

BRISTOL MYERS SQUIBB CO  
Form 10-Q/A  
June 28, 2004

[Draft June 16, 2004]

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

---

**FORM 10-Q/A**  
**(Amendment No. 1)**

---

**QUARTERLY REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF**  
**THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2004**

**Commission File Number 1-1136**

---

**BRISTOL-MYERS SQUIBB COMPANY**

**(Exact name of registrant as specified in its charter)**

---

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**22-079-0350**  
(IRS Employer  
Identification No.)

**345 Park Avenue, New York, N.Y. 10154**

(Address of principal executive offices)

**Telephone: (212) 546-4000**

---

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 is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

At March 31, 2004, there were 1,944,361,749 shares outstanding of the Registrant's \$.10 par value Common Stock.

---

**EXPLANATORY NOTE**

This Amendment No. 1 to Bristol-Myers Squibb Company's quarterly report on Form 10-Q for the period ended March 31, 2004 (the "10-Q/A") amends Items 1, 2 and 4 in Part I. This 10-Q/A is being filed (i) to make conforming corrections to each of the Section 302 certifications to include a statement that had been inadvertently omitted from the previously filing and (ii) to include certain conforming disclosures consistent with those added in connection with the Company's filing an Amendment No. 1 to its Annual Report on Form 10-K for the year ended December 31, 2003. In particular, such conforming disclosures include:

- (i) an expanded description of recent clinical testing results relating to PRAVACHOL;
- (ii) a further description of the remedial actions taken by the Company to improve the effectiveness of its disclosure controls and procedures and internal controls over financial reporting for income taxes;
- (iii) clarification of an aspect of the consignment accounting model under the Company's revenue recognition policy; and
- (iv) disclosure of expected market exclusivity less for the Company's key pharmaceutical products.

This 10-Q/A does not update any other information set forth in the original filing of the Company's quarterly report on Form 10-Q for the period ended March 31, 2004. This 10-Q/A does not reflect any events or developments occurring subsequent to May 10, 2004. For a discussion of events and developments occurring subsequent to May 10, 2004, see the following of the Company's Current Reports on Form 8-K dated:

May 10, 2004 (announced collaboration agreement with Merck & Co., Inc. for muraglitazar);

May 26, 2004 (announced receipt of FTC approval of supply and distribution agreement for PARAPLATIN with Pharmachemie B.V.); and

June 28, 2004 (announced expected increase in legal reserves of \$400 million).

---

**BRISTOL-MYERS SQUIBB COMPANY**

**INDEX TO FORM 10-Q/A**

**MARCH 31, 2004**

	<u>Page</u>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b>Item 1.</b>	
<u>Financial Statements:</u>	
<u>Consolidated Statement of Earnings for the three months ended March 31, 2004 and 2003</u>	3
<u>Consolidated Statement of Comprehensive Income and Retained Earnings for the three months ended March 31, 2004 and 2003</u>	4
<u>Consolidated Balance Sheet at March 31, 2004 and December 31, 2003</u>	5
<u>Consolidated Statement of Cash Flows for the three months ended March 31, 2004 and 2003</u>	6
<u>Notes to Consolidated Financial Statements</u>	7-28
<u>Report of Independent Registered Public Accounting Firm</u>	29
<b>Item 2.</b>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	30-41
<b>Item 3.</b>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	41
<b>Item 4.</b>	
<u>Controls and Procedures</u>	41
<b><u>PART II OTHER INFORMATION</u></b>	
<b>Item 1.</b>	
<u>Legal Proceedings</u>	42
<b>Item 4.</b>	
<u>Submission of Matters to a Vote of Security Holders</u>	42
<b>Item 6.</b>	
<u>Exhibits and Reports on Form 8-K</u>	43
<u>Signatures</u>	44

**PART I FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS**

**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENT OF EARNINGS**  
**(UNAUDITED)**

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(in millions, except per share data)</b>	
<b>EARNINGS</b>		
Net Sales	\$ 5,181	\$ 4,728
Cost of products sold	1,899	1,709
Marketing, selling and administrative	1,234	1,100
Advertising and product promotion	316	315
Research and development	583	475
Gain on sale of business	(295)	
Provision for restructuring and other items, net	12	12
Litigation income		(21)
Equity in net income of affiliates	(75)	(22)
Other (income)/expense, net	38	(3)
<b>Total expenses</b>	<b>3,712</b>	<b>3,565</b>
<b>Earnings Before Minority Interest and Income Taxes</b>	<b>1,469</b>	<b>1,163</b>
Provision for income taxes	398	316
Minority interest, net of taxes	107	55
<b>Net Earnings</b>	<b>\$ 964</b>	<b>\$ 792</b>
<b>Earnings per Common Share</b>		
Basic	\$ .50	\$ .41
Diluted	\$ .49	\$ .41
<b>Average Common Shares Outstanding</b>		
Basic	1,939	1,936
Diluted	1,976	1,940
Dividends declared per Common Share	\$ .28	\$ .28

The accompanying notes are an integral part of these financial statements.



**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENT OF**  
**COMPREHENSIVE INCOME AND RETAINED EARNINGS**  
**(UNAUDITED)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(dollars in millions)</b>	
<b>COMPREHENSIVE INCOME</b>		
Net Earnings	\$ 964	\$ 792
Other Comprehensive Income/(Loss):		
Foreign currency translation, net of tax benefit of \$22 in 2004 and \$86 in 2003	156	149
Deferred gains (losses) on derivatives qualifying as hedges, net of tax expense of \$48 in 2004 and net of tax benefit \$5 in 2003	109	(1)
Available-for-sale securities, net of tax benefit of \$1 in 2004 and 2003	(1)	(2)
	264	146
Total Other Comprehensive Income	264	146
Comprehensive Income	\$ 1,228	\$ 938
<b>RETAINED EARNINGS</b>		
Retained Earnings, January 1	\$ 19,439	\$ 18,503
Net Earnings	964	792
Cash dividends declared	(544)	(542)
	19,859	18,753
Retained Earnings, March 31	\$ 19,859	\$ 18,753

The accompanying notes are an integral part of these financial statements.

## BRISTOL-MYERS SQUIBB COMPANY

## CONSOLIDATED BALANCE SHEET

(UNAUDITED)

	March 31, 2004	December 31, 2003
(dollars in millions)		
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,065	\$ 2,444
Marketable securities	3,552	3,013
Receivables, net of allowances \$142 and \$154	3,106	3,646
Inventories, including consignment inventory	1,645	1,601
Deferred income taxes, net of valuation allowances	834	864
Prepaid expenses	530	350
	<u>12,732</u>	<u>11,918</u>
Total Current Assets	12,732	11,918
Property, plant and equipment, net	5,719	5,712
Goodwill	4,831	4,836
Other intangible assets, net	1,933	1,732
Deferred income taxes, net of valuation allowances	1,068	1,234
Other assets	2,077	2,039
	<u>28,360</u>	<u>27,471</u>
Total Assets	\$ 28,360	\$ 27,471
<b>LIABILITIES</b>		
Current Liabilities:		
Short-term borrowings	\$ 776	\$ 127
Accounts payable	1,687	1,893
Accrued expenses	2,627	2,967
Accrued rebates and returns	967	950
U.S. and foreign income taxes payable	633	707
Dividends payable	544	543
Accrued litigation liabilities	267	267
Deferred revenue on consigned inventory	49	76
	<u>7,550</u>	<u>7,530</u>
Total Current Liabilities	7,550	7,530
Other liabilities	1,642	1,633
Long-term debt	8,635	8,522
	<u>17,827</u>	<u>17,685</u>
Total Liabilities	17,827	17,685
Commitments and contingencies		
<b>STOCKHOLDERS EQUITY</b>		
Preferred stock, \$2 convertible series:		
Authorized 10 million shares; issued and outstanding 7,563 in 2004 and 8,039 in 2003, liquidation value of \$50 per share		
Common stock, par value of \$.10 per share:		
Authorized 4.5 billion shares; issued 2,201,130,337 in 2004 and 2,201,012,432 in 2003		
	220	220
Capital in excess of par value of stock	2,447	2,477
Restricted stock	(53)	(55)
Other accumulated comprehensive loss	(591)	(855)



Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Retained earnings	19,859	19,439
	<u>21,882</u>	<u>21,226</u>
Less cost of treasury stock 256,768,588 common shares in 2004 and 261,029,539 in 2003	(11,349)	(11,440)
	<u>10,533</u>	<u>9,786</u>
Total Stockholders' Equity	<u>\$ 28,360</u>	<u>\$ 27,471</u>
Total Liabilities and Stockholders' Equity	<u>\$ 28,360</u>	<u>\$ 27,471</u>

The accompanying notes are an integral part of these financial statements.

**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**  
**(UNAUDITED)**

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>(dollars in millions)</b>		
<b>Cash Flows From Operating Activities:</b>		
Net earnings	\$ 964	\$ 792
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Depreciation	133	105
Amortization	71	73
Provision for/(benefit of) deferred income taxes	48	(54)
Litigation settlement income		(21)
Provision for restructuring and other items	12	12
Gain on sale of Mead Johnson Adult Nutritional business	(295)	
Loss (gain) on disposal of property, plant and equipment	1	(9)
Undistributed (earnings)/losses of affiliates, net	(8)	26
Unfunded pension expense	40	19
Other, net	(1)	
Changes in operating assets and liabilities:		
Receivables	627	(197)
Inventories	(20)	69
Prepaid expenses	(11)	(11)
Other assets	(66)	55
Deferred revenue on consigned inventory	(27)	(296)
Litigation settlement payments		(544)
Accounts payable and accrued expenses	(387)	6
Product liability	(3)	(20)
U.S. and foreign income taxes payable	(25)	98
Other liabilities	28	57
<b>Net Cash Provided by Operating Activities</b>	<b>1,081</b>	<b>160</b>
<b>Cash Flows From Investing Activities:</b>		
Purchases, net of sales and maturities, of marketable securities	(539)	(368)
Additions to property, plant and equipment and capitalized software	(163)	(213)
Proceeds from disposal of property, plant and equipment	3	23
Proceeds from sale of Mead Johnson Adult Nutritional business	346	
ImClone milestone payment	(250)	
Investment in ImClone		(60)
Other		(2)
<b>Net Cash Used in Investing Activities</b>	<b>(603)</b>	<b>(620)</b>
<b>Cash Flows From Financing Activities:</b>		
Short-term borrowings, net of repayments	595	923
Long-term debt borrowings	3	52
Issuances of common stock under stock plans	63	12
Dividends paid	(543)	(542)

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

<b>Net Cash Provided by Financing Activities</b>	118	445
	<u>          </u>	<u>          </u>
Effect of Exchange Rates on Cash and Cash Equivalents	25	5
	<u>          </u>	<u>          </u>
Increase (Decrease) in Cash and Cash Equivalents	621	(10)
Cash and Cash Equivalents at Beginning of Period	2,444	2,367
	<u>          </u>	<u>          </u>
Cash and Cash Equivalents at End of Period	<u>\$ 3,065</u>	<u>\$ 2,357</u>

The accompanying notes are an integral part of these financial statements.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Basis of Presentation and New Accounting Standards**

Bristol-Myers Squibb Company (the Company) prepared these unaudited consolidated financial statements following the requirements of the Securities and Exchange Commission (SEC) and U.S. generally accepted accounting principles (GAAP) for interim reporting. Under those rules, certain footnotes and other financial information that are normally required by GAAP for annual financial statements can be condensed or omitted. The Company is responsible for the consolidated financial statements included in this Form 10-Q/A. These consolidated financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company's financial position at March 31, 2004 and December 31, 2003, the results of its operations and cash flows for the three months ended March 31, 2004 and 2003. These consolidated financial statements and the related notes should be read in conjunction with the consolidated financial statements and the related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003 (2003 Form 10-K). PricewaterhouseCoopers LLP (PwC), the Company's independent accountants, have performed a review of the unaudited consolidated financial statements included in this Form 10-Q/A, and their review report thereon accompanies this Form 10-Q/A.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Accordingly, the results and trends in these unaudited consolidated financial statements may not be the same as those for the full year.

The Company recognizes revenue when substantially all the risks and rewards of ownership have transferred to the customer, primarily at the time of shipment of products. In the case of certain sales made by the Nutritionals and Other Healthcare segments and certain non-U.S. businesses within the Pharmaceuticals segment, revenue is recognized on the date of receipt by the purchaser. Revenues are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenue.

In the case of sales made to wholesalers (i) as a result of incentives, (ii) in excess of the wholesaler's ordinary course of business inventory level, (iii) at a time when there was an understanding, agreement, course of dealing or consistent business practice that the Company would extend incentives based on levels of excess inventory in connection with future purchases and (iv) at a time when such incentives would cover substantially all, and vary directly with, the wholesaler's cost of carrying inventory in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are accounted for using the consignment model. The determination of when, if at all, sales to a wholesaler meet the foregoing criteria involves evaluation of a variety of factors and a number of complex judgments. Under the consignment model, the Company does not recognize revenue upon shipment of product. Rather, upon shipment of product the Company invoices the wholesaler, records deferred revenue at gross invoice sales price and classifies the inventory held by the wholesaler as consignment inventory at the Company's cost of such inventory. The Company recognizes revenue when the consignment inventory is no longer subject to the incentive arrangements described above, but not later than when such inventory is sold through to the wholesalers' customers, on a first-in first-out (FIFO) basis. Under the consignment model, consignment inventory is no longer subject to incentive arrangements (and accordingly revenue is recognized) when the consignment inventory ceases to be in excess of the wholesaler's ordinary course of business inventory level. The Company generally views approximately one month of supply as a desirable level of wholesaler inventory on a go-forward basis and as a level of wholesaler inventory representative of an industry average. In applying the consignment model to sales to Cardinal and McKesson, the Company defined inventory in excess of the wholesaler's ordinary course of business inventory level as inventory above two weeks and three weeks of supply, respectively, based on the levels of inventory that Cardinal and McKesson required to be used as the basis for negotiation of incentives granted. The Company determines when consignment inventory ceases to be in excess of the wholesaler's ordinary course of business inventory level based on information provided by Cardinal and McKesson. In 2003, the Company discontinued these incentives to its U.S. wholesalers and no longer accounts for sales under the consignment model, except for Oncology Therapeutics Network (OTN) sales.

The Company's estimates of inventory at the wholesalers and deferred revenue on consigned inventory are based on the projected prescription demand-based sales for its products, as well as the Company's analysis of third-party information, including information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and the Company's internal information. The Company's estimates are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations.

In addition, the Company includes alliance revenue in net sales. The Company has agreements to promote pharmaceuticals discovered by other companies. Alliance revenue is based upon a percentage of the Company's copromotion partners' net sales and is earned when the copromotion partners ship the related product and title passes to their customer.

The Company accounts for certain costs to obtain internal use software for significant systems projects in accordance with Statement of Position (SOP) 98-1. These costs, including external direct costs, interest costs and internal payroll and related costs for employees who are directly associated with such projects are capitalized and amortized over the estimated useful life of the software, which ranges from four to ten years. Costs to obtain software for projects that are not significant are expensed as incurred.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Basis of Presentation and New Accounting Standards (Continued)**

The preparation of financial statements in conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant assumptions are employed in estimates used in determining values of intangible assets, restructuring charges and accruals, sales rebate and return accruals, legal contingencies and tax assets and liabilities, as well as in estimates used in applying the revenue recognition policy and accounting for retirement and postretirement benefits (including the actuarial assumptions). Actual results could differ from the estimated results.

Certain prior year amounts have been reclassified to conform to the current year presentation.

In January 2004, the Financial Accounting Standards Board (FASB) issued Staff Position No. FAS 106-1, *Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003* (the Act). The Act introduces a prescription drug benefit under Medicare as well as a federal subsidy to sponsors of retiree health care benefit plans that provide a benefit that is at least actuarially equivalent to Medicare Part D. At present, detailed regulations necessary to implement the Act including how to account for the federal subsidy have not been issued. The Company has elected to defer recognizing the effects of the Act until authoritative guidance on the accounting for the federal subsidy is issued.

In December 2003, the Staff of the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*, which supersedes SAB 101, *Revenue Recognition in Financial Statements*. SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Additionally, SAB 104 rescinds the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, *Revenue Recognition*. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. The initial adoption of this accounting pronouncement did not have a material effect on the Company's consolidated financial statements.

In December 2003, the FASB amended Statement of Financial Accounting Standards (SFAS) No. 132, *Employer's Disclosures about Pensions and Other Post Retirement Benefits*. The amended Statement revises employer's disclosures about pension plans and other post-retirement benefit plans. It does not change the measurement or recognition of those plans required by FASB Statements No. 87, *Employers' Accounting for Pensions*, No. 88, *Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*, and No. 106, *Employers' Accounting for Postretirement Benefits Other Than Pensions*. Revisions included in the amended Statement are effective for financial statements for the fiscal years ended after December 15, 2003. The Company has provided the required disclosures (see Item 1. Financial Statements Note 14. Pension and Other Postretirement Benefit Plans and Note 15. Legal Proceedings and Contingencies).

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The Statement requires that an issuer classify a financial instrument within its scope as a liability. The provisions of SFAS No. 150

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

are effective for financial instruments entered into or modified after May 31, 2003; otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The initial adoption of this accounting pronouncement did not affect the consolidated financial statements.

In May 2003, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. This Issue addresses certain aspects of accounting by a vendor for arrangements under which it will perform multiple revenue generating activities. The provisions of EITF Issue No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Because the Company's revenue recognition policies already conformed to the requirements of the consensus, its initial adoption did not affect the consolidated financial statements.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends SFAS No. 133 by requiring that contracts with comparable characteristics be accounted for similarly. Specifically, the Statement clarifies under what circumstances a contract with an initial net investment meets the characteristics of a derivative, clarifies when a derivative contains a financing component, amends the definition of an underlying to conform with Interpretation No. 45, *Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45) (discussed below) and amends certain other existing pronouncements. The provisions of SFAS No. 149 are effective for contracts entered or modified after June 30, 2003, except as stated below and for hedging relationships designated after June 30, 2003. The initial adoption of this accounting pronouncement did not have a material effect on the consolidated financial statements.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Basis of Presentation and New Accounting Standards (Continued)**

In January 2003, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 46 (FIN 46 or Interpretation), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 clarifies the application of Accounting Research Bulletin (ARB) No. 51, *Consolidated Financial Statements*, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties; such entities are known as variable interest entities (VIEs). The FASB issued a revision to FIN 46 (FIN 46-R) in December 2003. FIN 46-R is effective for the interim period ending March 31, 2004 for all new or existing VIEs. The adoption of FIN 46 had no effect on the Company's financial statements.

If an entity does not meet the definition of a VIE under FIN 46, the Company accounts for the entity under the provisions of SFAS No. 94 *Consolidation of All Majority-Owned Subsidiaries*, which requires that the Company consolidate all majority (more than 50%) owned subsidiaries where it has the ability to exercise control. The Company accounts for 50% or less owned companies over which it has the ability to exercise significant influence using the equity method of accounting under the provisions of Accounting Principles Board (APB) Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. The Company's share of net income or losses of equity investments is included in equity in net income of affiliates in the consolidated statement of earnings. The Company periodically reviews these equity investments for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary.

Investments in securities, comprised of marketable equity securities and securities and investments for which market values are not readily available, are included in other assets. Marketable equity securities are classified as available-for-sale and reported at fair value. Fair value is based on quoted market prices as of the end of the reporting period. Securities and investments for which market values are not readily available are carried at cost. Unrealized gains and losses are reported, net of their related tax effects, as a component of accumulated other comprehensive income (loss) in stockholders' equity until sold. At the time of sale, any gains or losses are calculated by the specific identification method and recognized in other (income)/expense. Losses are also recognized in income when a decline in market value is deemed to be other than temporary.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The provisions of SFAS No. 148 are effective for financial statements for the year ended December 31, 2002. SFAS No. 148 did not have a material impact on the Company's consolidated financial statements as the adoption of this standard did not require the Company to change, and the Company does not plan to change, to the fair value based method of accounting for stock-based compensation.

In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, the following table summarizes the Company's results on a pro forma basis as if it had recorded compensation expense based upon the fair value at the grant date for awards under these plans consistent with the methodology prescribed under SFAS No. 123, *Accounting for Stock-Based Compensation*, for the three months ended March 31, 2004 and 2003:



	<u>Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
	(dollars in millions, except per share data)	
<b>Net Earnings:</b>		
As reported (including restricted stock amortization, net of related taxes, \$4 in 2004 and \$3 in 2003)	\$ 964	\$ 792
Deduct : Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(14)	(26)
	<u>          </u>	<u>          </u>
Pro forma	\$ 950	\$ 766
	<u>          </u>	<u>          </u>
<b>Basic earnings per share:</b>		
As reported	\$ .50	\$ .41
Pro forma	.49	.40
<b>Diluted earnings per share:</b>		
As reported	\$ .49	\$ .41
Pro forma	.48	.39

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Basis of Presentation and New Accounting Standards (Continued)**

In November 2002, the FASB issued FIN 45. FIN 45 requires a guarantor to recognize a liability at the inception of the guarantee for the fair value of the obligation undertaken in issuing the guarantee and include more detailed disclosure with respect to guarantees. The types of contracts the Company enters into that meet the scope of this interpretation are financial and performance standby letters of credit on behalf of wholly owned subsidiaries. FIN 45 is effective for guarantees issued or modified after December 31, 2002. The initial adoption of this accounting pronouncement did not have a material effect on the Company's consolidated financial statements.

**Note 2. Alliances and Investments**

**Sanofi-Synthelabo**

The Company has agreements with Sanofi-Synthelabo (Sanofi) for the codevelopment and cocommercialization of AVAPRO\*/AVALIDE\* (irbesartan), an angiotensin II receptor antagonist indicated for the treatment of hypertension, and PLAVIX\* (clopidogrel), a platelet aggregation inhibitor. The worldwide alliance operates under the framework of two geographic territories; one in the Americas (principally the United States, Canada, Puerto Rico and Latin American countries) and Australia and the other in Europe and Asia. Accordingly, two territory partnerships were formed to manage central expenses, such as marketing, research and development and royalties, and to supply finished product to the individual countries. In general, at the country level, agreements either to copromote (whereby a partnership was formed between the parties to sell each brand) or to comarket (whereby the parties operate and sell their brands independently of each other) are in place. The agreements expire on the later of (i) with respect to PLAVIX\*, 2013 and, with respect to AVAPRO\*/AVALIDE\*, 2012 in the Americas and Australia and 2013 in Europe and Asia and (ii) the expiration of all patents and other exclusivity rights in the applicable territory.

The Company acts as the operating partner for the territory covering the Americas and Australia and owns a 50.1% majority controlling interest in this territory. Sanofi's ownership interest in this territory is 49.9%. As such, the Company consolidates all country partnership results for this territory and records Sanofi's share of the results as a minority interest, net of taxes, which was \$101 million and \$52 million for the three months ended March 31, 2004 and 2003, respectively. For the three months ended March 31, 2004 and 2003, the Company recorded sales in this territory and in comarketing countries (Germany, Italy, Spain and Greece) of \$894 million and \$583 million, respectively.

Sanofi acts as the operating partner of the territory covering Europe and Asia and owns a 50.1% majority financial controlling interest in this territory. The Company's ownership interest in this territory is 49.9%. The Company accounts for the investment in partnership entities in this territory under the equity method and records its share of the results in equity in net income of affiliates in the consolidated statement of earnings. The Company's share of net income from these partnership entities before taxes was \$74 million and \$45 million for the three months ended March 31, 2004 and 2003, respectively.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

In 2001, the Company and Sanofi formed an alliance for the copromotion of irbesartan, as part of which the Company contributed the irbesartan distribution rights in the United States and Sanofi paid the Company a total of \$350 million in 2002 and 2001. The Company accounted for this transaction as a sale of an interest in a license and deferred and amortized the \$350 million into other income over the expected useful life of the license, which is approximately eleven years. The Company recognized in other income \$8 million in each of the three month periods ended March 31, 2004 and 2003.

### **Otsuka**

The Company has a worldwide commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka), to codevelop and copromote ABILIFY\* (aripiprazole), an antipsychotic agent indicated for schizophrenia and related psychotic disorders. Total milestone payments made to Otsuka from 1999 through December 2002 were \$207 million, of which \$157 million was expensed as acquired in-process research and development in 1999. The \$50 million of capitalized payments are being amortized over the remaining life of the agreement, which is approximately 9 years.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

The Company began copromoting the product with Otsuka in the United States and Puerto Rico in November 2002. The Company will also copromote the product in several European countries if marketing approval is received from the European authorities. Revenue is earned when Otsuka ships the product and title passes to the customer. The Company records alliance revenue for its 65% share of the net sales in these copromotion countries and records all expenses related to the product.

**Note 2. Alliances and Investments (Continued)**

The Company also has an exclusive right to sell ABILIFY\* in a number of countries in Europe, the Americas and Asia. In these countries, as sales commence, the Company will record 100% of the net sales and related cost of sales.

The agreement expires in November 2012 in the United States and Puerto Rico. For the countries in the European Union where the Company has the exclusive right to sell ABILIFY\*, on the tenth anniversary of the first commercial sale in the European Union. In each other country where the Company has the exclusive right to sell ABILIFY\*, the agreement expires on the later of the tenth anniversary of the first commercial sale in such country and expiration of the applicable patent in such country.

The Company recorded revenue for ABILIFY\* of \$115 million and \$37 million for the three months ended March 31, 2004 and 2003.

**ImClone**

The Company has a commercialization agreement expiring in September 2018 with ImClone, a biopharmaceutical company focused on developing targeted cancer treatments, for the codevelopment and copromotion of ERBITUX\* in the United States. In February 2004, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for ERBITUX\* for use in combination with irinotecan in the treatment of patients with Epidermal Growth Factor Receptor (EGFR) expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. In April 2004, the FDA accepted for filing and review ImClone's Chemistry, Manufacturing and Controls supplemental BLA for licensure of its BB36 manufacturing facility. In accordance with the terms of the agreement, the Company paid ImClone \$200 million, of which \$140 million was paid in March 2002 and \$60 million was paid in March 2003. The Company paid \$250 million in March 2004 as a milestone payment for the initial approval of ERBITUX\*. An additional \$250 million is payable upon FDA approval for use in treating an additional tumor type. Under the agreement, ImClone will receive a distribution fee based on a flat rate of 39% of product revenues in North America. In addition, the Company also has codevelopment and copromotion rights in Canada and Japan to the extent the product is commercialized in such countries.

With respect to the \$200 million of milestone payments the Company paid ImClone in 2002 and 2003, \$160 million was expensed in the first quarter of 2002 as acquired in-process research and development, and \$40 million was recorded as an additional equity investment to eliminate the income statement effect of the portion of the milestone payment for which the Company has an economic claim through its ownership interest in ImClone. The Company accounts for the \$250 million approval milestone paid in March 2004 as a license acquisition and amortizes

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

the payment into cost of sales over the expected useful life of the license, which is approximately fourteen years. The Company amortized into cost of sales \$1 million for the three months ended March 31, 2004.

In the first quarter of 2004 and 2003, the Company recorded \$1 million and \$23 million, respectively, of net loss for its share of ImClone's losses. Included in 2003 was a \$12 million charge reflecting the Company's estimate of its share of ImClone's net losses related to ImClone's restatement of its 2001 and later financial statements and certain of its earlier financial statements for certain withholding tax liabilities associated with the exercise of warrants and options held by its current and former officers, directors and employees. The Company records its share of the results in equity in net income of affiliates in the consolidated statement of earnings. The Company recorded net sales for ERBITUX\* of \$17 million since its approval by the FDA in February 2004.

The Company's recorded investment in ImClone common stock as of March 31, 2004 was \$63 million. On a per share basis, the carrying value of the ImClone investment and the closing market price of the ImClone shares as of March 31, 2004 were \$4.34 and \$50.75, respectively.

## BRISTOL-MYERS SQUIBB COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 3. Restructuring and Other Items**

In the first quarter of 2004, the Company recorded a pre-tax charge of \$12 million related to the termination benefits and other related costs for workforce reductions and downsizing and streamlining of worldwide operations primarily in Israel and the United States. Of this charge, \$8 million relates to employee termination benefits and related expenses for approximately 90 selling and administrative personnel, and \$1 million relates to asset impairments. The Company also recorded \$2 million of expense related to the consolidation of certain research facilities and \$1 million of retention bonuses.

Additionally, the Company recorded \$17 million in accelerated depreciation and assets impairments, of which \$13 million was recorded to cost of goods sold, and \$4 million to other income/expense, related to the closure of certain manufacturing facilities in North America expected to close by the end of 2006. These assets will continue to be depreciated until the facility closures are complete. The Company also paid \$5 million to Flamel Technologies as part of an in-license agreement related to the product Basulin.

The following table presents a detail of the charges by segment and type for the three months ended March 31, 2004. The Company expects to substantially complete these activities by late 2004.

	<u>Employees</u>	<u>Termination Benefits</u>	<u>Other Exit Costs</u>	<u>Asset Write- Downs</u>	<u>Relocation and Retention</u>	<u>Total</u>
Pharmaceuticals	67	\$ 3	\$ 3	\$ 1	\$ 3	\$ 10
Corporate	23	2				2
Restructuring and other as reflected in the statement of earnings	<u>90</u>	<u>\$ 5</u>	<u>\$ 3</u>	<u>\$ 1</u>	<u>\$ 3</u>	<u>\$ 12</u>

In the first quarter of 2003, the Company recorded a pre-tax charge of \$12 million, related to termination benefits for workforce reductions of 340 manufacturing employees in the Pharmaceuticals segment and downsizing and streamlining of worldwide manufacturing operations. In addition, the Company recorded \$10 million in cost of products sold for asset impairments and \$4 million in cost of products sold for accelerated depreciation of certain manufacturing facilities in North America expected to be closed by the end of 2004. These assets will continue to be depreciated until the facility closures are complete.

Restructuring charges and spending against accrued liabilities associated with prior and current actions are as follows:

Total

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

	Employee Termination Liability	Other Exit Cost Liability	_____
		(dollars in millions)	
Balance at December 31, 2002	\$ 67	\$ 42	\$ 109
Charges	47	3	50
Spending	(56)	(35)	(91)
Changes in Estimate	(7)	(3)	(10)
	_____	_____	_____
Balance at December 31, 2003	51	7	58
Charges	5	3	8
Spending	(8)		(8)
	_____	_____	_____
Balance at March 31, 2004 (unaudited)	\$ 48	\$ 10	\$ 58
	_____	_____	_____

**Note 4. Divestitures**

In February 2004, the Company completed the divestiture of its Adult Nutritional Business to Novartis for \$385 million, including \$20 million contingent on contractual requirements and a \$22 million upfront payment for a supply agreement. The Company recorded a preliminary pre-tax gain of \$295 million, which included a \$5 million reduction in Company goodwill associated with the Mead Johnson product lines. In the future, the Company expects to receive additional payments from Novartis on fulfillment of conditions related to the product line. The Company will record future adjustments to the gain upon the satisfaction of the contractual requirements and other post-closing matters.

## BRISTOL-MYERS SQUIBB COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 5. Earnings Per Share**

The numerator for both basic and diluted earnings per share is net earnings available to common stockholders. The denominator for basic earnings per common share is the weighted average number of common shares outstanding during the period. The denominator for diluted earnings per common share is the weighted average number of common shares outstanding during the period, plus the incremental shares outstanding assuming the exercise of dilutive stock options. The computations for basic and diluted earnings per common share are as follows:

	Three Months Ended March 31,	
	2004	2003
	(in millions, except per share data)	
<b>Basic:</b>		
Net Earnings	\$ 964	\$ 792
Average Common Shares Outstanding	1,939	1,936
Net Earnings per Share	\$ .50	\$ .41
<b>Diluted:</b>		
Net Earnings	\$ 964	\$ 792
Interest Expense on Convertible Debt, net of tax	1	
	\$ 965	\$ 792
Average Common Shares Outstanding	1,939	1,936
Conversion of Convertible Debt Bonds	29	
Incremental Shares Outstanding Assuming the Exercise of Dilutive Stock Options	8	4
	1,976	1,940
Net Earnings per Share	\$ .49	\$ .41

Weighted-average shares issuable upon the exercise of stock options, which were not included in the diluted earnings per share calculation because they were not dilutive, were 133 million for the three month period ended March 31, 2004 and 120 million for the three month period ended March 31, 2003.

**Note 6. Other (Income)/Expense, Net**



The components of other (income)/expense, net are:

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(dollars in millions)</b>	
Interest expense	\$ 69	\$ 81
Interest income	(17)	(20)
Foreign exchange transaction (gains)/losses	17	(40)
Other, net	(31)	(24)
<b>Other (income)/expense, net</b>	<b>\$ 38</b>	<b>\$ (3)</b>

Interest expense is primarily related to the \$5.0 billion debt issuance in conjunction with the DuPont and ImClone transactions. In addition, interest expense was reduced by net interest rate swap gains of \$41 million and \$22 million for the three months ended March 31, 2004 and 2003, respectively. Interest income relates primarily to cash, cash equivalents and investments in marketable securities.

#### **Note 7. Income Taxes**

The effective income tax rate on earnings before minority interest and income taxes was 27.1% for the three months ended March 31, 2004 and 27.2% for the three months ended March 31, 2003. The rate was affected by an increase in foreign tax credits due to a reorganization of foreign subsidiaries offset by a greater percentage of U.S. pre-tax earnings resulting from the sale of the Adult Nutritional business. U.S. federal income taxes have not been provided on substantially all of the unremitted earnings of non-U.S. subsidiaries, since it is management's practice and intent to indefinitely postpone their remittance.

## BRISTOL-MYERS SQUIBB COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 8. Inventories**

The major categories of inventories follow:

	March 31, 2004	December 31, 2003
	(dollars in millions)	
Finished goods	\$ 1,008	\$ 1,001
Work in process	441	416
Raw and packaging materials	193	180
Consignment inventory	3	4
	<u>\$ 1,645</u>	<u>\$ 1,601</u>

**Note 9. Property, Plant and Equipment**

The major categories of property, plant and equipment follow:

	March 31, 2004	December 31, 2003
	(dollars in millions)	
Land	\$ 245	\$ 241
Buildings	4,358	3,917
Machinery, equipment and fixtures	4,391	4,197
Construction in progress	599	1,087
	<u>9,593</u>	<u>9,442</u>
Less accumulated depreciation	3,874	3,730
Property, plant and equipment, net	<u>\$ 5,719</u>	<u>\$ 5,712</u>

**Note 10. Goodwill**

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

The changes in the carrying amount of goodwill for the year ended December 31, 2003 and the three months ended March 31, 2004, were as follows:

	Pharmaceuticals Segment	Nutritionals Segment	Other Healthcare Segment	Total
	(dollars in millions)			
Balance as of December 31, 2002 and 2003	\$ 4,528	\$ 118	\$ 190	\$ 4,836
Goodwill allocation of divested Adult Nutritional Business		(5)		(5)
Balance as of March 31, 2004	\$ 4,528	\$ 113	\$ 190	\$ 4,831

**Note 11. Intangible Assets**

As of March 31, 2004 and December 31, 2003, intangible assets consisted of the following:

	March 31, 2004	December 31, 2003
	(dollars in millions)	
Patents / Trademarks	\$ 254	\$ 253
Licenses	461	248
Technology	1,783	1,783
	2,498	2,284
Accumulated Amortization	565	552
Net Carrying Amount	\$ 1,933	\$ 1,732

## BRISTOL-MYERS SQUIBB COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 11. Intangible Assets (Continued)**

Amortization expense for intangible assets (the majority of which is included in cost of products sold) for the three months ended March 31, 2004 and 2003 was \$49 million and \$59 million, respectively. Expected amortization expense through 2009 related to the current balance of intangible assets is as follows:

	(dollars in millions)
For the year ended December 31:	
2004	\$ 163
2005	218
2006	215
2007	214
2008	213
2009	208

**Note 12. Accumulated Other Comprehensive Income (Loss)**

	Foreign Currency Translation	Available for Sale Securities	Deferred Loss on Effective Hedges	Minimum Pension Liability Adjustment	Total Accumulated Other Comprehensive Loss
			(dollars in millions)		
Balance at December 31, 2003	\$ (491)	\$ 24	\$ (258)	\$ (130)	\$ (855)
Other comprehensive income (loss)	156	(1)	109		264
Balance at March 31, 2004	\$ (335)	\$ 23	\$ (149)	\$ (130)	\$ (591)

**Note 13. Business Segments**

The Company has four reportable segments: Pharmaceuticals, Oncology Therapeutics Network (OTN), Nutritionals, and Other Healthcare. The Pharmaceuticals segment is comprised of the global pharmaceutical and international (excluding Japan) consumer medicines businesses. The OTN segment is a specialty distributor of anticancer medicines and related products. The Nutritionals segment consists of Mead Johnson Nutritionals, primarily an infant formula business. The Other Healthcare segment consists of the ConvaTec, Medical Imaging, and Consumer Medicines (United States and Japan) businesses.

	Three Months Ended March 31,			
	Net Sales		Earnings Before Minority Interest and Income Taxes	
	(dollars in millions)			
	2004	2003	2004	2003
Pharmaceuticals	\$ 3,691	\$ 3,365	\$ 1,035	\$ 1,024
Oncology Therapeutics Network	555	520	5	3
Nutritionals	502	458	178	100
Other Healthcare	433	385	118	74
<b>Total Segments</b>	<b>5,181</b>	<b>4,728</b>	<b>1,336</b>	<b>1,201</b>
Corporate/Other			133	(38)
<b>Total Company</b>	<b>\$ 5,181</b>	<b>\$ 4,728</b>	<b>\$ 1,469</b>	<b>\$ 1,163</b>

Corporate/Other principally consists of interest expense, income, certain administrative expenses and allocations to the segments. In 2004, Pharmaceuticals and Corporate/Other include the following items: Pharmaceuticals \$16 million of accelerated depreciation for facilities expected to be abandoned, \$2 million of relocation expenses and \$1 million of retention benefits. Corporate/Other \$295 million of pre-tax gain on the sale of the Mead Johnson Adult Nutritional business, \$10 million of restructuring charges and a \$5 million payment to Flamel Technologies S.A. as part of an in-license agreement related to Basulin. In 2003, Pharmaceuticals and Corporate/Other include the following items: Pharmaceuticals income of \$21 million from a vitamins litigation settlement, \$4 million of accelerated depreciation expense for facilities expected to be abandoned and a \$10 million asset impairment charge; Corporate/Other a \$12 million restructuring charge.

## BRISTOL-MYERS SQUIBB COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 14. Pension and Other Postretirement Benefit Plans**

The Company and certain of its subsidiaries have defined benefit pension plans and defined contribution plans for regular full-time employees. The principal pension plan is the Bristol-Myers Squibb Retirement Income Plan. The funding policy is to contribute amounts to provide for current service and to fund past service liability. Plan benefits are based primarily on years of credited service and on the participant's compensation. Plan assets consist principally of equity and fixed-income securities.

The Company also provides comprehensive medical and group life benefits for substantially all U.S. retirees who elect to participate in its comprehensive medical and group life plans. The medical plan is contributory. Contributions are adjusted periodically and vary by date of retirement and the original retiring Company. The life insurance plan is noncontributory. Plan assets consist principally of equity and fixed-income securities. Similar plans exist for employees in certain countries outside of the United States.

Cost of the Company's deferred benefits and postretirement benefit plans included the following components for March 31, 2004 and 2003:

	Pension Benefits		Other Benefits	
	2004	2003	2004	2003
	(dollars in millions)			
Service cost – benefits earned during the year	\$ 41	\$ 40	\$ 3	\$ 3
Interest cost on projected benefit obligation	72	77	13	15
Expected return on plan assets	(89)	(99)	(5)	(5)
Net amortization and deferral	38	20	5	2
Net periodic benefit cost	62	38	16	15
Curtailments and settlements	—	—	—	—
Total net periodic benefit cost	\$ 62	\$ 38	\$ 16	\$ 15

The Company has elected to defer recognition of the Medicare Prescription Drug Improvement and Modernization Act of 2003 at this time. The accumulated postretirement benefit obligation and net periodic postretirement benefit cost do not reflect the effect of the Act on the retiree medical plan. Specific authoritative guidance on the accounting for the federal subsidy is pending from the FASB and guidance, when issued, could require a change to previously reported information.

**Contributions**

The Company previously disclosed in its 2003 Form 10-K that as a result of improved investment returns in 2003 and significant contributions in recent years, there is no current plan to make cash contributions to the U.S. pension plans in 2004. The Company also disclosed that contributions to the international pension plans were expected to be in the \$50 to \$70 million range.

In the first quarter of 2004, there were no cash contributions to the U.S. pension plans and \$16 million was contributed to the international pension plans. There was no cash funding for other benefits.

Those cash benefit payments from the Company which are classified as contributions in the FAS 132 disclosure totaled \$6 million for pension benefits and \$15 million for other benefits as of March 31, 2004.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies**

Various lawsuits, claims, proceedings and investigations are pending against the Company and certain of its subsidiaries. In accordance with SFAS No. 5, *Accounting for Contingencies*, the Company records accruals for such contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. These matters involve antitrust, securities, patent infringement, the Employee Retirement Income Security Act of 1974, as amended (ERISA), pricing, sales and marketing practices, environmental, health and safety matters, product liability and insurance coverage. The most significant of these matters are described below.

In the fourth quarter of 2003, the Company established reserves for liabilities of \$250 million, comprised of \$150 million in relation to wholesaler inventory issues and certain other accounting matters as discussed below under Other Securities Matters, and \$100 million in relation to pharmaceutical pricing and sales and marketing practices as discussed below under Pricing, Sales and Promotional Practices Litigation and Investigations. It is not possible at this time to reasonably assess the final outcome of these matters. In accordance with GAAP, the Company has determined that the above amounts represent minimum expected probable losses with respect to these groups of matters. Eventual losses related to these matters may exceed these reserves, and the further impact of either one of these groups of matters could be material. The Company does not believe that the top-end of the range for these losses can be estimated. With the exception of the above accruals and ones for environmental and product liability proceedings, the Company has not established reserves for the matters described below. There can be no assurance that there will not be an increase in the scope of these matters or that any future lawsuits, claims, proceedings or investigations will not be material. Management continues to believe, as previously disclosed, that during the next few years, the aggregate impact, beyond current reserves, of these and other legal matters affecting the Company is reasonably likely to be material to the Company's results of operations and cash flows, and may be material to its financial condition and liquidity.

**PLAVIX\* Litigation**

The Company's U.S. territory partnership under its alliance with Sanofi is a plaintiff in two pending patent infringement lawsuits instituted in the U.S. District Court for the Southern District of New York entitled *Sanofi-Synthelabo, Sanofi-Synthelabo Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership v. Apotex Inc. and Apotex Corp.*, 02-CV-2255 (SHS) and *Sanofi-Synthelabo, Sanofi-Synthelabo Inc. and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership v. Dr. Reddy's Laboratories, LTD, and Dr. Reddy's Laboratories, Inc.*, 02-CV-3672 (SHS). Similar proceedings involving PLAVIX\* also have been instituted outside the United States.

The suits were filed on March 21, 2002 and May 14, 2002, respectively, and are based on U.S. Patent No. 4,847,265, a composition of matter patent, which discloses and claims, among other things, the hydrogen sulfate salt of clopidogrel, which is marketed as PLAVIX\*, and on U.S. Patent No. 5,576,328, which discloses and claims, among other things, the use of clopidogrel to prevent a secondary ischemic event. The plaintiffs later withdrew Patent No. 5,576,328 from the lawsuit. Plaintiffs' infringement position is based on defendants' filing of their Abbreviated New Drug Applications (ANDA) with the FDA, seeking approval to sell generic clopidogrel prior to the expiration of the composition of matter patent in 2011. The defendants responded by alleging that the patent is invalid and/or unenforceable. The cases were consolidated for discovery, and fact discovery closed on October 15, 2003.



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Teva Pharmaceuticals USA, or Teva, a generic drug manufacturer, has filed an ANDA with the FDA claiming that Patent No. 5,576,328 relating to PLAVIX\* is invalid and that two others will not be infringed by Teva. None of these patents is involved in the pending patent infringement litigation involving PLAVIX\*. The Teva filing does not challenge the patent at issue in the PLAVIX\* litigation and therefore is not expected to have any impact on that litigation; nor does it appear that Teva intends to commercialize a generic form of PLAVIX\* prior to the expiration or termination of the patent at issue in the litigation, although there can be no assurance that this will continue to be the case.

Net sales of PLAVIX\* were approximately \$2.5 billion in 2003 and are expected to grow substantially over the next several years. The Company anticipates that this revenue growth will be an important factor in offsetting expected decreases in sales of the Company's other products that recently have or will experience exclusivity losses during this period.

Currently, the Company expects PLAVIX\* to have market exclusivity in the United States until 2011. If the composition of matter patent for PLAVIX\* is found not infringed, invalid and/or unenforceable at the district court level, the FDA could then approve the defendants' ANDAs to sell generic clopidogrel, and generic competition for PLAVIX\* could begin, before the Company has exhausted its appeals. Such generic competition would likely result in substantial decreases in the sales of PLAVIX\* in the United States.

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

Although the plaintiffs intend to vigorously pursue enforcement of their patent rights in PLAVIX\*, it is not possible at this time reasonably to assess the outcome of these lawsuits, or, if the Company were not to prevail in these lawsuits, the timing of potential generic competition for PLAVIX\*. However, if such generic competition were to occur, the Company believes it is very unlikely to occur before sometime in the year 2005. It also is not possible reasonably to estimate the impact of these lawsuits on the Company. However, loss of market exclusivity of PLAVIX\* and the subsequent development of generic competition would be material to the Company's sales of PLAVIX\* and results of operations and cash flows and could be material to its financial condition and liquidity.

**Other Patent-Related Matters**

*PARAPLATIN.* The Company and Research Corporation Technologies, Inc. ( RCT ), holder of the patent for PARAPLATIN, or carboplatin, commenced patent infringement actions on August 8, 2001 and on March 22, 2002 against Pharmachemie B.V. (a subsidiary of Teva Pharmaceutical Industries) in the United States District Court for New Jersey, based on the latter's Abbreviated New Drug Applications ( ANDA ) for approval by the FDA of generic versions of carboplatin, with certifications that the patent is invalid or not infringed. On July 29, 2002, the District Court awarded summary judgment on the merits to the Company and RCT, and in October 2002 the District Court entered final judgment in favor of the Company and RCT. Pharmachemie appealed, and on March 17, 2004, the U.S. Court of Appeals for the Federal Circuit, by a 2-1 decision, reversed the District Court's grant of summary judgment and ordered the case remanded for further proceedings by the District Court. The Company and RCT filed a petition for rehearing in the appellate court, which was denied on April 21, 2004. Based on studies evaluating the use of carboplatin in the pediatric population the Company on April 30, 2004, obtained from the FDA a six-month extension of marketing exclusivity for PARAPLATIN beyond the expiration of its primary patent, which expired on April 14, 2004. On April 27, 2004, the Company announced an agreement to settle the patent litigation. Under the agreement, the Company will, in addition to continuing to distribute PARAPLATIN, sell product to Pharmachemie allowing it to distribute an unbranded version of carboplatin commencing June 24, 2004, subject to several conditions including approval by the Federal Trade Commission.

*MONOPRIL.* The Company (and its subsidiary E.R. Squibb & Sons, LLC) commenced two patent infringement actions against Andrx Pharmaceuticals, LLC and Andrx Pharmaceuticals, Inc., on April 10, 2003; these cases are pending before the United States District Court for the Southern District of Florida. Both actions relate to Andrx's filing of ANDAs for (1) generic Monopril and (2) generic Monopril/HCT<sup>®</sup> with certifications that the patent, expiring in July 2009, covering the formulations for Monopril<sup>®</sup> and Monopril/HCT<sup>®</sup>, is not infringed. A 30-month stay imposed by the filing of the lawsuit bars final approval of Andrx's ANDAs until August 2005, unless there is a court decision in Andrx's favor before that date. A trial was completed on April 30, 2004, and the case is awaiting a decision. Generic versions of MONOPRIL (fosinopril) are already being marketed by other companies. Generic versions of Monopril (HCT) are not yet marketed by others.

*TEQUIN.* The Company and Kyorin Pharmaceuticals Co., Ltd. ( Kyorin ) commenced a patent infringement action on March 23, 2004, against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Ltd. ( Teva ) in the United States District Court for the Southern District of New York, relating to the antibiotic gatifloxacin, for which Kyorin holds the composition of matter patent and which the Company sells as TEQUIN<sup>®</sup>. This action relates to Teva's filing of an ANDA for a generic version with a certification that the composition of matter patent, which expires in December 2007, is invalid or not infringed. The filing of the suit places a stay on the approval of Teva's generic product until June 2007, unless there is a court decision adverse to the Company and Kyorin before that date.

*PRAVACHOL*. In relation to PRAVACHOL, or pravastatin, on April 15, 2004, Apotex filed a declaratory judgment action against the Company in the United States District Court for the Southern District of New York, seeking a declaratory judgment that Apotex' proposed generic version does not infringe the three patents relating to Pravachol listed in the Orange Book, which expire from 2008 to 2011 in the United States. Many generic manufacturers have already made ANDA filings in relation to generic versions and submitted P(IV) certifications that these patents are invalid or not infringed by their products, and the Company did not file any suits in response. The primary patent in relation to PRAVACHOL expires in the United States in October 2005, and the Company has earned a six-month extension of market exclusivity for PRAVACHOL until April 2006. The primary patent has not been challenged. The initial generic ANDA filers, not including Apotex, are expected to have 180 days of semi-exclusivity after April 2006, but depending on the outcome of the Apotex declaratory judgment action, other generic manufacturers including Apotex might also be able to enter the market in less than 180 days after the expiration of pediatric exclusivity.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

*AQUACEL AG*. On June 10, 2003, AcryMed, Inc. commenced an action against the Company's ConvaTec division in United States District Court for the District of Oregon for breach of confidentiality, misappropriation of trade secrets, fraud and related claims based on alleged use of AcryMed information in development of ConvaTec's *AQUACEL Ag* wound care dressing containing silver. The complaint was later amended to include a claim of infringement of a patent issued to AcryMed on August 12, 2003, and to include, as an additional plaintiff, Medline Industries, Inc., an entity that holds an exclusive license in relation to AcryMed's wound dressing containing silver. ConvaTec maintains that *AQUACEL Ag* was created through an independent development effort with participation of Acordis Specialty Fibres, Ltd., a UK company whose principal business has been acquired by ConvaTec. Discovery and other pretrial proceedings are essentially complete, and trial is expected to begin in June 2004.

*ABATACEPT (CTLA4Ig)*. On August 17, 2000, Repligen Corporation (Repligen) and the University of Michigan instituted a lawsuit against the Company in the U.S. District Court for the Eastern District of Michigan. The suit alleged that Dr. Craig Thompson, formerly a professor at the University of Michigan, had been involved in a collaboration with certain of the Company's scientists, and that Thompson's activity in the collaboration made him a rightful inventor on several patents that the Company later obtained covering soluble forms of CTLA4 and related methods of use. After conducting a trial, in September 2003 the District Court ruled that Repligen and the University of Michigan had failed to prove that Thompson made any inventive contribution to the patents in suit, and thus he was not entitled to be added as a sole or joint inventor on the Company's patents. Repligen and the University of Michigan appealed the District Court's decision to the U.S. Court of Appeals for the Federal Circuit.

*ERBITUX\**. On October 28, 2003, a complaint was filed by Yeda Research and Development Company Ltd. (Yeda) against ImClone Systems and Aventis Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York. This action alleges and seeks that three individuals associated with Yeda should also be named as coinventors on U.S. Patent No. 6,217,866, which covers the therapeutic combination of any EGFR monoclonal antibody and anti-neoplastic agents, such as chemotherapeutic agents, for use in the treatment of cancer. If Yeda's action were successful, Yeda could be in a position to practice, or to license others to practice, the invention. This could result in product competition for *ERBITUX\** that might not otherwise occur. The Company, which is not a party to this action, is unable to predict the outcome at this stage in the proceedings.

On May 5, 2004, Repligen Corporation (Repligen) and Massachusetts Institute of Technology (MIT) filed a lawsuit in the United States District Court for the District of Massachusetts against ImClone Systems, Inc. claiming that ImClone's manufacture and sale of *ERBITUX\** infringes a patent which generally covers a process for protein production in mammalian cells. Repligen and MIT seek damages based on sales of *ERBITUX\** which commenced in February 2004. The patent expired on May 5, 2004, although Repligen and MIT are seeking extension of the patent. The Company, which is not a party to this action, is unable to predict the outcome at this stage in the proceedings.

**VANLEV Litigation**

In April, May and June 2000, the Company, its former chairman of the board and chief executive officer, Charles A. Heimbald, Jr., and its former chief scientific officer, Peter S. Ringrose, Ph.D., were named as defendants in a number of class action lawsuits alleging violations of

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

federal securities laws and regulations. These actions have been consolidated into one action in the U.S. District Court for the District of New Jersey. The plaintiff claims that the defendants disseminated materially false and misleading statements and/or failed to disclose material information concerning the safety, efficacy and commercial viability of its product VANLEV during the period November 8, 1999 through April 19, 2000.

In May 2002, the plaintiff submitted an amended complaint adding allegations that the Company, its present chairman of the board and chief executive officer, Peter R. Dolan, its former chairman of the board and chief executive officer, Charles A. Heimbald, Jr., and its former chief scientific officer, Peter S. Ringrose, Ph.D., disseminated materially false and misleading statements and/or failed to disclose material information concerning the safety, efficacy, and commercial viability of VANLEV during the period April 19, 2000 through March 20, 2002. A number of related class actions, making essentially the same allegations, were also filed in the U.S. District Court for the Southern District of New York. These actions have been transferred to the U.S. District Court for the District of New Jersey. The Company has filed a motion for partial judgment in its favor based upon the pleadings. The plaintiff has opposed the motion, in part by seeking again to amend its complaint, including another attempt to expand the proposed class period. The court has not ruled on the Company's motion to dismiss nor the plaintiff's motion for leave to amend. Discovery is ongoing. The plaintiff purports to seek compensatory damages, costs and expenses on behalf of shareholders.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

It is not possible at this time reasonably to assess the final outcome of this litigation or reasonably to estimate the possible loss or range of loss with respect to this litigation. If the Company were not to prevail in final, non-appealable determinations of this litigation, the impact could be material.

**Other Securities Matters**

During the period March through May 2002, the Company and a number of its current and former officers were named as defendants in a number of securities class action suits. The suits variously alleged violations of federal securities laws and regulations in connection with three different matters: (1) VANLEV (as discussed above), (2) sales incentives and wholesaler inventory levels, and (3) ImClone, and ImClone's product, ERBITUX\*. As discussed above, the allegations concerning VANLEV have been transferred to the U.S. District Court for the District of New Jersey and consolidated with the action pending there. The remaining actions have been consolidated and are pending in the U.S. District Court for the Southern District of New York. Plaintiffs filed a consolidated class action complaint on April 11, 2003 against the Company and certain current and former officers alleging a class period of October 19, 1999 through March 10, 2003. The consolidated class action complaint alleges violations of federal securities laws in connection with, among other things, the Company's investment in and relationship with ImClone and ImClone's product, ERBITUX\*, and certain accounting issues, including issues related to wholesaler inventory and sales incentives, the establishment of reserves, and accounting for certain asset and other sales. The plaintiffs seek compensatory damages, costs and expenses. On March 29, 2004, the U.S. District Court granted the Company's motion to dismiss the consolidated class action complaint and dismissed the case with prejudice.

In addition, an action was filed in early October 2003, in New York State Court, making similar factual allegations and asserting a variety of claims including, among others, common law fraud and negligent misrepresentation. No discovery has been taken in this matter. On January 9, 2004, the Company moved to dismiss the complaint. There has been no decision on the motion. Oral arguments on the motion were held on April 16, 2004.

Beginning in October 2002, a number of the Company's current and former officers and directors were named as defendants in three shareholder derivative suits pending in the U.S. District Court for the Southern District of New York. A number of the Company's current and former officers and directors were named as defendants in three shareholder derivative suits filed during the period March 2003 through May 2003 in the U.S. District Court for the District of New Jersey. In July 2003 the U.S. District Court for the District of New Jersey ordered the three shareholder derivative lawsuits that were filed in that court transferred to the U.S. District Court for the Southern District of New York. Subsequently, the U.S. District Court for the Southern District of New York ordered all six federal shareholder derivative suits consolidated. Plaintiffs have filed a consolidated, amended, verified shareholder complaint against certain members of the board of directors, current and former officers and PricewaterhouseCoopers (PwC), the Company's independent auditors. As is customary in derivative suits, the Company has been named as a defendant in this action. As a nominal defendant, the Company is not liable for any damages in the suit nor is any specific relief sought against the Company. The consolidated amended complaint alleges, among other things, violations of federal securities laws and breaches of fiduciary duty by certain individual defendants in connection with the Company's conduct concerning, among other things: safety, efficacy and commercial viability of VANLEV (as discussed above); the Company's sales incentives to certain wholesalers and the inventory levels of those wholesalers; the Company's investment in and relations with ImClone and ImClone's product ERBITUX\*; and alleged anticompetitive behavior in connection with BUSPAR and TAXOL®. The lawsuit also alleges malpractice (negligent misrepresentation and negligence) by PwC. The

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

plaintiffs seek restitution and rescission of certain officers and directors' compensation and alleged improper insider trading proceeds; injunctive relief; fees, costs and expenses; contribution from certain officers for alleged liability in the consolidated securities class action pending in the U.S. District Court for the Southern District of New York (as discussed above); and contribution and indemnification from PwC. No discovery has been taken in this matter. On December 19, 2003, the Company moved to dismiss the consolidated amended complaint. Two similar actions are pending in New York State court. Plaintiffs seek equitable relief, damages, costs and attorneys' fees.

The SEC and the U.S. Attorney's Office and a grand jury in the District of New Jersey are investigating the activities of the Company and certain current and former members of the Company's management in connection with the wholesaler inventory issues referenced above and certain other accounting issues. As part of these investigations, among other things, documents have been produced by the Company and individuals have appeared for interviews and testimony. The Company is continuing to cooperate with these investigations. The investigations could result in the assertion of civil and/or criminal claims against the Company and/or current and/or former members of the Company's management. The Company's understanding is that the SEC, the U.S. Attorney's Office and the grand jury are investigating possible violations of the federal securities laws and other laws. The SEC has the authority to seek civil remedies and the U.S. Attorney's Office and the grand jury could bring criminal charges.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

It is not possible at this time reasonably to assess the final outcome of these litigations and investigations or reasonably to estimate the possible loss or range of loss with respect to these litigations and investigations. If the Company were not to prevail in final, non-appealable determinations of these litigations and investigations, the impact could be material.

**ERISA Litigation**

In December 2002 and the first quarter of 2003, the Company and others were named as defendants in five class actions brought under the Employee Retirement Income Security Act of 1974, as amended (ERISA) in the U.S. District Courts for the Southern District of New York and the District of New Jersey. These actions have been consolidated in the Southern District of New York under the caption *In re Bristol-Myers Squibb Co. ERISA Litigation*, 02 CV 10129. An Amended Consolidated Complaint alleging a class period of January 1, 1999 through March 10, 2003, was served on August 18, 2003. The Amended Consolidated Complaint was brought on behalf of four named plaintiffs and a putative class consisting of all participants in the Bristol-Myers Squibb Company Savings and Investment Program (Savings Plan)-and their beneficiaries for whose benefit the Savings Plan held and/or acquired Company stock at any time during the class period (excluding the defendants, their heirs, predecessors, successors and assigns). The named defendants are the Company, the Bristol-Myers Squibb Company Savings Plan Committee (Committee), thirteen individuals who presently serve on the Committee or who served on the Committee in the recent past, Charles A. Heimbold, Jr. and Peter R. Dolan (the past and present Chief Executive Officer, respectively, of the Company). The Amended Consolidated Complaint generally alleges that the defendants breached their fiduciary duties under ERISA during the class period, by, among other things, continuing to offer the Company Stock Fund and Company stock as investment alternatives under the Savings Plan; continuing to invest Company matching contributions in the Company Stock Fund and Company stock; and failing to disclose that the investments in Company stock were (allegedly) imprudent. The Savings Plan's purchases of Company stock after January 1, 1999 are alleged to have been transactions prohibited by ERISA. Finally, Defendants Heimbold and Dolan are alleged to have breached their fiduciary duties under ERISA by failing to monitor the actions of the Committee. These ERISA claims are predicated upon factual allegations similar to those raised in Other Securities Matters above, concerning, among other things: safety, efficacy and commercial viability of VANLEV; the Company's sales incentives to certain wholesalers and the inventory levels of those wholesalers; the Company's investment in and relations with ImClone and ImClone's product ERBITUX\*; and alleged anticompetitive behavior in connection with BUSPAR and TAXOL®.

There has not been any significant discovery. On October 2, 2003, the Company and all other defendants moved to dismiss the Amended Consolidated Complaint. The plaintiffs have opposed the motion to dismiss, and the defendants have replied. Oral arguments have not been scheduled yet. It is not possible at this time reasonably to predict the final outcome or reasonably to estimate the possible loss or range of loss with respect to the consolidated litigation. If the Company were not to prevail in final, non-appealable determinations of these matters, the impact could be material.

**Pricing, Sales and Promotional Practices Litigation and Investigations**

The Company, together with a number of other pharmaceutical manufacturers, is a defendant in several private class actions and in actions brought by the Nevada and Montana Attorneys General and the Counties of Suffolk, Westchester and Rockland, New York that are pending in



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

federal and state courts relating to the pricing of certain Company products. The federal cases have been consolidated for pre-trial purposes under the caption *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 in the U.S. District Court for the District of Massachusetts (AWP Multidistrict Litigation).

On June 18, 2003, the Court in the AWP Multidistrict Litigation granted the private plaintiffs' motion for leave to file an amended Master Consolidated Complaint (Amended Master Complaint). The Amended Master Complaint contains two sets of allegations against the Company. First, it alleges that the Company's and many other pharmaceutical manufacturers' reporting of prices for certain drug products (20 listed drugs in the Company's case) had the effect of falsely overstating the Average Wholesale Price (AWP) published in industry compendia, which in turn improperly inflated the reimbursement paid to medical providers and others who prescribed and administered those products. Second, it alleges that the Company and certain other defendant pharmaceutical manufacturers conspired with one another in a program called the Together Rx Card Program to fix AWP's for certain drugs made available to consumers through the Program. The Amended Master Complaint asserts claims under the federal RICO and antitrust statutes and state consumer protection and fair trade statutes.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

The Amended Master Complaint is brought on behalf of two main proposed classes, that are further divided into sub-classes: (1) all persons or entities who, from 1991 forward, (a) directly paid any portion of the price of a listed drug, which price was calculated with reference to AWP or (b) contracted with a pharmacy benefit manager to provide others with the drugs listed in the Amended Consolidated Complaint; and (2) all persons or entities who, from 2002 forward, paid or reimbursed any portion of the purchase price of a drug covered by the Together Rx Card Program based in whole or in part on AWP.

The Company and the other defendants moved to dismiss the Amended Master Complaint on the grounds it fails to state claims under the applicable statutes. These motions were denied on February 24, 2004, although the Court dismissed one of the plaintiffs' claims for failure to plead a cognizable RICO enterprise. Accordingly, the Company and the other defendants will be required to answer the Amended Master Complaint. In addition, the Company is one of five (5) defendants who have been ordered by Judge Saris to engage in fast track discovery. Discovery will continue as to these five defendants until January 30, 2005.

The Nevada and Montana Attorneys General complaints assert claims similar to those in the Amended Master Complaint under state law, but also assert claims in the name of their respective States for alleged violations of state Medicaid fraud statutes. The Nevada and Montana Attorneys General cases were originally commenced in their respective state courts but were later removed to the AWP Multidistrict Litigation. Each Attorney General moved to have its case remanded to state court on the ground that there is no federal jurisdiction. On June 11, 2003, the Court in the AWP Multidistrict Litigation ruled that the Nevada action, in which the Company is named, should be remanded to state court on the ground that not all defendants had joined in the original removal petition. The case is now proceeding in Nevada state court. The Court retained jurisdiction over the Montana case. The defendants moved to dismiss the Montana and a second Nevada case, in which the Company is not named. Oral argument was heard on that motion on December 12, 2003, but no ruling has issued.

Finally, the Company is a defendant in related state court proceedings commenced in New York, New Jersey, California, Arizona and Tennessee, in proceedings by the Attorney General of Pennsylvania and in federal court proceedings commenced by the Counties of Suffolk, Westchester and Rockland, New York (collectively, the New York Counties AWP cases). Those proceedings were transferred to the AWP Multidistrict Litigation for pre-trial purposes, although plaintiffs in the California, Arizona and New Jersey actions sought to remand their cases to the state courts. The California remand motions were denied, the Arizona remand motion was granted, and any other remand motions remain pending. The New York Counties AWP cases allege RICO claims similar to those made in the Amended Master Consolidated Complaint in the AWP Multidistrict Litigation, however, the claims are on behalf of the counties as contributors to New York State's Medicaid obligations. Defendants in the first-filed Suffolk County case have moved to dismiss the amended complaint in that action. Oral argument was heard on that motion on December 12, 2003, but no ruling has issued. With respect to the case remanded to Arizona state court, defendants have filed motions to dismiss or for a stay. A hearing on these motions is currently scheduled for June 10, 2004, with merits discovery stayed until then.

These cases are at a very preliminary stage, and the Company is unable to assess the outcome and any possible effect on its business and profitability, or reasonably estimate possible loss or range of loss with respect to these cases. If the Company were not to prevail in final, non-appealable determinations of these litigations and investigations, the impact could be material.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

The Company, together with a number of other pharmaceutical manufacturers, also has received subpoenas and other document requests from various government agencies seeking records relating to its pricing, sales and marketing practices, and Best Price reporting for drugs covered by Medicare and/or Medicaid. The requests for records have come from the U.S. Attorney's Office for the District of Massachusetts, the Office of the Inspector General of the Department of Health and Human Services in conjunction with the Civil Division of the Department of Justice, the Office of the Inspector General for the Office of Personnel Management in conjunction with the U.S. Attorney's Office for the Eastern District of Pennsylvania and several states. In addition, a request for information has come from the House Committee on Energy & Commerce in connection with an investigation that the Committee is currently conducting into Medicaid Best Price issues. Finally, the Company has received a civil investigative demand from the Attorney General for the State of Missouri relating to direct-to-consumer advertising for PRAVACHOL for the period of 2001-2003. The Company also received notice of a putative class action lawsuit involving the same issues, filed on February 23, 2004, in circuit court of Jackson County Missouri at Kansas City, captioned Richard Summers v. Bristol-Myers Squibb Company. The Company was served with this complaint on March 23, 2004.

On July 22, 2003, the Company announced that it had recently initiated an internal review of certain of its sales and marketing practices. That review focuses on whether these practices comply with applicable anti-kickback laws. It also includes an analysis of these practices with respect to compliance with (1) Best Price reporting and rebate requirements under the Medicaid program and

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

certain other U.S. governmental programs, which reference the Medicaid rebate program and (2) applicable FDA requirements. The Company has met with representatives of the U.S. Attorney's Office for the District of Massachusetts to discuss the review. The Company has received a subpoena from the U.S. Attorney's Office for the District of Massachusetts. The Company is also analyzing its past and proposed systems for calculating prices for reporting under governmental rebate and reimbursement programs. The Company's internal review is expected to continue until resolution of pending governmental investigations of related matters.

The Company is producing documents and actively cooperating with these investigations, which could result in the assertion of civil and/or criminal claims. The Company is unable to assess the outcome of, or to reasonably estimate the possible loss or range of loss with respect to, these investigations, which could include the imposition of fines, penalties, administrative remedies and/or liability for additional rebate amounts. If the Company were not to prevail in final, non-appealable determinations of these litigations and investigations, the impact could be material.

**Product Liability Litigation**

The Company is a party to product liability lawsuits involving allegations of injury caused by the Company's pharmaceutical and over-the-counter medications. The majority of these lawsuits involve certain over-the-counter medications containing phenylpropanolamine (PPA), or the Company's SERZONE and STADOL NS prescription drugs. In addition to lawsuits, the Company also faces unfiled claims involving the same products.

*PPA.* In May 2000, Yale University published the results of its Hemorrhagic Stroke Project, which concluded that there was evidence of a suggestion that PPA may increase the risk of hemorrhagic stroke in a limited population. In November 2000, the FDA issued a Public Health Advisory and requested that manufacturers of PPA-containing products voluntarily cease manufacturing and marketing them. At that time, the only PPA-containing products manufactured or sold by the Company were COMTREX (liquid gel formulations only) and NALDECON. On or about November 6, 2000, the Company, as well as other manufacturers of PPA containing products, discontinued the manufacture and marketing of PPA containing products and allowed customers to return any unused product that they had in their possession.

In January 2001, the Company was served with its first PPA lawsuit. The Company currently is a defendant in approximately 98 personal injury lawsuits, filed on behalf of approximately 247 plaintiffs, in federal and state courts throughout the United States. The majority of these lawsuits involve multiple defendants. Among other claims, plaintiffs allege that PPA causes hemorrhagic and ischemic strokes, that the defendants were aware of the risk, failed to warn consumers and failed to remove PPA from their products. Plaintiffs seek compensatory and punitive damages. All of the federal cases have been transferred to the U.S. District Court for the Western District of Washington, *In re Phenylpropanolamine (PPA) Products Liability Litigation*, MDL No. 1407. The District Court has denied all motions for class certification and there are no class action lawsuits pending against the Company in this litigation.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

On June 18, 2003, the District Court issued a ruling effectively limiting the plaintiffs' claims to hemorrhagic and ischemic strokes. Rulings favorable for the defendants included the inadmissibility of expert testimony in cases alleging injuries occurring more than three days after ingestion of a PPA containing product and cases involving psychoses, seizures and cardiac injuries. The Company expects to be dismissed from additional cases in which its products were never used by the plaintiffs and where plaintiffs' alleged injury occurred more than three days after ingestion of a PPA containing product or where a plaintiff suffered from cardiac injuries or psychoses.

*SERZONE*. *SERZONE* (nefazodone hydrochloride) is an antidepressant that was launched by the Company in May 1994 in Canada and in March 1995 in the United States. In December 2001, the Company added a black box warning to its *SERZONE* label warning of the potential risk of severe hepatic events including possible liver failure and the need for transplantation and risk of death. Within several months of the black box warning being added to the package insert for *SERZONE*, a number of lawsuits, including several class actions, were filed against the Company. Plaintiffs allege that the Company knew or should have known about the hepatic risks posed by *SERZONE* and failed to adequately warn physicians and users of the risks. They seek compensatory and punitive damages, medical monitoring, and refunds for the costs of purchasing *SERZONE*.

At present, the Company has 179 lawsuits, on behalf of 2,035 plaintiffs, pending against it in federal and state courts throughout the United States. Twenty-four of these cases are pending in New York state court and have been consolidated for pretrial discovery. In addition, there are approximately 652 alleged, but unfiled, claims of injury associated with *SERZONE*. In August 2002, the federal cases were transferred to the U.S. District Court for the Southern District of West Virginia, *In Re Serzone Products Liability*

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

*Litigation*, MDL 1477. Although discovery is still at a very early stage it appears that very few of these cases involve liver failure. In June 2003, the District Court dismissed the class claims in all but two of the class action complaints. Although a number of the class action complaints filed against the Company had sought the certification of one or more personal injury classes, the remaining class action complaints do not seek the certification of personal injury classes. On March 29, 2004, the court issued an order setting the hearing on class certification for December 20, 2004. In addition to the cases filed in the United States, there are three national class actions filed in Canada.

*STADOL NS*. STADOL NS was approved in 1992 by the FDA as an unscheduled opioid analgesic nasal spray. In February 1995 the Company asked the FDA to schedule STADOL NS as a Schedule IV, low potential for abuse, drug due to post-marketing reports suggestive of inappropriate use of the product. On October 31, 1997, it became a Schedule IV drug. Since 1997, the Company has received a number of lawsuits involving STADOL. In late 2002, the number of filed suits increased due to newly passed tort reform legislation, which became effective on January 1, 2003. Most, if not all, of the plaintiffs in these new suits had previously asserted claims against the Company for their alleged injuries.

The Company is a party in 51 cases pending, on behalf of a total of approximately 908 plaintiffs, in federal and state courts throughout the United States. Plaintiffs claim that the Company committed fraud on the FDA and wrongfully promoted STADOL NS as non-addictive. Further, plaintiffs allege that the Company failed to adequately warn of the addiction and dependency risk associated with the use of STADOL NS. The Company has reached an agreement in principle to settle 23 lawsuits involving 289 plaintiffs. In addition to these lawsuits, there are approximately 43 active, alleged and unfiled claims. The majority of the cases and claims are pending in Mississippi.

In addition to the cases filed in the United States, there are two class actions and one individual case filed in Canada.

*BREAST IMPLANT LITIGATION*. The Company, together with its subsidiary Medical Engineering Corporation (MEC) and certain other companies, remains a defendant in a number of claims and lawsuits alleging damages for personal injuries of various types resulting from polyurethane-covered breast implants and smooth-walled breast implants formerly manufactured by MEC or a related company. The vast majority of claims against the Company in direct lawsuits have been resolved through settlements or trial. Likewise, claims or potential claims against the Company registered in the nationwide class action settlement approved by the Federal District Court in Birmingham, Alabama (Revised Settlement), have been or will be resolved through the Revised Settlement. The Company has established accruals in respect of breast implant product liability litigation. The Company believes that any possible loss in addition to the amounts accrued will not be material.

The Company is vigorously defending its product liability lawsuits and believes that the majority of these cases and claims are without merit. While it is not possible at this time to reasonably assess the final outcome of the Company's pending product liability lawsuits and unfiled claims with certainty, management is of the opinion that the ultimate disposition of these matters should not have a material adverse effect on the Company's financial position. The Company believes that it has adequate self-insurance reserves and commercially available excess insurance to cover potential loss related to its product liability cases and claims.

**PLATINOL Litigation**

On February 13, 2004, a class action complaint was filed by North Shore Hematology-Oncology Associates, P.C. against the Company in the U.S. District Court for the District of Columbia. This is a putative class action brought on behalf of direct purchasers of PLATINOL that alleges that the Company violated federal antitrust laws by maintaining a monopoly in the U.S. market. The allegations focus on the Company's actions concerning U.S. Patent No. 5,562,925 ( '925 patent), including the procurement of the '925 patent, submission of information relating to the '925 patent for listing in the Orange Book, and initiation of previous lawsuits against potential generic manufacturers based on the '925 patent. Plaintiffs seek declaratory judgment and damages (including treble damages).

The Company markets PLATINOL under exclusive patent licenses from Research Corporation Technologies (RCT). Generic versions of PLATINOL (cisplatin) have been approved and marketed since 1999.

The Federal Trade Commission (FTC) also opened an investigation relating to PLATINOL. This matter was settled with the entry of a consent decree, which is in effect until April 14, 2013.

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

It is not possible at this time reasonably to assess the final outcome of this litigation or reasonably to estimate the possible loss or range of loss with respect to this litigation. If the Company were not to prevail in final, non-appealable determinations of this litigation, the impact could be material.

**TAXOL<sup>®</sup> Litigation**

In 2000, 2001 and 2002, a number of putative class actions were brought against the Company, alleging antitrust, consumer protection and similar claims concerning the Company's actions to obtain and enforce patent rights relating to TAXOL. A number of state attorneys general brought similar claims, and certain insurers asserted similar claims without filing suits. All of these matters have been settled, and those that required court approval had been given final approval by the supervising court. The total amount of the settlements was \$144 million. Of that amount, \$135 million was accrued in 2002. The remaining \$9 million was accrued in 2003.

The FTC also opened an investigation relating to TAXOL<sup>®</sup>. This matter was settled with the entry of a consent decree, which is in effect until April 14, 2013.

An additional case based on the same allegations was brought by, Xechem, a small generic drug manufacturer in 2003. The Company moved to dismiss that case, and the court granted the motion in July 2003. The plaintiff sought reconsideration of this decision and was unsuccessful. The plaintiff has filed a notice of appeal in the U.S. Court of Appeals for the Seventh Circuit. It is not possible at this time reasonably to assess the final outcome of this suit or reasonably to estimate the possible loss or range of loss if the dismissal were reversed. If the dismissal were reversed, and if the Company were not to prevail in a final, non-appealable determination of the action, the impact could be material.

**Environmental Proceedings**

The following discussion describes (1) environmental proceedings with a governmental authority which may involve potential monetary sanctions of \$100,000 or more (the threshold prescribed by specific SEC rule), (2) a civil action or an environmental claim that could result in significant liabilities, (3) updates of ongoing matters, or the resolution of other matters, disclosed in recent public filings and (4) a summary of environmental remediation costs.

The preliminary results of an internal audit performed at the Company's facility in Hopewell, N.J. indicate that operations at the site's wastewater treatment plant and related discharges may not be in compliance with the New Jersey Water Pollution Control Act and its implementing regulations or the terms of the Company's discharge permits. The Company reported its findings to the New Jersey Department of Environmental



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Protection (NJDEP) in February 2004, and is currently engaged in settlement discussions with the State. None of the results of the audit suggest that there has been any adverse impact to public health. The Company has taken, and will continue to take, corrective actions to address identified deficiencies and to prevent future occurrences.

In January 2004, NJDEP sent the Company and approximately five other companies an information request letter relating to a site in North Brunswick Township, N.J. where waste materials from E.R. Squibb & Sons (Squibb), a wholly owned subsidiary of BMS, may have been disposed of from the 1940s through the 1960s. Fill material containing industrial waste and heavy metals in excess of residential standards was discovered in Fall 2003 during an expansion project at the North Brunswick Township High School. The school board and the Township, who are the current owners of the site, submitted a workplan to the NJDEP and have asked the Company to contribute to the cost of remediation. The Company is in discussions with NJDEP, the site owners and other potentially responsible parties. The site investigation is ongoing, and no claims have been asserted against the Company.

In September 2003, the NJDEP issued an administrative enforcement Directive and Notice under the New Jersey Spill Compensation and Control Act requiring the Company and approximately 65 other companies to perform an assessment of natural resource damages and to implement unspecified interim remedial measures to restore conditions in the Lower Passaic River. The Directive alleges that the Company is liable because it historically sent bulk waste to the former Inland Chemical Company facility in Newark, New Jersey, and that releases of hazardous substances from this facility have migrated into Newark Bay and continue to have an adverse impact on the Lower Passaic River watershed. Subsequently, the U.S. Environmental Protection Agency (USEPA) also issued a notice letter under the U.S. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to numerous parties but not including BMS seeking their cooperation in a study of conditions in substantially the same stretch of the Passaic River that is the subject of NJDEP's Directive. USEPA estimates this study will cost \$20 million. This study may also lead to clean-up actions, directed by USEPA and the Army Corps of Engineers.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

The extent of any liability, under either the Directive or USEPA's notice letter, cannot yet be determined. Although the Company does not believe BMS has caused or contributed to any contamination in the Lower Passaic River watershed, the Company has informed NJDEP that it is willing to discuss their allegations against the Company. The NJDEP Directive states that if the responsible parties do not cooperate, the NJDEP may perform the damage assessment and restoration and take civil action to recover its remedial costs, treble damages for administrative costs, and penalties.

On October 16, 2003 the Michigan Department of Environmental Quality (MDEQ) sent the Company a Letter of Violation (LOV) alleging that, over an unspecified period of time, emissions from certain digestion tanks at Mead Johnson's Zeeland, Michigan facility exceeded an applicable limit in the facility's renewable operating air permit. The LOV requires the Company to take corrective action and to submit a compliance program report. Although MDEQ has not demanded fines or penalties, further enforcement action could result in penalties or injunctive relief. The Company is contesting the allegations in the LOV.

In May 2003, the Environmental Quality Board of Puerto Rico issued a notice to Bristol-Myers Squibb alleging five violations of the federal Resource Recovery and Conservation Act relating to recordkeeping or storage requirements for hazardous wastes at the Company's facility in Humacao. Based on its prior dealings with the EQB and the technical nature of the alleged violations, the Company believes that any penalties imposed will not be significant.

The Company is one of several defendants in a class action suit filed in superior court in Puerto Rico in February 2000 by residents alleging that air emissions from a government owned and operated wastewater treatment facility in Barceloneta have caused respiratory ailments and violated local air rules. The Company believes its wastewater discharges to the treatment facility are in material compliance with the terms of the Company's permit. The Company believes that this litigation will be resolved for an immaterial amount, nevertheless, this suit is still at an initial stage and, in the event of an adverse judgment, the Company's ultimate financial liability could be significantly greater than anticipated.

The Company is also responsible under various state, federal and foreign laws, including CERCLA, for certain costs of investigating or remediating contamination resulting from past industrial activity at the Company's current or former sites or at waste disposal or reprocessing facilities operated by third parties. The Company estimates these costs based on information obtained from the USEPA, the relevant agency, and/or studies prepared by independent consultants, including the total estimated costs for the site and the expected cost-sharing, if any, other potentially responsible parties (PRP), and the Company accrues liabilities when they are probable and reasonably estimable. As of December 31, 2003, the Company estimated its share of the total future costs for these sites is approximately \$58 million which represents the sum of best estimates or, where no simple estimate can reasonably be made, estimates of minimums of such costs (without taking into account any potential recoveries from other parties, which are not currently expected). The Company has paid less than \$4 million (excluding legal fees) in each of the last five years for investigation and remediation of such matters, including liabilities under CERCLA and other on-site remediations.

Although it is not possible to predict with certainty the outcome of these environmental proceedings or the ultimate costs of remediation, the Company does not believe that any reasonably possible expenditures that the Company may incur in excess of existing reserves will have a material adverse effect on its business, financial position, or results of operations.

**Indemnification of Officers and Directors**

The Company's corporate by-laws require that, to the extent permitted by law, the Company shall indemnify its officers and directors against judgments, fines, penalties and amounts paid in settlement, including legal fees and all appeals, incurred in connection with civil or criminal actions or proceedings, as it relates to their services to the Company and its subsidiaries. The by-laws provide no limit on the amount of indemnification. Indemnification is not permitted in the case of willful misconduct, knowing violation of criminal law, or improper personal benefit. As permitted under the laws of the state of Delaware, the Company has for many years purchased directors and officers insurance coverage to cover claims made against the directors and officers. The amounts and types of coverage have varied from period to period as dictated by market conditions. There are various excess policies that provide additional coverage. The litigation matters and regulatory actions described above involve certain of the Company's current and former directors and officers, all of whom are covered by the aforementioned indemnity and if applicable, certain prior period insurance policies. However, certain indemnification payments may not be covered under the Company's directors and officers insurance coverage. The Company cannot predict with certainty the extent to which the Company will recover from its insurers the indemnification payments made in connection with the litigation matters and regulatory actions described above.

On July 31, 2003, one of the Company's insurers, Federal Insurance Company, filed a lawsuit in New York Supreme Court against the Company and several current and former officers and members of the board of directors, seeking rescission, or in the alternative,

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 15. Legal Proceedings and Contingencies (Continued)**

declarations allowing Federal to avoid payment under certain Directors and Officers insurance policies and certain Fiduciary Liability insurance policies with respect to potential liability arising in connection with the matters described under the VANLEV Litigation, Other Securities Matters and ERISA Litigation sections above. No discovery has been taken in this matter. On October 3, 2003, another of the Company's insurers, SR International Business Insurance Co. Ltd. (SRI), informed the Company that it intended to try to avoid certain insurance policies issued to the Company on grounds of alleged material misrepresentation or non-disclosure, and that it had initiated arbitration proceedings in London, England. SRI has indicated that it intends to rely upon allegations similar to those described in the Other Securities Matters section above in support of its avoidance action. It is not possible at this time reasonably to assess the final outcome of these matters or reasonably to estimate the possible loss or range of loss with respect to these matters. If the Company were not to prevail in final, non-appealable determinations of these matters, the impact could be material.

---

**BRISTOL-MYERS SQUIBB COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 16. Subsequent Events**

In April 2004, the Company entered into a collaboration agreement with Merck & Co., Inc. for worldwide codevelopment and copromotion for muraglitazar, the Company's dual PPAR (peroxisome proliferator activated receptor) agonist, currently in Phase III clinical development for use in treating Type 2 diabetes. Under the terms of the agreement, the Company received a \$100 million upfront payment in May 2004, and is entitled to receive \$275 million in additional payments upon the achievement of certain regulatory milestones. The Company and Merck will jointly develop the clinical and marketing strategy for muraglitazar, share equally in future development and commercialization costs and copromote the product to physicians on a global basis, with Merck to receive payments based on net sales levels. As announced previously, an NDA for muraglitazar is expected to be submitted to the FDA within the next nine to twelve months for U.S. regulatory approval. In addition, the collaboration includes a back-up compound to muraglitazar, with the same mechanism of action (PPAR), which is anticipated to enter Phase II clinical trials for the treatment of Type 2 diabetes this year.

In April 2004, the FDA accepted for filing and review ImClone's Chemistry, Manufacturing and Controls supplemental BLA for licensure of its BB36 manufacturing facility for ERBITUX\*.

In April 2004, the Company and Pierre Fabre Medicament S.A., entered into an agreement to develop and commercialize Javlor® (vinflunine), a novel investigational anti-cancer agent. Javlor® is currently in Phase III clinical trials in Europe for the treatment of bladder and non-small cell lung cancer, and Phase II clinical trials in breast and ovarian cancer. Under the terms of the agreement, the Company will receive an exclusive license to Javlor® in the United States, Canada, Japan, Korea, and select Southeast Asian markets. Pierre Fabre Medicament will be responsible for the development and marketing of Javlor® in all other countries including Europe. The agreement has been cleared under the Hart Scott Rodino Act. Under the agreement, the Company will make and expense an upfront payment of \$25 million, with the potential for an additional \$185 million in milestone payments over time.

In April 2004, the Company announced the completion of the acquisition of Acordis Speciality Fibres, a privately held company based in the United Kingdom that licenses patent rights and supplies materials to ConvaTec for its Wound Therapeutics line. The newly acquired business will be incorporated as part of the Company's ConvaTec division. This acquisition will enable ConvaTec to strengthen its position in the field of wound care management and continue to provide new treatment options for patients with acute or chronic wound care needs.

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors

and Stockholders of

Bristol-Myers Squibb Company:

We have reviewed the accompanying consolidated balance sheet of Bristol-Myers Squibb Company and its subsidiaries as of March 31, 2004, and the related consolidated statements of earnings, comprehensive income and retained earnings and of cash flows for each of the three-month periods ended March 31, 2004 and 2003. These interim financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying consolidated interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We previously audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2003, and the related consolidated statements of earnings, comprehensive income and retained earnings and of cash flows for the year then ended (not presented herein), and in our report dated March 9, 2004 we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2003, is fairly stated in all material respects in relation to the consolidated balance sheet from which it has been derived.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania

May 4, 2004

---

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

**Summary**

For the first quarter of 2004, the Company reported global sales of \$5.2 billion. Sales increased 10% from the prior year level, reflecting volume increases of 6% and a 5% favorable impact from foreign exchange fluctuations, partially offset by net price decreases of 1%. U.S. sales increased 5%, while international sales increased 18%, including a 14% favorable foreign exchange impact.

Earnings before minority interest and income taxes increased 26% to \$1,469 million in 2004 from \$1,163 million in 2003. Net earnings were \$964 million, or \$.50 and \$.49 per share on a basic and diluted basis, respectively, compared to \$792 million, or \$.41 per share on both a basic and diluted basis in 2003. While the Company expects exclusivity losses and new product mix to challenge its margins, the Company remains committed to investing in its businesses to maximize key growth drivers and to advance its pipeline. Several items affected the comparability of the results between 2004 and 2003, as discussed below under **Earnings** and **Outlook for 2004**.

At March 31, 2004, the Company held \$6.6 billion in cash, cash equivalents, and marketable debt securities. Substantially all of such cash, cash equivalents, and marketable securities were held by the Company's foreign subsidiaries, the majority of which the Company does not expect to repatriate in the foreseeable future. In 2004, the Company expects cash generated by its U.S. operations, together with borrowings from the capital markets, to sufficiently cover cash needs for working capital, capital expenditures and dividends in the U.S. Repatriation to the United States would require additional tax provisions not reflected in the consolidated financial statements.

Long-term debt increased to \$8.6 billion at March 31, 2004 from \$8.5 billion at December 31, 2003. Cash provided from operating activities was \$1.1 billion in the first quarter of 2004. Working capital was \$5.2 billion at March 31, 2004, an improvement of \$0.8 billion primarily driven by increases in cash and cash equivalents.

The Company and its subsidiaries are the subject of a number of significant pending lawsuits, claims, proceedings and investigations. It is not possible at this time reasonably to assess the final outcome of these investigations or litigations. Management continues to believe, as previously disclosed, that during the next few years, the aggregate impact, beyond current reserves, of these and other legal matters affecting the Company is reasonably likely to be material to the Company's results of operations and cash flows, and may be material to its financial condition and liquidity. For additional discussion of this matter, see **Item 1. Financial Statements Note 15. Legal Proceedings and Contingencies**.

In the first quarter of 2004, consistent with the Company's mission to extend and enhance human life by developing the highest-quality products, the Company invested \$583 million in research and development, a 23% growth over 2003. Research and development dedicated to pharmaceutical products, including milestone payments for in-licensing and development programs, was \$547 million and as a percentage of pharmaceutical sales was 14.8% compared to 13.3% in 2003.

**Net Sales**

Worldwide sales for the first quarter of 2004 increased 10% to \$5,181 million from \$4,728 million in 2003. The increase in sales in the first quarter of 2004 is driven by a 6% increase in volume and a 5% increase due to foreign exchange rate fluctuations, partially offset by a 1% decrease due to changes in selling prices. U.S. sales increased 5% to \$3,063 million in 2004 from \$2,930 million in 2003, international sales

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

increased 18%, including a 14% favorable foreign exchange impact, to \$2,118 million in 2004 from \$1,798 million in 2003. In general, the Company's business is not seasonal. For information on U.S. pharmaceuticals prescriber demand, reference is made to the table within Business Segments under the Pharmaceuticals section below, which sets forth a comparison of changes in net sales to the estimated total prescription growth (for both retail and mail order customers) for certain of the Company's primary care pharmaceutical products.

Under GAAP, revenue is recognized when substantially all the risks and rewards of ownership have transferred. Historically, the Company recognized revenue for sales upon shipment of products to its customers. In the case of sales made to wholesalers (1) as a result of incentives, (2) in excess of the wholesaler's ordinary course of business inventory level, (3) at a time when there was an understanding, agreement, course of dealing or consistent business practice that the Company would extend incentives based on levels of excess inventory in connection with future purchases and (4) at a time when such incentives would cover substantially all, and vary directly with, the wholesaler's cost of carrying inventory in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are accounted for using the consignment model. The determination of when, if at all, sales to a wholesaler meet the foregoing criteria involves evaluation of a variety of factors and a number of complex judgments.



Under the situations described above, utilizing the consignment model, the Company does not recognize revenue upon shipment of product. Rather, upon shipment of product the Company invoices the wholesaler, records deferred revenue at gross invoice sales price and classifies the inventory held by the wholesalers as consignment inventory at the Company's cost of such inventory. The Company recognizes revenue (net of discounts, rebates, estimated sales allowances and accruals for returns) when the consignment inventory is no longer subject to the incentive arrangements described above, but not later than when such inventory is sold through to the wholesalers' customers, on a first-in first-out (FIFO) basis. Under the consignment model, consignment inventory is no longer subject to incentive arrangements (and accordingly revenue is recognized) when the consignment inventory ceases to be in excess of the wholesaler's ordinary course of business inventory level. The Company generally views approximately one month of supply as a desirable level of wholesaler inventory on a go-forward basis and as a level of wholesaler inventory representative of an industry average. In applying the consignment model to sales to Cardinal and McKesson, the Company defined inventory in excess of the wholesaler's ordinary course of business inventory level as inventory above two weeks and three weeks of supply, respectively, based on the levels of inventory that Cardinal and McKesson require to be used as the basis for negotiation of incentives granted. The Company determines when consignment inventory ceases to be in excess of the wholesaler's ordinary course of business inventory level based on information provided by Cardinal and McKesson.

The Company determined that shipments of product to Cardinal Health, Inc. (Cardinal) and shipments of product to McKesson Corporation (McKesson) met the consignment model criteria set forth in the Company's revenue recognition policy as of July 1, 1999 and July 1, 2000, respectively, and, continued through December 2002 for McKesson and February 2003 for Cardinal. Accordingly, the consignment model was required to be applied to such shipments. All shipments to McKesson in the first quarter of 2003, other than those for the Oncology Therapeutics Network (OTN) business, and all shipments to Cardinal after February 2003 were accounted for as sales upon shipment.

At March 31, 2004, the Company's aggregate cost of the pharmaceutical products held by Cardinal and McKesson that were accounted for using the consignment model (and, accordingly, were reflected as consignment inventory on the Company's consolidated balance sheet) was approximately \$3 million. The deferred revenue, recorded at gross invoice sales price, related to the inventory of pharmaceutical products accounted for using the consignment model, and consignment inventory reflected on the Company's balance sheet at March 31, 2004 were not significant as the sell-through to the wholesalers' customers was substantially complete by the end of 2003. The Company expects to account for certain pharmaceutical sales relating to OTN using the consignment model until its agreement with McKesson expires in 2006. Sales of ERBITUX\* through OTN and McKesson under an agreement ending February 2005 are accounted for on a consignment basis.

The Company estimates, based on available information including that obtained under inventory management agreements between the Company and certain wholesalers, that the inventory of pharmaceutical products held by U.S. pharmaceutical wholesalers was in the range of one month of supply at March 31, 2004. This estimate is subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations.

## Earnings

In the first quarter of 2004, earnings before minority interest and income taxes increased 26% to \$1,469 million from \$1,163 million in 2003. The increase was principally due to a pre-tax gain of \$295 million on the sale of the Mead Johnson Adult Nutritional business. In addition, the increase in 2004 was also due to higher sales, increase in net income of affiliates, partially offset by increases in cost of products sold due to a change in product mix, foreign exchange losses in 2004 compared with gains in 2003 and income from a litigation settlement in 2003. Net earnings in the first quarter of 2004 increased 22% to \$964 million compared to \$792 million in 2003. The effective income tax rate on earnings before minority interest and income taxes was 27.1% in the first quarter of 2004 compared with 27.2% in 2003. In 2004, basic earnings per share increased 22% to \$.50 from \$.41 in 2003, while diluted earnings per share increased 20% to \$.49 from \$.41 in 2003. Basic and diluted average shares outstanding for the first quarter were 1,939 million and 1,976 million, respectively, compared to 1,936 million and 1,940 million, respectively, in 2003.

During the quarters ended March 31, 2004 and 2003, the Company recorded several (income)/expense items that affected the comparability of results of the periods presented herein, which are set forth in the following table. For a discussion of these items, see Item 1. Financial

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Statements Note 3. Restructuring and Other Items and Note 4. Divestitures .

	Three Months Ended March 31,	
	2004	2003
	(unaudited, dollars in millions)	
Litigation income <sup>(1)</sup>	\$	\$ (21)
Restructuring and other items <sup>(2)</sup>	34	26
Gain on sale of business	(295)	
	(261)	5
Income taxes on items above	104	2
	\$ (157)	\$ 7

- (1) In 2003, the Company recognized \$21 million in pre-tax income from the settlement of antitrust litigation involving vitamins manufacturers.
- (2) Restructuring and other items consist of the following:

**Three Months Ended March 31, 2004**

	Cost of Products Sold	Other (Income) /Expense	Research and Development	Provision for Restructuring and Other	Total
(dollars in millions)					
Accelerated depreciation of assets	\$ 12	\$ 4	\$	\$	\$ 16
Termination benefits and asset impairments	1			9	10
Licensing Payment			5		5
Relocation and Retention				3	3
	<u>\$ 13</u>	<u>\$ 4</u>	<u>\$ 5</u>	<u>\$ 12</u>	<u>\$ 34</u>

**Three Months Ended March 31, 2003**

	Cost of Products Sold	Provision for Restructuring and Other	Total
(dollars in millions)			
Asset impairment charges	\$ 10	\$	\$ 10
Accelerated depreciation of assets	4		4
Termination benefits and other exit costs		12	12
	<u>\$ 14</u>	<u>\$ 12</u>	<u>\$ 26</u>

Gross margin percentages were 63.3% and 63.9% for the three months ended March 31, 2004 and 2003, respectively. Gross margins were negatively impacted in 2004 due to increased sales of lower-margin products in the OTN segment, unfavorable mix and exclusivity losses in the U.S. pharmaceuticals business, and lower average selling prices.

The effective income tax rate on earnings before minority interest and income taxes was 27.1% for the three months ended March 31, 2004 and 27.2% for the three months ended March 31, 2003. The effective tax rate was affected by an increase in foreign tax credits due to reorganization of foreign subsidiaries offset by a greater percentage of U.S. pre-tax earnings resulting from the sale of the Adult Nutritional business.

## Expenses

Total costs and expenses, excluding gain on sale of business, as a percentage of sales, were 77.3% in the first quarter of 2004 compared to 75.4% in 2003.

Cost of products sold, as a percentage of sales, increased to 36.7% in 2004 from 36.1% in 2003. This increase is primarily due to increased sales of lower margin products from OTN and the unfavorable impact of U.S. Pharmaceuticals sales mix. Cost of products sold also included \$12 million of accelerated depreciation and a \$1 million charge for asset impairments in 2004, and in 2003, a \$10 million charge for asset impairments and \$4 million of accelerated depreciation related to the closure of manufacturing facilities in North America expected to be completed by the end of 2006.

Marketing, selling, and administrative expenses increased 12% to \$1,234 million in 2004 from \$1,100 million in 2003. As a percentage of sales, marketing, selling and administrative expenses increased to 23.8% in the first quarter of 2004 from 23.3% in 2003. The increase was primarily driven by increased sales and marketing support for in-line products and franchises, including additional sales representatives supporting ABILIFY\*. In addition, the increase was also related to increased spending on non-clinical grants, higher information knowledge management spending, costs associated with the implementation of enhanced financial disclosures under Sarbanes-Oxley and unfavorable foreign exchange driven by the strengthening of the euro.

Expenditures for advertising and promotion in support of new and existing products were consistent with 2003 at \$316 million, reflecting increased spending on new products including ABILIFY\*, ERBITUX\* and REYATAZ offset by lower spending on in-line and non-exclusive products.

Research and development expenditures increased 23% to \$583 million in 2004 from \$475 million in 2003. Pharmaceutical research and development spending increased 22% from the prior year and, as a percentage of pharmaceutical sales, was 14.8% in the first quarter of 2004 and 13.3% in the first quarter of 2003. This increase is primarily due to higher spending on new development projects, including new alliances, new facilities and investments in the area of biologics. The increase also reflects the Company's new strategic focus on ten disease areas—cancer, HIV/AIDS, psychiatric disorders, atherosclerosis/thrombosis, diabetes, Alzheimer's disease, hepatitis, obesity, rheumatoid arthritis and solid organ transplantation.

Restructuring programs were implemented in the first quarter of 2004 to downsize and streamline worldwide operations. The programs include costs for the termination of approximately 90 selling and administrative employees primarily in the Pharmaceuticals segment. As a result of these actions, the Company expects the annual benefit to earnings before minority interest and income taxes to be approximately \$8 million in future periods. The Company expects to substantially complete these activities by late 2004. For additional information on restructuring, see Item 1. Financial Statements Note 3. Restructuring and Other Items.

Litigation income of \$21 million in 2003 was from the settlement of anti-trust litigation involving vitamin manufacturers. For additional information on litigation, see Item 1. Financial Statements Note 15. Legal Proceedings and Contingencies.

Gain on sale of business of \$295 million in 2004 relates to the sale of the Mead Johnson Adult Nutritional business. The Company expects to record future adjustments to the gain upon the satisfaction of the contractual requirements and other post-closing matters. For additional information on the sale of the Adult Nutritional business, see Item 1. Financial Statements Note 4. Divestitures.

Equity in net income of affiliates for the first three months of 2004 and 2003 was \$75 million and \$22 million, respectively. Equity in net income of affiliates principally related to the Company's joint venture with Sanofi and investment in ImClone. In 2004, the increase in equity in net income of affiliates primarily relates to higher net income in the Sanofi joint venture and lower ImClone losses. For additional information on equity in net income of affiliates, see Item 1. Financial Statements Note 2. Alliances and Investments.

Other (income)/expense, net was \$38 million of expense in the first quarter of 2004 compared to \$3 million of income in the first quarter of 2003. Other (income)/expense, net, includes interest expense, interest income, foreign exchange gains and losses, income from contract manufacturing, royalty income, and gains and losses on disposal of property, plant and equipment. The unfavorability was primarily due to foreign exchange losses of \$17 million in 2004 compared with gains of \$40 million in 2003.

## **Business Segments**

### *Pharmaceuticals*

Sales for the Pharmaceuticals segment in the three months ended March 31, 2004 increased 10%, including a 6% favorable foreign exchange impact, to \$3,691 million from \$3,365 million in 2003. Domestic pharmaceutical sales increased 3% to \$1,966 million in the first quarter of 2004 from \$1,914 million in 2003. This increase is primarily due to increased sales of PLAVIX\*, PARAPLATIN and continuing growth in ABILIFY\* and REYATAZ, which were launched in the fourth quarter of 2002 and third quarter of 2003, respectively. This growth was partially offset by declined sales of GLUCHOPHAGE\* XR and MONOPRIL, both of which were due to lost exclusivity, CEFZIL and TEQUIN due to a weak flu season, as well as ZERIT, COUMADIN and SERZONE. The Company recorded sales adjustments of \$13 million for rebate claims from prior years by certain states, primarily in relation to Medicaid utilization of oncology products that states had not previously reported to the Company. The potential amount of such claims from other states cannot reasonably be estimated at this time.

International sales for the Pharmaceuticals segment increased 19% to \$1,725 million in 2004, including a 15% favorable foreign exchange impact, from \$1,451 million in 2003. Sales in Europe increased 21%, including a 17% favorable foreign exchange impact, partially offset by price declines in Germany, Italy and Spain. Japan realized sales growth of 13% primarily as a result of favorable foreign exchange. The growth was driven by PRAVACHOL, AVAPRO\*/AVALIDE\*, PLAVIX\*, SUSTIVA, analgesics in Europe and TAXOL in Japan.

Sales of selected products in the first quarter of 2004 were as follows:

Total revenue for ABILIFY\* which is primarily alliance revenue for the Company's 65% share of net sales in co-promotion countries with Otsuka Pharmaceutical Co. Ltd. (Otsuka), increased over 200% to \$115 million from \$37 million in 2003. The antipsychotic agent, indicated for schizophrenia, was introduced in the U.S. in November 2002 and has achieved a weekly new prescription share of the U.S. antipsychotic market of approximately 8%. The Company and Otsuka received an approvable letter for a Supplemental New Drug Application (sNDA) for ABILIFY\* for the treatment of acute mania in

patients with bipolar disorder. An sNDA for bipolar maintenance was also submitted to the U.S. Food and Drug Administration (FDA) early this year. Following a positive opinion of the Committee for Proprietary Medicinal Products in 2004 the Company is expecting initial approval for sale of ABILIFY\* in Europe in the second quarter. Market exclusivity protection for ABILIFY\* is expected to expire in 2009 in the U.S. (and may be extended until 2014 if a pending statutory term extension is granted). The Company also has the right to copromote ABILIFY\* in several European countries (the United Kingdom, France, Germany and Spain) and to act as exclusive distributor for the product in the rest of the EU if marketing approval is received from the European authorities. Market exclusivity protection for ABILIFY\* is expected to expire in 2009 for the EU. The Company's right to market ABILIFY\* expires in November 2012 in the U.S. and Puerto Rico and, for the countries in the EU where the Company has the exclusive right to market ABILIFY\*, on the tenth anniversary of the first commercial sale which has not yet occurred.

ERBITUX\*, an injection used in combination with irinotecan in the treatment of patients with Epidermal Growth Factor Receptor (EGFR)-expressing metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy, was approved by the FDA in February 2004. Introductory sales for the first quarter were \$17 million. Market exclusivity protection for ERBITUX\* expires in September 2018 in the U.S. and Japan. The Company does not, but others do, market ERBITUX\* in countries in the EU.

Sales of PLAVIX\*, a platelet aggregation inhibitor, increased 71%, including a 5% favorable foreign exchange impact, to \$697 million in 2004 from \$408 million in 2003. Domestic sales of PLAVIX\* increased 75% to \$585 million in 2004 from \$335 million in 2003 primarily due to prescription growth and the effect of the declines in wholesaler inventories in the first quarter of 2003. Sales of AVAPRO\*/AVALIDE\* increased 13%, including an 8% favorable foreign exchange impact, to \$197 million in 2004 from \$175 million in 2003. PLAVIX\* and AVAPRO\*/AVALIDE\* are cardiovascular products launched from the alliance between the Company and Sanofi-Synthelabo. Market exclusivity protection for AVAPRO\*/AVALIDE\* (known in the EU as APROVEL/KARVEA) is expected to expire in 2011 in the U.S. and 2012 in countries in the EU; AVAPRO\*/AVALIDE\* is not currently marketed in Japan. This belief is subject to any adverse determination that may occur with respect to the PLAVIX\* patent litigation. For additional information on the PLAVIX\* patent litigation see Item 1. Financial Statements Note 15. Legal Proceedings and Contingencies.

Worldwide sales of the PRAVACHOL franchise (PRAVACHOL), the Company's cholesterol-lowering agent, increased 9%, including an 8% favorable foreign exchange impact, to \$671 million in 2004 from \$613 million in 2003, largely due to stronger sales in Europe. PRAVACHOL sales in the U.S. were consistent with the prior year at \$343 million. The Company estimates quarter-end U.S. wholesaler inventory levels for PRAVACHOL at a five week supply. Market exclusivity protection for PRAVACHOL is expected to expire in 2006 in the U.S. and between 2002 and 2007 in countries in the EU. The Company does not (but Sankyo does) market pravastatin in Japan.

Sales of TAXOL® and PARAPLATIN, the Company's leading anti-cancer agents, were \$243 million and \$228 million, respectively, compared to \$209 million each in 2003. International sales of TAXOL® increased 19%, including favorable foreign exchange effect of 17%, to \$229 million from \$192 million in 2003, led by sales growth in Japan. Generic competition in Europe was lower than expected and is anticipated to increase in the second quarter. Domestic sales of TAXOL® decreased 18% to \$14 million from \$17 million in 2003, due to generic competition. PARAPLATIN sales increased by 9% driven by sales in the United States. Market exclusivity protection for TAXOL® expired in 2002 in the U.S., in 2003 in the EU and is expected to expire between 2003 and 2013 in Japan. Market exclusivity protection for PARAPLATIN expires in the U.S. in October 2004. Market exclusivity protection for PARAPLATIN expired in 2000 in the EU and in 1998 in Japan. Some exclusivity losses for PARAPLATIN are now expected earlier in 2004 based on the recently disclosed patent litigation settlement and related distribution arrangement with a generic manufacturer. For additional information on the PARAPLATIN patent litigation settlement, see Outlook for 2004 discussed below.

Sales of the GLUCOPHAGE\* franchise decreased 35% to \$161 million in 2004 from \$247 million in 2003 due to generic competition. GLUCOPHAGE\*IR sales decreased 16% to \$31 million in 2004 from \$37 million in 2003 while GLUCOVANCE\* sales decreased 6% to \$102 million in 2004 from \$108 million in 2003. GLUCOPHAGE\*XR Extended Release tablets sales also decreased 81% to \$19 million in 2004 from \$101 million in 2003.

Sales of SUSTIVA, an anti-retroviral agent, decreased 7%, including a 6% favorable foreign exchange impact, to \$139 million in 2004 from \$150 million in 2003, primarily due to declines in wholesaler inventories in the first quarter of 2004. Market exclusivity protection for SUSTIVA is expected to expire in 2013 in the U.S. and in countries in the EU; The Company does not (but others do)

market SUSTIVA in Japan.

Sales for REYATAZ, a protease inhibitor for the treatment of HIV/AIDS launched in the United States in July 2003, were \$75 million. Market exclusivity protection for REYATAZ is expected to expire in 2017 in the U.S., in countries in the EU and Japan.

Sales of VIDEX/VIDEX EC decreased 1% to \$71 million from \$72 million in 2003, mainly due to a decrease in domestic sales, offset by favorable foreign exchange impact. The Company has a licensing arrangement with the U.S. Government for VIDEX/VIDEX EC, which by its terms became non-exclusive in 2001. The U.S. Government's method of use patent expires in 2007 in the U.S. (which includes an earned pediatric extension) and in Japan and between 2006 and 2009 in countries in the EU. With respect to VIDEX/VIDEX EC, the Company has patents covering the reduced mass formulation of VIDEX/VIDEX EC that expire in 2012 in the U.S., the EU and Japan.

Sales of ZERIT/ZERIT ER, an antiretroviral agent, were \$58 million in 2004, a decrease of 50%, including a 5% favorable foreign exchange impact, from \$115 million in 2003. Market exclusivity protection for ZERIT/ZERIT ER is expected to expire in 2008 in the U.S., between 2007 and 2011 in countries in the EU and 2008 in Japan.



In most instances, the basic exclusivity loss date indicated above is the expiration date of the patent that claims the active ingredient of the drug or the method of using the drug for the approved indication. In some instances, the basic exclusivity loss date indicated is the expiration date of the data exclusivity period. In situations where there is only data exclusivity without patent protection, a competitor could seek regulatory approval by submitting its own clinical trial data to obtain marketing approval. The Company assesses the market exclusivity period for each of its products on a case-by-case basis. The length of market exclusivity for any of the Company's products is difficult to predict with certainty because of the complex interaction between patent and regulatory forms of exclusivity and other factors. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that the Company currently anticipates. For further discussion of market exclusivity protection, including a chart showing net sales of key products together with the year in which basic exclusivity loss occurred or is expected to occur in the U.S., the EU and Japan, see Item 1. Business Products and Intellectual Property and Product Exclusivity in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2003.

The following table sets forth a comparison of reported net sales changes and the estimated total prescription growth (for both retail and mail order customers) for certain of the Company's U.S. pharmaceutical prescription products. The estimated prescription growth amounts are based on third-party data provided by IMS Health, a supplier of market research to the pharmaceutical industry. A significant portion of the Company's domestic pharmaceutical sales is made to wholesalers. Where changes in reported net sales differ from prescription growth, this change in net sales may not reflect underlying prescriber demand.

	Three Months Ended		Three Months Ended	
	March 31, 2004		March 31, 2003	
	% Change in		% Change in	
	Total		Total U.S.	
	% Change in	U.S.	% Change in	Total U.S.
	U.S. Net Sales <sup>(a)</sup>	Prescriptions <sup>(b)</sup>	U.S. Net Sales <sup>(a)</sup>	Prescriptions <sup>(b)</sup>
	(unaudited)			
PLAVIX*	75	30	(18)	30
PRAVACHOL		(1)	3	
AVAPRO*/AVALIDE*	(1)	17	18	15
SUSTIVA	(27)	7	7	20
ABILIFY (total revenue)	**	**		
MONOPRIL	(102)	(69)	(29)	(13)
GLUCOVANCE*	(7)		91	9
GLUCOPHAGE*XR	(81)	(70)	28	6
ZERIT	(76)	(30)	2	(21)
CEFZIL	(52)	(28)	13	(8)
COUMADIN	(63)	(18)	14	(14)
VIDEX/VIDEX EC	(17)	(1)	(3)	5

\*\* In Excess of 200%.

(a) Reflects change in net sales in dollar terms, compared with the same period in the prior year, including change in average selling prices and wholesaler buying patterns.

(b) Reflects change in total prescriptions in unit terms, compared with the same period in the prior year, based on third-party data.

Earnings before minority interest and income taxes for the Pharmaceuticals segment increased to \$1,035 million in the first quarter of 2004 from \$1,024 million in 2003. The increase in earnings before minority interest and income taxes was driven by higher sales, mostly offset by gross margin erosion due to generic competition and product mix, additional sales representatives supporting ABILIFY\*, higher spending in research and development, higher non-clinical grants and litigation settlement income in 2003.

*Oncology Therapeutics Network*

Sales by OTN, a specialty distributor of third-party anticancer medicines and related products, increased 7% to \$555 million in 2004 from \$520 million in 2003. The lower growth rate compared to previous quarters was due to unchanged pharmaceutical prices and to the growth of distribution of medication through insurers.

As is characteristic of the U.S. market for oncology pharmaceuticals, a small number of products account for a majority of OTN sales. OTN's top ten revenue-generating products for 2003 comprised 77% of 2003 revenues. One is a monoclonal antibody that comprised 11% of 2003 revenues, five are chemotherapeutic agents that comprised 28% of 2003 revenues, and four are colony-stimulating factors that comprised 38% of 2003 revenues.

Earnings before minority interest and income taxes increased to \$5 million in the first quarter of 2004 from \$3 million in 2003.

*Nutritionals*

Sales for the Nutritionals segment increased 10%, including a 1% favorable foreign exchange impact, to \$502 million for the three months ended March 31, 2004 compared to sales of \$458 million in 2003. International sales increased 11%, including a 2% favorable foreign exchange impact, and U.S. sales increased 9%. Mead Johnson continues to be the leader in the U.S. infant formula market. ENFAMIL, the Company's largest-selling infant formula, had sales of \$208 million in 2004 from \$165 million in 2003, an increase of 26% from the prior year. This increase is primarily due to higher worldwide demand of infant formula containing DHA/ARA. Sales of

ENFAGROW, a children's nutritional supplement, increased 12% to \$46 million in 2004 from \$41 million in 2003. The strong sales in infant formula sales were partly offset by lower adult nutritional products due to the divestiture of the Adult Nutritional business in February 2004.

ENFAMIL sales include ENFAMIL LIPIL, which the Company introduced in the United States in 2002, and which is the first infant formula in the United States to contain the nutrients DHA (docosahexanoic acid) and ARA (Arachidonic acid). Also naturally found in breast milk, DHA and ARA are believed to support infant brain and eye development. The Company obtains these nutrients from a sole provider pursuant to a non-exclusive licensing and supply arrangement, under which there is no guaranty of supply and pricing is subject to change. The agreement expires beginning in 2024 on a country-by-country basis 25 years after the Company commences sales in a country.

Earnings before minority interest and income taxes for the Nutritionals segment increased to \$178 million in 2004 from \$100 million in 2003, driven by increased global infant formula sales, favorable manufacturing variances and tight operating expense management.

#### *Other Healthcare*

Sales in the Other Healthcare segment increased 12%, including a 6% favorable foreign exchange impact, to \$433 million in 2004 from \$385 million in 2003. The Other Healthcare segment is comprised of the ConvaTec, Medical Imaging and Consumer Medicines (United States and Japan) businesses.

ConvaTec sales for the three months ended March 31, 2004 increased 20%, including an 11% favorable foreign exchange impact, to \$217 million from \$181 million in 2003. Sales of ostomy products increased 14% to \$127 million in 2004 compared to prior year sales of \$111 million. Sales of modern wound therapeutics products increased 28% to \$87 million in 2004 compared to prior year sales of \$68 million primarily due to the growth of the wound therapeutics market.

Medical Imaging sales for the three months ended March 31, 2004, increased 15%, including a 2% favorable foreign exchange impact, to \$139 million from \$121 million in 2003. The increase in Medical Imaging sales was primarily due to a 23% increase in CARDIOLITE sales to \$92 million in 2004 from \$75 million in 2003. This increase was primarily due to a change in revenue recognition as a result of new distribution agreements entered into in January 2004, partially offset by slower market growth.

Consumer Medicines sales for the three months ended March 31, 2004 decreased 7% to \$77 million from \$83 million in 2003, including a 3% favorable foreign exchange impact, primarily due to lower sales of BUFFERIN and cough/cold remedies.

Earnings before minority interest and income taxes for the Other Healthcare segment increased to \$118 million in 2004 from \$74 million in 2003 primarily due to sales growth in the ConvaTec and Medical Imaging businesses and lower advertising costs in the Consumer Medicines business.

#### **Developments**

In April 2004, the Company entered into a collaboration agreement with Merck & Co., Inc. for worldwide codevelopment and copromotion for muraglitazar, the Company's dual PPAR (peroxisome proliferator activated receptor) agonist, currently in Phase III clinical development for use in treating Type 2 diabetes. Under the terms of the agreement, the Company received a \$100 million upfront payment in May 2004, and is entitled to receive \$275 million in additional payments upon the achievement of certain regulatory milestones. The Company and Merck will

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

jointly develop the clinical and marketing strategy for muraglitazar, share equally in future development and commercialization costs and copromote the product to physicians on a global basis, with Merck to receive payments based on net sales levels. As announced previously, an NDA for muraglitazar is expected to be submitted to the FDA within the next nine to twelve months for U.S. regulatory approval. In addition, the collaboration includes a back-up compound to muraglitazar, with the same mechanism of action (PPAR), which is anticipated to enter Phase II clinical trials for the treatment of Type 2 diabetes this year.

In February 2004, the FDA approved the Biologics License Application (BLA) for ERBITUX\*, the anticancer agent that the Company is developing in partnership with ImClone. ERBITUX\* Injection is for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. In accordance with the agreement, the Company paid ImClone \$250 million in March 2004 as a milestone payment for the approval of ERBITUX\* by the FDA. Sales recorded for ERBITUX\* were \$17 million for the quarter ended March 31, 2004.

The Company is the exclusive distributor of ERBITUX\* in North America through OTN. Under the terms of an agreement with McKesson, McKesson provides OTN with warehousing, packing and shipping for filling orders for ERBITUX\*. To maintain the integrity of the product, special storage conditions and handling are required. Accordingly, all sales of ERBITUX\*, including purchase requests from other wholesalers, are processed through OTN, and McKesson will only ship ERBITUX\* to end-users of the product and not to other intermediaries to hold for later sales. Either the Company or McKesson may unilaterally terminate the agreement on not less than six months prior notice to the other party.

In April 2004, the FDA accepted for filing and review ImClone's Chemistry, Manufacturing and Controls supplemental BLA for licensure of its BB36 manufacturing facility for ERBITUX\*.

In April, 2004, the Company and Pierre Fabre Medicament S.A., entered into an agreement to develop and commercialize Javlor® (vinflunine), a novel investigational anti-cancer agent. Javlor® is currently in Phase III clinical trials in Europe for the treatment of bladder and non-small cell lung cancer, and Phase II clinical trials in breast and ovarian cancer. Under the terms of the agreement, the Company will receive an exclusive license to Javlor® in the United States, Canada, Japan, Korea, and select Southeast Asian markets. Pierre Fabre Medicament will be responsible for the development and marketing of Javlor® in all other countries, including Europe. The agreement has been cleared under the Hart Scott Rodino Act. Under the agreement, the Company will make and expense an upfront payment of \$25 million, with the potential for an additional \$185 million in milestone payments over time.

In April 2004, the Company announced the completion of the acquisition of Acordis Speciality Fibres, a privately held company based in the United Kingdom that licenses patent rights and supplies materials to ConvaTec for its Wound Therapeutics line. The newly acquired business will be incorporated as part of the Company's ConvaTec division. This acquisition will enable ConvaTec to strengthen its position in the field of wound care management and continue to provide new treatment options for patients with acute or chronic wound care needs.

In March 2004, the Company announced that its Medical Imaging business entered into an agreement with Kereos, Inc. (Kereos) for the development and commercialization of novel molecular imaging agents. Under the terms of the agreement, the companies will work together to develop molecular imaging agents for cardiovascular diseases and cancer using Kereos' core technology. Medical Imaging has obtained exclusive worldwide rights to develop and commercialize select cardiovascular molecular imaging agents for magnetic resonance imaging (MRI). Kereos has obtained exclusive worldwide rights to use a family of Medical Imaging targeting molecules with Kereos' core technology to develop and commercialize molecular cancer imaging agents and targeted therapeutics, including KI-001 Kereos' lead candidate for early MRI detection of tumors.

In April 2004, the Company announced the creation within the Pharmaceutical Research Institute (PRI) of the Development Center of Excellence, which is intended to combine the pharmaceutical development and related manufacturing activities of PRI and Technical Operations in a single unit, with significant cost savings. Steps to implement the changes are under review.

In February 2004, Mead Johnson, a wholly owned subsidiary of the Company, completed the sale of its Adult Nutritional business, brands, trademarks, patents and intellectual property rights to Novartis for \$385 million, including \$20 million contingent on contractual requirements and a \$22 million upfront payment for a supply agreement. As a result of this transaction, the Company recorded a pre-tax gain of \$295 million in the first quarter of 2004. The Company will record future adjustments to the gain upon the satisfaction of the contractual requirements and other post-closing matters. In 2003, adult nutritional products recorded sales of over \$200 million.

#### **Financial Position, Liquidity and Capital Resources**

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Cash, cash equivalents and marketable debt securities totaled approximately \$6.6 billion at March 31, 2004 compared to \$5.5 billion at December 31, 2003. The Company continues to maintain a high level of working capital, which was \$5.2 billion at March 31, 2004, increasing from \$4.4 billion at December 31, 2003. Substantially all of such cash, cash equivalents and marketable debt securities were held by the Company's foreign subsidiaries, which the Company does not expect to repatriate in the foreseeable future. Repatriation to the United States would require additional tax provisions not reflected in the consolidated financial statements. Due to the complexities in the tax laws and the assumptions that would have to be made, it is not practicable to estimate the amounts of the income taxes that would have to be provided. In 2004 and future periods, the Company expects cash generated by its U.S. operations, together with borrowings from the capital markets, to sufficiently cover cash needs for working capital, capital expenditures, and dividends in the United States. Cash and cash equivalents, marketable debt securities, the conversion of other working-capital items and borrowings are expected to fund near-term operations.

Cash and cash equivalents at March 31, 2004 primarily consisted of U.S. dollar denominated bank deposits with an original maturity of three months or less. Marketable securities at March 31, 2004 primarily consisted of U.S. dollar denominated floating rate instruments with an AAA/aaa credit rating. Due to the nature of these instruments, the Company considers it reasonable to expect that their fair market values will not be significantly impacted by a change in interest rates, and that they can be liquidated for cash at short notice.

Short-term borrowings were \$776 million at March 31, 2004, compared with \$127 million at December 31, 2003, primarily as a result of the issuance of commercial paper.

Long-term debt increased to \$8.6 billion at March 31, 2004 from \$8.5 billion at December 31, 2003. The Moody's Investors Service long-term and short-term credit ratings for the Company are currently A1 and Prime-1, respectively. Moody's long-term credit rating remains on negative outlook. On March 10, 2004, Standard & Poor's placed both the long-term AA- and the short-term A-1+ credit ratings for the Company on watch with negative implications.

Net cash provided by operating activities was \$1,081 million in the three months ended March 31, 2004 as compared to \$160 million in 2003. The increase in cash provided by operating activities for 2004 is mainly attributable to litigation settlement payment in 2003 of \$544 million, growth in net earnings and effective management of working capital. The significant changes in working capital between the first quarter of 2004 compared to the first quarter of 2003 are: receivables decreased \$824 million primarily due to purchases by U.S. wholesalers earlier in the first quarter of 2004 in anticipation of price increases; deferred revenue on consigned inventory decreased \$269 million due to the workdown of the consignment inventory in 2003; and decreases in accounts payable and accrued expenses of \$393 million related to higher purchasing activities in the fourth quarter of 2003, research and development projects and royalty payments.

Net cash used in investing activities was \$603 million in the three months ended March 31, 2004 compared to \$620 million in 2003. The Company received \$346 million in cash proceeds from the sale of its Adult Nutritional business, which was mostly offset by a milestone payment of \$250 million to ImClone and increased investment in marketable securities.

During the three months ended March 31, 2004 and 2003, the Company did not purchase any of its common stock.

For each of the three month periods ended March 31, 2004 and 2003, dividends declared per common share were \$.28. The Company paid \$543 million and \$542 million in dividends for the first quarters of 2004 and 2003, respectively.

### **Contractual Obligations**

For a discussion of the Company's contractual obligations, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's 2003 Form 10-K. No material changes have occurred to contractual obligations subsequent to December 31, 2003.

### **Retirement Benefits**

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

For a discussion of the Company's retirement benefits, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's 2003 Form 10-K.

### **Critical Accounting Policies**

For a discussion of the Company's critical accounting policies, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's 2003 Form 10-K.

### **Outlook for 2004**

The Company expects to have both growth opportunities and exclusivity challenges over the next several years. The opportunities include expected growth from in-line, recently launched and potential new products. Such growth contributed significantly to results for the current quarter. Expectations of continued sales growth are subject to the outcome of the previously disclosed Plavix patent litigation and risks of product development and regulatory approval. Also, the Company expects changes in product mix to pressure Company margins because the products losing exclusivity carry higher margins than products expected to increase in sales.



In relation to exclusivity, the Company has estimated declines in net sales for 2004 in the range of \$1.2 to \$1.3 billion from the 2003 levels for products, which have lost or will lose exclusivity protections in 2003 or 2004, specifically the metformin franchise (GLUCOPHAGE/GLUCOVANCE) in the United States, TAXOL® in Europe, MONOPRIL in the United States and Canada, Pravastatin in certain countries in Europe, PARAPLATIN in the United States and SERZONE in the United States. GLUCOVANCE in the United States and TAXOL® in Europe have not yet suffered some of the previously anticipated competition and subsequent sales declines following loss of exclusivity.

Some exclusivity losses for PARAPLATIN are now expected earlier in 2004 based on the recently disclosed patent litigation settlement and related distribution arrangement with a generic manufacturer, which is subject to the Federal Trade Commission (FTC) approval. The settlement would provide that, in addition to the Company continuing to market PARAPLATIN, the generic manufacturer would enter the market before the anticipated expiration of exclusivity. The estimates above assume receiving approval from the FDA of a six-month extension of exclusivity for PARAPLATIN to October 2004 based on pediatric studies, which was received on April 30, 2004, and approval from the FTC. The approval from the FTC is not assured.

Substantial incremental exclusivity losses are expected in each of 2005 to 2007 representing continuing declines in sales of the products described above for 2003 and 2004, and additional declines attributable to loss of exclusivity protection primarily for PRAVACHOL in the United States (2006), MONOPRIL in Europe (2001–2008), ZERIT in Europe (2007–2011), CEFZIL (U.S. 2005; EU 2004–2009) and VIDEX/VIDEX EC (2004–2009 license on patent expiring in 2007 became non-exclusive in 2001 though no other licenses have yet been granted). Information on the dates of expected loss of exclusivity protection and sales for the most recent year for the Company's major products are set forth in Item 1. Business of the Company's Form 10-K/A Annual Report for 2003, and interim sales information and information on the dates of expected losses of exclusivity are included under the Pharmaceuticals section above. The timing and amounts of sales reductions from exclusivity losses, their realization in particular periods and the eventual levels of remaining sales revenues are uncertain and dependent on the levels of sales at the time exclusivity protection ends, the timing and degree of development of generic competition (speed of approvals, market entry and impact) and other factors.

PRAVACHOL, a cholesterol-reducing HMG CoA reductase inhibitor (statin), was the Company's largest product ranked by net sales in 2003 (\$2.8 billion). While the product has begun to lose exclusivity in some markets, between now and its anticipated loss of U.S. exclusivity in 2006, its expected rate of decline in market share could be accelerated by the recently reported results of clinical studies. PRAVACHOL has been the subject to numerous clinical trials that have demonstrated that PRAVACHOL, when combined with a heart-healthy diet and exercise, reduces the risk of first heart attack in patients with elevated cholesterol and no clinical evidence of coronary heart disease and also reduced the risk of a subsequent cardiovascular event in patients with normal to moderately elevated cholesterol and clinical evidence of coronary heart disease. A recent clinical study sponsored by a competitor found that treatment with the competitor's statin resulted in no progression of atherosclerotic disease compared to treatment with PRAVACHOL which showed some progression, as demonstrated intravascular ultrasound. Another recent study sponsored by the Company found that acute coronary syndrome patients treated within ten days of their event benefited more from intensive statin therapy with a competitor's product than from standard statin therapy with PRAVACHOL in the reduction of the risk of later major cardiovascular events. Since the release of the most recent of these studies in early March 2004, PRAVACHOL has experienced a modest decline in U.S. prescription market share, consistent with market share declines for PRAVACHOL in recent prior periods during which there was growth in sales of competitive products including a new product launch.

The Company has historically reviewed and will continue to review its cost base. Decisions that may be taken based on these reviews may result in restructuring or other charges later this year or in future periods. At the same time, the Company expects to invest behind in-line products and in its research and development pipeline, particularly late-stage products. External development and in-licensing from others will remain important elements of the Company's strategy, but the potential cost and impact of any such transactions that may be entered into the future are not built into the Company's plans.

The Company and its subsidiaries are the subject of a number of significant pending lawsuits, claims, proceedings and investigations. It is not possible at this time reasonably to assess the final outcome of these investigations or litigations. Management continues to believe, as previously disclosed, that during the next few years, the aggregate impact, beyond current reserves, of these and other legal matters affecting the Company is reasonably likely to be material to the Company's results of operations and cash flows, and may be material to its financial condition and

liquidity.

#### **Cautionary Factors that May Affect Future Results**

This Quarterly Report on Form 10-Q/A (including documents incorporated by reference) and other written and oral statements the Company makes from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as should, expect, anticipate, estimate, target, may, will, project, guidance, intend, plan, believe and other words and terms in expression in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, the Company's goals, plans and projections regarding its financial position, results of operations, market position, product development, product approvals, sales efforts, expenses, performance or results of current and anticipated products and the outcome of contingencies such as legal proceedings, and financial results, which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years.

Although it is not possible to predict or identify all factors, they may include but are not limited to the following:

New government laws and regulations, such as (i) health care reform initiatives in the United States at the state and federal level and in other countries; (ii) changes in the FDA and foreign regulatory approval processes that may cause delays in approving, or preventing the approval of, new products; (iii) tax changes such as the phasing out of tax benefits heretofore available in the United States and certain foreign countries; (iv) new laws, regulations and judicial decisions affecting pricing or marketing within or across jurisdictions; and (v) changes in intellectual property law.

Competitive factors, such as (i) new products developed by competitors that have lower prices or superior performance features or that are otherwise competitive with Bristol-Myers Squibb's current products; (ii) generic competition as the Company's products mature and patents expire on products; (iii) technological advances and patents attained by competitors; (iv) problems with licensors, suppliers and distributors; and (v) business combinations among the Company's competitors or major customers.

Difficulties and delays inherent in product development, manufacturing and sale, such as (i) products that may appear promising in development but fail to reach market for any number of reasons, including efficacy or safety concerns, the inability to obtain necessary regulatory approvals and the difficulty or excessive cost to manufacture; (ii) failure of any of our products to achieve or maintain commercial viability; (iii) seizure or recall of products; (iv) the failure to obtain, the imposition of limitations on the use of, or loss of patent and other intellectual property rights; (v) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other application regulations and quality assurance guidelines that could lead to temporary manufacturing shutdowns, product shortages and delays in product manufacturing; and (vi) other manufacturing or distribution problems.

Legal difficulties, including lawsuits, claims, proceedings and investigations, any of which can preclude or delay commercialization of products or adversely affect operations, profitability, liquidity or financial condition, including (i) intellectual property disputes; (ii) adverse decisions in litigation, including product liability and commercial cases; (iii) the inability to obtain adequate insurance with respect to this type of liability; (iv) recalls of pharmaceutical products or forced closings of manufacturing plants; (v) government investigations including those relating to wholesaler inventory, financial restatement and product pricing and promotion; (vi) claims asserting violations of securities, antitrust, federal and state pricing and other laws; (vii) environmental matters; and (viii) tax liabilities. There can be no assurance that there will not be an increase in scope of these matters or that any future lawsuits, claims, proceedings or investigations will not be material.

Increasing pricing pressures worldwide, including rules and practices of managed care groups and institutional and governmental purchasers, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement and pricing in general.

Fluctuations in buying patterns and inventory levels of major distributors, retail chains and other trade buyers, which may result from seasonality, pricing, wholesaler buying decisions (including the effect of incentives offered), the Company's wholesaler inventory management policies (including the workdown or other changes in wholesaler inventory levels) or other factors.

Greater than expected costs and other difficulties, including unanticipated effects and difficulties of acquisitions, dispositions and other events, including obtaining regulatory approvals in connection with evolving business strategies, legal defense costs, insurance expense, settlement costs and the risk of an adverse decision related to litigation.

Changes to advertising and promotional spending and other categories of spending that may affect sales.

Changes in product mix that may affect margins.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

Changes in the Company's structure, operations, revenues, costs, staffing or efficiency resulting from acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives.

Economic factors over which the Company has no control such as changes of business and economic conditions including, but not limited to, changes in interest rates and fluctuation of foreign currency exchange rates.

Changes in business, political and economic conditions due to political or social instability, military or armed conflict, nationalization of assets, debt or payment moratoriums, other restrictions on commerce, and actual or threatened terrorist attacks in the United States or other parts of the world and related military action.

Changes in accounting standards promulgated by the FASB, the SEC or the AICPA, which may require adjustments to financial statements.

Capacity, efficiency, reliability, security and potential breakdown, invasion, destruction or interruption of information systems.

Reliance of the Company on vendors, partners and other third parties to meet their contractual, regulatory and other obligations in relation to their arrangements with the Company.

Results of clinical studies relating to the Company's or a competitor's products.

Although the Company believes it has been prudent in its plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. The Company undertakes no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

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

In the three months ended March 31, 2004, the Company purchased \$204 million notional amount of foreign exchange Japanese yen call options, sold \$671 million notional amount of forward contracts (in several currencies) and bought \$217 million notional amount of primarily Japanese yen forward contracts to partially hedge the exchange impact primarily related to forecasted intercompany inventory purchases for up to the next 32 months.

### **Item 4. CONTROLS AND PROCEDURES**

As of the end of the period covered by this Form 10-Q/A, the Company carried out an evaluation, under the supervision and with the participation of its chief executive officer and chief financial officer, of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15e or 15d-15e under the Securities Exchange Act of 1934.)

In making this evaluation the Company has considered the reportable condition (as defined under standards established by the American Institute of Certified Public Accountants) relating to its internal controls over its financial reporting for income taxes that was identified and communicated to the Company and its Audit Committee by the Company's independent auditors. The reportable condition identified by the Company's independent auditors was the need to enhance the tax accounting function to provide for timely analysis and reconciliation of the tax provision and related tax assets and liabilities. This reportable condition initially was identified and communicated by the Company's independent auditors in connection with their audit of the Company's consolidated financial statements for the year ended December 31, 2002. The Company engaged in extensive remediation efforts with respect to this reportable condition in 2003, including engaging an outside consultant to assist the Company's personnel to conduct a comprehensive and detailed review of certain of the Company's tax reporting and accounting, in particular with respect to developing more effective processes for establishing and monitoring deferred income taxes, valuation allowances and the Company's annual effective tax rate. In connection with their audit of the Company's consolidated financial statements for the year ended December 31, 2003, the Company's outside auditors communicated to the Company and its Audit Committee that, despite the Company's extensive 2003 remediation efforts, they believed a reportable condition still exists with respect to income tax accounting. In connection with the Company's evaluation of its financial and internal controls, the Company considered the mitigating controls established with respect to its financial reporting for income taxes pending remediation of this reportable condition. The Company's efforts to strengthen its financial and internal controls continue (including its financial and internal controls over its financial reporting for income taxes), and the Company expects to complete remediation of this reportable condition by the end of 2004.

Based on this evaluation, the Company's chief executive officer and chief financial officer concluded that as of the evaluation date, such disclosure controls and procedures were reasonably designed to ensure that information required to be disclosed by the Company in reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

Other than as described above, since the evaluation date by the Company's management of its internal controls over financial reporting, there have not been any change in the Company's internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect the Company's internal controls over financial reporting.

**PART II OTHER INFORMATION****Item 1. LEGAL PROCEEDINGS**

Information pertaining to legal proceedings can be found in Item 1. Financial Statements Note 15. Legal Proceedings and Contingencies, to the interim consolidated financial statements, and is incorporated by reference herein.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

The Annual Meeting of Stockholders was held on May 4, 2004 for the purpose of:

- A. election of three directors;
- B. ratification of the appointment of PricewaterhouseCoopers LLP as independent auditors for 2004;
- C. voting on a stockholder proposal relating to the publication of political contributions;
- D. voting on a stockholder proposal relating to the separation of the chairman and chief executive officer positions;
- E. voting on a stockholder proposal relating to HIV/AIDS-TB-Malaria; and
- F. voting on a stockholder proposal relating to director vote threshold;

The following persons were elected to serve as directors and received the number of votes set opposite their respective names:

	<u>For</u>	<u>Withheld</u>
Peter R. Dolan	1,622,644,311	81,022,850
Louis V. Gerstner, Jr.	1,644,664,256	59,002,906
Leif Johansson	1,597,502,822	106,164,339

The terms of the following directors continued after such meeting: Vance D. Coffman, Ellen V. Futter, Louis W. Sullivan, M.D., Robert E. Allen, Lewis B. Campbell, Laurie H. Glimcher, M.D. and James D. Robinson III.

The appointment of PricewaterhouseCoopers LLP was ratified by a vote of 1,612,942,050 shares in favor of the appointment, with 78,149,662 shares voting against, 12,790,154 shares abstaining.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q/A

The stockholder-proposed resolution relating to the publication of political contributions received a vote of 92,488,660 shares in favor, with 1,155,015,599 shares voting against, 105,070,446 shares abstaining and 351,092,456 broker non-votes.

The stockholder-proposed resolution relating to the separation of the chairman and chief executive officer positions received a vote of 517,258,130 shares in favor, with 812,540,790 shares voting against, 22,697,632 shares abstaining and 351,143,609 broker non-votes.

The stockholder-proposed resolution relating to HIV/AIDS-TB-Malaria received a vote of 97,621,616 shares in favor, with 1,140,103,802 shares voting against, 114,861,515 shares abstaining and 351,080,228 broker non-votes.

The stockholder-proposed resolution relating to the director vote threshold received a vote of 97,480,507 shares in favor, with 1,219,281,369 shares voting against, 35,801,733 shares abstaining and 351,103,552 broker non-votes.

A stockholder-proposed resolution relating to the prohibition of political contributions that was submitted for consideration at the Annual Meeting was not voted on because the stockholder proponent was not present at the meeting to introduce the proposal.



**Item 6. EXHIBITS AND REPORTS ON FORM 8-K**

a) Exhibits (listed by number corresponding to the Exhibit Table of Item 601 in Regulation S-K).

<u>Exhibit Number and Description</u>	<u>Page</u>
15 Letter Regarding Unaudited Interim Financial Information	E-15
31a Section 302 Certification Letter	E-31-1
31b Section 302 Certification Letter	E-31-2
32a Section 906 Certification Letter	E-32-1
32b Section 906 Certification Letter	E-32-2

b) Reports on Form 8-K

On January 29, 2004, the Registrant filed a Form 8-K reporting its financial results for the fourth quarter of 2003 and full year 2003. Attached as an exhibit to such Form 8-K is its press release dated January 29, 2004.

On March 15, 2004, the Registrant filed a Form 8-K announced that it filed its 2003 Form 10-K and restated its prior periods financial results. Attached as an exhibit to such Form 8-K is its press release dated March 15, 2004.

On March 31, 2004, the Registrant filed a Form 8-K concerning its statement regarding the Paraplatin® pediatric submission and federal appeals court reversal on patent. Attached as an exhibit to such Form 8-K is its press release dated March 31, 2004.

On April 2, 2004, the Registrant filed a Form 8-K concerning the dismissal by the U.S. District Court for the Southern District of New York of the consolidated amended complaint in the civil class action suits against Bristol-Myers Squibb and other defendants in relation to alleged violations of federal securities laws.

On April 28, 2004, the Registrant filed a Form 8-K attaching its press release dated April 28, 2004 regarding earnings for the first quarter of 2004 and certain supplemental information not included in the press release.

On May 10, 2004, the Registrant filed a Form 8-K attaching its press release dated April 28, 2004 announcing a global development and commercialization alliance with Merck & Co., Inc. for muraglitazar and described certain provisions of the alliance.

\* Indicates, in this Form 10-Q/A, brand names of products which are registered trademarks not owned by the Company or its subsidiaries. ERBITUX is a trademark of ImClone Systems Incorporated; AVAPRO/AVALIDE and PLAVIX are trademarks of Sanofi-Synthelabo S.A.; GLUCOPHAGE, GLUCOPHAGE XR and GLUCOVANCE are trademarks of Merck Sante S.A.S., an associate of Merck KGaA of Darmstadt, Germany; and ABILIFY is a trademark of Otsuka Pharmaceutical Company, Ltd.

**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.

BRISTOL-MYERS SQUIBB COMPANY

(REGISTRANT)

Date: June 28, 2004

By: /s/ Peter R. Dolan

\_\_\_\_\_  
Peter R. Dolan

*Chairman of the Board and Chief Executive Officer*

Date: June 28, 2004

By: /s/ Andrew R. J. Bonfield

\_\_\_\_\_  
Andrew R. J. Bonfield

*Senior Vice President and Chief Financial Officer*