subsidiaries (the "Company") and related notes as contained in the Annual Report on Form 10-K for the fiscal year ended December 28, 2003. 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 presentation of such statements. NOTE 2 - FINANCIAL INSTRUMENTS The Company follows the provisions of SFAS 133 requiring that all derivative instruments be recorded on the balance sheet at fair value. As of March 28, 2004, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was

$128 million after-tax. For additional information, see Note 8. The Company expects that substantially all of this amount will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. 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. Transactions with third parties will cause the amount in accumulated other comprehensive income to affect net earnings. The maximum length of time over which the Company is hedging is 18 months. For the fiscal first quarter ended March 28, 2004, the net impact of the hedges' ineffectiveness to the Company's financial statements was insignificant. For fiscal first quarter ended March 28, 2004, the Company has recorded a net loss of $1 million after tax in the "other (income) expense, net" category of the consolidated statement of earnings, representing the impact of discontinuance of cash flow hedges because it is probable that the originally forecasted transactions will not occur by the end of the originally specified time period. Refer to Note 8 for disclosures of movements in Accumulated Other Comprehensive Income. NOTE 3 - INCOME TAXES The worldwide effective income tax rates for the fiscal first quarter of 2004 and 2003 were 28.8% and 29.3%. The decrease in the effective tax rate of 0.5% is due to the increase in taxable income in lower tax jurisdictions relative to taxable income in higher tax jurisdictions. NOTE 4 - INVENTORIES (Dollars in Millions) March 28, 2004 December 28, 2003 Raw materials and supplies $ 1,079 966 Goods in process 1,229 981 Finished goods 1,214 1,641 $ 3,522 3,588 9 NOTE 5 - INTANGIBLE ASSETS Intangible assets that have definite useful lives are amortized over their useful lives. Goodwill and non- amortizable intangible assets are assessed annually for impairment. The impairment assessment was completed in the fiscal fourth quarter of 2003 and no impairment was determined. Future impairment tests will be performed in the fiscal fourth quarter, annually. (Dollars in Millions) March 28, 2004 December 28, 2003 Goodwill $ 6,072 6,085 Less accumulated amortization 702 695 Goodwill - net 5,370 5,390 Trademarks (non-amortizable) 1,095 1,098 Less accumulated amortization 136 136 Trademarks (non-amortizable)- net 959 962 Patents and trademarks 3,812 3,798 Less accumulated amortization 890 818 Patents and trademarks - net 2,922 2,980 Other amortizable intangibles 3,212 3,187 Less accumulated amortization 1,021 980 Other intangibles - net 2,191 2,207 Total intangible assets 14,191 14,168 Less accumulated amortization 2,749 2,629 Total intangibles - net $11,442 11,539 Goodwill as of March 28, 2004 as allocated by segment of business is as follows: (Dollars in Millions) Med. Dev Consumer Pharm & Diag Total Goodwill, net of accumulated amortization at December 28, 2003 $882 781 3,727 5,390 Acquisitions - - - - Translation & Other - (5) (15) (20) Goodwill as of March 28, 2004 882 776 3,712 5,370 The weighted average amortization periods for patents and trademarks and other intangible assets were 16 years and 18 years, respectively. The amortization expense of amortizable intangible assets for the fiscal first quarter ended March 28, 2004 was $123 million before tax and the estimated amortization expense for the five succeeding years approximates $490 million before tax, per year, respectively. 10 NOTE 6 - SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS (Dollars in Millions) SALES BY SEGMENT OF BUSINESS Fiscal First Quarter Percent 2004 2003 Change Consumer U.S. $ 1,081 1,000 8.1 International 966 791 22.1 2,047 1,791 14.3% Pharmaceutical U.S. $ 3,643 3,263 11.6 International 1,733 1,403 23.5 5,376 4,666 15.2% Med Devices and Diagnostics U.S. $ 2,194 1,748 25.5 International 1,942 1,616 20.2 4,136 3,364 22.9% U.S. $ 6,918 6,011 15.1 International 4,641 3,810 21.8 Worldwide $ 11,559 9,821 17.7% OPERATING PROFIT BY SEGMENT OF BUSINESS Fiscal First Quarter Percent 2004 2003 Change Consumer $ 440 413 6.5 Pharmaceutical 2,085 1,859 12.2 Med. Dev. & Diag. 1,067 731 46.0 Segments total 3,592 3,003 19.6 Expenses not allocated to segments (88) (74) Worldwide total $ 3,504 2,929 19.6% 11 SALES BY GEOGRAPHIC AREA Fiscal First Quarter Percent 2004 2003 Change U.S. $ 6,918 6,011 15.1 Europe 2,708 2,218 22.1 Western Hemisphere, excluding U.S. 597 472 26.5 Asia-Pacific, Africa 1,336 1,120 19.3 Total $ 11,559 9,821 17.7% NOTE 7 - EARNINGS PER SHARE The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal first quarters ended March 28, 2004 and March 30, 2003. (Shares in Millions) Fiscal Quarter Ended March 28, March 30, 2004 2003 Basic net earnings per share $ .84 .70 Average shares outstanding - basic 2,967.8 2,968.4 Potential shares exercisable under stock option plans 119.4 179.6 Less: shares which could be repurchased under treasury stock method (97.4) (144.4) Convertible debt shares 14.8 14.9 Adjusted average shares outstanding - diluted 3,004.6 3,018.5 Diluted earnings per share $ .83 .69 The diluted earnings per share calculation included the dilution effect of convertible debt that was offset by the related decrease in interest expense of $4 million each for the fiscal first quarters ended March 28, 2004 and March 30, 2003, respectively. The diluted earnings per share excluded 135 million and 47 million shares related to options for the fiscal first quarters ended March 28, 2004 and March 30, 2003, respectively as the exercise price per share of these options was greater than the average market value, resulting in an anti-dilutive effect on diluted earnings per share. NOTE 8 - ACCUMULATED OTHER COMPREHENSIVE INCOME The total comprehensive income for the fiscal first quarter endedMarch 28, 2004 was $2.5 billion, compared with $2.1 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 available for sale securities and net gains and losses on derivative instruments 12 qualifying and designated as cash flow hedges. The following table sets forth the components of accumulated other comprehensive income. Total Unrld Gains/ Accum For. Gains/ Pens (Losses) Other Cur. (Losses) Liab on Deriv Comp Trans. on Sec Adj. & Hedg Inc/ (Loss) December 28, 2003 $ (373) 27 (64) (180) (590) 2004 Three Months changes Net change associated with current period hedging transactions - - - 261 Net amount reclassed to net earnings - - - (209)* Net Three Months changes (61) 1 - 52 (8) March 28, 2004 $ (434) 28 (64) (128) (598) Note: All amounts, other than foreign currency translation, are net of tax. Foreign currency translation adjustments are not currently adjusted for income taxes, as they relate to permanent investments in non-US subsidiaries. *Primarily offset by changes in value of the underlying transactions. NOTE 9 - MERGERS, ACQUISITIONS AND DIVESTITURES There were no acquisitions in the fiscal first quarter of 2004. DePuy's Castings business was divested in the fiscal first quarter of 2004, which did not have a material effect on the Company's results of operations, cash flows or financial position. On January 29, 2003, Johnson & Johnson acquired certain assets of Orquest, Inc., a privately held biotechnology company focused on developing biologically based implants for orthopedic and spine surgery. Orquest's principal product, HEALOS Bone Graft Substitute, is designed to reduce the time and pain associated with standard bone graft harvesting and represents a therapeutic advance for patients requiring bone graft material for spine fusion. The Company incurred a charge for In-process Research and Development (IPR&D) of approximately $11 million before tax and $8 million after tax. On February 10, 2003, Johnson & Johnson acquired Orapharma, Inc., a specialty pharmaceutical company focused on the development and commercialization of unique therapeutics. Orapharma's initial product, ARESTIN, is the first locally administered, time-released antibiotic encapsulated in microspheres that controls the germs that can cause periodontal disease. The transaction was valued at approximately $85 million, net of cash. On March 28, 2003, Johnson & Johnson acquired 3- Dimensional Pharmaceuticals, Inc., a company with a technology platform 13 focused on the discovery and development of potential new drugs in early stage development for the treatment of cardiovascular disorders, oncology and inflammation. The transaction was valued at approximately $88 million, net of cash. The Company incurred a

before and after tax charge for in- process research and development (IPR&D) of approximately $7 million. NOTE 10 - PRO FORMA STOCK BASED COMPENSATION At March 28, 2004, the Company had 21 stock-based employee compensation plans. The Company accounted for those plans under the recognition and measurement principles of Accounting Principle Board Opinion No. 25 "Accounting for Stock Issued to Employees" and its related Interpretations. Compensation costs were not recorded in net income for stock options, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. As required by SFAS No. 148, "Accounting for Stock- Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123," the following table shows the estimated effect on net income and earnings per share if the Company had applied the fair value recognition provision of SFAS No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation. (Dollars in Millions Except Per Share Data) March 28, 2004 March 30, 2003 Net income, as reported $ 2,493 2,070 Less: Compensation expense(1) 80 85 Pro forma $ 2,413 1,985 Earnings per share: Basic - as reported $.84 $.70 - pro forma .81 .67 Diluted - as reported $.83 $.69 - pro forma .81 .66 (1) Determined under fair value based method for all awards, net of tax. 14 NOTE 11 - PENSIONS AND OTHER POSTRETIREMENT BENEFITS Components of Net Periodic Benefit Cost Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for the fiscal first quarter of 2004 and 2003 include the following components: (Dollars in Millions) Retirement Plans Other Benefit Plans March 28, March 30, March 28, March 30, 2004 2003 2004 2003 Service cost $ 108 81 13 7 Interest cost 119 98 26 18 Expected return on plan assets (131) (124) (1) (1) Amortization of prior service cost 4 5 (1) (1) Amortization of net transition asset (1) (1) - - Recognized actuarial losses (gains) 44 16 11 1 Net periodic benefit cost $ 143 75 48 24 Company Contributions The Company contributed $155 million to its U.S. retirement plans on April 15, 2004. The Company is not expected to further fund its U.S. retirement plans in 2004 in order to meet minimum statutory funding requirements. International plans will be funded in accordance with local regulations. NOTE 12 - LEGAL PROCEEDINGS The information called for by this footnote is incorporated herein by reference to Item 1 ("Legal Proceedings") included in Part II of this Report on Form 10-Q. Item 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS Results of Operations Analysis of Consolidated Sales For the fiscal first quarter of 2004, worldwide sales were $11.6 billion, an increase of 17.7% over 2003 fiscal first quarter sales of $9.8 billion. The impact of foreign currencies accounted for 5.4% of the total reported fiscal first quarter 2004 increase. Sales by U.S. companies were $6.9 billion in the fiscal first quarter of 2004, which represented an increase of 15.1%. Sales by international companies were $4.6 billion, which represented an increase of 21.8%, of which 14.0% was due to currency fluctuations. All geographic areas throughout the world posted sales increases during the fiscal first quarter of 2004 as sales increased 22.1% in Europe, 26.5% in the Western Hemisphere (excluding the U.S.) and 19.3% in the Asia- Pacific, Africa regions. These sales gains include the positive impact of currency fluctuations between 15 the U.S. dollar and foreign currencies in Europe of 16.3%, in the Western Hemisphere (excluding the U.S.) of 11.5% and in the Asia-Pacific, Africa region of 10.5%. Analysis of Sales by Business Segments Consumer Consumer segment sales in the fiscal first quarter of 2004 were $2.0 billion, an increase of 14.3% over the same period a year ago with 8.7% of operational growth and a positive currency impact of 5.6%. U.S. Consumer segment sales increased by 8.1% while international sales gains of 22.1% included a positive currency impact of 12.5%. Major Consumer Franchise Sales Total Operations Currency 2004 2003 %Change %Change %Change McNeil $ 563 $ 487 15.6% 13.6% 2.0% Skin Care 562 465 20.9 13.5 7.4 Women's Health 348 313 11.2 3.9 7.3 Baby & Kids Care 343 304 12.9 5.8 7.1 Consumer segment sales growth is attributable to strong sales performance in the major franchises in this segment including Skin Care, Baby & Kids Care, McNeil Consumer over- the-counter pharmaceutical and nutritional products and the Women's Health Franchise. The Skin Care franchise sales growth was attributed to NEUTROGENA(r), due to new product introductions in cosmetics; AVEENO(r), with strong growth in the facial care line; RoC(r) with the relaunch of Retinol Gold(r) in Europe; and CLEAN & CLEAR(r), with new products such as Morning Burst(tm) and Acne Advantage(tm). The Baby & Kids Care franchise growth was led by new products, the continued strength of BabyCenter and the sales growth of Balmex(r) Diaper Rash Ointment, which was acquired in 2003. McNeil Consumer over-the-counter pharmaceutical and nutritional products franchise sales increase was primarily due to the SPLENDA(r) Tabletop brand no calorie sweetener that continued to build on its number one share position established in 2003. Another franchise contributing to the overall sales growth in the Consumer segment was the Women's Health franchise due to the growth in sanitary protection products in international markets. In February 2004, the Company announced an agreement with Tate & Lyle related to the production of sucralose and the SPLENDA brand. This transaction was completed on April 2, 2004 and resulted in the Company being responsible for the worldwide sales and marketing of the tabletop category of SPLENDA(r), with Tate & Lyle responsible for the manufacturing of sucralose and the marketing of ingredient sales. Also in the fiscal first quarter of 2004, the Company announced an agreement to acquire the remaining 50% stake in the Johnson & Johnson/Merck non-prescription pharmaceuticals joint venture with the Company in Europe. This agreement was consummated in the fiscal second quarter of 2004 resulting in 100% ownership and a fully owned subsidiary. 16 Pharmaceutical Pharmaceutical segment sales in the fiscal first quarter of 2004 were $5.4 billion, an increase of 15.2% over the same period a year ago with 10.9% of this change due to operational increases and the remaining 4.3% increase related to the positive impact of currency. The U.S. Pharmaceutical sales increase was 11.6% and the growth in international Pharmaceutical sales was 23.5% which included 14.4% related to the positive impact of currency. Top Pharmaceutical Product Sales Total Operations Currency 2004 2003 %Change %Change %Change PROCRIT(r)/EPREX(r) $ 977 $ 997 (2.0%) (6.0%) 4.0% RISPERDAL(r) 731 601 21.7 15.3 6.4 REMICADE(r) 464 409 13.4 13.4 0.0 DURAGESIC(r) 455 395 15.0 8.9 6.1 LEVAQUIN(r)/FLOXIN(r) 383 298 28.2 28.1 0.1 TOPAMAX(r) 328 231 41.9 38.2 3.7 Hormonal Contraceptives 305 268 13.8 11.9 1.9 Pharmaceutical segment sales growth was adversely affected by the decline of PROCRIT(r) (Epoetin alfa) and EPREX(r) (Epoetin alfa) due to increased competition. Combined, PROCRIT and EPREX sales declined 2.0% in the fiscal first quarter of 2004 versus the same period a year ago. The Company continues to implement programs to improve its competitive position that include steps to ensure that PROCRIT is priced competitively, as well as conducting clinical development programs, which will provide comparative data with competitive products. Strong product growth drivers in the Pharmaceutical segment included RISPERDAL(r) (risperidone), a medication that treats the symptoms of schizophrenia, fueled by the successful launch of RISPERDAL(r) CONSTA(tm) and REMICADE(r) (infliximab), a novel monoclonal antibody therapy indicated to treat Crohn's disease and rheumatoid arthritis, continued to maintain its leadership position in the growing Anti-TNF- a (tumor necrosis factor alpha) market. Net sales for DURAGESIC(r) (fentanyl transdermal system) in the U.S. were negatively impacted by the establishment of a return reserve related to a product recall. LEVAQUIN(r) (levofloxacin), FLOXIN(r) (ofloxacin), and TOPAMAX(r) (topiramate) had strong growth over the same period a year ago. The hormonal contraceptive franchise had strong performance in ORTHO EVRA(r) (norelgestromin/ethinyl estradiol), the first contraceptive patch approved by the

FDA, as well as, a reduction in sales of ORTHO TRI-CYCLEN(r) (norgestimate/ethinyl estradiol) due to generic competition offset by an adjustment to customer rebates. Excluding the adjustment to customer rebates; hormonal contraceptive sales would have been flat over the same period a year ago. There was also strong growth achieved in other brands, including DOXIL(r) (doxorubicin), an anti-cancer treatment, DITROPAN XL(r) (oxybutynin) for the treatment of overactive bladder, and REMINYL(r) (galantamine (HBr)), a treatment for patients with mild to moderate Alzheimer's disease, and NATRECOR(r) (nesiritide) to treat acute congestive heart failure. On March 25, 2004 a U.S. District Court upheld the validity of 17 the DURAGESIC(r) product patent guaranteeing that generic competition could not occur prior to July 23, 2004. The Company has submitted the judge's order to the FDA with a request that the six-month pediatric extension granted in 2003 for DURAGESIC(r) be honored. If the extension is honored, generic competition will not begin until 2005. Medical Devices and Diagnostics Medical Devices and Diagnostics segment sales in the fiscal first quarter of 2004 were $4.1 billion, an increase of 22.9% over the same period a year ago with 16.1% of this change due to operational increases and the remaining 6.8% increase related to the positive impact of currency. The U.S. Medical Devices and Diagnostics sales increase was 25.5% and the growth in international Medical Devices and Diagnostics sales was 20.2% which included 14.3% related to the positive impact of currency. Major Medical Devices and Diagnostics Franchise Sales Total Operations Currency 2004 2003 %Change %Change %Change Cordis $ 877 $ 420 108.7% 101.2% 7.5% DePuy 839 740 13.5 7.8 5.7 Ethicon 681 629 8.4 (0.1) 8.5 Ethicon Endo-Surgery 665 623 6.7 0.0 6.7 LifeScan 400 348 15.0 8.7 6.3 Vision Care 354 300 18.3 11.0 7.3 Ortho-Clinical Diagnostics 303 287 5.2 (1.1) 6.3 Strong sales growth in this segment was led by the Cordis and DePuy franchises. The Cordis franchise was a key contributor to the Medical Devices and Diagnostics segment results. The primary driver of this sales growth was the CYPHER(r) Sirolimus-eluting Stent that was approved in the U.S. by the Food and Drug Administration in April 2003. A competing drug-eluting stent product was launched in the U.S. in early March 2004, but it is too early to quantify the impact on the rate of CYPHER(r) sales going forward. On February 27, 2004, Cordis Corporation, a Johnson & Johnson Company, announced a strategic alliance with Guidant Corporation for the co-promotion of drug-eluting stents and the advancement of new technology. Additionally, the agreement provides the Company an opportunity to participate with Guidant in the future platform of bioabsorbable vascular stents. On April 2, 2004, Cordis Cardiology, a division of Cordis Corporation, a Johnson & Johnson Company, received a warning letter from the FDA regarding observations concerning Good Manufacturing Practice regulations. These observations followed standard post-approval site inspections completed in 2003, including sites involved in the production of the CYPHER stent. The company's management has submitted its response plan to the FDA. DePuy franchise growth was primarily due to DePuy's orthopaedic joint reconstruction products including the shoulder and knee product lines, along with the continued success of the Global 18 Advantage System(tm) in the shoulder market and the continuing trend towards mobile bearings and minimally invasive unicompartmental knees. Strong performance was also reported in the area of spine, led by the continued success in new product sales, which include the Monarch(tm) Ti system, Moss Miami SI(tm) and Crossover(tm). Ethicon Endo-Surgery franchise experienced growth in Endocutter sales that include products used in performing bariatric procedures, an important focus for the franchise. LifeScan franchise growth was due to increased sales of OneTouch(r) Ultra(r) and OneTouch(r) FastTake(r) brands. Vision Care franchise growth was led by the continued success in the Japanese market as well as strong growth in the U.S. market led by the introduction of Acuvue(r) Advance(tm) with HydraClear(tm), a silicone hydrogel material launched nationwide in January 2004. Cost of Goods Sold and Selling, General and Administrative Expenses Consolidated costs of goods sold increased to 29.1% from 27.7% of sales over the same period a year ago. This increase was primarily due to the change in product mix. Consolidated selling, general and administrative expenses increased 11.9% over the same period a year ago. Selling, general and administrative expenses as a percent to sales were 31.5% versus 33.1% for the same period a year ago, which represents an improvement of 1.6% as a percent of sales. This improvement was primarily due to the leveraging of the strong sales growth in the Medical Devices and Diagnostics segment as well as the Company focusing on managing expenses under the "Funding Our Future" initiative. Research & Development Research activities represent a significant part of the Company's business. These expenditures relate to the development of new products, improvement of existing products, technical support of products and compliance with governmental regulations for the protection of the consumer. Worldwide costs of research activities, for the fiscal first quarter of 2004 were $1.1 billion an increase of 17.0% over the same period a year ago. The level of research and development spending remained the same as a percent to sales as compared to the same period a year ago, excluding the in- process research & development charge of $18 million before tax in 2003. 19 In-Process Research & Development In the fiscal first quarter of 2003, the Company recorded in-process research & development (IPR&D) charges of $15 million after-tax ($18 million before tax) related to acquisitions. These acquisitions included certain assets of Orquest, Inc., a privately-held biotechnology company focused on developing biologically-based implants for orthopaedics spine surgery and 3-Dimensional Pharmaceuticals, Inc., a company with a technology platform focused on the discovery and development of potential new drugs in early stage development for the treatment of cardiovascular diseases, oncology and inflammation. Other (Income) Expense, Net Other (income) expense included gains and losses related to the sale and write-down of certain equity securities of the Johnson & Johnson Development Corporation, losses on the disposal of fixed assets, currency gains & losses, minority interests, litigation settlement expense as well as royalty income. The favorable change in other (income) expense as compared to the same period a year ago was due primarily to the gain associated with business divestitures in the fiscal first quarter of 2004. OPERATING PROFIT BY SEGMENT Consumer Segment Operating profit for the Consumer segment as a percent to sales in the fiscal first quarter of 2004 was 21.5% versus 23.1% over the same period a year ago. This decrease is primarily due to ongoing costs associated with a plant closure and investment spending in developing markets outside the U.S. Pharmaceutical Segment Operating profit for the Pharmaceutical segment as a percent to sales in the fiscal first quarter of 2004 was 38.8% versus 39.8% over the same period a year ago. Operating profit was primarily impacted by the change in sales due to the product mix. Medical Devices and Diagnostics Segment Operating profit for the Medical Devices and Diagnostics segment as a percent to sales in the fiscal first quarter of 2004 was 25.8% versus 21.7% over the same period a year ago. The driver of the Medical Devices and Diagnostics segment margin growth was primarily due to operating expense leveraging on increased sales volume on CYPHER(r) Stent sales. Interest (Income) Expense Interest income in the fiscal first quarter of 2004 increased by $1 million due primarily to the increase in the cash balance offset by a decline in the average rate of investment of 0.5%. The cash balance, which includes marketable securities at the end of the fiscal first quarter of 2004, was $10.4 billion which is $2.6 billion higher than the same period a year ago. Interest expense in the fiscal first quarter of 2004 increased by $7 million over the same period a year ago primarily due to an increase in the average debt rate of 0.9% due to the conversion of short term debt to long term. 20 Provision For Taxes on Income The worldwide effective income tax rates for the fiscal first quarter of 2004 and 2003 were 28.8% and 29.3%. The decrease in the effective tax rate of 0.5% is due to the increase in taxable income in lower tax jurisdictions relative to taxable income in higher tax

jurisdictions. LIQUIDITY AND CAPITAL RESOURCES Cash Flows Cash generated from operations provided the major sources of funds for the growth of the business, including working capital, capital expenditures, acquisitions, share repurchases, dividends and debt repayments. In the fiscal first quarter of 2004, cash flow from operations was $2.7 billion, an increase of $0.6 billion over the same period a year ago. Major factors contributing to the increase were an increase in net income of $0.4 billion and a decrease in the growth of working capital of $0.2 billion. Net cash used by investing activities was relatively the same versus the same period a year ago due to a decrease in capital spending, no acquisition activity in 2004 and an increase in the purchases of marketable securities in the fiscal first quarter of 2004. Net cash used by financing activities increased by $.5 billion primarily due to the repayment of commercial paper. Cash and current marketable securities were $10.4 billion at the end of the fiscal first quarter of 2004 as compared with $9.5 billion at year-end 2003. Dividends On January 5, 2004, the Board of Directors declared a regular cash dividend of $0.24 per share, payable on March 9, 2004 to shareholders of record as of February 17, 2004. This represented an increase of 17.1% from the fiscal first quarter of 2003 dividend. On April 22, 2004, the Board of Directors declared a regular cash dividend of $0.285 per share, payable on June 8, 2004 to shareholders of record as of May 18, 2004. This represented an increase of 18.8% and was the 42nd consecutive year of cash dividend increases. The Company expects to continue the practice of paying regular cash dividends. OTHER INFORMATION New Accounting Standards In January 2003, the FASB issued FIN 46, "Consolidation of Variable Interest Entities - an interpretation of ARB No. 51", and in December 2003, issued a revised FIN 46(R), "Consolidation of Variable Interest Entities - an interpretation of ARB No. 51", both of which address consolidation of variable interest entities. FIN 46 expanded the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPEs) to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. This interpretation was immediately applicable to variable interest entities created after January 31, 2003. The adoption of this portion of FIN 46 did not have a 21 material effect on the Company's results of operations, cash flows or financial position. FIN 46 is applicable in 2004 to variable interest entities in which an enterprise holds a variable interest that was acquired before February 1, 2003. The adoption of this portion of FIN 46 did not have a material effect on the results of operations, cash flows and financial position of the Company. In December 2003, the FASB issued SFAS No. 132 (revised 2003), "Employers' Disclosures about Pensions and Other Postretirement Benefits - an amendment of FASB Statement No. 87, 88 and 106," which was effective for the fourth quarter of 2003. This Statement revises employers' disclosures about pension plans and other postretirement benefit plans and these disclosures are included in Note 11. In December 2003, the FASB issued FASB Staff Position (FSP) FAS No. 106-1, "Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003", which is effective for interim or annual financial statements of fiscal years ending after December 7, 2003. The Company has elected to defer adoption of FSP FAS No. 106-1 until authoritative guidance is issued, as allowed by the Standard. The Company's adoption of FSP FAS No. 106-1 is not expected to have a material effect 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 1993 - 2003, 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). Inflation rates, even though moderate in many parts of the world during 2003, 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 result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement. On December 8, 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 was enacted that introduces a prescription drug benefit under Medicare as well as a subsidy to sponsors of retiree health care benefit plans. The Company has elected to defer the recognition of the Act until such time when the authoritative guidance is issued. Any measures of the accumulated postretirement benefit obligation or 22 net periodic postretirement benefit cost in the Company's financial statements do not reflect the effect of the Act. The Company also operates in an environment which is becoming 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 competition typically results in creating a loss of market exclusivity and may result in a significant reduction in sales. For further information see the discussion on "Litigation Against Filers of Abbreviated New Drug Applications" in Note 12. CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS This Form 10-Q contains forward-looking statements. Forward- looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. Forward-looking statements may be identified by the use of words like "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things, discussions of future operations, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures. Forward-looking statements are based on current expectations of future events. The Company cannot guarantee that any forward-looking statement will be accurate, although the Company believes that it has been reasonable in its expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or that unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Investors are therefore cautioned not to place undue reliance on any forward-looking statements. The Company assumes no obligation to update any forward-looking statements as a result of new information or future events or developments. Risks and uncertainties include general industry conditions and competition; economic conditions, 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; U.S. and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; product efficacy or safety concerns resulting in product recalls or regulatory action. The Company's report on Form 10-K for the year ended December 28, 2003 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 23 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 a nd Qualitative Disclosures

About Market Risk," in its Annual Report on Form 10-K for the fiscal year ended December 28, 2003. Item 4 - CONTROLS AND PROCEDURES-EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES Disclosure controls and procedures. As of 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 the Company records, processes, summarizes and reports in a timely manner the information the Company must disclose in its reports filed under the Securities Exchange Act. William C. Weldon, Chairman and Chief Executive Officer, and Robert J. Darretta, Vice Chairman and Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Weldon and Darretta concluded that, as of the date of their evaluation, the Company's disclosure controls and procedures were effective. Internal control. Since the date of the evaluation described above, there have not been any significant 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. Part II - OTHER INFORMATION Item 1. Legal Proceedings Product Liability Litigation The Company is involved in numerous product liability cases in the United States, many of which concern adverse reactions to drugs and medical devices. The damages claimed are substantial, and while the Company is confident of the adequacy of the warnings and instructions for use which accompany such products, it is not feasible to predict the ultimate outcome of litigation. However, the Company believes that if any liability results from such cases, it will be substantially covered by existing amounts accrued in the Company's balance sheet under its self-insurance program and by third party product liability insurance. One group of cases against the Company concerns the Janssen Pharmaceutica product PROPULSID, which was withdrawn from general sale and restricted to limited use in 2000. In the wake of publicity about those events, numerous lawsuits have been filed against Janssen, which is a wholly owned subsidiary of the Company, and the Company regarding PROPULSID, in state and federal courts across the country. There are approximately 444 such cases 24 currently pending, including the claims of approximately 5,837 plaintiffs. In the active cases, 400 individuals are alleged to have died from the use of PROPULSID. These actions seek substantial compensatory and punitive damages and accuse Janssen and the Company of inadequately testing for and warning about the drug's side effects, of promoting it for off-label use and of over promotion. In addition, Janssen and the Company have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitations with respect to the potential claims (tolling agreements) of a significant number of individuals while those attorneys evaluate whether or not to sue Janssen and the Company on their behalf. In September 2001, the first ten plaintiffs in the Rankin case, which comprises the claims of 155 PROPULSID plaintiffs, went to trial in state court in Claiborne County, Mississippi. The jury returned compensatory damage verdicts for each plaintiff in the amount of $10 million, for a total of $100 million. The trial judge thereafter dismissed the claims of punitive damages. On March 4, 2002, the trial judge reduced these verdicts to a total of $48 million, and denied the motions of Janssen and the Company for a new trial. Janssen and the Company believe these verdicts, even as reduced, are insupportable and have appealed. In the view of Janssen and the Company, the proof at trial demonstrated that none of these plaintiffs were injured by PROPULSID and that no basis for liability existed. In April 2002, a state court judge in New Jersey denied plaintiffs' motion to certify a national class of PROPULSID users for purposes of medical monitoring and refund of the costs of purchasing PROPULSID. An effort to appeal that ruling has been denied. In June 2002, the federal judge presiding over the PROPULSID Multi-District Litigation in New Orleans, Louisiana similarly denied plaintiffs' motion there to certify a national class of PROPULSID users. Plaintiffs in the Multi-District Litigation have said they are preserving their right to appeal that ruling, and other complaints filed against Janssen and the Company include class action allegations, which could be the basis for future attempts to have classes certified. On February 5, 2004, Janssen announced that it had reached an agreement in principle with the Plaintiffs Steering Committee (PSC), of the PROPULSID Federal Multi-District Litigation (MDL), to resolve federal lawsuits related to PROPULSID. There are approximately 4,000 individuals included in the Federal MDL of whom approximately 300 are alleged to have died from use of the drug. The agreement becomes effective once 85 percent of the death claims, and 75 percent of the remainder, agree to the terms of the settlement. In addition, 12,000 individuals who have not filed lawsuits, but whose claims are the subject of tolling agreements suspending the running of the statutes of limitations against those claims, must also agree to participate in the settlement before it will become effective. Those agreeing to participate in the settlement will submit medical records to an independent panel of physicians who will determine whether the claimed injuries were caused by PROPULSID and otherwise meet the standards for 25 compensation. If those standards are met, a court-appointed special master will determine compensatory damages. If the agreement becomes effective, Janssen will pay as compensation a minimum of $69.5 million and a maximum of $90 million, depending upon the number of plaintiffs who enroll in the program. Janssen will also establish an administrative fund not to exceed $15 million, and will pay legal fees to the PSC up to $22.5 million, subject to court approval. With respect to all the various PROPULSID actions against them, Janssen and the Company dispute the claims in those lawsuits and are vigorously defending against them except where, in their judgment, settlement is appropriate. Janssen and the Company believe they have adequate self-insurance accruals and third party product liability insurance with respect to these cases. In communications to the Company, the excess insurance carriers have raised certain defenses to their liability under the policies and to date have declined to reimburse Janssen and the Company for PROPULSID- related costs despite demand for payment. However, in the opinion of the Company, those defenses are pro forma and lack substance and the carriers will honor their obligations under the policies either voluntarily or after litigation. The Company recently commenced arbitration against Allianz Underwriters Insurance Company, which issued the first layer of applicable excess insurance coverage, to obtain reimbursement of PROPULSID-related costs. The Company's Ethicon, Inc. subsidiary has over the last several years had a number of claims and lawsuits filed against it relating to VICRYL sutures. The actions allege that the sterility of VICRYL sutures was compromised by inadequacies in Ethicon's systems and controls, causing patients who were exposed to these sutures to incur infections which would not otherwise have occurred. Ethicon on several occasions recalled batches of VICRYL sutures in light of questions raised about sterility but does not believe any contamination of suture products in fact occurred. In November 2003, a trial judge in West Virginia certified for class treatment all West Virginia residents who had VICRYL sutures implanted during Class I or II surgeries from May 1, 1994 to December 31, 1997. The certification is subject to later challenge following the conclusion of discovery. No trial date has been set in this matter and Ethicon has been and intends to continue vigorously defending against the claims. Affirmative Stent Patent Litigation In patent infringement actions tried in Delaware Federal Court in late 2000, Cordis Corporation, a subsidiary of Johnson & Johnson, obtained verdicts of infringement and patent validity, and damage awards, against Boston Scientific Corporation and Medtronic AVE, Inc., based on a number of Cordis vascular stent patents. On December 15, 2000, the jury in the damage action against Boston Scientific returned a verdict of $324 million and on December 21, 2000, the jury in the Medtronic AVE action returned a verdict of $271 million. These sums represent lost profit and reasonable royalty damages to compensate Cordis for infringement but do not include pre or post judgment interest. In February 2001 a hearing 26 was held on the claims

of Boston Scientific and Medtronic AVE that the patents at issue were unenforceable owing to alleged inequitable conduct before the patent office. In March and May 2002, the district judge issued post trial rulings that confirmed the validity and enforceability of the main Cordis stent patent claims but found certain other Cordis patents unenforceable. Further, the district judge granted Boston Scientific a new trial on liability and damages and vacated the verdict against Medtronic AVE on legal grounds. On August 12, 2003, the Court of Appeals for the Federal Circuit found the trial judge erred in vacating the verdict against Medtronic AVE and remanded the case to the trial judge for further proceedings. Cordis filed motions before the trial court on October 14, 2003 to reinstate the verdicts against both Medtronic AVE and Boston Scientific and to award interest and enter injunctions against the stent products at issue in those two cases (the GFX and MicroStent stents of Medtronic AVE and the NIR stent of Boston Scientific) and colorable variations thereof. Medtronic AVE and Boston Scientific are resisting reinstatement of these verdicts and will likely attempt to appeal to the Court of Appeals for the Federal Circuit once judgments are entered. In January 2003, Cordis filed an additional patent infringement action against Boston Scientific in Delaware Federal Court accusing its Express2 and TAXUS stents of infringing one of the Cordis patents involved in the earlier actions against Boston Scientific and Medtronic AVE. In February 2003, Cordis moved in that action for a preliminary injunction seeking to bar the introduction of the TAXUS stent based on that patent. On November 21, 2003, the district judge denied that request for a preliminary injunction and Cordis filed an appeal with the Court of Appeals for the Federal Circuit. A decision by the Federal Circuit is expected in the 2nd or 3rd quarter of 2004. Cordis also has pending in Delaware Federal Court another action against Medtronic AVE accusing Medtronic AVE of infringement by sale of stent products introduced by Medtronic AVE subsequent to its GFX and MicroStent products, subject to the earlier action referenced above. In early June 2003, an arbitration panel in Chicago, in a preliminary ruling, found in favor of Cordis in its arbitration against ACS/Guidant involving infringement by ACS/Guidant of a Cordis stent patent. On August 19, 2003, the panel confirmed that ruling, rejecting the challenge of ACS/Guidant. Under the terms of an earlier agreement between Cordis and ACS/Guidant, the arbitration panel's ruling obligated ACS/Guidant to make a payment of $425 million to Cordis which was made in the fiscal fourth quarter of 2003. As a result of resolving this matter, in the fiscal fourth quarter, $230 million was recorded in other income and expense (approximately $142 million after tax) relating to past periods. The balance of the award, $195 million (approximately $120 million after tax), will be recognized in income in future periods over the estimated remaining life of the intellectual property. No additional royalties for ACS/Guidant's continued use of the technology and no injunction are involved. 27 Patent Litigation Against Various Johnson & Johnson Operating Companies The products of various Johnson & Johnson operating companies are the subject of various patent lawsuits, which could potentially affect the ability of those operating companies to sell those products, or require the payment of past damages and future royalties. The following patent lawsuits concern important products of Johnson & Johnson operating companies: Medtronic AVE v. Cordis Corporation: This action, filed in April 2002 in federal district court in Texas and thereafter transferred to the federal district court in Delaware, asserts certain patents owned by Medtronic AVE against the Cordis Bx VELOCITY Stent, which is also the stent structure used in the CYPHER drug-eluting product. Boston Scientific Corporation (BSC) v. Cordis Corporation: This action, filed in Delaware Federal Court in March 2003, asserts that the CYPHER drug-eluting Stent infringes several patents assigned to Boston Scientific. Boston Scientific seeks damages and a permanent injunction. Boston Scientific Corporation (BSC) v. Cordis Corporation: This action, filed in Delaware Federal Court in December 2003, asserts that the Cordis CYPHER drug-eluting Stent infringes several patents assigned to BSC by NeoRx pertaining to pharmaceutical compounds for use on stents. BSC is seeking damages and a permanent injunction. Medinol Ltd. v. Cordis Europe NV (Netherlands) and Medinol Ltd. v. Cordis Holding Belgium B.V.B.A. and Janssen Pharmaceutica N.V. (Belgium): On July 3, 2003, the Appeal Court of the Hague overturned a lower court and granted Medinol, an Israeli stent manufacturer, a preliminary injunction based on patent infringement prohibiting Cordis from making or selling the Bx VELOCITY and CYPHER Stents in the Netherlands. The injunction became effective on August 26, 2003. On March 31, 2004, the underlying patent was cancelled by the European Patent Office, resulting in the lifting of the injunction. In Belgium, Medinol had filed a patent infringement suit based on the same patent it asserted in the Netherlands, and moved for a preliminary injunction seeking to prevent the defendants from making or selling the Bx VELOCITY and CYPHER Stents there. That motion was denied by the trial court on November 10, 2003. Medinol had appealed, but the cancellation of the underlying patent by the European Patent Office negates the appeal. Cordis currently uses a Janssen Pharmaceutica facility in Belgium to coat CYPHER Stents with sirolimus principally for the ex- U.S. market. Rockey v. Cordis Corporation: This is an action against Cordis by the heirs of Dr. Rockey concerning a patent he licensed to Cordis in 1996, shortly before Cordis was acquired by Johnson & Johnson. The plaintiffs assert that Dr. Rockey's patent, which expired in February 2004, covers all stent products ever marketed by Cordis and seek a 10% royalty on those sales. Trial of the action, which is pending in federal court in Miami, Florida, was scheduled for March 2004, but has been adjourned while the trial court considers Cordis' motion for summary judgment. On February 24, 2004, ASC/Guidant and Cordis Corporation entered into a strategic alliance for the co-promotion of drug-eluting 28 stents. As a result of this agreement, all pending litigation between the companies has been settled. With respect to all of these matters, the Johnson & Johnson operating company involved is vigorously defending against the claims of infringement and disputing where appropriate the validity and enforceability of the patent claims asserted against it. Litigation Against Filers of Abbreviated New Drug Applications (ANDAs) The following lawsuits are against generic firms 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 subsidiary of the Company involved is not successful in these actions, the firms involved will then introduce generic versions of the product at issue resulting in very substantial market share and revenue losses for the product of the Company's subsidiary. Ortho-McNeil Pharmaceutical, Inc. and Daiichi, Inc. v. Mylan Laboratories and Ortho- McNeil Pharmaceutical, Inc. and Daiichi, Inc. v. Teva Pharmaceutical: These matters, the first of which was filed in February 2002 in federal court in West Virginia and the second in June 2002 in federal court in New Jersey, concern the efforts of Mylan and Teva to invalidate and establish non-infringement and unenforceability of the patent covering LEVAQUIN (levofloxacin) tablets. The patent is owned by Daiichi and exclusively licensed to Ortho-McNeil. The first phase of the trial of the Mylan case concluded in December 2003 and the second phase should be concluded in May 2004. No trial date has been set in the Teva matter. Ortho-McNeil Pharmaceutical, Inc. and Daiichi v. Bedford Laboratories: This matter was filed in federal district court in New Jersey in April 2003 and involves the effort of Bedford to invalidate and assert non-infringement and unenforceability of the same Daiichi patent on LEVAQUIN involved in the above proceedings. In this case, however, Bedford is challenging the patent's application to its products which it asserts are equivalent to LEVAQUIN injection pre-mix and injection vials, rather than tablets. Ortho-McNeil Pharmaceutical, Inc. and Daiichi v. American Pharmaceutical Partners and Sicor Pharmaceutical: In December 2003, Ortho-McNeil Pharmaceutical, Inc. and Daiichi filed suits in the federal district court in New

Jersey against American Pharmaceutical Partners and Sicor Pharmaceutical in respect of ANDAs filed by those entities involving the same Daiichi patent on LEVAQUIN for injection pre- mix and single use vials. Janssen Pharmaceutica Inc. and ALZA Corporation v. Mylan Laboratories: This action, filed in federal district court in Vermont in January 2002, concerns Mylan's effort to invalidate and assert non-infringement and unenforceability of ALZA's patent covering the DURAGESIC (fentanyl transdermal system) product. In March 2004, the trial court issued its ruling upholding the validity of the patent and finding it infringed by Mylan's generic. Despite having lost the patent case, Mylan has stated publicly that it intends to launch its generic to 29 DURAGESIC in July 2004 because it asserts Janssen and ALZA forfeited the benefits of the FDA grant of pediatric exclusivity by filing their lawsuit late. Janssen and ALZA vigorously dispute this contention and have requested FDA to recognize DURAGESIC (fentanyl transdermal system) marketing exclusivity until January 2005. Janssen Pharmaceutica N.V. v. EON Labs Manufacturing: This action was filed in federal court in the Eastern District of New York in April 2001 and concerns EON's effort to invalidate and establish non- infringement of Janssen's patent covering SPORANOX (itraconozole). Trial in this matter is scheduled to commence in May 2004. Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.: This lawsuit was filed in federal court in New Jersey in November 2002 and concerns the attempt of Kali to invalidate and establish non-infringement of Ortho-McNeil's patent covering ULTRACET (tramadol/acetaminophen) tablets. No trial date has been set for this case. Ortho-McNeil Pharmaceutical, Inc. v. Teva Pharmaceuticals USA: This lawsuit was filed in federal court in New Jersey in February 2004 and concerns Teva's attempts to invalidate and assert non-infringement and unenforceability of the same Ortho- McNeil patent on ULTRACET involved in the above proceeding with Kali. ALZA Corporation v. Mylan Laboratories: This action was filed in federal district court in West Virginia in May 2003 and concerns Mylan's effort to invalidate and assert non-infringement of an ALZA patent covering the Ortho- McNeil product DITROPAN XL (oxybutynin chloride). Trial has been scheduled for February 2005 in this case. ALZA Corporation v. IMPAX Laboratories: This action was filed in federal court in California in September 2003 and concerns Impax's effort to invalidate and assert non-infringement of the same ALZA patent covering DITROPAN XL involved in the above Mylan case. No trial date has been set in this matter. Ortho-McNeil Pharmaceutical, Inc. v. Barr Laboratories, Inc.: This action, filed in federal district court in New Jersey in October 2003, concerns the effort of Barr Laboratories to assert non- infringement, invalidity and unenforceability of Ortho-McNeil's patent on ORTHO TRI- CYCLEN LO (norgestimate/ethinyl estradiol), an oral contraceptive product. Janssen Pharmaceutica N.V. v. Mylan Pharmaceuticals Inc.: This action, filed in federal district court in New Jersey in December 2003, concerns Mylan's effort to invalidate the Janssen patent covering RISPERDAL (risperidone) tablets. Janssen Pharmaceutica N.V. v. Dr. Reddy's Laboratories, Inc.: This action, filed in federal district court in New Jersey, concerns Dr. Reddy's efforts to invalidate the same Janssen patent covering RISPERDAL tablets as in the immediately preceding Mylan case. Ortho- McNeil Pharmaceutical, Inc. v. Mylan Pharmaceuticals Inc.: This action, filed in federal district court in New Jersey in April 2004, concerns Mylan's effort to invalidate the Ortho- McNeil patent covering TOPAMAX (topiramate) tablets. Eisai Inc. v. Dr. Reddy's Laboratories, Inc.: This action, filed by Janssen's U.S. co-promotion partner Eisai Inc. in federal court in New York, concerns Dr. Reddy's effort to invalidate and assert non-infringement of an Eisai patent covering ACIPHEX (rabeprazole sodium) tablets. No trial date has been set. Eisai Inc. v. Teva 30 Pharmaceuticals USA: This action, also filed by Janssen's U.S. co-promotion partner Eisai Inc., concerns Teva's efforts to invalidate and assert non-infringement of the same Eisai patent involved in the immediately preceding Dr. Reddy's case. No trial date has been set in that matter. Eisai Inc. v. Mylan Pharmaceuticals Inc.: In January 2004, Janssen's U.S. co- promotion partner Eisai Inc. filed this action in federal district court in New York against Mylan Pharmaceuticals Inc. regarding Mylan's efforts to invalidate and assert non-infringement of the same Eisai patent covering ACIPHEX tablets as in the above Dr. Reddy's and Teva cases. No trial date has been set. Janssen Pharmaceutica Inc. is not a party to the Eisai actions. With respect to all of the above matters, the Johnson & Johnson operating company involved is vigorously defending the validity and enforceability and asserting the infringement of its own or its licensor's patents. Average Wholesale Price (AWP) Litigation Johnson & Johnson and its pharmaceutical operating companies, 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. Most of these cases, both federal actions and state actions removed to federal court, have been consolidated for pre- trial purposes in a Multi-District Litigation (MDL) in federal court in Boston, Massachusetts. The plaintiffs in these cases include 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. Ethicon Endo-Surgery, Inc., a Johnson & Johnson operating company which markets endoscopic surgical instruments, and the Company, are named defendants in a North Carolina state court class action lawsuit alleging AWP inflation and improper marketing activities against TAP Pharmaceuticals. Ethicon Endo-Surgery, Inc. is a defendant based on claims that several of its former sales representatives are alleged to have been involved in arbitrage of a TAP drug. The allegation is that these sales representatives persuaded certain physicians in states where the drug's price was low to purchase from TAP excess quantities of the drug and then resell it in states where its price was higher. Ethicon Endo- Surgery, Inc. and the Company deny any liability for the claims made against them in this case and are vigorously defending against it. The trial judge recently certified a national class of purchasers of the TAP product at issue and trial is likely in 2004. Other The New York State Attorney General's office and the Federal Trade Commission issued subpoenas in January and February 2003 seeking documents relating to the marketing of sutures and endoscopic instruments by the Company's Ethicon, Inc. and Ethicon Endo- 31 Surgery, Inc. subsidiaries. The Connecticut Attorney General's office also issued a subpoena for the same documents. These subpoenas focus on the bundling of sutures and endoscopic instruments in contracts offered to Group Purchasing Organizations and individual hospitals in which discounts are predicated on the hospital achieving specified market share targets for both categories of products. The operating companies involved are responding to the subpoenas. On June 26, 2003, the Company received a request for records and information from the U.S. House of Representatives' Committee on Energy and Commerce in connection with its investigation into pharmaceutical reimbursements and rebates under Medicaid. The Committee's request focuses on the drug REMICADE (infliximab), marketed by the Company's Centocor, Inc. subsidiary. On July 2, 2003, Centocor received a request that it voluntarily provide documents and information to the criminal division of the U.S. Attorney's Office, District of New Jersey, in connection with its investigation into various Centocor marketing practices. Both the Company and Centocor are responding to these requests for documents and information. On August 1, 2003, the Securities and Exchange Commission (SEC) advised the Company of its informal investigation under the Foreign Corrupt Practices Act of allegations of payments to Polish governmental officials by U.S. pharmaceutical companies. On November 21, 2003, the SEC advised the company the investigation had become formal and issued a subpoena for the information previously requested in an informal fashion, plus other background documents. The Company and its operating units in Poland are

responding to these requests. On December 8, 2003, the Company's Ortho-McNeil Pharmaceutical unit received a subpoena from the United States Attorney's office in Boston, Massachusetts seeking documents relating to the marketing, including alleged off- label marketing, of the drug TOPAMAX (topiramate) which is approved for anti-epilepsy therapy. Ortho-McNeil is cooperating in responding to the subpoena. On January 20, 2004, the Company's Janssen unit received a subpoena from the Office of the Inspector General of the United States Office of Personnel Management seeking documents concerning any and all payments to physicians in connection with sales and marketing of, and clinical trials for, RISPERDAL from 1997 to 2002. Janssen is cooperating in responding to the subpoena. After a remand from the Federal Circuit Court of Appeals in January 2003, a partial retrial was commenced in October and concluded in November 2003 in Boston, Massachusetts in the action Amgen v. Transkaryotic Therapies, Inc. (TKT) and Aventis Pharmaceutical, Inc. The matter is a patent infringement action brought by Amgen against TKT, the developer of a gene-activated EPO product, and Aventis, which holds marketing rights to the TKT product, asserting that TKT's product infringes various Amgen patent claims. TKT and Aventis dispute infringement and are 32 seeking to invalidate the Amgen patents asserted against them. The district court has issued preliminary rulings that upheld the district court's initial findings in 2001. A further opinion from the district court is expected in the second quarter of 2004. Further proceedings and an appeal will follow. The Amgen patents at issue in the case are exclusively licensed to Ortho Biotech Inc., a Johnson & Johnson operating company, in the U.S. for non- dialysis indications. Ortho Biotech Inc. is not a party to the action. The Company is also involved in a number of other patent, trademark and other lawsuits incidental to its business. The ultimate legal and financial liability of the Company in respect to all claims, lawsuits and proceedings referred to above cannot be estimated with any certainty. However, in the opinion of management, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of these legal proceedings, net of liabilities already accrued in the Company's consolidated balance sheet, is not expected to have a material adverse effect on the Company's consolidated financial position, although the resolution in any reporting period of one or more of these matters could have a significant impact on the Company's results of operations and cash flows for that period. 33 Item 5. Exhibits and Reports on Form 8-K (a) Exhibit Exhibit 99.3 Certifications Under Rule 13a-14(a) of the Securities Exchange Act Pursuant to Section 302 of the Sarbanes-Oxley Act. Exhibit 99.15 Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act. (b) Reports on Form 8-K A report on Form 8-K was furnished on January 16, 2004, which included a press release announcing the decision of James T. Lenehan to retire from the Company as of June 30, 2004 and resign as Vice Chairman of the Board of Directors and President effective February 1, 2004. A report on Form 8-K was furnished on January 20, 2004, which included the Press Release for the period ended December 28, 2003. Also included in this filing are the unaudited comparative supplementary sales data and condensed consolidated statement of earnings for the fiscal fourth quarter of 2003 and fiscal year 2003. A report on Form 8-K was filed on March 1, 2004, which included the audited consolidated financial statements for the three year period ended December 28, 2003. A report on Form 8-K was filed on March 1, 2004, which included a Press Release announcing the strategic alliance with Guidant Corporation for the co-promotion of drug-eluting stents. A Report on Form 8-K was filed on April 5, 2004, which included a press release dated April 2, 2004 reporting that Cordis had received a warning letter from the U.S. Food and Drug Administration (FDA) regarding FDA's observations concerning the Good Manufacturing Practice (GMP) regulations. A report on Form 8-K was furnished on April 13, 2004, which included the Press Release for the period ended March 28, 2004. Also included in this filing are the unaudited comparative supplementary sales data and condensed consolidated statement of earnings for the fiscal first quarter of 2004. A report on Form 8-K was furnished on April 26, 2004, which included a Press Release announcing an increase in the Company's quarterly dividend. 34 SIGNATURES Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized. JOHNSON & JOHNSON (Registrant) Date: May 4, 2004 By /s/ R. J. DARRETTA R. J. DARRETTA Vice Chairman (Chief Financial Officer) Date: May 4, 2004 By /s/ S. J. COSGROVE S. J. COSGROVE Controller (Chief Accounting Officer) 35