

BRISTOL MYERS SQUIBB CO  
Form 10-K/A  
June 28, 2004  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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

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

For the fiscal year ended December 31, 2003

Commission File Number 1-1136

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**BRISTOL-MYERS SQUIBB COMPANY**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

(Address of principal executive offices)

Telephone: (212) 546-4000

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.10 Par Value	New York Stock Exchange Pacific Exchange, Inc.
\$2 Convertible Preferred Stock, \$1 Par Value	New York Stock Exchange Pacific Exchange, Inc.

Securities registered pursuant to Section 12(g) of the Act: None

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the 1,940,460,562 shares of voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2003) was approximately \$52,683,504,258. Bristol-Myers Squibb has no non-voting common equity. At February 18, 2004, there were 1,941,090,408 shares of common stock outstanding.

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**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the 2004 Proxy Statement filed on March 26, 2004. Part III

**Amendment to Annual Report on Form 10-K/A for the Year Ended December 31, 2003**

This Amendment No. 1 to Bristol-Myers Squibb Company's Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 10-K/A") amends Item 1 in Part I and Items 7, 8 and 9A in Part II. This 2003 10-K/A is being filed to address comments received by the Company from the Securities and Exchange Commission (SEC) in connection with the Company's filing of its Registration Statement on Form S-4 filed on March 31, 2004. This 2003 10-K/A (i) provides in additional locations disclosure already provided in other locations in the Company's initial Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 15, 2004, (ii) includes disclosure that was previously provided in reports filed with the SEC prior to the filing of the Company's initial Annual Report on Form 10-K filed on March 15, 2004, and (iii) includes disclosure that was previously provided in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2004, filed on May 10, 2004. This 2003 10-K/A also includes:

- (i) an expanded description of recent clinical testing results to PRAVACHOL;
- (ii) expanded disclosure of the termination provisions of the Company's strategic alliances;
- (iii) 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 and tax reporting and accounting;
- (iv) an expanded discussion of the restatement adjustment for goods-in-transit in connection with the 2003 Restatement discussed below in the Explanatory Note;
- (v) clarification of an aspect of the consignment accounting model under the Company's revenue recognition policy; and
- (vi) expanded disclosure of the Company's \$69 million asset write-down in the fourth quarter of 2002 relating to the planned shutdown of research facilities in the United States.

The Company has also made conforming corrections to each of its Section 302 certifications to include a statement that had been inadvertently omitted from the previous filing.

This 2003 10-K/A, including information that is being added or amended to reflect the matters discussed above, does not reflect any events or developments occurring subsequent to March 15, 2004. For a discussion of events and developments occurring subsequent to March 15, 2004, see the Company's Quarterly Report on Form 10-Q/A for the period ended March 31, 2004 and the Company's Current Reports on Form 8-K dated:

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March 31, 2004 (announced filing of application for pediatric exclusivity extension for PARAPLATIN; announced developments with respect to patent litigation to PARAPLATIN);

April 2, 2004 (announced dismissal by U.S. District Court for the Southern District of New York of complaint in civil class action suits alleging federal securities laws violations in connection with, among other things, ImClone and ImClone's product, Erbitux, and certain accounting issues, including wholesaler inventory and sales incentives, the establishment of reserves, and accounting for certain assets and other sales);

April 28, 2004 (announced 2004 first quarter earnings);

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).

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### **Explanatory Note Regarding Previously Filed 2003 Restatement**

The Company has restated its consolidated balance sheet at December 31, 2002, and consolidated statements of earnings, cash flows, and comprehensive income and retained earnings for the years ended December 31, 2002 and 2001 (the 2003 Restatement). The restatement affected periods prior to 2001. The impact of the restatement on such prior periods was reflected as an adjustment to opening retained earnings as of January 1, 2001. The restatement was reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 15, 2004, was reported in amendments to the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2003, June 30, 2003 and September 30, 2003, in each case filed on March 31, 2004 and is reported in this 2003 10-K/A.

The 2003 Restatement (i) corrects certain of the Company's historical accounting policies to conform to generally accepted accounting principles (GAAP) and (ii) corrects certain errors made in the application of GAAP, including a revision of inappropriate accounting with respect to the Company's accounting for tax contingency reserves. The 2003 Restatement includes adjustments to (i) earnings from continuing operations before minority interest and income taxes, (ii) minority interest, net of taxes, (iii) the provision of income taxes, (iv) earnings from discontinued operations and (v) cash and cash equivalents.

The restatement adjustments increased the Company's net earnings and diluted earnings per share in the year ended December 31, 2002 by approximately \$71 million or \$0.03 per share, and reduced net earnings and diluted earnings per share in the year ended December 31, 2001 by approximately \$172 million or \$0.09 per share.

The restatement adjustment to the Company's consolidated balance sheet decreased the amount of cash and cash equivalents at December 31, 2002 by approximately \$1.6 billion and increased marketable securities by the same amount. If the consolidated balance sheet at December 31, 2001 were restated, cash and cash equivalents would decrease by approximately \$0.9 billion with marketable securities increased by the same amount. The restatement adjustment to statements of cash flows increased the amount of net cash used in investing activities for the years ended December 31, 2001 and 2002, by approximately \$0.9 billion and \$0.7 billion, respectively. There is no impact on periods prior to 2001.

For a discussion of the individual restatement adjustments, see Item 8. Financial Statements Note 2. Restatement of Previously Issued Financial Statements for Years Ended December 31, 2002 and 2001. Additionally, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. For more information on the impact of the restatement on years 2000 and 1999, see Item 6. Selected Financial Data in Part II of this report.

The Company did not amend its Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for periods affected by the restatement that ended prior to March 31, 2003, and the financial statements and related financial information contained in such reports should no longer be relied upon.

All referenced amounts in this Annual Report for prior periods and prior period comparisons reflect the balances and amounts on a restated basis.

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**PART I**

**Item 1. BUSINESS.**

**General**

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS or the Company) was incorporated under the laws of the State of Delaware in August 1933 under the name Bristol-Myers Company, as successor to a New York business started in 1887. In 1989, Bristol-Myers Company changed its name to Bristol-Myers Squibb Company as a result of a merger. The Company, through its divisions and subsidiaries, is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceuticals and other healthcare related products.

**Acquisitions and Divestitures**

On October 1, 2001, the Company acquired the DuPont Pharmaceuticals business (DuPont Pharmaceuticals) from E.I. du Pont de Nemours and Company for \$7.8 billion in cash. DuPont Pharmaceuticals was primarily a domestic pharmaceutical and imaging product business focused on research and development. In addition, in November 2001, the Company purchased 14.4 million shares of ImClone Systems Incorporated (ImClone) for \$70 per share, or \$1,007 million, which represented 19.9% of the shares outstanding just prior to the Company's commencement of a public tender offer for ImClone shares. The equity investment in ImClone is part of a strategic agreement between the Company and ImClone that also includes an arrangement to codevelop and copromote the cancer drug, ERBITUX\*. These transactions were financed with proceeds from the issuance of \$1.5 billion of commercial paper, the issuance of \$5.0 billion of medium-term notes and internal cash flows.

In 2000, as part of the Company's strategy to focus on its pharmaceutical and other healthcare businesses, the Company decided to divest its Clairol and Zimmer businesses. Accordingly, the operations of these businesses have been reflected as discontinued operations in the accompanying consolidated financial statements. On November 15, 2001, the Company completed the sale of Clairol for \$4.95 billion, and on August 6, 2001, the Company spun off Zimmer Holdings, Inc. in a tax-free distribution.

**Bristol-Myers Squibb Website**

The Company's internet website address is [www.bms.com](http://www.bms.com). The Company makes available free of charge on its website its annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after the Company electronically files such material with, or furnishes such material to, the Securities and Exchange Commission.

Information relating to corporate governance at Bristol-Myers Squibb, including the Company's Corporate Governance Guidelines, Standards of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers and information concerning the Company's Executive Committee, Board of Directors, Board Committees, including Committee charters, and transactions in Bristol-Myers Squibb securities by Directors and officers, is available on the Company's website at [www.bms.com](http://www.bms.com) under the Investors Corporate Governance caption. Any waivers to or material

amendments to the Code of Ethics will be posted promptly on the Company's website. Information relating to stockholder services, including the Company's Dividend Reinvestment Plan and direct deposit of dividends, is available on the Company's website at [www.bms.com](http://www.bms.com) under the Investors Stockholder Services caption.

The Company incorporates by reference certain information from parts of its proxy statement for the 2004 Annual Meeting of Stockholders. The SEC allows the Company to disclose important information by referring to it in that manner. Please refer to such information. The Company's proxy statement for the 2004 Annual Meeting of Stockholders and 2003 Annual Report are available on the Company's website ([www.bms.com](http://www.bms.com)) under the Investors SEC Filings caption.

## **Business Segments**

The Company has four reportable segments: Pharmaceuticals, Oncology Therapeutics Network (OTN), Nutritionals and Other Healthcare. The Pharmaceuticals segment is made up of the global pharmaceutical and international (excluding Japan) consumer medicines business. The OTN segment provides oncology products, supportive care products and related supplies to office-based oncologists in the United States. The Nutritionals segment consists of Mead Johnson Nutritionals (Mead Johnson), primarily an infant formula business. The Other Healthcare segment consists of ConvaTec, Medical Imaging and Consumer Medicines (North America and Japan) businesses. For additional information about these segments, see Item 8. Financial Statements Note 19. Segment Information.

### *Pharmaceuticals Segment*

The Pharmaceuticals segment discovers, develops, licenses, manufactures, markets, distributes and sells branded pharmaceuticals. These products are sold worldwide, primarily to wholesalers, retail pharmacies, hospitals, government entities and

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the medical profession. The Company manufactures these products in the United States and Puerto Rico and in fifteen foreign countries. Pharmaceuticals sales accounted for approximately 71% of the Company's sales in 2003 and in 2002 and 75% of the Company's sales in 2001. Domestic Pharmaceuticals sales accounted for 56% of total Pharmaceuticals sales in 2003, 57% of total Pharmaceuticals sales in 2002 and 62% of total Pharmaceuticals sales in 2001, while Pharmaceuticals sales in Europe accounted for 30% of total Pharmaceuticals sales in 2003, 28% of total Pharmaceuticals sales in 2002 and 23% of total Pharmaceuticals sales in 2001, and Pharmaceuticals sales in Japan accounted for 3% of total Pharmaceuticals sales in each of the years 2003, 2002 and 2001.

The Company's strategy is to build its pipeline and support sustainable growth by focusing its discovery and development efforts in ten disease areas, increasing its sales and marketing emphasis on specialists and high value primary care prescribers, investing in research and development and establishing a biologics business. In addition to discovering and developing products through its own research and development efforts, the Company actively pursues products through research collaborations and strategic alliances with others in the pharmaceutical industry. For additional information, see Strategic Alliances and Research and Development below.

The Pharmaceuticals segment competes with other worldwide research-based drug companies, smaller research companies and generic drug manufacturers. The Company expects to lose certain revenues over the next several years as a result of the expiration of market exclusivity protection for certain of its products. For 2004, the Company estimates reductions of net sales in the range of \$1.2 billion 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 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. Sales rose in 2003, resulting in a higher base, and generic competition did not develop in 2003 as expected, thereby increasing the expected level of exclusivity losses in 2004. In addition, the impact of exclusivity losses for PARAPLATIN anticipated to occur primarily in 2005 will be accelerated into 2004 if an anticipated six-month extension of exclusivity protection based on pediatric studies is not obtained by April 2004. The 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. Subject to these uncertainties, the Company estimates that there will be incremental exclusivity losses, as measured against the net sales levels at the time exclusivity will be lost, of between \$1 billion and \$1.3 billion in each of the years 2005, 2006 and 2007, resulting, together with the estimated reductions in net sales for 2004 described above, in total estimated exclusivity losses of \$2.2 to \$2.6 billion in 2005, \$3.2 to \$3.9 billion in 2006 and \$4.2 to \$5.2 billion in 2007.

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 of 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 reduces 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.

The Company also believes that this revenue loss will be more or less offset by growth in its in-line products, including PLAVIX\*, AVAPRO\*/AVALIDE\* and SUSTIVA, the growth of recently launched products ABILIFY\* and REYATAZ, the growth of the recently FDA approved product ERBITUX\*, and (subject to regulatory approval) by the introduction of late-stage pipeline products such as ABATACEPT (CTLA4Ig), entecavir and muraglitazar that may be approved within the next thirty-six months and begin to contribute significantly by 2007. Additionally, OTN sales growth is expected to continue. This belief is subject to any adverse determination that may occur with respect to the PLAVIX\* patent litigation. In addition, there can be no assurance as to when or if the Company will obtain the required regulatory approvals for its late-stage pipeline products. The Company expects the resulting product mix to preserve company margins because the products losing exclusivity protection carry higher margins than products expected to grow sales.



For more information about these and other matters, see *Products*, *Competition* and *Research and Development* below, *Item 7. Management Discussion and Analysis of Financial Condition and Results of Operations Outlook for 2004*, and *Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies*.

### *Products*

Most of the Company's pharmaceutical revenues come from products in the following therapeutic classes: cardiovascular and metabolic, oncology, infectious diseases, including human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), and affective (psychiatric) disorders.

In the pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. Market exclusivity is based upon patent rights and/or certain regulatory forms of exclusivity. When these patent rights and other forms of exclusivity expire and generic versions of a medicine are approved and marketed, there are often very substantial and rapid declines in the sales of the original innovative product. The Company's business is focused on innovative pharmaceutical products, and the Company relies on patent rights and other forms of protection to maintain the market exclusivity of its products. For further discussion of patents rights and regulatory forms of exclusivity, see *Intellectual Property and Product Exclusivity* below. For further discussion of the impact of generic competition on the Company's business, see *Generic Competition* below.

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The chart below shows the net sales of key products in the Pharmaceuticals segment, together with the year in which the basic exclusivity loss (patent rights or data exclusivity) occurred or is expected to occur in the United States, the European Union (EU) and Japan. The Company also sells its pharmaceutical products in other countries; however, data is not provided on a country-by-country basis because individual country sales are not significant outside the United States, the EU and Japan. In most instances, the basic exclusivity loss date listed below 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 listed in the chart 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.

Pharmaceutical Product	2003	Restated 2002	Restated 2001	Past or Currently Expected	Past or Currently Expected	Past or Currently Expected
				Year of U.S. Basic Exclusivity Loss	Year of EU Basic Exclusivity Loss(a)	Year of Japanese Basic Exclusivity Loss
(dollars in millions)						
PRAVACHOL	\$ 2,827	\$ 2,266	\$ 2,101	2006	2002-2007	++
PLAVIX*	2,467	1,890	1,171	2011	2013	++
TAXOL®	934	857	1,112	2002	2003	2003-2013
PARAPLATIN	905	727	592	2004	2000	1998
AVAPRO*/AVALIDE*	757	586	487	2011	2012	++
SUSTIVA	544	455	68	2013	2013	++
MONOPRIL	470	426	413	2003	2001-2008	++
GLUCOVANCE*	424	246	269	2004	++	++
GLUCOPHAGE* XR	395	297	230	2003	++	++
ZERIT/ZERIT ER	354	443	515	2008	2007-2011	2008
COUMADIN	303	300	63	1997	(b)	++
ABILIFY*	283	25		2009	++	++
VIDEX/VIDEX EC	267	262	240	2001	2001	2001
TEQUIN	208	184	250	2007	++	++
GLUCOPHAGE* IR	118	220	1,838	2000	++	++
SERZONE	98	221	334	2003	++	++
REYATAZ	88			2017	++	2017
BUSPAR	35	53	297	2001	1999	++

\* Indicates brand names of products, which are registered trademarks not owned by the Company or its subsidiaries.

Note: The currently expected year of basic exclusivity loss includes any statutory extensions of exclusivity that have been earned, but not those that are speculative. In some instances, there may be later-expiring patents that cover particular forms or compositions of the drug, as well as methods of manufacture or methods of using the drug. Such patents may sometimes result in a favorable market position for the Company's product, but product exclusivity beyond the date specified cannot be predicted or assured.

++ The Company does not currently market the product in the jurisdiction indicated.

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- (a) References to the EU throughout this Form 10-K include the following current 15 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and the United Kingdom. In some instances the date of basic exclusivity loss will be different in various EU member states. In such instances, the earliest and latest dates of basic exclusivity loss are listed. For those EU countries where the basic patent was not obtained, there may be data protection available.
  
- (b) EU basic exclusivity expired before BMS acquired the product.

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Below is a summary of the indication, intellectual property position, licensing arrangements, if any, and third-party manufacturing arrangements, if any, for each of the above products in the United States and where applicable, the EU and Japan.

**PRAVACHOL** Pravastatin sodium, a cardiovascular product, is an HMG Co-A reductase inhibitor indicated as an adjunct to diet for patients with primary hypercholesterolemia, for lowering the risk of a first heart attack in people without clinically evident coronary heart disease who have elevated cholesterol, and for reducing the risk of heart attack and stroke in patients with clinically evident coronary heart disease.

The Company has licensed a patent covering pravastatin, marketed by the Company in the U.S. as PRAVACHOL, from Sankyo Company, Ltd. of Japan (Sankyo), with the agreement expiring as exclusivity expires on a market-by-market basis. Exclusivity in the U.S. under the patent (including pediatric extension) lasts until April 2006. Under the terms of the license, the Company may market and sell pravastatin throughout the world, excluding Japan, Korea, Taiwan and Thailand (markets in which Sankyo retains exclusive patent rights). Sankyo also copromotes and comarkets pravastatin in certain European and Latin American countries.

The composition of matter patent was scheduled to expire in the United States in October 2005, but has been extended for six months to April 2006 under the law that provides exclusivity extensions for pediatric research. In the EU, the composition of matter patent was not obtained in Greece, Luxembourg or Portugal and expired in Spain in July 2002. The composition of matter patent will expire in August 2004 in Belgium, Denmark, Finland, Germany, Ireland, the Netherlands and the United Kingdom. In Austria, expiration will occur in November 2004. In France and Sweden, expiration will occur in August and March 2006, respectively. In Italy, expiration will occur on January 1, 2008.

The Company's bulk requirements for pravastatin are supplied by Sankyo under an arrangement that includes a royalty payment based on product sales. BMS finishes the product in its own facilities.

**PLAVIX\*** Clopidogrel bisulfate, a cardiovascular product, is a platelet aggregation inhibitor, which is approved for protection against fatal or non-fatal heart attack or stroke in patients with a history of heart attack, stroke, peripheral arterial disease or acute coronary syndrome.

Clopidogrel was codeveloped and is jointly marketed with Sanofi-Synthelabo (Sanofi). The worldwide alliance operates under the framework of two geographic territories: one in the Americas and Australia (BMS's primary territory) and the other in Europe and Asia (Sanofi's primary territory). 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. At the country level, agreements either to copromote (whereby a partnership was formed between the parties to sell a single brand) or to comarket (whereby the parties operate and sell their brands independently of each other) are in place.

The composition of matter patent in the United States will expire in 2011 (which includes a statutory patent term extension). This patent is currently the subject of litigation. The Company continues to believe that the patent is valid and that it is infringed, and with its alliance partner and patent-holder Sanofi, is vigorously pursuing the litigation. It is not possible at this time reasonably to assess the outcome of this litigation, or if there were an adverse determination in this litigation, the timing of potential generic competition for PLAVIX\*. For more information about this litigation, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies. For more information about the potential effects of generic competition on PLAVIX\*, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Outlook for 2004. In the EU, regulatory data exclusivity extends to 2008 and the key composition of matter patent will expire in 2013.

Bulk requirements for clopidogrel are supplied to each partnership by Sanofi, which produces bulk clopidogrel in its own facilities and obtains a portion of the bulk clopidogrel requirements from a third party, under an arrangement that includes royalty payments based on product sales, and each partnership then produces finished product for sale. For more information about the Company's arrangements with Sanofi, see Strategic Alliances below and Item 8. Financial Statements Note 3. Alliances and Investments.

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**TAXOL®**

Paclitaxel, an oncology product, is used in the treatment of refractory ovarian cancer, first-line treatment of ovarian cancer in combination with cisplatin, second-line treatment of AIDS related Kaposi's Sarcoma, treatment of metastatic breast cancer after failure of combination chemotherapy, adjuvant treatment of node positive breast cancer and in the treatment of non-small cell lung carcinoma with cisplatin.

Paclitaxel was developed under a collaborative research and development agreement with the U.S. Government. Under the agreement, the Company obtained rights to the U.S. Government's TAXOL® data.

The active ingredient in TAXOL®, paclitaxel, did not have patent protection in the United States, the EU or Japan but did have regulatory protection in the form of data exclusivity. Data exclusivity in the United States expired in 1997, an initial approval for a generic version was granted and revoked in 2000 and final marketing approval for generic paclitaxel did not occur until January 2002. Data exclusivity in the EU expired in September 2003. Data exclusivity for TAXOL® in Japan expired in July 2003. A patent claiming the approved dosing and administration schedule expires in Japan in 2013. Numerous factors make it impossible to predict when loss of market exclusivity in Japan will actually occur. For information regarding recently settled litigation involving TAXOL®, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

The Company is supplied with its bulk requirements for paclitaxel from third parties and produces finished goods in its own facilities.

**PARAPLATIN**

Carboplatin, an oncology product, is a chemotherapeutic agent used in the treatment of ovarian cancer.

The Company holds an exclusive patent license for carboplatin from Research Corporation Technology (RCT) and the University of Michigan for which the Company pays a royalty based on a percentage of product sales. Under the license, the Company has rights to market PARAPLATIN worldwide.

The patent for carboplatin will expire in the United States in April 2004. The Company is conducting pediatric clinical studies examining carboplatin. Upon completion of those studies and timely submission of the results to the U.S. Food and Drug Administration (FDA), the Company could earn an exclusivity extension that would extend the exclusivity period in the United States to October 2004. There is no assurance that the exclusivity for carboplatin will be extended as a result of these studies. In the EU, the basic patent covering carboplatin was obtained in France, Germany, the Netherlands, Sweden and the United Kingdom. The last patent to expire in these countries was France in 2000. In Japan, the basic patent expired in 1998.

The Company obtains its bulk requirements for carboplatin from a third party and produces finished goods in its own facilities.

**AVAPRO\*/AVALIDE\***

Irbesartan/irbesartan-hydrochlorothiazide, a cardiovascular product, is an angiotensin II receptor antagonist indicated for the treatment of hypertension and diabetic nephropathy.

Irbesartan was codeveloped and is jointly marketed with Sanofi. The Company's alliance with Sanofi operates under the framework of two geographic territories: one in BMS's primary territory, and the other in Sanofi's

primary territory.

The basic composition of matter patent in the United States expires in 2011 and in the EU in 2012. Data exclusivity in the EU expires in 2007.

Irbesartan is manufactured by both Bristol-Myers Squibb and Sanofi. Bulk irbesartan is sold to the territory joint ventures at a fixed percentage per kilo. Under intellectual property license arrangements, Sanofi collects a royalty based on a percentage of net sales. For more information about the Company's arrangements with Sanofi, see Strategic Alliances below and Item 8. Financial Statements Note 3. Alliances and Investments.

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SUSTIVA

Efavirenz, a virology product, is an antiretroviral drug used in the treatment of HIV/AIDS.

Rights to market efavirenz in the United States, the United Kingdom, France, Germany, Ireland, Italy and Spain were acquired as part of the DuPont Pharmaceuticals acquisition, which was completed on October 1, 2001. Rights related to this product are licensed from Merck & Co. for a royalty based on a percentage of net sales.

The basic composition of matter patent expires in 2013 in the United States. A separate method of use patent expires in 2014. The basic composition of matter patents in the United Kingdom, Ireland, France, Germany, Italy and Spain expire in 2013. Data exclusivity in the EU expires in 2009.

The Company obtains its bulk requirements for efavirenz from third parties and produces finished goods in its own facilities.

MONOPRIL

Fosinopril sodium, a cardiovascular product, is a second-generation angiotensin converting enzyme (ACE) inhibitor with once-a-day dosing indicated for the treatment of hypertension.

MONOPRIL was developed internally.

The basic composition of matter patent in the United States expired in June 2003. The basic composition of matter patent expired in Denmark, Greece and Portugal in 2001 and in Spain in October 2002. A composition of matter patent was not obtained in Finland. For the rest of the EU, the composition of matter patent will expire on a country-by-country basis through 2008.

GLUCOPHAGE\* IR/

Metformin hydrochloride/glyburide and metformin hydrochloride, metabolics products, are oral anti-diabetic agents for type 2 diabetes.

GLUCOPHAGE\* XR/

GLUCOVANCE\*

Metformin was developed by Merck Santé S.A.S. (Merck Santé). Under the terms of the arrangement, the Company may market and sell metformin in the United States. The Company purchases bulk metformin at a price (including a royalty) based on a percentage of net sales.

Data exclusivity for GLUCOPHAGE\* IR expired in March 2000. Regulatory exclusivity expired for GLUCOPHAGE\* XR in October 2003 and for GLUCOVANCE\* in July 2003. The Company earned a pediatric exclusivity extension for GLUCOVANCE\* that extended its regulatory exclusivity until January 2004.

The Company obtains its bulk requirements for metformin from Merck Santé and produces the finished product in its own facilities.

ZERIT/ZERIT ER

Stavudine, a virology product, is used in the treatment of HIV/AIDS.



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The Company holds an exclusive patent license for ZERIT from Yale University pursuant to which it pays a royalty based on product sales. In Japan, the Company has an exclusive license for ZERIT from Yamasa Corporation pursuant to which it pays a royalty based on net sales in Japan.

The use patent expires in the United States in June 2008. However, a pediatric extension has been earned, and thus, exclusivity is expected to expire in December 2008. This patent series expires in the EU from 2007 through 2011 (patent applications are pending in Denmark and Finland), and in Japan in December 2008.

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**COUMADIN** Warfarin sodium, a cardiovascular product, is an oral anti-coagulant used predominantly in patients with atrial fibrillation or deep venous thrombosis/pulmonary embolism.

Warfarin was acquired as part of the DuPont Pharmaceuticals acquisition, which was completed on October 1, 2001.

Market exclusivity expired in the United States in 1997. Basic patent protection and regulatory data protection had expired before BMS acquired COUMADIN.

The Company obtains its bulk requirements for warfarin from a third party and produces the majority of finished goods in its own facilities.

**ABILIFY\*** Aripiprazole, a neuroscience product, is an atypical antipsychotic agent for patients with schizophrenia. ABILIFY\* was introduced in the United States in November 2002.

The Company's partner, Otsuka Pharmaceutical Co., Ltd. (Otsuka) received approval for a supplemental New Drug Application (sNDA) for aripiprazole for maintaining stability in patients with schizophrenia, and has announced that it submitted a sNDA for ABILIFY\* for the treatment of acute mania in patients with bipolar disorder to the FDA. Otsuka holds the New Drug Application (NDA) for aripiprazole in the United States and the Marketing Authorization Application (MAA) for the EU. In the United States, Germany, Spain and France, the Company receives a fee of approximately 65% of net sales. In the rest of the EU, the Company purchases finished product at approximately 35% of net sales and books all sales.

Aripiprazole is copromoted in the United States by the Company and Otsuka. BMS's rights to commercialize aripiprazole in the United States terminate in 2012. Thereafter, Otsuka has the sole right to commercialize aripiprazole in the United States. 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. On February 25, 2004, Otsuka received a recommendation for marketing approval for ABILIFY\* in the EU by the Committee on Proprietary Medicinal Products, an expert advisory body to the European Commission. Marketing authorization is granted in the EU by the European Commission. The Company is the exclusive licensee for the product in the rest of the world, excluding Japan and certain other countries. For more information about the Company's arrangement with Otsuka, see Strategic Alliances below and Item 8. Financial Statements Note 3. Alliances and Investments.

The basic U.S. composition of matter patent expires in 2009 (and may be extended until 2014 if pending supplemental protection extensions are granted). There is no composition of matter patent in Austria, Belgium, Finland, Greece, Ireland, Luxembourg and Portugal. For the other EU member states, the composition of matter patent expires in 2009 (and may be extended until 2014 if pending supplemental protection certificates are granted).

Otsuka supplies the bulk requirements for aripiprazole and both Otsuka and Bristol-Myers Squibb produce the finished product in their own facilities.



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VIDEX/VIDEX EC

Didanosine, a virology product, is an antiretroviral drug used in the treatment of adult and pediatric patients with HIV/AIDS. Didanosine is marketed by the Company in three different formulations. The first is for use in an oral solution. The second is a reduced mass tablet. The third is an enteric coated capsule formulation (VIDEX EC).

The Company has a license to the U.S. Government's patent series that claims the method of using didanosine to treat HIV. This patent series covers the approved use of all three of the aforementioned formulations. The Company's license became non-exclusive in October 2001. Because the Company's license under the use patent is non-exclusive, another company could potentially obtain a license from the U.S. Government and seek marketing approval.

The U.S. Government's method of use patent expires in 2007 in the United States (which includes an earned pediatric extension) and Japan. In Europe, the U.S. Government was granted the use patent in Austria, Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Sweden, the United Kingdom and the patent is pending in Ireland. Expiration of this use patent in the EU occurs between 2006 and 2009 on a country-by-country basis. This method of use patent was not obtained by the U.S. Government in Denmark, Finland, Greece, Portugal or Spain.

VIDEX (reduced mass formulation): the Company has patents covering the reduced mass formulation of VIDEX in the United States, EU and Japan that expire in 2012. Another company may attempt to develop a reduced mass formulation of didanosine that does not infringe these patents.

VIDEX EC (enteric coated capsule): the Company also has pending patent applications that cover the VIDEX EC formulation in the United States, the EU and Japan. If these patents issue, expiration will be in 2018. Another company may attempt to develop an enteric coated capsule formulation of didanosine that does not infringe these pending patent applications.

U.S. data exclusivity for VIDEX EC expires in May 2004. Japanese data exclusivity for VIDEX EC expires in March 2005.

The Company obtains the materials necessary for bulk manufacture of didanosine from a third party and produces the finished product in its own facilities.

TEQUIN

Gatifloxacin, an infectious disease product, is a broad-spectrum 8-methoxy fluoroquinolone antibiotic indicated for the treatment of respiratory tract infections in adults 18 years or older, such as acute bacterial exacerbation of chronic bronchitis, acute sinusitis and community-acquired pneumonia caused by indicated susceptible strains of gram-positive and gram-negative bacteria.

Gatifloxacin is licensed from Kyorin Pharmaceuticals Co., Ltd. The Company purchases bulk gatifloxacin, inclusive of a royalty, based on a percentage of net sales.

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The basic U.S. patent expires in 2007; however, it is expected that the patent will be eligible for a statutory patent term extension until 2009. This patent term extension is granted to compensate patent holders for a portion of the patent life lost during the regulatory approval process.

Gatifloxacin is manufactured by a third party.

SERZONE

Nefazodone hydrochloride, a neuroscience product, is an anti-depressant treatment. SERZONE is the subject of pending product liability litigation in which plaintiffs allege that the Company knew or should have known about certain risks associated with the product and that it failed to adequately warn physicians and users of such risks. For a discussion of this litigation, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

Nefazodone was developed internally.

The basic patent expired in the United States in September 2003. SERZONE is no longer marketed in Europe, Canada, Australia and Asia.

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REYATAZ Atazanavir sulfate, a virology product, is a protease inhibitor for the treatment of HIV/AIDS. REYATAZ was launched in the United States in July 2003.

The Company developed atazanavir under a worldwide license from Novartis for which it pays a royalty based on a percentage of net sales.

The basic composition of matter patent expires in the United States in 2017. Atazanavir has received marketing approval from the European authorities, and in many of the current EU member states applications for the basic composition of matter patent are still pending. If issued, these patents will expire in 2017. In Japan, the basic composition of matter patent expires in 2017.

BUSPAR Buspirone hydrochloride, a neuroscience product, is an anti-anxiety agent for persistent anxiety with or without accompanying depressive symptoms. For information regarding recently settled litigation involving BUSPAR, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

Buspirone was developed internally.

The U.S. anxiolytic use patent expired in 2000 although final marketing approval for generic buspirone did not occur until March 2001. Patents outside of the United States expired in 1999.

ERBITUX\* (cetuximab), a biologics product, is an IgG1 monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor (EGFR), which is expressed on the surface of certain cancer cells in multiple tumor types as well as some normal cells. ERBITUX\* is designed to bind to and internalize EGFR and prevent natural ligands called growth factors from binding to the receptor and activating signaling to the tumor. ERBITUX\* was approved by the FDA on February 12, 2004 for the treatment in combination with irinotecan of patients with EGFR-expressing metastatic colorectal cancer who had failed an irinotecan-based regimen and as monotherapy for patients who are intolerant of irinotecan. ERBITUX\* is also being studied in earlier stages of colorectal cancer, as well as in other types of cancer that frequently express the EGF receptor, including lung, pancreatic, ovarian and head and neck cancers. ERBITUX\* is marketed in North America by Bristol-Myers Squibb under a distribution and copromotion agreement with ImClone. 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. The Company and ImClone will share distribution rights to ERBITUX\* with Merck KGaA in Japan. For a description of the Company's alliance with ImClone, see Strategic Alliances below and Item 8. Financial Statements Note 3. Alliances and Investments. For a description of the Company's supply agreement with ImClone, see Manufacturing and Quality Assurance below.

There is no composition of matter patent that specifically claims ERBITUX\*. ERBITUX\* has been approved for monotherapy, for which there is no use patent. The use of ERBITUX\* in combination with an anti-neoplastic agent is also approved by the FDA. Such combination use is claimed in a granted U.S. patent that expires in 2017. For more information about biologics patents, see Intellectual Property and Product Exclusivity below. The inventorship of this use patent is being challenged by three scientists from the Weizmann Institute who claim they should have been named as co-inventors. For more information about this litigation, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies. The European equivalent of this use patent has been opposed.

In addition to the pharmaceutical products discussed above, the Company's Pharmaceuticals segment also includes the Company's wholly owned UPSA business in Europe. The UPSA brand of acetaminophen, EFFERALGAN, is marketed for pain relief across the continent. The Company also markets ASPIRINE UPSA, DAFALGAN and FERVEX in Europe and other overseas markets.

*Strategic Alliances*

The Company enters into strategic alliances with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are owned by such third parties. These alliances can take many forms, including licensing arrangements, codevelopment and comarketing agreements, copromotion arrangements and joint ventures. Such alliances reduce the risk of research and development expenses that do not lead to revenue-generating products; however, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins on the Company's own products because profits from alliance products are shared with the Company's alliance partners. While there can be no assurance that new alliances will be formed, the Company actively pursues such arrangements, and views alliances as an important complement to its own discovery and development activities. The Company's most significant current alliances are those with Sanofi for PLAVIX\* and AVAPRO\*, Otsuka for ABILIFY\*, ImClone for ERBITUX\* and Sankyo for PRAVACHOL, each of which is discussed in more detail below. Additionally, the Company has licensing arrangements with RCT for PARAPLATIN, with Yale for ZERIT, with the U.S. Government for VIDEX, with Novartis for REYATAZ and with Kyorin for TEQUIN. In general, the Company's strategic alliances are for periods co-extensive with the periods of market exclusivity protection on a country-by-country basis. Based on the

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Company's current expectations with respect to the expiration of market exclusivity in the Company's significant markets, the licensing arrangements with RCT for PARAPLATIN are expected to expire in April 2004 in the U.S. subject to an anticipated six-month pediatric exclusivity extension; with Yale for ZERIT are expected to expire in 2008 in the U.S., between 2007-2011 in the EU and in 2008 in Japan; with the U.S. Government for VIDEX, which by its terms became non-exclusive in 2001, are expected to expire in 2007 in the U.S. (which includes an earned pediatric extension) and Japan and in EU countries between 2006-2009; with Novartis for REYATAZ are expected to expire in 2017 in the U.S., the EU and Japan and with Kyorin for TEQUIN are expected to expire in 2007 in the U.S. 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 Products and Intellectual Property and Product Exclusivity.

Each of the Company's strategic alliances contain customary early termination provisions typically found in agreements of this kind and are generally based on the other party's material breach or bankruptcy (voluntary or involuntary) and product safety concerns. The amount of notice required for early termination generally ranges from immediately upon notice to 90 days after receipt of notice. Termination immediately upon notice is generally available where the other party files a voluntary bankruptcy petition. Termination upon 30 to 90 days notice is generally available where an involuntary bankruptcy petition has been filed (and not been dismissed) or a material breach by the other party has occurred (and not been cured). Early termination due to product safety concerns typically arises when a product is determined to create significant risk of harm to patients due to concerns regarding the product's efficacy or level of toxicity. The Company's strategic alliances typically do not otherwise contain any provisions that provide the other party the right to terminate the alliance on short notice. In general, where the other party to the Company's strategic alliance will continue to have exclusivity protection upon the expiration or termination of the alliance, the Company does not retain any rights to the product or to the other party's intellectual property. The loss of rights to one or more products that are marketed and sold by the Company pursuant to strategic alliance arrangements with third parties in one or more countries or territories could be material to the Company's results of operations and cash flows and, in the case of PLAVIX\*, could be material to its financial condition and liquidity. As is customary in the pharmaceutical industry, the term of the Company's strategic alliances generally is co-extensive with the exclusivity period, which as discussed above may vary on a country-by-country basis. As discussed below, the Company's strategic alliance with Otsuka expires in November 2012 in the United States and Puerto Rico, which may be prior to expiration of market exclusivity protection for ABILIFY\* which is expected to expire in 2009 in the U.S. but may be extended until 2014 if a pending statutory patent term extension is granted.

Sanofi In 1993, the Company entered into codevelopment and commercialization agreements, which were subsequently restructured in 1997, with Sanofi for two products: AVAPRO\*/AVALIDE\* (irbesartan), an angiotensin II receptor antagonist indicated for the treatment of hypertension and diabetic nephropathy, which is copromoted in certain countries outside the U.S. under the tradename APROVEL\* and comarketed in certain countries outside the U.S. by the Company under the tradename KARVEA; and PLAVIX\* (clopidogrel), a platelet aggregation inhibitor, which is copromoted in certain countries outside the U.S. under the tradename PLAVIX\* and comarketed in certain countries outside the U.S. by the Company under the tradename ISCOVER.

The worldwide alliance operates under the framework of three territorial partnerships: Territory A for PLAVIX\* and AVAPRO\*/AVALIDE\* in Europe and Asia, Territory B for PLAVIX\* in the Americas (principally the U.S., Canada, Puerto Rico and Latin American countries) and Australia and AVAPRO\*/AVALIDE\* in Australia and the Americas not including the U.S., and the U.S. for AVAPRO\*/AVALIDE\*. This last partnership was formed in the fourth quarter of 2001, when the Company and Sanofi modified their previous exclusive license to the Company for AVAPRO\*/AVALIDE\* in the U.S. to form a copromotion joint venture, as part of which the Company contributed the AVAPRO\*/AVALIDE\* intellectual property and Sanofi agreed to pay the Company a total of \$200 million in 2001 and \$150 million in 2002. The Company accounts for these as a sale of an interest in a license and defers and amortizes the total amount of \$350 million into income over the expected life of the license, which is approximately eleven years.

The territory partnerships manage central expenses, such as marketing, research and development and royalties and supply finished product to the individual country marketing entities. At the individual country level, agreements either to copromote or to comarket are in place with the parties' local affiliates.



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The territory partnerships are governed by a series of committees with enumerated functions, powers and responsibilities. Each territory has two senior committees (the Senior Committees ) which have final decision making authority with respect to that territory as to the enumerated functions, powers and responsibilities within its jurisdiction.

The Company acts as the operating partner for the territories covering the Americas and Australia and owns the majority controlling interest in these territories. As such, the Company consolidates all country partnership results for these territories and records Sanofi's share of the results as a minority interest expense, net of taxes, which was \$351 million in 2003, \$292 million in 2002 and \$174 million in 2001. The Company recorded sales in these territories and in comarketing countries (Germany, Italy, Spain and Greece) of \$3,224 million in 2003, \$2,476 million in 2002 and \$1,658 million in 2001.

Sanofi acts as the operating partner for Territory A (covering Europe and Asia) and owns the majority controlling interest in this territory. The Company accounts for the investment in partnership entities in this territory under the equity method and records its

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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 \$187 million in 2003, \$120 million in 2002 and \$78 million in 2001. For further discussion of this matter, see Item 8. Financial Statements - Note 3. Alliances and Investments.

The agreements with Sanofi 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 alliance arrangements may be terminated by the Company or Sanofi, either in whole or in any affected country or Territory, depending on the circumstances, in the event of (i) voluntary or involuntary bankruptcy or insolvency, which in the case of involuntary bankruptcy continues for 60 days or an order or decree approving same continues unstayed and in effect for 30 days; (ii) a material breach of an obligation under a major alliance agreement that remains uncured for 30 days following notice of the breach except where commencement and diligent prosecution of cure has occurred within 30 days after notice; or (iii) deadlocks of one of the Senior Committees which render the continued commercialization of the product impossible in a given country or Territory or, in the case of AVAPRO\*/AVALIDE\* in the U.S., with respect to advertising and promotion spending levels or the amount of sales force commitment; (iv) an increase in the combined cost of goods and royalty which exceeds a specified percentage of the net selling price of the product; or (v) a good faith determination by the terminating party that commercialization of a product should be terminated for reasons of patient safety.

In the case of each of these termination rights, the agreements include provisions for the termination of the relevant alliance with respect to the applicable product in the applicable country or territory or, in the case of a termination due to bankruptcy or insolvency or material breach, both products in the applicable territory. Each of these termination procedures is slightly different; however, in all events, the Company could lose all rights to either or both products, as applicable, in the relevant country or territory even in the case of a bankruptcy or insolvency or material breach where the Company is not the defaulting party.

Otsuka In 1999, the Company entered into a worldwide (excluding Japan and several other countries) commercialization agreement with Otsuka, to codevelop and commercialize ABILIFY\* (aripiprazole) for the treatment of schizophrenia. Total milestone payments made to Otsuka from 1999 through December 2002 were \$207 million, which were expensed. The Company began copromoting the product with Otsuka in the United States and Puerto Rico in November 2002. The Company also has the right to copromote the product in several European countries if marketing approval is received from the European authorities. 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. The Company also has an exclusive right to sell ABILIFY\* in a number of countries in Europe, Latin America 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 which has not yet occurred. 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, if any, in such country. Early termination is available based on the other party's voluntary or involuntary bankruptcy, failure to make minimum payments, failure to commence the first commercial sale with three months after receipt of all necessary approvals and material breach. The amount of notice required for early termination of the strategic alliance is immediately upon notice (i) in the case of voluntary bankruptcy, (ii) where minimum payments are not made to Otsuka, (iii) if first commercial sale has not occurred within three months after receipt of all necessary approvals, 30 days where a material breach has occurred (and not been cured or commencement of cure has not occurred within 90 days after notice of such material breach) and 90 days in the case where an involuntary bankruptcy petition has been filed (and not been dismissed). In addition, termination is available to Otsuka upon 30 days notice in the event that the Company were to challenge Otsuka's patent rights or, on a market-by-market basis, the Company were to market a product in direct competition with ABILIFY. Upon termination or expiration of the alliance, the Company does not retain any rights to ABILIFY\*. The Company recorded revenue for ABILIFY\* of \$283 million in 2003 and \$25 million in 2002. For further discussion of this matter, see Item 8. Financial Statements - Note 3. Alliances and Investments.

ImClone In November 2001, the Company purchased 14.4 million shares of ImClone for \$70 per share, or \$1,007 million, which represented approximately 19.9% of the ImClone shares outstanding just prior to the Company's commencement of a public tender offer for those ImClone

shares. ImClone is a biopharmaceutical company focused on developing targeted cancer treatments, which include growth factor blockers, cancer vaccines, and anti-angiogenesis therapeutics. The equity investment in ImClone is part of a strategic agreement between the Company and ImClone that also included an arrangement expiring in September 2018 to codevelop and copromote the cancer drug, ERBITUX\*, for a series of payments originally totaling \$1 billion. The Company paid ImClone a milestone payment of \$200 million in 2001. On March 5, 2002, the agreement with ImClone was revised to reduce the total payments to \$900 million from \$1 billion. Under the revised agreement, the Company paid ImClone \$140 million in March 2002, \$60 million in March 2003, and \$250 million in March 2004 for the approval of ERBITUX\* by the FDA, and will pay an additional \$250 million upon FDA approval for use in treating an additional tumor type. Payments made subsequent to the March 2004 approval will be capitalized and amortized to cost of products sold over the remaining term of the agreement. Under the agreement, ImClone will receive a distribution fee based

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on a flat rate of 39% of product revenues in North America. The Company will purchase all of its commercial requirements for bulk ERBITUX\* from ImClone at a price equal to manufacturing cost plus 10%. For further discussion of this matter, see Item 8. Financial Statements Note 3. Alliances and Investments. Early termination is available based on material breach and is effective 60 days after notice of the material breach (and such material breach has not been cured or commencement of cure has not occurred). Upon termination or expiration of the alliance, the Company does not retain any rights to ERBITUX\*.

The Company is the exclusive distributor of ERBITUX\* in North America through OTN. Under the terms of an agreement with McKesson entered into in February 2004, 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.

Sankyo The Company has licensed a patent covering pravastatin, marketed by the Company in the U.S. as PRAVACHOL, from Sankyo Company, Ltd. of Japan (Sankyo), with the agreement expiring as exclusivity expires on a market-by-market basis. Exclusivity in the U.S. under the patent (including pediatric extension) lasts until April 2006. Under the terms of the license, the Company may market and sell pravastatin throughout the world, excluding Japan, Korea, Taiwan and Thailand (markets in which Sankyo retains exclusive patent rights). Sankyo also copromotes and comarkets pravastatin in certain European and Latin American countries. Early termination is available based on the other party's voluntary or involuntary bankruptcy and material breach. The amount of notice required for early termination of the strategic alliance is immediately upon notice in the case of either voluntary or involuntary bankruptcy and 90 days after notice in the case where a material breach has occurred (and not been cured or commencement of cure has not occurred). Upon termination or expiration of the alliance, the Company does not retain any patent or other exclusivity rights in relation to pravastatin.

In 2003, the Company entered into the following significant alliances for products in clinical development:

Corgentech On October 13, 2003, the Company and Corgentech Inc., a biopharmaceutical company, entered into an agreement to jointly develop and commercialize Corgentech's E2F Decoy (edifoligide sodium), a novel treatment for the prevention of vein graft failure following coronary artery bypass graft and peripheral artery bypass graft surgery. In the U.S. the parties co-promote the product and the agreement will continue, and the parties will share profit or loss, for so long as either party is engaged in the manufacture, use or sale of the product in such country. In the rest of the world where Corgentech receives royalties, the right of Corgentech to receive royalties expires on a country-by-country basis upon the later of (i) 10 years from the first commercial sale of such product in such country, and (ii) expiration of the last to expire valid claim of an issued Corgentech patent covering the manufacture, use or sale of such product in such country. The agreement may be terminated early (i) by the Company, with or without cause, at any time and as to any country, upon six months' prior notice, or (ii) if material breach has occurred and not been cured within 90 days after notice of breach has been provided (such termination is limited only to those countries affected by the material breach). Upon termination of the alliance, in the event of the Company's material breach or in the event the Company terminates the alliance without cause, the Company does not retain any rights to the product. The product is currently in Phase III clinical trials and the FDA has granted fast track status for both indications. The Company made and expensed an initial payment of \$45 million in October 2003, with the potential for an additional \$205 million in clinical and regulatory milestone payments over time, and arrangements for profit sharing.

Flamel Technologies S.A. On August 27, 2003, the Company entered into an exclusive license agreement with Flamel Technologies S.A. to develop and market BASULIN, the first controlled release, unmodified human insulin to be developed as a once-daily injection for patients with type 1 or type 2 diabetes. The agreement expires on the later of (i) 10 years from the first commercial sale or (ii) the expiration of the last Flamel patent right on a country-by-country basis. BASULIN has entered Phase II clinical development. Either party has the right to terminate the agreement based on the other party's material breach or voluntary or involuntary bankruptcy. Early termination is also available, in the Company's sole discretion for scientific, technical, medical, regulatory or commercial reasons. The amount of notice required for early termination of the strategic alliance is immediately upon notice in the case of voluntary bankruptcy, 60 days in the case where an involuntary

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bankruptcy petition has been filed (and not been dismissed), 60 days after notice where a material breach has occurred (and not been cured or commencement of cure has not occurred) and 90 days after notice where termination is for scientific, technical, medical, regulatory or commercial reasons. Under the agreement, the Company will lead and assume the cost of future development and manufacturing efforts for BASULIN and will have exclusive worldwide rights to the product. The Company paid and expensed \$20 million in October 2003, with the potential for an additional \$145 million in clinical and regulatory milestone payments over time, and royalty payments on product sales.

For information on alliances relating to drug discovery, see [Research and Development](#) below.

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**Table of Contents***Oncology Therapeutics Network Segment*

OTN is a leading specialty distributor of oncology drugs, supportive care products and related supplies to office-based oncologists in the United States. The wholesale market for cancer pharmaceuticals in the United States has seen a shift from the administration of chemotherapy almost exclusively in the hospital setting to increased administration of chemotherapy in physicians' offices outside the hospital. Hospital-based oncologists are typically served by drug wholesalers, who provide daily deliveries of large quantities of pharmaceutical products, including oncology drugs and related supplies, to hospital pharmacies. Hospital-based oncologists rely on hospital pharmacies to order, receive and inventory drugs as well as to maintain clinical drug information. Office-based oncologists, lacking a hospital pharmacy and related services and support, generally face significant administrative burdens when ordering, stocking and paying for oncology drugs and related supplies. OTN's objective is to address the cost containment needs and reduce the administrative burdens of office-based oncologists by attempting to serve as a convenient, cost-effective, single source of supply of oncology drugs and related supplies, to reduce inventory and other associated carrying costs, to increase the productivity of the oncology office, and to provide reliable, customer-oriented service. OTN contracts with individual healthcare providers as well as certain professional organizations, which negotiate discounts and terms on behalf of member healthcare providers.

OTN provides a full range of oncology products and supplies from a variety of manufacturers, eliminating the need for its customers to interact with multiple suppliers. OTN's product catalog has over 2,700 line items from over 190 manufacturers. However, as is characteristic of the U.S. market for oncology pharmaceuticals, a small number of products account for a majority of OTN's 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. OTN sales accounted for 11% of the Company's net sales in 2003, 10% of the Company's net sales in 2002 and 8% of the Company's net sales in 2001. The dollar volume of products shipped by OTN in 2003 was \$2,241 million compared to \$1,900 million in 2002 and \$1,433 million in 2001. Sales could be negatively affected by new Medicare legislation that could impact oncologists and their treatment patterns as reimbursement levels have been reduced. For further discussion of the new Medicare legislation, see [Government Regulation and Price Constraints](#) below.

*Nutritionals Segment*

The Nutritionals segment, through Mead Johnson, manufactures, markets, distributes and sells infant formulas and other nutritional products, including the entire line of ENFAMIL products. In 2002, the Company commenced sales of ENFAMIL LIPIL, the first infant formula in the United States to contain the nutrients DHA (docosahexaenoic acid) and ARA (arachidonic acid). The Company obtains these nutrients from a sole provider under a licensing and supply arrangement. 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.

The Company's Nutritionals products are generally sold by wholesalers and retailers and are promoted primarily to healthcare professionals. The Company also promotes Nutritionals products directly to consumers worldwide through advertising. The Company manufactures these products in the United States and in seven foreign countries. Nutritionals sales accounted for 10% of the Company's sales in 2003, 2002 and 2001. Domestic Nutritionals sales accounted for 54% of total Nutritionals sales in 2003, 53% of total Nutritionals sales in 2002 and 57% of total Nutritionals sales in 2001, while international Nutritionals sales accounted for 46% of total Nutritionals sales in 2003, 47% of total Nutritionals sales in 2002 and 43% of total Nutritionals sales in 2001. Approximately one-half of U.S. sales of infant formula are subject to rebates issued under the Women, Infants and Children (WIC) program. Sales subject to WIC rebates have much lower margins than those of non-WIC sales.

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Net sales of selected products and product categories in the Nutritionals segment were as follows:

	<b>2003</b>	<b>Restated 2002</b>	<b>Restated 2001</b>
	<u>          </u>	<u>          </u>	<u>          </u>
	<b>(dollars in millions)</b>		
ENFAMIL / ENFALAC	\$ 808	\$ 746	\$ 753
NUTRAMIGEN	138	127	139
Children's Nutritional	421	383	308

On December 13, 2003, as part of its strategy to focus on infant and children's nutrition, Mead Johnson agreed to sell its Adult Nutritional business to Novartis Nutrition Corporation, a business unit of Novartis AG. Mead Johnson Adult Nutritional brands involved in the sale include BOOST, a complete oral nutritional beverage, ISOCAL, an isotonic tube-feeding formula, and ULTRACAL, a general tube-feeding formula. In 2003, Adult Nutritional products recorded sales of over \$200 million. Under the terms of the agreement, Mead Johnson sold to Novartis the finished goods inventory, brands, trademarks, patents and intellectual

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property rights of the Mead Johnson global adult medical nutrition business for \$385 million including \$20 million contingent on a product conversion and a \$22 million upfront payment for a supply agreement. Mead Johnson will continue to manufacture and supply the majority of the sold products. The transaction closed in February 2004 and a pre-tax gain of approximately \$290 million is expected to be recorded in the first quarter of 2004.

### *Other Healthcare Segment*

The Other Healthcare segment consists of ConvaTec, Medical Imaging and Consumer Medicines (North America and Japan). Other Healthcare sales accounted for 8% of the Company's sales in 2003, 9% of the Company's sales in 2002 and 7% of the Company's sales in 2001. Domestic Other Healthcare sales accounted for 55% of total Other Healthcare sales in 2003, 57% of total Other Healthcare sales in 2002 and 51% of total Other Healthcare sales in 2001, while international Other Healthcare sales accounted for 45% of total Other Healthcare sales in 2003, 43% of total Other Healthcare sales in 2002 and 49% of total Other Healthcare sales in 2001.

### *ConvaTec*

ConvaTec manufactures, distributes and sells ostomy and modern wound and skin care products. Principal brands of ConvaTec include NATURA, SUR-FIT, ESTEEM, AQUACEL and DUODERM. These products are marketed worldwide, primarily to hospitals, the medical profession and medical suppliers. The Company mainly relies on an internal sales force, and sales are made through various distributors around the world. The Company manufactures these products in the United States and the United Kingdom.

ConvaTec sales accounted for approximately 4% of the Company's sales in each of 2003, 2002 and 2001. Domestic ConvaTec sales accounted for 33% of total ConvaTec sales in 2003 and 34% of total ConvaTec sales in 2002 and in 2001, while international ConvaTec sales accounted for 67% of total ConvaTec sales in 2003 and 66% of total ConvaTec sales in 2002 and in 2001.

The Company announced in January 2004 that it has agreed to acquire Acordis Speciality Fibres (Acordis), a privately held company based in the United Kingdom that licenses patent rights and supplies materials to ConvaTec for its Wound Therapeutics line. The transaction is subject to regulatory approval which has not been received. If the transaction is completed, the Company expects to record an in-process research and development charge between \$50 to \$70 million.

### *Medical Imaging*

Medical Imaging manufactures, distributes and sells cardiovascular imaging products including radiopharmaceuticals and ultra-sound agents. Principal brands of Medical Imaging include CARDIOLITE and DEFINITY. These products are marketed through an internal sales force and sold worldwide, primarily to radiopharmacies, hospitals, clinics and the medical profession, using a small and concentrated network of radiopharmacies for distribution. In connection with the Company's international business, Medical Imaging owns certain radiopharmacies outside the United States. CARDIOLITE is covered by a series of patents that claim its components. The patent coverage differs somewhat on a country-by-country basis. In the United States, these patents expire between December 2004 and 2008, and the Company's currently expected year of basic exclusivity loss is 2008. In the EU, these patents expire between December 2006 through 2008. In Japan, these patents expire between August 2006 and 2008. The Company manufactures these products in the United States and Puerto Rico.



Medical Imaging was purchased as part of the DuPont Pharmaceuticals acquisition, which closed on October 1, 2001. Medical Imaging sales accounted for 2% of the Company's sales in 2003, 3% of the Company's sales in 2002 and 1% of the Company's sales in 2001. Domestic Medical Imaging sales accounted for 85% of total Medical Imaging sales in 2003, 84% of total Medical Imaging sales in 2002 and 86% of total Medical Imaging sales in 2001, while international Medical Imaging sales accounted for 15% of total Medical Imaging sales in 2003, 16% of total Medical Imaging sales in 2002 and 14% of total Medical Imaging sales in 2001. On January 1, 2004, the Company entered into a new license and supply agreement with Cardinal Health Nuclear Pharmacy Services, which provides Cardinal the right to sell CARDIOLITE from its licensed pharmacy locations.

#### *Consumer Medicines*

Consumer Medicines manufactures, distributes and sells over-the-counter health care products. Principal consumer health care brands include the EXCEDRIN brand of products for headache relief, BUFFERIN analgesics, COMTrex for cold, cough and flu, and the KERI line of moisturizers. In addition, the Company began marketing its ChoiceDM line of diabetic care products in August 2003. These products are generally sold to retailers and promoted primarily to consumers in the United States and Japan through advertising. These products are manufactured in the United States, Puerto Rico and Japan.

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Consumer Medicines sales accounted for 2% of the Company's sales in each of 2003, 2002 and 2001. North American Consumer Medicines sales accounted for 67% of Consumer Medicines sales in 2003, 68% of Consumer Medicines sales in 2002 and 72% of Consumer Medicines sales in 2001, while Consumer Medicines sales in Japan accounted for 28% of Consumer Medicines sales in 2003 and in 2002 and 24% of Consumer Medicines sales in 2001.

## **Sources and Availability of Raw Materials**

In general, Bristol-Myers Squibb purchases its raw materials in the open market. Substantially all such materials are obtainable from a number of sources, and the loss of any one source of supply would not likely have a material adverse effect on the Company. For further discussion of sourcing, see "Manufacturing and Quality Assurance" below and discussions of particular products.

## **Manufacturing and Quality Assurance**

The Company seeks to design and operate its manufacturing facilities and maintain inventory in a way that will allow it to meet all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. Pharmaceutical production processes are complex, highly regulated and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures and regulatory approvals. For further discussion of the regulatory impact on the Company's manufacturing, see "Government Regulation and Price Constraints" below.

Pharmaceutical manufacturing facilities require significant ongoing capital investment for both maintenance and to comply with increasing regulatory requirements. In addition, as the Company adds to its product line and realigns its focus, the Company expects to close, partially close or modify many of its existing facilities and devote substantial resources in excess of historical levels to convert its facilities or to meet heightened processing standards that may be required for sterile or newly introduced products, in particular biologics. Biologics manufacturing involves more complex processes than those of traditional pharmaceutical operations. Although the Company does have the capacity to manufacture biologics for clinical trials and commercial launch, its capacity to manufacture larger commercial volumes of these products is limited. As biologics become more important to the Company's product portfolio, the Company may continue to make arrangements with third-party manufacturers or may make substantial investments in facilities to increase and maintain its capacity to produce biologics on a commercial scale.

The Company relies on third parties to manufacture, or to supply it with active ingredients necessary for it to manufacture certain products, including PRAVACHOL, PLAVIX, ABILIFY\*, COUMADIN, PARAPLATIN, SUSTIVA, TAXOL®, TEQUIN and VIDEX/VIDEX EC. To maintain a stable supply of these products, the Company takes a variety of actions designed to ensure that there is an adequate safety stock of these ingredients held by the third-party supplier, Bristol-Myers Squibb or both, so that the Company's manufacturing operations are not interrupted. As an additional protection, in some cases, the Company takes steps to maintain an approved back-up source where available.

The Company relies on ImClone to supply ERBITUX\* (cetuximab) for all of its bulk requirements for commercial use in North America and Japan. ImClone is currently seeking, with the Company's support, FDA approval to manufacture ERBITUX\* at ImClone's manufacturing facility in Somerville, New Jersey. ImClone has contracted with Lonza Biologics plc (Lonza) to act as the manufacturer of cetuximab for commercial launch and Cardinal Health, Inc. (Cardinal) will provide the finishing. There can be no assurance that ImClone will be granted regulatory approval to manufacture ERBITUX\*, or that such approval will occur before the supply of cetuximab obtained from Lonza is exhausted.

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The Company also expects to rely on Lonza to manufacture ABATACEPT (CTLA4Ig) and LEA29Y on a commercial scale if these products are commercialized. ABATACEPT (CTLA4Ig) and LEA29Y are investigational biologics compounds in late stage development. The Company has not made any filings with the FDA seeking approval for Lonza to manufacture or for the Company to market and sell these products, and there can be no assurance that regulatory approval of either of these products will be obtained. However, the Company has entered into an agreement with Lonza to reserve a portion of Lonza's biologics manufacturing capacity for the Company's future requirements of these products if regulatory approval is obtained. Under the terms of the agreement, the Company has minimum purchase requirements and will be obligated to pay Lonza a one-time termination fee if these products do not obtain regulatory approval. For additional information about ABATACEPT and LEA29Y, see Research and Development below.

If the Company or any third-party manufacturer that the Company relies on for existing or future products is unable to maintain a stable supply of products, operate at sufficient capacity to meet its order requirements, comply with government regulations for manufacturing pharmaceuticals or meet the heightened processing requirements for biologics, the Company's business performance and prospects could be negatively impacted. Additionally, if the Company or any of its third-party suppliers were to experience extended plant shutdowns or substantial unplanned increases in demand or suspension of manufacturing for regulatory reasons, the Company could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

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In connection with divestitures, licensing arrangements or distribution agreements of certain of the Company's pharmaceuticals or in certain other circumstances, the Company has entered into agreements under which the Company has agreed to supply such products to third parties. In addition to liabilities that could arise from the Company's failure to supply such products under the agreements, these arrangements could require the Company to invest in facilities for the production of non-strategic products, result in additional regulatory filings and obligations or cause an interruption in the manufacturing of its own products.

The Company's success depends in great measure upon customer confidence in the quality of its products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of the Company's operations, including research and development, purchasing, facilities planning, manufacturing, and distribution. The Company maintains quality-assurance procedures relating to the quality and integrity of scientific information and production processes.

Control of production processes involves rigid specifications for ingredients, equipment and facilities, manufacturing methods, processes, packaging materials, and labeling. The Company performs tests at various stages of production processes and on the final product to assure that the product meets all regulatory requirements and the Company's standards. These tests may involve chemical and physical chemical analyses, microbiological testing, or a combination of these along with other analyses. Quality control is provided by business unit/site quality assurance groups that monitor existing manufacturing procedures and systems used by the Company, its subsidiaries and third-party suppliers.

## **Intellectual Property and Product Exclusivity**

The Company owns or is licensed under a number of patents in the United States and foreign countries primarily covering its pharmaceutical products. The Company has also developed many brand names and trademarks for products in all areas. The Company considers the overall protection of its patent, trademark, license and other intellectual property rights to be of material value and acts to protect these rights from infringement.

In the pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. When market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the product's sales. The rate of this decline varies by country and by therapeutic category. For a discussion of how generic versions of a product can impact that product's sales, see "Generic Competition" below.

A product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovative drug is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory intellectual property rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the United States, the EU and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. Regulatory intellectual property rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients.

Regulatory intellectual property rights are independent of any patent rights that the Company may possess and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

The Company assesses the likely market exclusivity period for each of its products on a case-by-case basis. It is not possible to predict the length of market exclusivity for any of the Company's products with certainty because of the complex interaction between patent and regulatory forms of exclusivity, and inherent uncertainties about the enforceability of certain intellectual property rights. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that the Company currently anticipates. The Company expects to have continued exclusivity challenges over the next several years. For further discussion of these exclusivity challenges, see Pharmaceuticals Segment above and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Outlook for 2004 below.

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In addition to patents and regulatory forms of exclusivity, the Company also holds intellectual property in the form of trademarks, on products such as EXCEDRIN, ENFAMIL, THERAGRAN, KERI and BUFFERIN. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Specific aspects of the law governing market exclusivity for pharmaceuticals vary from country to country. The following summarizes key exclusivity rules in markets representing significant Company sales:

### *United States*

A company seeking to market an innovative pharmaceutical in the United States must file a complete set of safety and efficacy data to the FDA. The type of application filed depends on whether the drug is a chemical (a small molecule) or a biological product (a large molecule). If the innovative pharmaceutical is a chemical, the company files a NDA. If the medicine is a biological product, a Biologics License Application is filed. The type of application filed affects regulatory exclusivity rights.

A competitor seeking to launch a generic substitute of a chemical innovative drug in the United States must file an Abbreviated New Drug Application (ANDA) with the FDA. In the ANDA, the generic manufacturer needs to demonstrate only bioequivalence between the generic substitute and the approved NDA drug. The ANDA relies upon the safety and efficacy data previously filed by the innovator in its NDA.

Medicines approved under an NDA can receive several types of regulatory data protection. An innovative chemical pharmaceutical (also known as a new chemical entity) is entitled to five years of regulatory data protection, during which an ANDA cannot be filed with the FDA. If an innovator's patent is challenged, as described below, the generic manufacturer may file its ANDA after the fourth year of the five-year data protection period. A pharmaceutical drug product that contains an active ingredient that has been previously approved in an NDA, but is approved in a new formulation or for a new indication on the basis of new clinical trials, receives three years of data protection. Finally, an NDA that is designated as an Orphan Drug, which is a drug that gains an indication for treatment of a condition that occurs only rarely in the United States, can receive seven years of exclusivity for the orphan indication. During this time period neither NDAs nor ANDAs for the same drug product can be approved for the same orphan use.

Because a significant portion of patent life can be lost during the time it takes to obtain regulatory approval, the innovator can extend one patent to compensate the innovator for the lost patent term, at least in part. More specifically, the innovator may identify one patent, which claims the product or its approved method of use, and, depending on a number of factors, may extend the expiration of that patent. There are two limits to these extensions. First, the maximum a patent can be extended is 5 years, and second, the extension cannot cause the patent to be in effect for more than 14 years from the date of NDA approval.

A company may also earn six months of additional exclusivity for a drug where specific clinical trials are conducted at the written request of the FDA to study the use of the medicine to treat pediatric patients, and submission to the FDA is made prior to the loss of basic exclusivity. This six-month period extends all forms of exclusivity (patent and regulatory) that are listed with the FDA at the time the studies are completed and submitted to the FDA.

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Currently, generic versions of biological products cannot be approved under U.S. law; however, the FDA is taking steps toward allowing generic versions of biologics, and these laws could change in the near future. Competitors seeking approval of biological products must file their own safety and efficacy data.

Beyond the minimum period of regulatory exclusivity provided by U.S. law, many (but not all) innovative drugs are also covered by patents held by the NDA sponsor.

The innovator company is required to list certain of its patents covering the medicine with the FDA in what is commonly known as the Orange Book. Absent a successful patent challenge, the FDA cannot approve an ANDA until after the innovator's listed patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA and allege that one or more of the patents listed in the Orange Book under an innovator's NDA is either invalid or not infringed. This allegation is commonly known as a Paragraph IV certification. The innovator then must choose whether to file suit against the generic manufacturer to protect its patents. If one or more of the NDA-listed patents are successfully challenged, or if the innovator chooses not to sue, the first filer of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity as against all other generic manufacturers. From time to time ANDAs, including Paragraph IV certifications, are filed with respect to certain of the Company's products. The Company evaluates these ANDAs on a case-by-case basis and, where warranted, files suit against the generic manufacturer to protect its patent rights.

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Several recent developments in the United States have increased the likelihood of generic challenges to innovators' intellectual property, and thus, increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. For a discussion of one such litigation related to patent challenges by generic companies, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies PLAVIX\* Litigation. This is a reflection of the statutory incentive to challenge patents' six months of semi-exclusivity in certain situations as described above. Second, new statutory and regulatory provisions in the United States limit the ability of an innovator company to prevent generic drugs from being approved and launched while patent litigation is ongoing. Third, the FDA is actively considering abbreviated regulatory approval processes for drugs that are similar to, but not generic copies of, innovative drugs. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular Company product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. For more information about new legislation, see Government Regulation and Price Constraints below.

### *European Union*

In the EU, most innovative pharmaceuticals are entitled to ten years of regulatory data protection if marketing approval is obtained via the centralized procedure. Consequently, regardless of whether or not the innovative medicine is covered by patents, generic copies relying on the innovator's data usually cannot be approved for a minimum of ten years after approval. For innovative pharmaceuticals that gain marketing approval using the non-centralized mutual recognition procedure, this period is six or ten years depending on the individual EU member state. However, regardless of regulatory exclusivity, competitors may obtain approval of an identical product on the basis of their own safety and efficacy data at any time. For more information regarding the regulation of pharmaceutical products in the EU, see Government Regulation and Price Constraints below.

Patents on pharmaceutical products are generally enforceable in the EU. However, in contrast to the United States, patents are not listed with regulatory authorities. Generic copies can be approved after data protection expires, regardless of whether the innovator holds patents covering its drug. Thus, it is possible that an innovator may be seeking to enforce its patents against a generic competitor that is already marketing its product. Also, the European patent system has an opposition procedure in which generic manufacturers may challenge the validity of patents covering innovator products within nine months of grant. As in the United States, patents in the EU may be extended to compensate for the patent term lost during the regulatory review process. Such extensions are granted on a country-by-country basis.

In general, EU law treats chemically synthesized drugs and biologically derived drugs the same with respect to intellectual property and market exclusivity.

### *Japan*

In Japan, medicines of new chemical entities are entitled to six years of protection for approved indications and dosage. Patents on pharmaceutical products are enforceable. Generic copies can receive regulatory approval after data protection and patent expirations. As in the United States, patents in Japan may be extended to compensate for the patent term lost during the regulatory review process.

In general, Japanese law treats chemically synthesized and biologically derived drugs the same with respect to intellectual property and market exclusivity.



*Rest of World*

In countries outside of the United States, the EU and Japan, there is a wide variety of legal systems with respect to intellectual property and market exclusivity of pharmaceuticals. Most other developed countries utilize systems similar to either the United States (e.g., Canada) or the EU (e.g., Switzerland). Among less developed countries, some have adopted patent laws and/or regulatory exclusivity laws, while others have not. Some less developed nations have formally adopted laws in order to comply with World Trade Organization (WTO) commitments, but have not taken steps to implement these laws in a meaningful way. Enforcement of WTO obligations is a long process, and there is no assurance of the outcome. Thus, in assessing the likely future market exclusivity of the Company's innovative drugs in less developed countries, the Company takes into account not only formal legal rights but political and other factors as well.

**Marketing, Distribution and Customers**

In the Company's Pharmaceuticals segment and in its ConvaTec and Medical Imaging businesses, the Company promotes its products in medical journals and directly to health care providers such as doctors, nurse practitioners, physician assistants, pharmacists, hospitals, Pharmacy Benefit Managers (PBMs), Managed Care Organizations (MCOs) and government agencies. The Company also markets directly to consumers in the United States through direct-to-consumer print, radio and television advertising. In addition, the Company sponsors general advertising to educate the public about its innovative medical research. For a discussion of the regulation of promotion and marketing of pharmaceuticals, see Government Regulation and Price Constraints below.

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Through the Company's sales and marketing organizations, the Company explains the approved uses and advantages of its products to medical professionals. The Company works to gain access to health authority, PBM and MCO formularies (lists of recommended or approved medicines and other products) and reimbursement lists by demonstrating the qualities and treatment benefits of its products. The Company also works with MCOs and PBMs to assist them with disease management, patient education and other tools that benefit patients by improving their medical treatment routines.

Marketing of prescription pharmaceuticals is limited to the approved uses of the particular product, but the Company continues to develop information about its products and provides such information in response to inquiries from doctors and other medical professionals. All drugs must complete clinical trials required by regulatory authorities to show they are safe and effective for treating one or more medical problems. A manufacturer may choose, however, to undertake additional studies, including comparative clinical trials with competitive products, to demonstrate additional advantages of a compound. Those studies can be costly and take years to complete, and the results are uncertain. Balancing these considerations makes it difficult to decide whether and when to undertake such additional studies. But, when they are successful, such studies can have a major impact on approved marketing claims and strategies.

The Company's operations include several pharmaceutical sales organizations. Each sales organization markets a distinct group of products and is typically based on particular therapeutic areas or physician groups. These sales organizations often focus on selling new products when they are introduced, and marketing to physicians is increasingly targeted at specialists and high value primary care physicians.

The Company's prescription pharmaceutical products are sold principally to wholesalers, but the Company also sells directly to retailers, hospitals, clinics, government agencies and pharmacies. In 2003, sales to three pharmaceutical wholesalers in the United States, McKesson Corporation (McKesson), Cardinal and AmerisourceBergen Corporation (AmerisourceBergen) accounted for approximately 15%, 12% and 12%, respectively, of the Company's total net sales. In 2002, sales to AmerisourceBergen and McKesson each accounted for approximately 14% of the Company's total net sales and sales to Cardinal accounted for 13% of the Company's total net sales. In 2001, sales to AmerisourceBergen, Cardinal and McKesson each accounted for approximately 14% of the Company's total net sales. Sales to these U.S. wholesalers were concentrated in the Pharmaceuticals segment. Apart from these instances, none of the Company's business segments is dependent on any one customer or group of related customers.

The Company experienced a substantial buildup of wholesaler inventories in its U.S. pharmaceuticals business over several years, primarily in 2000 and 2001. This buildup was primarily due to sales incentives offered by the Company to its wholesalers. These incentives were generally offered towards the end of a quarter in order to incentivize wholesalers to purchase products in an amount sufficient to meet the Company's quarterly sales projections established by the Company's senior management. In April 2002, the Company disclosed this substantial buildup of wholesaler inventories in its U.S. pharmaceuticals business, and developed and subsequently undertook a plan to work down in an orderly fashion these wholesaler inventory levels by reducing the amount of sales made by the Company to wholesalers relative to the amount of sales made by wholesalers to customers thereby reducing the inventories of the Company's products held by wholesalers. For further discussion see

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Restatement of Previously Issued Financial Statements. In 2003, the Company took steps intended to moderate investment buying by U.S. pharmaceutical wholesalers, which can result in sales fluctuations unrelated to consumer demand. In 2003, the Company entered into new inventory management agreements (IMAs) with AmerisourceBergen, Cardinal, McKesson and other wholesalers. The agreements have terms of 2 years, cancelable by either parties after 1 year. The IMAs generally establish limits on inventory levels of BMS pharmaceutical products held by the wholesalers, permit limited buy-ins of BMS pharmaceutical products by the wholesalers after price increases, at pre-price increase prices and require the wholesalers to provide the Company with data in association with the wholesalers' sales and inventory levels of BMS pharmaceutical products.

OTN acts as BMS's exclusive sales distributor for BMS oncology products to office-based oncologists. OTN believes that its extensive customer base, coupled with its overall competitive pricing and customer service, make it attractive to drug manufacturers that wish to serve the office-based oncologist community through a focused distribution channel. OTN provides services to manufacturers that include support for product launch, customer specific marketing programs, data services and rapid market research. In 2001, the Company entered into an agreement with McKesson under which McKesson acts as the exclusive distributor of pharmaceutical products to OTN. Under the terms of the

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agreement, McKesson provides warehousing, packing, shipping, purchasing and inventory management and administrative support services for BMS products and other pharmaceutical products, which are marketed, promoted and sold by OTN. OTN recognizes revenue under the terms of the McKesson agreement using the consignment model as described in Item 8. Financial Statements Note 1. Accounting Policies, Revenue Recognition.

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

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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.

For information on sales and marketing of consumer medicines and nutritionals, see [Nutritionals Segment](#) and [Other Healthcare Segment Consumer Medicines](#) above.

## **Competition**

The markets in which Bristol-Myers Squibb competes are generally broad-based and highly competitive. The principal means of competition vary among product categories and business groups.

The Company's Pharmaceuticals segment competes with other worldwide research-based drug companies, many smaller research companies with more limited therapeutic focus and generic drug manufacturers. Important competitive factors include product efficacy, safety and ease of use, price and demonstrated cost-effectiveness, marketing effectiveness, product labeling, service and research and development of new products and processes. Sales of the Company's products can be impacted by new studies that indicate a competitor's product has greater efficacy for treating a disease or particular form of disease than one of the Company's products. The Company's sales also can be impacted by additional labeling requirements for better tolerability, safety or convenience that may be imposed on its products by the FDA or by similar regulatory agencies in different countries. If competitors introduce new products and processes with therapeutic or cost advantages, the Company's products can be subject to progressive price reductions or decreased volume of sales, or both. For example, in the growing market for statins, which reduce cholesterol, PRAVACHOL, the Company's largest product by net sales (\$2.8 billion), competes with established brands and new entrants of several of the world's largest pharmaceutical companies. 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 of 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 reduces the incidence 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.

To successfully compete for business with managed care and pharmacy benefits management organizations, the Company must often demonstrate that its products offer not only medical benefits but also cost advantages as compared with other forms of care. Most new products that the Company introduces must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. In certain countries outside the United States, patent protection is weak or nonexistent and the Company must compete with generic versions shortly after it launches its innovative product.

Many other companies, large and small, manufacture and sell one or more products that are similar to those marketed by the Company's Nutritionals and Other Healthcare segments. Sources of competitive advantage include product quality and efficacy, brand identity, advertising and promotion, product innovation, broad distribution capabilities, customer satisfaction and price. Significant expenditures for advertising, promotion and marketing are generally required to achieve both consumer and trade acceptance of these products.

The Company believes its long-term competitive position depends upon its success in discovering and developing innovative, cost-effective products that serve unmet medical needs, together with its ability to manufacture the products efficiently and to market them effectively in a highly competitive environment. There can be no assurance that the Company's research and development efforts will result in commercially successful products or that its products or processes will not become outmoded from time to time as a result of products or processes developed by its competitors.

*Managed Care Organizations*

The growth of MCOs in the United States has been a major factor in the competitive make-up of the healthcare marketplace. Over half the U.S. population now participates in some version of managed care. Because of the size of the patient population covered by MCOs, marketing of prescription drugs to them and the PBMs that serve many of those organizations has become important to the Company's business. MCOs can include medical insurance companies, medical plan administrators, health-maintenance organizations, alliances of hospitals and physicians and other physician organizations. Those organizations have been consolidating into fewer, even larger entities, enhancing their purchasing strength and importance to the Company.

A major objective of MCOs is to contain and, where possible, reduce health care expenditures. They typically use formularies, volume purchases and long-term contracts to negotiate discounts from pharmaceutical providers. MCOs and PBMs typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their generally lower cost, generic medicines are often favored. The breadth of the products covered by formularies can vary considerably from one MCO to another, and many formularies include alternative and competitive products for treatment of particular medical problems. MCOs use a variety of means to encourage patients' use of products listed on their formularies.

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Exclusion of a product from a formulary can lead to its sharply reduced usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their products included. Where possible, companies compete for inclusion based upon unique features of their products, such as greater efficacy, better patient ease of use or fewer side effects. A lower overall cost of therapy is also an important factor. Products that demonstrate fewer therapeutic advantages must compete for inclusion based primarily on price. The Company has been generally, although not universally, successful in having its major products included on MCO formularies.

### *Generic Competition*

One of the biggest competitive challenges that the Company faces in the United States and internationally is from generic pharmaceutical manufacturers. Upon the expiration or loss of market exclusivity on a product, the Company can lose the major portion of sales of that product in a very short period of time. In the United States, the FDA approval process exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, and allows generic manufacturers to rely on the safety and efficacy of the pioneer product. Therefore, generic competitors operate without the Company's large research and development expenses and its costs of conveying medical information about the product to the medical community. For more information about market exclusivity, see Intellectual Property and Product Exclusivity above.

The rate of sales decline of a product after the expiration of exclusivity varies by country. In general, the decline in the U.S. market is more rapid than in most other developed countries. Also, the declines in developed countries tend to be more rapid than in less developed countries.

The rate of sales decline after the expiration of exclusivity has also historically been influenced by product characteristics. For example, drugs that are used in a large patient population (e.g., those prescribed by primary care physicians) tend to experience more rapid declines than drugs in specialized areas of medicine (e.g., oncology). Drugs that are more complex to manufacture (e.g., sterile injectable products) usually experience a slower decline than those that are simpler to manufacture.

As noted above, MCOs that focus primarily on the immediate cost of drugs often favor generics over brand-name drugs. Many governments also encourage the use of generics as alternatives to brand-name drugs in their health care programs. Laws in the United States generally allow, and in some cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be therapeutically equivalent to a brand-name drug. The substitution must be made unless the prescribing physician expressly forbids it. These laws and policies provide an added incentive for generic manufacturers to seek marketing approval as the automatic substitution removes the need for generic manufacturers to incur the sales and marketing costs, which innovators must incur.

### **Research and Development**

The Company invests heavily in research and development because it believes it is critical to its long-term competitiveness. Pharmaceutical research and development is carried out by the Bristol-Myers Squibb Pharmaceutical Research Institute, which has major facilities in Princeton, Hopewell and New Brunswick, New Jersey and Wallingford, Connecticut. Pharmaceutical research and development is also carried out at various other facilities in the United States and in Belgium, Canada, France, and the United Kingdom. Management continues to emphasize leadership, innovation, productivity and quality as strategies for success in the Pharmaceutical Research Institute.

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The Company spent \$2,279 million in 2003, \$2,206 million in 2002 and \$2,157 million in 2001 on Company sponsored research and development activities. Company sponsored pharmaceutical research and development spending (including certain payments under third-party collaborations and contracts), as a percentage of Pharmaceutical sales, was 14.2% in 2003, compared with 16.5% in 2002 and 15.5% in 2001. At the end of 2003, the Company employed approximately 7,000 people in research and development throughout the Company, including 5,300 in the Pharmaceutical Research Institute, including a substantial number of physicians, scientists holding graduate or postgraduate degrees and higher skilled technical personnel.

The Company concentrates its pharmaceutical research and development efforts in the following ten disease areas: Affective (psychiatric) Disorders, Alzheimer s/Dementia, Atherosclerosis/Thrombosis, Diabetes, Hepatitis, HIV/AIDS, Obesity, Oncology, Rheumatoid Arthritis and Related Diseases and Solid Organ Transplant. However, the Company continues to analyze and selectively pursue promising leads in other therapeutic areas. In addition to discovering and developing new chemical compounds, the Company looks for ways to expand the value of existing products through new uses and formulations that can provide additional benefits to patients.

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To supplement the Company's internal efforts, the Company collaborates with independent research organizations, including educational institutions and research-based pharmaceutical and biotechnology companies, and the Company contracts with others for the performance of research in their facilities. The Company uses the services of physicians, hospitals, medical schools and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of new products. The Company actively seeks out investments in external research and technologies that hold the promise to complement and strengthen its own research efforts. These investments can take many forms, including licensing arrangements, codevelopment and comarketing agreements, copromotion arrangements and joint ventures.

Drug development is time-consuming, expensive and risky. In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through preclinical tests and controlled clinical evaluation. Before a new drug may be marketed in the United States, recorded data on preclinical and clinical experience are included in the NDA or the Biological Product License Application (BPLA) to the FDA for the required approval. The development of certain other products is also subject to government regulations covering safety and efficacy in the United States and many foreign countries. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed for any particular disease indication.

On average, only about one in ten thousand chemical compounds discovered by pharmaceutical industry researchers proves to be both medically effective and safe enough to become an approved medicine. The process from discovery to regulatory approval typically takes ten years or longer. Drug candidates can fail at any stage of the process, and even late-stage product candidates sometimes fail to receive regulatory approval. The Company believes its investments in research, both internally and in collaboration with others, have been rewarded by the number of new pharmaceutical compounds and indications it has in all stages of development.

Bristol-Myers Squibb's drug discovery program includes many alliances and collaborative agreements. These agreements bring new products into the pipeline or help the company remain on the cutting edge of technology in the search for novel medicines. For example, in December 2003, the Company formed a partnership with Lexicon Genetics Incorporated (Lexicon) expiring in December 2006 to develop drugs in the field of depression, anxiety, schizophrenia, pain and Alzheimer's disease. Under the terms of the agreement, Lexicon will contribute the products of 13 of its drug discovery programs and the alliance will give the Company exclusive access to discoveries in the neurological sciences field from a Lexicon gene analysis program known as Genome5000. Lexicon received an upfront payment of \$36 million from Bristol-Myers Squibb in the fourth quarter of 2003 (which was expensed by the Company) and will receive a minimum of \$30 million in research funding over the first three years of the agreement. Bristol-Myers Squibb has the option to extend part of the agreement for another two years until December 2008 in return for providing additional research funding of up to \$50 million. Lexicon will receive further funding for each novel drug developed under the alliance, and it will earn royalties on sales of any drugs commercialized by Bristol-Myers Squibb. On December 18, 2003, the Company also announced the extension and expansion of its oncology research collaboration with Exelixis, Inc. (Exelixis) under which the two companies will continue to identify and validate molecular targets implicated in the genesis of cancer. The original agreement was established for a three-year term in July 2001. Under the terms of the extended collaboration, BMS provided Exelixis with an upfront payment of \$3 million and increased annual research funding and milestone payments on certain cancer targets arising from the collaboration. Exelixis and Bristol-Myers Squibb agreed to extend their collaboration until December 2006, and Bristol-Myers Squibb has the right to continue the collaboration until July 2009. The goal of the extension is to increase the total number and degree of validation of cancer targets that Exelixis will deliver to the Company. Exelixis and Bristol-Myers Squibb will each maintain the option to obtain exclusive worldwide rights to equal numbers of validated targets arising from the collaboration.

Listed below are several investigational compounds that the Company has in the later stages of development. All of these compounds are in or entering Phase IIb or Phase III clinical trials. Whether or not any of these investigational compounds ultimately becomes one of the Company's marketed products depends on the results of pre-clinical and clinical studies, the competitive landscape of the potential product's market and the manufacturing processes necessary to produce the potential product on a commercial scale. The Company expects to file for FDA approval of ABATACEPT (CTLA4Ig), Entecavir and Muraglitazar in 2004 or early 2005. However, as noted above, there can be no assurance that the Company will seek regulatory approval of any of these compounds or that, if such approval is sought, it will be obtained. At this stage of development, the Company cannot determine all intellectual property issues or all the patent protection that may, or may not, be available for these investigational compounds. The patent coverage highlighted below does not include potential term extensions.





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ABATACEPT	CTLA4Ig, a biological product which has been developed internally and is currently in Phase III clinical trials, is a fusion protein with novel immunosuppressive activity targeted initially at rheumatoid arthritis. The Company has a series of patents covering CTLA4Ig and its method of use. The latest of the composition of matter patents expires in the United States in 2016. Repligen Corporation (Repligen) has a patent that claims the use of CTLA4Ig to treat specific autoimmune diseases, including rheumatoid arthritis. Litigation concerning the inventorship of CTLA4Ig is also ongoing. For more information about this litigation, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.
Entecavir	Entecavir, which has been developed internally and is currently in Phase III clinical trials, is a potent and selective inhibitor of hepatitis B virus. The Company has a composition of matter patent that expires in the United States in 2010.
E2F Decoy	Edifoligide, which is being developed jointly with Corgentech and is entering Phase III clinical trials, is a novel treatment for the prevention of vein graft failure following coronary artery bypass graft and peripheral artery bypass graft surgery. The Company has a license to Corgentech's numerous issued and pending patent applications that cover the product. Two such patents that have been issued in the United States expire in 2015.
Ixabepilone	Ixabepilone, an epothilone, which has been developed internally and is currently in Phase III clinical trials, is a novel tubulin inhibitor for multiple tumor types. The Company has a composition of matter patent in the United States that will expire in 2018.
Muraglitazar	Muraglitazar, which has been developed internally and is currently in Phase III clinical trials, is a dual PPAR agonist for the treatment of type 2 diabetes and other metabolic disorders. The Company has a composition-of-matter patent which expires in the United States in 2020.
LEA29Y	LEA29Y, a biological product, which is being developed internally and is currently in Phase IIb clinical trials, is a fusion protein with novel immunosuppressive activity targeted at solid organ transplant. The Company has pending patent applications in the United States, the EU and Japan covering LEA29Y.
Razaxaban	Razaxaban, which is currently in Phase IIb clinical trials, is a factor Xa inhibitor for the prevention of deep vein thrombosis. Razaxaban was acquired as part of the Company's acquisition of DuPont Pharmaceuticals and is being developed internally. The Company has a composition of matter patent which expires in the United States in 2018.

The Company's competitors also devote substantial funds and resources to research and development. In addition, the consolidation that has occurred in the Company's industry has created companies with substantial research and development resources. The extent to which the Company's competitors are successful in their research could result in erosion of the sales of its products and unanticipated product obsolescence.

**Government Regulation and Price Constraints**

The pharmaceutical industry is subject to extensive global regulation by regional, country, state and local agencies. The Federal Food, Drug, and Cosmetic Act (FDCA), other federal statutes and regulations, various state statutes and regulations, and laws and regulations of foreign governments govern to varying degrees the testing, approval, production, labeling, distribution, post-market surveillance, advertising, dissemination of information, and promotion of the Company's products. The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for required governmental approvals is extremely costly and can significantly delay product introductions in a given market. Promotion, marketing, manufacturing, and distribution of pharmaceutical products are extensively regulated in all major world markets. In addition, the Company's operations are subject to complex federal, state, local, and foreign environmental and occupational safety laws and regulations. The Company anticipates that the laws and regulations affecting the manufacture and sale of current products and the introduction of new products will continue to require substantial scientific and technical effort, time, expense and significant capital investment.

Of particular importance is the FDA in the United States. It has jurisdiction over virtually all of the Company's businesses and imposes requirements covering the testing, safety, effectiveness, manufacturing, labeling, marketing, advertising and post-



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marketing surveillance of the Company's pharmaceutical products. The FDA also regulates most of the Company's Nutritionals and Other Healthcare products. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States.

The Company's pharmaceutical products are subject to pre-market approval requirements in the United States. New drugs are approved under, and are subject to, the FDC Act and related regulations. Biological drugs are subject to both the FDC Act and the Public Health Service Act, known as the PHS Act, and related regulations. Biological drugs are licensed under the PHS Act.

The FDA mandates that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices (cGMP) established by the FDA. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that the product meets applicable specifications and other requirements to ensure product safety and efficacy. The FDA periodically inspects drug manufacturing facilities to ensure compliance with applicable cGMP requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Adverse experiences with the use of products must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The federal government has extensive enforcement powers over the activities of pharmaceutical manufacturers, including authority to withdraw product approvals, commence actions to seize and prohibit the sale of unapproved or non-complying products, to halt manufacturing operations that are not in compliance with cGMPs, and to impose or seek injunctions, voluntary recalls, and civil monetary and criminal penalties. Such a restriction or prohibition on sales or withdrawal of approval of products marketed by the Company could materially adversely affect its business, financial condition and results of operations.

Marketing authorization for the Company's products is subject to revocation by the applicable governmental agencies. In addition, modifications or enhancements of approved products or changes in manufacturing locations are in many circumstances subject to additional FDA approvals, which may or may not be received and which may be subject to a lengthy application process.

The distribution of pharmaceutical products is subject to the Prescription Drug Marketing Act, known as PDMA, as part of the FDC Act, which regulates such activities at both the federal and state level. Under the PDMA and its implementing regulations, states are permitted to require registration of manufacturers and distributors who provide pharmaceuticals even if such manufacturers or distributors have no place of business within the state. States are also permitted to adopt regulations limiting the distribution of product samples to licensed practitioners. The PDMA also imposes extensive licensing, personnel record keeping, packaging, quantity, labeling, product handling and facility storage and security requirements intended to prevent the sale of pharmaceutical product samples or other diversions.

The Company is also subject to the jurisdiction of various other federal and state regulatory and enforcement departments and agencies, such as the Federal Trade Commission (FTC), the Department of Justice and the Department of Health and Human Services in the United States. The Company is also licensed by the U.S. Drug Enforcement Agency to procure and produce controlled substances. The Company is, therefore, subject to possible administrative and legal proceedings and actions by those organizations. Such actions may result in the imposition of civil and criminal sanctions, which may include fines, penalties and injunctive or administrative remedies.

Various federal and state agencies have regulatory authority regarding the manufacture, storage, transportation and disposal of many Medical Imaging products because of their radioactive nature.

The Company's activities outside the United States are also subject to regulatory requirements governing the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of the Company's products. These regulatory requirements vary from country to country. In the EU, there are two ways that a company can obtain marketing authorization for a pharmaceutical product. The first route is the centralized procedure. This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, but also is available for certain new chemical compounds and products. A product that receives approval under the centralized procedure automatically receives approval in every member state of the EU. However, a company then must obtain pricing and reimbursement for the pharmaceutical product, which is typically subject to member state law. The pricing and reimbursement procedure can take months, and sometimes years, to obtain. The second route to obtain marketing authorization in the EU is the mutual recognition procedure. Applications are made to a single member state, and if the member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states. As set forth above, pricing and reimbursement of the product continues to be the subject of member state law.

Whether or not FDA approval or approval of the European Medicines Evaluation Agency has been obtained for a product, approval of the product by comparable regulatory authorities of countries outside of the United States or the EU, as the case may be,

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must be obtained prior to marketing the product in those countries. The approval process may be more or less rigorous from country to country and the time required for approval may be longer or shorter than that required in the United States. Approval in one country does not assure that such product will be approved in another country.

In most markets outside the United States, the Company operates in an environment of government-mandated, cost-containment programs. Several governments have placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and/or enacted across-the-board price cuts as methods of cost control. With the exception of Germany and the United Kingdom, no European country has market pricing for new medicines. Pricing freedom is limited in the United Kingdom by the operation of a profit control scheme and in Germany by the operation of a reference price system. Companies also face significant delays in market access for new products, and more than two years can elapse before new medicines become available on some national markets. Additionally, member states of the EU have regularly imposed new or additional cost containment measures for pharmaceuticals. In recent years, Italy, for example, has imposed mandatory price decreases.

The existence of price differentials within Europe due to the different national pricing and reimbursement laws leads to significant parallel trade flows.

In recent years, Congress and some state legislatures have considered a number of proposals and have enacted laws that could effect major changes in the health care system, either nationally or at the state level. Driven in part by budget concerns, Medicaid access and reimbursement restrictions have been implemented in some states and proposed in many others. Similar issues exist in many foreign countries where the Company does business.

On December 8, 2003, new Medicare legislation was enacted that provides outpatient prescription drug coverage to senior citizens in the United States. Under the legislation, an interim drug discount card program is scheduled to begin in June 2004, while the main drug benefit, eligibility for a stand-alone drug plan, is scheduled to begin in 2006. The new drug benefit will be administered regionally through private insurance plans or pharmacy benefit managers, and the law allows Medicare to negotiate directly with pharmaceutical companies in regions without a private drug benefit program. The legislation allows for the importation of less expensive prescription drugs from Canada, but only if the U.S. Health and Human Services Department certifies safety, which it has so far not done. There can be no assurance that this certification requirement will be maintained in future legislation or that the certification will continue to be withheld. The Company cannot predict the potential impact that this legislation will have on its business, because it is not clear how the law will be implemented by regulators or received by consumers and physicians. The impact will be negative for the Company's U.S. oncology business in 2004, as reimbursement levels have been reduced for certain oncology products administered in the outpatient setting, including PARAPLATIN. The impact could also be negative over the intermediate and longer term for the Company's U.S. pharmaceutical business generally as greater federal involvement and budget constraints may increase the likelihood of pricing pressures or controls in the future.

Federal and state governments also have pursued direct methods to reduce the cost of drugs for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid, to provide discounts for outpatient medicines purchased by certain Public Health Service entities and disproportionate share hospitals (hospitals meeting certain criteria), and to provide minimum discounts off of a defined non-federal average manufacturer price for purchases by certain components of the federal government such as the Department of Veterans Affairs and the Department of Defense.

In the United States, governmental cost-containment efforts have extended to the federally funded Special Supplemental Nutrition Program for WIC. All states participate in WIC and have sought and obtained rebates from manufacturers of infant formula whose products are used in the program. All states have conducted competitive bidding for infant formula contracts, which require the use of specific infant formula products by the state WIC program, unless a physician requests a non-contract formula for WIC customer. States participating in WIC are required to

engage in competitive bidding or to use another cost containment measure that yields savings equal to or greater than the savings generated by a competitive bidding system. Mead Johnson participates in this program and approximately 50% of its U.S. sales are subject to rebates under WIC.

Pending pharmaceutical legislation in the EU, which is expected to be adopted this year, will have an impact on the procedures for authorization of pharmaceutical products in the EU under both the centralized and mutual recognition procedures. In particular, the legislation contains new data protection provisions. All products (regardless of whether they have been approved under the centralized or the national/mutual recognition procedures) will be subject to an 8+2+1 regime. Eight years after the innovator has received its first community authorization for a medicinal product, a generic company may file a marketing authorization application for that product with the health authorities. However, the generic company may not commercialize the product until after either ten or eleven years have elapsed from the initial marketing authorization granted to the innovator. The possible one year extension is available if the innovator, during the first eight years of the marketing authorization, obtains an additional indication that is of significant clinical benefit in comparison with existing treatments. There is a transitional provision for these new data protection requirements, and it is expected that these provisions will apply as new innovator products are approved under the new legislation.

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In Japan, recently adopted regulations for the filing of new drugs effective July 2003 may streamline the filing process for international companies introducing new compounds in Japan by allowing some international clinical and non-clinical data to be used in the filing process. The planned merger of two Japanese pharmaceutical regulatory offices may also lead to gains in efficiency and timeliness of drug registration in Japan. However, the pricing policy for pharmaceuticals in Japan remains challenging due to bi-annual government mandated price reductions.

## **Environmental Regulation**

The Company's facilities and operations are subject to extensive U.S. and foreign laws and regulations relating to environmental protection and human health and safety, including those governing discharges of pollutants into the air and water, the use, management and disposal of hazardous, radioactive and biological materials and wastes, and the cleanup of contamination. Pollution controls and permits are required for many of the Company's operations, and these permits are subject to modification, renewal or revocation by the issuing authorities.

A corporate environment, health and safety group monitors operations around the world, providing the Company with an overview of regulatory requirements and overseeing the implementation of company standards for compliance. The Company also incurs operating and capital costs for such matters on an ongoing basis. The Company expended approximately \$60 million and \$55 million on capital environmental projects undertaken specifically to meet environmental requirements in 2002 and 2003, respectively, and expects to spend approximately \$50 million in 2004. Although the Company believes that it is in substantial compliance with applicable environmental, health and safety requirements and the permits required for its operations, the Company nevertheless could incur additional costs, including civil or criminal fines or penalties, clean-up costs, or third-party claims for property damage or personal injury, for violations or liabilities under these laws.

Many of the Company's current and former facilities have been in operation for many years, and, over time, the Company and other operators of those facilities have generated, used, stored or disposed of substances or wastes that are considered hazardous under environmental laws. As a result, the soil and groundwater at or under certain of these facilities is or may be contaminated, and the Company may be required to make significant expenditures to investigate, control and remediate such contamination. The Company is also potentially responsible for environmental conditions at a number of waste disposal or reprocessing facilities operated by third parties. Currently, the Company is involved in investigation or remediation activities at approximately 56 sites, and has been named as a potentially responsible party (PRP) under the U.S. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) at approximately 24 of these sites.

CERCLA and similar state statutes may impose liability for the entire cost of investigation or remediation of contaminated sites on any party, regardless of fault or ownership at the time of the disposal or release. Generally, where there are multiple potentially responsible parties, liability has been apportioned based on the nature and amount of hazardous substances disposed of by each party at the site and the number of financially viable parties.

Based on the Company's current estimates of cleanup costs and its expected share of financial responsibility, the Company does not expect expenditures in connection with CERCLA or other remediation matters to be material. Expenditures could rise in the future if substantial unknown contamination is discovered at one of the Company's current or former facilities, or if other PRPs fail to participate in cost-sharing at any site at which it has financial responsibility.

For additional information about these matters, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.



## **Employees**

Bristol-Myers Squibb employed approximately 44,000 people at December 31, 2003.

## **Foreign Operations**

The Company has significant operations outside the United States. They are conducted both through the Company's subsidiaries and through distributors, and involve three of the same business segments—Pharmaceuticals, Nutritionals and Other Healthcare—as the Company's U.S. operations.

Revenues from operations outside the United States of \$8.0 billion accounted for 38% of the Company's total revenues in 2003. In 2003, revenues exceeded \$500 million in each of France, Japan, Germany, Spain, Italy and Canada. No single country outside the United States contributed more than 10% of the Company's total revenues. For a geographic breakdown of net sales and year-end assets, see the table captioned Geographic in Item 8. Financial Statements Note 19. Segment Information and for further discussion of the Company's sales by geographic area see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Geographic Areas.

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International operations are subject to certain risks, which are inherent in conducting business abroad, including currency fluctuations, possible nationalization or expropriation, price and exchange controls, limitations on foreign participation in local enterprises and other restrictive governmental actions. The Company's international businesses are also subject to government-imposed constraints, including laws on pricing or reimbursement for use of products.

Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or reduce the reported dollar value of the Company's net assets and results of operations. In 2003, the change in foreign exchange rates had a net favorable impact on revenues. While the Company cannot predict with certainty future changes in foreign exchange rates or the effect they will have on it, the Company attempts to mitigate their impact through operational means and by using various financial instruments. See the discussion under Item 8. Financial Statements Note 18. Financial Instruments.

At December 31, 2003, approximately \$5.4 billion of cash, cash equivalents and marketable securities was held by the Company's foreign subsidiaries, 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 of this cash to the United States would require additional tax provisions, which are not reflected in the consolidated financial statements. For a further discussion of this matter, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Income Taxes.

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Bristol-Myers Squibb's world headquarters is located at 345 Park Avenue, New York, New York, where it leases approximately 406,000 square feet of floor space, approximately 215,000 square feet of which is sublet to others.

Bristol-Myers Squibb manufactures products at 38 major worldwide locations with an aggregate floor space of approximately 13,789,000 square feet. All facilities are owned by Bristol-Myers Squibb. The following table illustrates the geographic location of the Company's significant manufacturing facilities by business segment.

	<u>Total Company</u>	<u>Pharmaceuticals</u>	<u>Nutritionals</u>	<u>Other Healthcare</u>
United States	13	8	3	2
Europe, Middle East and Africa	12	10	1	1
Other Western Hemisphere	6	5	1	
Pacific	7	4	3	
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total</b>	<b>38</b>	<b>27</b>	<b>8</b>	<b>3</b>
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

Portions of these facilities and other facilities owned or leased by Bristol-Myers Squibb in the United States and elsewhere are used for research, administration, storage and distribution. For further information about the Company's facilities, see Item 1. Business Manufacturing and Quality Assurance.

**Item 3. LEGAL PROCEEDINGS.**

Information pertaining to legal proceedings can be found in Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies and is incorporated by reference herein.

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

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2003.

**Table of Contents****PART IA****Executive Officers of the Registrant**

Listed below is information on executive officers of the Company as of March 11, 2004. Executive officers are elected by the Board of Directors for an initial term, which continues until the first Board meeting following the next annual meeting of stockholders and thereafter are elected for a one-year term or until their successors have been elected. All executive officers serve at the pleasure of the Board of Directors.

<b><u>Name and Current Position</u></b>	<b><u>Age</u></b>	<b><u>Employment History for the Past 5 Years</u></b>
Lamberto Andreotti  <i>Senior Vice President and President International</i>  <i>Member of the Executive Committee</i>	53	1998 to 1999 Vice President and General Manager of Italy & Oncology Europe, a division of the company.  1999 to 2000 Senior Vice President and General Manager of Italy, CEEI & European Oncology, a division of the Company.  2000 to 2002 - President, Europe.  2002 to present Senior Vice President and President International.
Harrison M. Bains, Jr.  <i>Vice President, Tax and Treasury, Corporate Staff</i>	60	1989 to 2002 Vice President and Treasurer, Corporate Staff of the Company.  2002 to 2002 Vice President, Acting Chief Financial Officer, Corporate Staff of the Company.  2002 to present Vice President, Tax & Treasury, Corporate Staff of the Company.
Stephen E. Bear  <i>Senior Vice President, Human Resources,</i>  <i>Corporate Staff</i>  <i>Member of the Executive Committee</i>	52	1998 to 1999 - Vice President, Strategic Business Development, Worldwide Beauty Care/Nutritionals & Medical Devices, Corporate Staff of the Company.  1999 to 2001 - Vice President, Marketing and Business Development of the New York Botanical Gardens, a non-profit organization.  2001 to present Senior Vice President, Human Resources, Corporate Staff of the Company.
Andrew G. Bodnar, M.D.  <i>Senior Vice President, Strategy and</i>  <i>Medical &amp; External Affairs, Corporate Staff</i>  <i>Member of the Executive Committee</i>	56	1998 to 1999 Vice President, Strategic Business Development, Worldwide Medicines Group, a division of the Company.  1999 to 2000 Vice President, Corporate Development, Worldwide Medicines Group, a division of the Company.  2000 to 2001 Vice President, Medical and External Affairs, Corporate Staff of the Company.

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		2001 to 2002	Senior Vice President, Medical and External Affairs, Corporate Staff of the Company.
		2002 to present	Senior Vice President, Strategy and Medical & External Affairs, Corporate Staff of the Company.
Andrew R. J. Bonfield	41	1998 to 1999	Deputy Finance Director SmithKline Beecham PLC.
<i>Senior Vice President and Chief Financial Officer, Corporate Staff</i>		1999 to 2000	Chief Financial Officer, SmithKline Beecham PLC.
<i>Member of the Executive Committee</i>		2000 to 2002	Executive Director, Finance, BG Group PLC.
		2002 to present	Senior Vice President and Chief Financial Officer, Corporate Staff of the Company.
Wendy L. Dixon, Ph.D	48	1996 to 2001	Vice President, Marketing, Merck & Co.
<i>Chief Marketing Officer and President, Global Marketing</i>		2001 to 2001	Senior Vice President, Merck & Co.
<i>Member of the Executive Committee</i>		2001 to present	Chief Marketing Officer and President, Global Marketing, Worldwide Medicines Pharmaceuticals Group, a division of the Company.

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<u>Name and Current Position</u>	<u>Age</u>	<u>Employment History for the Past 5 Years</u>
Peter R. Dolan <i>Chairman of the Board and Chief Executive Officer</i> <i>Member of the Executive Committee</i>	48	1998 to 2000 Senior Vice President, Strategy and Organizational Effectiveness, Corporate Staff of the Company. 2000 to 2001 President and Director of the Company. 2001 to present Chairman of the Board and Chief Executive Officer of the Company.
Donald J. Hayden <i>Executive Vice President and President, Americas</i> <i>Member of the Executive Committee</i>	48	1998 to 2000 Senior Vice President and President, Worldwide Medicines Group, a division of the Company. 2000 to 2001 Executive Vice President, e-Business & Strategy, Corporate Staff of the Company. 2001 to 2001 Executive Vice President, e-Business & Strategy, Investor Relations and Corporate Intelligence, Corporate Staff of the Company. 2001 to 2002 Executive Vice President, Health Care Group. 2002 to 2002 Executive Vice President and President, North America Medicines. 2002 to present Executive Vice President and President, Americas.
Anthony C. Hooper <i>President, U.S. Pharmaceuticals</i> <i>Member of the Executive Committee</i>	49	1999 to 2000 Vice President and General Manager, Northern Europe, International Medicines. 2000 to 2001 President, Asia-Pacific, Middle East & Southern Africa, International Medicines. 2001 to 2002 President, Intercontinental, International Medicines. 2002 to 2004 President, Europe, ME & Africa, Worldwide Medicines Group. 2004 to present President, U.S. Pharmaceuticals, Worldwide Medicines Group.
Tamar D. Howson <i>Senior Vice President, Corporate Development, Corporate Staff</i> <i>Member of the Executive Committee</i>	55	1998 to 2000 Senior Vice President and Director, Business Development of SmithKline Beecham Corporation. 2000 to 2001 biotechnology consultant to chief executive officers and other business executives. 2001 to present Senior Vice President, Corporate Development, Corporate Staff of the Company.
Paul W. Karr <i>Vice President and Financial Controller,</i>	49	1995 to 2003 Deputy Controller, GE Capital Services. 2003 to 2003 Senior Vice President and Chief Accounting Officer, GE Capital Markets Services.

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<i>Corporate Staff</i>		2003 to present	Vice President and Financial Controller, Corporate Staff of the Company.
Sandra Leung	43	1997 to 1999 -	Associate Counsel, Corporate Staff of the Company.
<i>Vice President and Corporate Secretary,</i>		1999 to 1999	Counsel, Corporate Staff of the Company.
<i>Corporate Staff</i>		1999 to 2002	Corporate Secretary, Corporate Staff of the Company.
		2002 to present	Vice President and Corporate Secretary, Corporate Staff of the Company.

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<u>Name and Current Position</u>	<u>Age</u>	<u>Employment History for the Past 5 Years</u>
<p>John L. McGoldrick</p> <p><i>Executive Vice President and General Counsel, Corporate Staff</i></p> <p><i>Member of the Executive Committee</i></p>	63	<p>1998 to 2000 General Counsel and Senior Vice President, Corporate Staff of the Company and President, Medical Devices Group, a division of the Company.</p> <p>2000 to 2001 Executive Vice President and General Counsel, Corporate Staff of the Company and President, Medical Devices Group, a division of the Company.</p> <p>2001 to present Executive Vice President and General Counsel, Corporate Staff of the Company.</p>
<p>James B. D. Palmer M.D., F.R.C.P.</p> <p><i>Chief Scientific Officer, Corporate Staff</i></p> <p><i>and President, Pharmaceutical Research Institute</i></p> <p><i>Member of the Executive Committee</i></p>	50	<p>1998 to 2000 Senior Vice President and Director, Group Medical Regulatory and Product Strategy, Glaxo Wellcome Research and Development.</p> <p>2000 to 2002 Senior Vice President, New Product Development, GlaxoSmith Kline.</p> <p>2002 to present Chief Scientific Officer, Corporate Staff of the Company and President, Pharmaceutical Research Institute, a division of the Company.</p>
<p>Elliott Sigal, M.D., Ph.D.</p> <p><i>Senior Vice President, Global Clinical and Pharmaceutical Development, Pharmaceutical Research Institute</i></p> <p><i>Member of the Executive Committee</i></p>	52	<p>1997 to 1999 Vice President, Applied Genomics, Pharmaceutical Research Institute, a division of the Company.</p> <p>1999 to 2001 Senior Vice President, Early Discovery and Applied Technology, Pharmaceutical Research Institute, a division of the Company.</p> <p>2001 to 2002 Senior Vice President, Drug Discovery &amp; Exploratory Development, Pharmaceutical Research Institute, a division of the Company.</p> <p>2002 to present Senior Vice President, Global Clinical and Pharmaceutical Development, Pharmaceutical Research Institute, a division of the Company.</p>
<p>John L. Skule</p> <p><i>Senior Vice President, Corporate and Environmental Affairs, Corporate Staff</i></p> <p><i>Member of the Executive Committee</i></p>	60	<p>1998 to present Senior Vice President, Corporate and Environmental Affairs, Corporate Staff of the Company.</p>



**Table of Contents****PART II****Item 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS.****Market Prices**

Bristol-Myers Squibb common and preferred stocks are traded on the New York Stock Exchange and the Pacific Exchange, Inc. (symbols: BMY; BMYPR). A quarterly summary of the high and low market prices is presented below:

Common:

	2003		2002	
	High	Low	High	Low
First Quarter	\$ 25.41	\$ 21.13	\$ 51.30	\$ 39.50
Second Quarter	28.86	21.85	40.40	25.14
Third Quarter	27.60	25.17	26.17	20.55
Fourth Quarter	28.60	24.25	27.84	21.05

Preferred:

	2003		2002	
	High	Low	High	Low
First Quarter	*	*	*	*
Second Quarter	\$ 398.00	\$ 398.00	*	*
Third Quarter	433.00	430.00	*	*
Fourth Quarter	429.50	429.50	\$ 460.00	\$ 460.00

\* During the first, second and third quarters of 2002 and the first quarter of 2003, there were no trades of the Company's preferred stock. The preferred stock pays a quarterly dividend of \$.50 per share.

 **Holders of Common Stock**

The number of record holders of common stock at December 31, 2003 was 96,752.

The number of record holders is based upon the actual number of holders registered on the books of Bristol-Myers Squibb at such date and does not include holders of shares in street names or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

**Voting Securities and Principal Holders**

Reference is made to the 2004 Proxy Statement to be filed on or before March 26, 2004 with respect to voting securities and principal holders, which is incorporated herein by reference and made a part hereof in response to the information required by this Item 5.

**Dividends**

Dividends declared per share in 2003 and 2002 were:

	2003		2002	
	High	Low	High	Low
First Quarter	\$ .28	\$ .28	\$ .50	\$ .50
Second Quarter	.28	.28	.50	.50
Third Quarter	.28	.28	.50	.50
Fourth Quarter	.28	.28	.50	.50
	<b>\$ 1.12</b>	<b>\$ 1.12</b>	<b>\$ 2.00</b>	<b>\$ 2.00</b>

In December 2003, the Board of Directors of the Company declared a quarterly dividend of \$.28 per share on the common stock of the Company, which was paid on February 2, 2004 to shareholders of record as of January 2, 2004.

**Table of Contents****Item 6. SELECTED FINANCIAL DATA.**

The Five-Year Financial Summary set forth in this Item 6 has been revised to reflect the restatement. For a discussion of the restatement, see Item 8. Financial Statements. Note 2. Restatement of Previously Issued Financial Statements for Years Ended December 31, 2002 and 2001.

**Five-Year Financial Summary**

<b>Income Statement Data:</b> <sup>(1)</sup>	<b>2003</b>	<b>Restated 2002</b>	<b>Restated 2001</b>	<b>Restated 2000<sup>(2)</sup></b>	<b>Restated 1999<sup>(2)</sup></b>
	(in millions, except per share data)				
Net Sales	\$ 20,894	\$ 18,106	\$ 18,044	\$ 17,519	\$ 16,491
Earnings from Continuing Operations Before Minority Interest and Income Taxes	4,694	2,761	2,263	5,263	4,733
Earnings from Continuing Operations	3,106	2,067	1,871	3,686	3,664
Earnings from Continuing Operations per Common share:					
Basic	\$ 1.60	\$ 1.07	\$ .96	\$ 1.87	\$ 1.85
Diluted	\$ 1.59	\$ 1.06	\$ .95	\$ 1.85	\$ 1.81
Average common shares outstanding					
Basic	1,937	1,936	1,940	1,965	1,984
Diluted	1,950	1,942	1,965	1,997	2,027
Dividends paid on common and preferred stock	\$ 2,169	\$ 2,168	\$ 2,137	\$ 1,930	\$ 1,707
Dividends declared per Common Share	\$ 1.12	\$ 1.12	\$ 1.11	\$ 1.01	\$ .89
<b>Financial Position Data at December 31:</b> <sup>(3)</sup>					
Total Assets	\$ 27,471	\$ 25,022	\$ 27,864	\$ 17,924	\$ 17,310
Cash and cash equivalents	2,444	2,367	4,552	3,085	2,646
Marketable securities	3,013	1,622	1,102	300	311
Long-term debt	8,522	6,261	6,237	1,336	1,342
Stockholders' Equity	9,786	8,756	8,762	7,634	7,538

(1) The Company recorded several items that affected the comparability of results, which are set forth in the table under Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Earnings for the years 2003, 2002 and 2001. For a discussion of these items, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Net Sales, Item 8. Financial Statements Note 3. Alliances and Investments, Note 4. Restructuring and Other Items, Acquisitions and Divestitures and Note 6. Discontinued Operations.

(2) The 2003 Restatement adjustments affecting the years 2000 and 1999 are set forth in the following table:

(3) Includes discontinued operations for the years 1999 and 2000.

<b>2000</b>		<b>1999</b>	
<b>As Previously Reported</b>	<b>As Restated</b>	<b>As Previously Reported</b>	<b>As Restated</b>

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				(dollars in millions)
Net Sales	\$ 17,538	\$ 17,519	\$ 16,502	\$ 16,491
Earnings from Continuing Operations	3,830	3,686	3,423	3,664
Earnings from Continuing Operations per Common Share:				
Basic	\$ 1.95	\$ 1.87	\$ 1.73	\$ 1.85
Diluted	\$ 1.92	\$ 1.85	\$ 1.69	\$ 1.81
Financial Position Data (at December 31):				
Total Assets	\$ 17,756	\$ 17,924	\$ 17,101	\$ 17,310
Stockholder s Equity	7,888	7,634	7,644	7,538

The 2003 Restatement adjustments affecting the years 2000 and 1999 are adjustments with respect to net sales, intercompany foreign exchange gains and losses, international pension and employee benefit plan accruals, income taxes and other restatement items, as described in Item 8. Financial Statements Note 2. Restatement of Previously Issued Financial Statements.

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**Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*The Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in this Item 7 has been revised to reflect the restatement.*

**Summary**

For 2003, the Company reported annual global sales of \$20.9 billion. Sales increased 15% from the prior year level, reflecting volume increases of 9%, net price increases of 2%, and a 4% impact from foreign exchange fluctuations. U.S. sales increased 14%, partly due to the impact on 2002 sales from the workdown of non-consignment wholesaler inventory, while international sales increased 18%, including a 10% favorable foreign exchange impact. In 2003, the Company had two product lines with sales of over \$2.0 billion each - PRAVACHOL and PLAVIX\*. PRAVACHOL sales grew 25%, including a 7% favorable foreign exchange impact, to \$2.8 billion, and PLAVIX\* sales grew 31%, including a 3% favorable foreign exchange impact, to \$2.5 billion. In addition to these two products, the Company had 45 product lines with more than \$50 million each in annual sales, including 29 product lines with more than \$100 million each in annual sales, of which six had annual sales in excess of \$500 million each.

Earnings from continuing operations before minority interest and income taxes increased 70% to \$4,694 million in 2003 from \$2,761 million in 2002. Net earnings from continuing operations were \$3,106 million, or \$1.60 and \$1.59 per share on a basic and diluted basis, respectively, compared to \$2,067 million, or \$1.07 and \$1.06 per share each on a basic and diluted basis in 2002. 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 2003 and 2002, as discussed below under Earnings and Outlook for 2004.

At December 31, 2003, the Company held almost \$5.5 billion in cash, cash equivalents, and marketable securities. Approximately \$5.4 billion of such cash, cash equivalents, and marketable securities were held by the Company's foreign subsidiaries, 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. For a further discussion of this matter, see Critical Accounting Policies - Income Taxes below.

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 8. Financial Statements - Note 22. Legal Proceedings and Contingencies.

Long-term debt increased to \$8.5 billion at December 31, 2003 from \$6.3 billion at December 31, 2002 primarily due to the \$1.0 billion of fixed rate notes and \$1.2 billion of floating rate convertible debentures issued in August 2003 and October 2003, respectively. The proceeds from these issuances were used to repay short-term borrowings and fund the cash needs of the U.S. operations. Cash provided from operating activities was \$3.5 billion in 2003, and working capital was \$4.4 billion at December 31, 2003. The Company paid dividends of approximately \$2.2 billion, which provided a dividend yield of 4.4% in 2003.

In 2003, consistent with the Company's mission to extend and enhance human life by developing the highest-quality products, the Company invested \$2.3 billion in research and development, a 3% growth over 2002. Research and development dedicated to pharmaceutical products, including milestone payments for in-licensing and development programs, was \$2.1 billion and as a percentage of Pharmaceutical sales was 14.2% compared to 16.5% in 2002. The compound annualized growth in pharmaceutical research and development spending was 9% over the past five years.

#### **Restatement of Previously Issued Financial Statements**

The Company is restating its consolidated balance sheet at December 31, 2002, and consolidated statements of earnings, cash flows, and comprehensive income and retained earnings for the years ended December 31, 2002 and 2001, and its financial statements for the first, second and third quarters of 2003, including comparable interim periods in 2002 (the 2003 Restatement). The restatement affects periods prior to 2001. The impact of the restatement on such prior periods is reflected as an adjustment to opening retained earnings as of January 1, 2001. The restatement is reported in this Annual Report on Form 10-K for the year ended December 31, 2003 and will be reported in amendments to our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2003, June 30, 2003, and September 30, 2003. The 2003 Restatement (i) corrects certain of the Company's historical accounting policies to conform to U.S. generally accepted accounting principles (GAAP) and (ii) corrects certain errors made in the application of GAAP.

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As previously disclosed, the Company experienced a substantial buildup of wholesaler inventories in its U.S. pharmaceuticals business over several years, primarily in 2000 and 2001. This buildup was primarily due to sales incentives offered by the Company to its wholesalers. These incentives were generally offered towards the end of a quarter in order to incentivize wholesalers to purchase products in an amount sufficient to meet the Company's quarterly sales projections established by the Company's senior management. In April 2002, the Company disclosed this substantial buildup, and developed and subsequently undertook a plan to work down in an orderly fashion these wholesaler inventory levels by reducing the amount of sales made by the Company to wholesalers relative to the amount of sales made by wholesalers to customers thereby reducing the inventories of the Company's products held by wholesalers.

In late October 2002, based on further review and consideration of the previously disclosed buildup of wholesaler inventories in the Company's U.S. pharmaceuticals business and the incentives offered to certain wholesalers, and on advice from the Company's independent auditors, PricewaterhouseCoopers LLP, the Company determined that it was required to restate its sales and earnings to correct errors in timing of revenue recognition for certain sales to certain U.S. pharmaceuticals wholesalers. Since that time, the Company has undertaken an analysis of its transactions and incentive practices with U.S. pharmaceuticals wholesalers. The Company determined that certain incentivized transactions with certain wholesalers should be accounted for under the consignment model rather than recognizing revenue for such transactions upon shipment. This determination involved evaluation of a variety of criteria and a number of complex accounting judgments. As a result of its analysis, the Company determined that certain of its previously recognized U.S. sales to Cardinal Health, Inc. (Cardinal) and McKesson Corporation (McKesson), two of the largest wholesalers for the U.S. pharmaceuticals business, should be accounted for under the consignment model, based in part on the relationship between the amount of incentives offered to these wholesalers and the amount of inventory held by these wholesalers.

Following that determination, the Company also determined that it would correct its historical accounting policies to conform the accounting to GAAP and known errors made in the application of GAAP that were previously not recorded because in each such case the Company believed the amount of any such error was not material to the Company's consolidated financial statements. In addition, as part of the restatement process, the Company investigated its accounting practices in areas that involve significant judgments and determined to restate additional items with respect to which the Company concluded errors were made in the application of GAAP, including revisions of inappropriate accounting.

Senior management set aggressive targets for each of the Company's businesses. The errors and inappropriate accounting which are corrected by the restatement arose, at least in part, from a period of unrealistic expectations for, and consequent over-estimation of the anticipated performance of, certain of the Company's products and programs.

In March 2003, the Company completed the restatement of its financial statements for these items and restated its financial statements for the three years ended December 31, 2001, including the corresponding interim periods, and the first and second quarters of 2002, including comparable prior interim periods in 2001 (the 2002 Restatement).

After completing the 2002 Restatement, the Company continued to identify and implement actions to improve the effectiveness of its disclosure controls and procedures and internal controls over financial reporting. In connection with this effort, the Company (i) has substantially strengthened the organization and personnel of the senior financial and control functions, (ii) adopted more rigorous policies and procedures with respect to its balance sheet review process, (iii) focused its internal audit function on financial reporting controls, (iv) engaged a consultant to assist in the evaluation and documentation of certain financial reporting and disclosure processes throughout the Company, in particular with respect to designing standard operating procedures and implementing tools to ensure that disclosure issues are effectively identified, managed and controlled globally and (v) engaged a 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 addition, at the request of the Company's Audit Committee, the Company's independent auditors performed more extensive procedures with respect to the Company's interim financial information during 2003 and, based on the auditors' assessment of the Company's risk profile, expanded the scope and amount of field work to be performed for certain areas in connection with its audit of the Company for 2003. These actions contributed significantly to the Company identifying additional errors relating to prior periods not reflected in the 2002 Restatement. For a discussion of the individual restatement adjustments, see Item 8. Financial Statements Note 2. Restatement of Previously Issued Financial Statements for Years Ended December 31,

2002 and 2001.

In connection with their audits of the 2002 Restatement and the Company's consolidated financial statements for the year ended December 31, 2002, the Company's independent auditors, PricewaterhouseCoopers LLP (PwC), identified and communicated to the Company and the Audit Committee two material weaknesses (as defined under standards established by the American Institute of Certified Public Accountants) relating to lack of adequate resources and processes to ensure timely identification and recognition of matters to be considered in connection with the determination of the appropriate accounting and public financial reporting of significant matters and to lack of processes to ensure proper initial recording and management review and oversight of certain accounting matters, including certain liabilities and other income and expense items. In addition, at that time, PwC identified and communicated to the Company and its Audit Committee a reportable condition (as defined under standards established by the American Institute of Certified Public Accountants) relating to the Company's internal controls over its financial reporting for income



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taxes. In 2003, as described above in the preceding paragraph, the Company dedicated substantial resources to improving its controls over its accounting and financial disclosure and reporting, and the auditors have not identified material weaknesses in connection with their audit of the 2003 financial statements. In addition, the Company has devoted substantial resources towards remedying the reportable condition in relation to taxes. The Company also retained a consultant to assist in a comprehensive and detailed review of certain aspects of its tax accounting and reporting. The Company examined its financial reporting for taxes in each significant jurisdiction where the Company or one of its subsidiaries was subject to tax. As a result of this review, a number of prior period errors were identified, which are reflected in the 2003 Restatement. In addition, the Company undertook a review to evaluate certain issues that had been raised concerning the manner in which the Company determined its provision for income taxes. The Company has determined that prior to 2000 there were certain inappropriate adjustments to tax contingency reserves made for the improper purpose of recording a provision for income taxes consistent with the Company's projected effective tax rate. In addition, there may have been inappropriate adjustments in 2001 and 2002. The Company has completed a review and has not been able to determine whether or not any of the errors relating to its tax contingency reserves being corrected in the restatement are related to inappropriate accounting. In connection with the audit of the Company's consolidated financial statements for the year ended December 31, 2003, PwC has advised the Company and its Audit Committee that the reportable condition in the income tax accounting area remains, and the Company expects to complete remediation of this reportable condition by the end of 2004.

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 and other accounting issues referenced above. 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. In the fourth quarter of 2003, the Company established a reserve of \$150 million in relation to these investigations and litigation related to the wholesaler inventory issues and other accounting issues referenced above and other matters, all as discussed in Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies Other Securities Matters. It is not possible at this time to reasonably assess the final outcome of these litigations and investigations or reasonably to estimate possible loss or range of loss with respect to these litigations and investigations. In accordance with GAAP, the Company has determined that the \$150 million amount represents the minimum expected probable loss and that eventual losses related to these matters may exceed this reserve and the further impact of these matters could be material. As previously disclosed, management continues to believe 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.

Throughout Management's Discussion and Analysis of Financial Condition and Result of Operations, all referenced amounts for prior periods and prior period comparisons reflect the balances and amounts on a restated basis.

**Net Sales**

Sales in 2003 were \$20.9 billion, an increase of 15% from the prior year. The increase in sales in 2003 is driven by volume, which increased over 2002 levels, partly due to the impact on 2002 sales from the workdown of non-consignment wholesaler inventory. U.S. sales increased 14% to \$12,897 million in 2003 compared to a decrease of 4% to \$11,348 million in 2002, while international sales increased 18% to \$7,997 million in 2003, including a 10% favorable foreign exchange impact, compared to an increase of 8% to \$6,758 million in 2002 (with no significant foreign exchange impact). 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. Sales in 2002 were \$18.1 billion compared with \$18.0 billion in 2001, an increase of 1%. Sales in 2002 and 2001 included approximately \$1,540 million and \$331 million, respectively, of sales related to products acquired as part of the DuPont Pharmaceuticals acquisition (DuPont Pharmaceuticals), which was completed on October 1, 2001. Domestic sales in 2002 decreased 4% to \$11,348 million, while international sales increased 8% to \$6,758 million in 2002 (foreign exchange had no significant impact).

The composition of the net increase in sales is as follows:

	<u>2003</u>	<u>Restated 2002</u>
Volume	9%	3%
Selling prices, net	2%	(3%)
Foreign exchange	4%	
	<u>          </u>	<u>          </u>
Increase in sales	15%	
	<u>          </u>	<u>          </u>

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A significant portion of the Company's U.S. pharmaceuticals sales is made to wholesalers. The Company experienced a substantial buildup of wholesaler inventories in its U.S. pharmaceuticals business over several years, primarily in 2000 and 2001. This buildup was primarily due to sales incentives offered by the Company to its wholesalers, including discounts, buy-ins in anticipation of price increases, and extended payment terms to certain U.S. pharmaceuticals wholesalers. These were generally offered toward the end of a quarter as an incentive to wholesalers to purchase products in an amount sufficient to meet the Company's quarterly sales projections established by the Company's senior management. In April 2002, the Company disclosed this substantial buildup of wholesaler inventories in its U.S. pharmaceuticals business, and developed and subsequently undertook a plan to work down in an orderly fashion these wholesaler inventory levels by reducing the amount of sales made by the Company to wholesalers relative to the amount of sales made by wholesalers to customers thereby reducing the inventories of the Company's products held by wholesalers.

The timing of the Company's recognition of revenue from its sales to wholesalers differs by wholesaler and by period. Historically, the Company recognized revenue for sales upon shipment of products to its customers. Under GAAP, revenue is recognized when substantially all the risks and rewards of ownership have transferred. 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 should be 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 incentive arrangements 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. For additional discussion of the Company's revenue recognition policy, see Item 8. Financial Statements Note 1. Accounting Policies.

In the 2002 Restatement, the Company restated its previously issued financial statements for the period 1999 through the second quarter of 2002 to correct the timing of revenue recognition for certain previously recognized U.S. pharmaceuticals sales to Cardinal Health, Inc. (Cardinal) and McKesson Corporation (McKesson), two of the largest wholesalers for the Company's U.S. pharmaceuticals business, that, based on the application of the criteria above, were recorded in error at the time of shipment and should have been accounted for using the consignment model.

At December 31, 2003 and 2002, 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 \$4 million and \$58 million, respectively, of which approximately \$2 million and \$1 million at December 31, 2003 and 2002, respectively, related to oncology products sold through the Oncology Therapeutics Network (OTN). The deferred revenue, recorded at gross invoice sales price, related to the inventory of pharmaceutical products accounted for using the consignment model was approximately \$76 million and \$470 million at December 31, 2003 and 2002, respectively, of which approximately \$64 million and \$39 million at December 31, 2003 and 2002, respectively, related to OTN. As a result of the restatement for the application of the consignment model, approximately \$1,980 million of sales (excluding OTN and net of discounts, rebates and other adjustments) had been reversed from the period 1999 through 2001, of

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which approximately \$321 million and \$1,397 million were recognized in 2003 and 2002, respectively, as consigned inventory held by Cardinal and McKesson was worked down. This reversal reduced the amount of previously reported pre-tax earnings from 1999 through 2001 by approximately \$1,587 million. A significant portion of the 2003 workdown was recognized in the first quarter. The corresponding effect on earnings from continuing operations before minority interest and income taxes was an increase of \$237 million and \$1,095 million in 2003 and 2002, respectively. Sales to Cardinal and McKesson represented approximately 66%, 70% and 60% of U.S. Pharmaceuticals net sales in 2003, 2002 and 2001, respectively.

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The Company estimates, based on the data noted above, that the inventory of pharmaceutical products held by the other U.S. pharmaceutical wholesalers was in the range of approximately \$100 million in excess of or below approximately one month of supply at December 31, 2003. 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. The Company expects to account for certain pharmaceutical sales relating to OTN using the consignment model until its agreement with McKesson expires in 2006.

**Earnings**

In 2003, earnings from continuing operations before minority interest and income taxes increased 70% to \$4,694 million from \$2,761 million in 2002. The increase was primarily a result of the sales increase and specified charges of \$1,207 million recorded in 2002 for litigation settlements, asset impairments and write-offs for in-process research and development. This increase was partially offset by increased investment in advertising and promotion, and in marketing, selling and administrative expenses. Earnings from continuing operations increased 50% in 2003 to \$3,106 million from \$2,067 million in 2002. In 2003, basic and diluted earnings per share from continuing operations increased 50% each to \$1.60 and \$1.59, respectively, each from \$1.07 and \$1.06 in 2002, respectively. In 2002, earnings from continuing operations before minority interest and income taxes increased 22% to \$2,761 million from \$2,263 million in 2001. Earnings from continuing operations in 2002 increased 10% to \$2,067 million from \$1,871 million in 2001. In 2002, basic and diluted earnings per share from continuing operations increased 11% and 12% to \$1.07 and \$1.06, respectively, from \$.96 and \$.95 in 2001, respectively. Net earnings margins for continuing operations increased to 14.9% in 2003 from 11.4% in 2002 and 10.4% in 2001.

During the years ended December 31, 2003, 2002 and 2001, the Company recorded several 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 8. Financial Statements Note 3. Alliances and Investments, Note 4. Restructuring and Other Items, Note 5. Acquisitions and Divestitures and Note 6. Discontinued Operations.

	2003	Restated 2002	Restated 2001
	_____	_____	_____
	(dollars in millions)		
Acquired in-process research and development	\$	\$ 169	\$ 2,772
Litigation charge, net	199	659	77
Asset impairment charge for investment in ImClone		379	
Restructuring and other items <sup>(1)</sup>	195	68	588
Gain on sales of businesses/product liens		(30)	(475)
	_____	_____	_____
	394	1,245	2,962
Income tax benefit on above items	(36)	(472)	(1,057)
Settlement of prior year tax matters		(261)	
	_____	_____	_____
	\$ 358	\$ 512	\$ 1,905
	_____	_____	_____

(1) Restructuring and other items consist of the following:

Year ended December 31, 2003	Cost of Products	R&D	Provision for Restructuring &	Total
_____	_____	_____	_____	_____

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	<u>Sold</u>	<u>Other</u>	
		(dollars in millions)	
Up-front payments for four licensing agreements*	\$	\$ 102	\$ 102
Accelerated depreciation of assets	53		53
Termination benefits and other exit costs			50
Relocation expenses			13
Asset impairment charges	14		14
Retention benefits			2
Change in estimates			(39)
	<u>\$ 67</u>	<u>\$ 102</u>	<u>\$ 26</u>
			<u>\$ 195</u>

\* Represents payments made to Corgentech Inc., (\$45 million), Lexicon Genetics Inc. (\$36 million), Flamel Technologies S.A. (\$20 million) and QDose (\$1 million).

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<b>Year ended December 31, 2002</b>	<b>Cost of Products Sold</b>	<b>R&amp;D</b>	<b>Provision for Restructuring &amp; Other</b>	<b>Total</b>
	(dollars in millions)			
Termination benefits	\$	\$	\$ 71	\$ 71
Other exit costs			38	38
Accelerated depreciation of assets		69		69
Asset write-down and impairment charges	2		51	53
Change in estimates	(17)		(146)	(163)
	<u>\$ (15)</u>	<u>\$ 69</u>	<u>\$ 14</u>	<u>\$ 68</u>
<b>Year ended December 31, 2001</b>	<b>Decrease in Net Sales</b>	<b>Cost of Products Sold</b>	<b>Provision for Restructuring &amp; Other</b>	<b>Total</b>
	(dollars in millions)			
Downsized and rationalized operations and facilities	\$	\$	\$ 519	\$ 519
Abandonment of non-strategic pharmaceutical product lines	74			74
Change in estimates		58	(63)	(5)
	<u>\$ 74</u>	<u>\$ 58</u>	<u>\$ 456</u>	<u>\$ 588</u>

Gross margin percentages were 63.7%, 63.9% and 69.4% in 2003, 2002 and 2001, respectively. Gross margins were negatively impacted in 2003 due to increased sales of lower-margin products in the OTN segment, \$53 million in accelerated depreciation charges and a \$14 million charge for asset impairment and other restructuring expenses largely offset by increased sales of higher margin products such as PRAVACHOL. The lower gross margin in 2002 compared to 2001 was principally due to the impact of generic competition in the United States for GLUCOPHAGE\* IR, TAXOL® and BUSPAR, and an adverse change in product mix due to increased sales in the OTN segment.

The effective income tax rate on earnings from continuing operations before minority interest and income taxes was 25.9% in 2003 compared with 14.2% in 2002 and 9.4% in 2001. The increase in the 2003 effective tax rate over the 2002 effective tax rate is primarily due to the decrease in effective tax rate benefit from operations in Ireland, Puerto Rico and Switzerland, treatment of provisions for certain litigation reserves as non-deductible, and an increase in estimates for contingent tax matters in 2003 compared to 2002. The increase in the 2002 effective tax rate over the 2001 effective tax rate was primarily due to the decrease in effective tax rate benefit from operations in Ireland, Puerto Rico and Switzerland, and the provision of \$205 million of valuation allowances, comprised of \$112 million related to certain state and foreign net deferred tax assets, \$93 million related to certain state and foreign tax net operating loss and tax credit carryforwards, partially offset by a \$261 million net release of tax contingency reserves related primarily to the settlement of prior year tax matters, and the determination by the Company as to the expected settlement of ongoing tax litigation, which was resolved in 2003. The Company currently believes that the state net deferred tax assets, state net operating loss and tax credit carryforwards, and foreign net operating loss and tax credit carryforwards for which valuation allowances have been provided, more likely than not, will not be realized in the future. The lower effective income tax rate in 2001 results primarily from lower pre-tax income in the United States, due to the write-off of acquired in-process research and development, as well as proportionately greater tax benefits from income earned in lower tax rate jurisdictions such as Ireland, Puerto Rico and Switzerland.

**Expenses**

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Total costs and expenses, as a percentage of sales, were 77.5% in 2003 compared with 84.8% in 2002 and 87.5% in 2001.

Cost of products sold, as a percentage of sales, increased over the last three years to 36.3% in 2003 compared with 36.1% in 2002 and 30.6% in 2001, principally due to increased sales of lower-margin products from OTN largely offset by increased sales of higher margin products such as PRAVACHOL. In 2003, cost of products sold includes \$53 million of accelerated depreciation of assets in manufacturing facilities in North America expected to be closed by the end of 2006 and a \$14 million charge for asset impairment and other restructuring expenses. Cost of products sold in 2002 included a \$15 million reversal of prior period reserves for inventory write-offs related to cancelled actions and in 2001 included \$58 million of other restructuring expenses.

Marketing, selling and administrative expenses, as a percentage of sales, decreased to 22.3% in 2003 from 22.8% in 2002. In 2003, marketing, selling and administrative expenses increased 13% to \$4,660 million from \$4,124 million in 2002 primarily due to increased sales support for ABILIFY\* and AVAPRO\*/AVALIDE\*, higher pension costs, higher charges related to system infrastructure, higher insurance premiums, and unfavorable foreign exchange impact, principally related to the euro. Marketing, selling and administrative expenses, as a percentage of sales, increased to 22.8% in 2002 from 22.5% in 2001, or 2% to \$4,124 million from \$4,058 million. This slight increase was mainly due to higher sales force expenses as a result of the addition of the Medical Imaging business, acquired in October 2001.



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Advertising and promotion expenses increased to \$1,416 million in 2003 from \$1,143 million in 2002, primarily as a result of promotional support for the ABILIFY\* and REYATAZ launches and PLAVIX\* in the United States, and additional support for in-line products and unfavorable foreign exchange impact in Europe. In 2002, advertising and promotion expenses decreased to \$1,143 million from \$1,201 million in 2001, primarily as a result of reduced spending on the metformin franchise and VANIQA\*, partially offset by ABILIFY\* product launch expenses and increased support of PLAVIX\* and AVAPRO\*/AVALIDE\* in the United States. As a percentage of sales, 2003 advertising and promotion expenses increased to 6.8% from 6.3% in 2002 and 6.7% in 2001.

The Company's investment in research and development totaled \$2,279 million in 2003, an increase of 3% over 2002 and an increase from 2002 of 2% over 2001, but as a percentage of sales decreased to 10.9% in 2003 compared with 12.2% in 2002 and 12.0% in 2001. Research and development costs included \$102 million of charges related to the up-front payments for licensing agreements in 2003 and \$69 million of accelerated depreciation on research facilities in 2002. In 2003, research and development spending dedicated to pharmaceutical products decreased to 14.2% of Pharmaceuticals sales compared with 16.5% and 15.5% in 2002 and 2001, respectively. The Company is focusing its research and development activities so that it can fully realize the value of its research and development pipeline. The new priorities include rebalancing drug discovery and development to increase support for the Company's full late-stage development pipeline and closing unnecessary facilities. They also include devoting greater resources to ensuring successful near-term product launches and increasing the Company's efforts on in-licensing opportunities.

In 2002, the charges related to acquired in-process research and development were \$169 million, primarily related to milestone payments to ImClone Systems Incorporated (ImClone) for ERBITUX\*. Of the \$200 million milestone payment to ImClone, \$160 million was expensed as acquired in-process research and development in the first quarter of 2002. The remaining \$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 acquired in-process research and development charge in 2001 was \$2,772 million, including \$2,009 million related to the DuPont Pharmaceuticals acquisition and \$735 million attributable to the ImClone equity investment. In addition, acquired in-process research and development for 2002 and 2001 includes charges of \$9 million and \$28 million, respectively, for licensing payments related to products not yet approved for marketing.

Restructuring programs were implemented to downsize, realign and streamline operations in order to increase productivity, reduce operating expenses and rationalize the Company's manufacturing network, research facilities and administrative functions. Actions under the 2003 restructuring program are expected to be complete by 2006 while actions under the 2002 and 2001 restructuring programs were substantially complete at December 31, 2003. As a result of these actions, the Company expects the future annual benefit to earnings from continuing operations before minority interest and income taxes to be approximately \$64 million, \$150 million and \$400 million for the 2003, 2002 and 2001 programs, respectively. For additional information on restructuring, see Item 8. Financial Statements Note 4. Restructuring and Other Items.

Litigation charges, net of settlement income, were \$199 million in 2003, compared to \$659 million in 2002 and \$77 million in 2001. In the fourth quarter of 2003, the Company established reserves for liabilities in the total amount of \$250 million, comprised of \$150 million in relation to wholesaler inventory issues and certain other accounting matters, and \$100 million in relation to pharmaceutical pricing and sales and marketing practices. In addition, the Company recorded charges of \$31 million for other litigation matters and recognized income of \$82 million. The \$82 million income consists primarily of \$30 million of income for patent defense cost reimbursement, \$27 million in litigation settlement income and \$21 million from the settlement of anti-trust litigation involving vitamin manufacturers. The 2002 charges of \$659 million primarily related to BUSPAR and TAXOL® proposed settlements. For additional information on litigation, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

Equity in net income of affiliates for 2003 was \$151 million, compared with \$80 million and \$78 million in 2002 and 2001, respectively. Equity in net income of affiliates principally related to the Company's joint venture with Sanofi and investment in ImClone. In 2003, the increase in equity in net income of affiliates primarily reflects higher net income in the Sanofi joint venture. For additional information on equity in net income of affiliates, see Item 8. Financial Statements Note 3. Alliances and Investments.

Other expenses, net of income were \$179 million, \$229 million and \$98 million in 2003, 2002 and 2001, respectively. Other expenses include net interest expense, interest income, foreign exchange gains and losses, royalty income, and gains and losses on disposal of property, plant and equipment. The decrease in expenses in 2003 from 2002 was primarily due to net gains from interest rate swaps. The increase in expenses in 2002 compared to 2001 was principally due to higher interest expenses related to borrowings of \$6.5 billion related to the DuPont Pharmaceuticals and ImClone transactions in 2001.

**Table of Contents****Business Segments**

The Company operates in four reportable segments: Pharmaceuticals, OTN, Nutritionals and Other Healthcare. In 2003, OTN, which was previously included in the Pharmaceuticals segment, met the quantitative thresholds of a reportable segment as outlined in SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information*. Accordingly, prior periods have been reclassified to conform with current year presentations. The percent of the Company's sales by segment were as follows:

	% of Total Sales		
	2003	Restated 2002	Restated 2001
Pharmaceuticals	71	71	75
Oncology Therapeutics Network	11	10	8
Nutritionals	10	10	10
Other Healthcare	8	9	7

*Pharmaceuticals*

In 2003, worldwide Pharmaceuticals sales increased 16% to \$14,925 million, reflecting a 2% price increase, 9% volume increase and a 5% increase in foreign exchange. Domestic sales in 2003 increased 16% to \$8,431 million primarily due to increased sales of PLAVIX\*, the PRAVACHOL franchise, ABILIFY\* (total revenue), GLUCOVANCE\* and PARAPLATIN and partly due to the impact on 2002 sales from the workdown of non-consignment wholesaler inventory, partially offset by decreased sales of GLUCOPHAGE\* IR and TAXOL® primarily due to generic competition. REYATAZ was launched in July 2003, with \$83 million in domestic sales. International sales in 2003 increased 17% to \$6,494 million, including an 11% favorable foreign exchange impact, primarily due to increased sales of PRAVACHOL, TAXOL®, PLAVIX\*, AVAPRO\*/AVALIDE\* and Analgesic products in Europe partially offset by price declines principally in Germany and Italy.

In 2002, worldwide pharmaceuticals sales decreased 6% to \$12,812 million, reflecting a 4% price decline, 2% volume decline, and no foreign exchange impact. Domestic sales declined 14% to \$7,273 million, primarily due to generic competition in the United States on GLUCOPHAGE\* IR, TAXOL® and BUSPAR, partially offset by increased sales of PLAVIX\* and the addition of products acquired from the DuPont Pharmaceuticals acquisition, which was completed on October 1, 2001. In addition, the decrease in domestic pharmaceutical sales was impacted by the buildup in the prior period of inventory levels at those U.S. wholesalers not accounted for under the consignment model and the subsequent workdown in 2002. Approximately \$1,395 million of sales (calculated net of discounts, rebates and other adjustments) recognized in the year ended December 31, 2002 had been reversed from prior years. International sales increased 9% to \$5,539 million (with no significant foreign exchange impact) primarily due to increased sales of PRAVACHOL and PLAVIX\* in Europe, TAXOL® in Japan and the addition of products acquired from the DuPont Pharmaceuticals acquisition.

Key pharmaceutical products and their sales include the following:

Total revenue for ABILIFY\*, which is primarily domestic alliance revenue for the Company's 65% share of net sales in copromotion countries with Otsuka Pharmaceutical Co., Ltd. (Otsuka), was \$283 million. The schizophrenia agent was introduced in the United States in November 2002 and by December 2003, had achieved more than a 7% weekly new prescription share of the U.S.

antipsychotic market. The Company received approval for a Supplemental New Drug Application (sNDA) for ABILIFY\* for maintaining stability in patients with schizophrenia, and has announced that it submitted an sNDA for ABILIFY\* for the treatment of acute mania in patients with bipolar disorder to the U.S. Food and Drug Administration (FDA). ABILIFY\* is being developed and marketed by Bristol-Myers Squibb and its partner Otsuka. 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.

Sales of the PRAVACHOL franchise increased 25%, including a 7% favorable foreign exchange impact, to \$2,827 million in 2003. Domestic sales increased 22% to \$1,605 million in 2003, while international sales increased 28%, including a 17% favorable foreign exchange impact, to \$1,222 million. Sales for the PRAVACHOL franchise increased 8% to \$2,266 million in 2002 from \$2,101 million in 2001. A six-month exclusivity extension was granted through April 2006. 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.

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Sales of PLAVIX\*, a platelet aggregation inhibitor, increased 31%, including a 3% favorable foreign exchange impact, to \$2,467 million in 2003. Sales of AVAPRO\*/AVALIDE\*, an angiotensin II receptor blocker for the treatment of hypertension, increased 29%, including a 6% favorable foreign exchange impact, to \$757 million in 2003. Sales of PLAVIX\* and AVAPRO\*/AVALIDE\* increased 61% and 20% to \$1,890 million and \$586 million, respectively, in 2002. Sales of PLAVIX\* and AVAPRO\*/AVALIDE\* were \$1,171 million and \$487 million in 2001. PLAVIX\* and AVAPRO\*/AVALIDE\* are cardiovascular products that were launched from the alliance between Bristol-Myers Squibb and Sanofi. 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. See Item 1. Business Competition and Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

Sales of TAXOL® and PARAPLATIN, the Company's leading anticancer agents, increased 9%, including a 12% favorable foreign exchange impact, to \$934 million and 24% to \$905 million (with no significant foreign exchange impact), respectively, in 2003. International sales of TAXOL® increased 23%, including a 14% favorable foreign exchange impact, to \$882 million, led by strong sales in Japan and France. Domestic sales of TAXOL® decreased 62% to \$52 million due to generic competition. Domestic sales of PARAPLATIN increased 26% to \$769 million. In 2002, TAXOL® sales decreased 23% to \$857 million from \$1,112 million in 2001 and PARAPLATIN sales increased 23% to \$727 million from \$592 million in 2001. 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 April 2004 (subject to an anticipated six-month pediatric exclusivity extension). Market exclusivity protection for PARAPLATIN expired in 2000 in the EU and in 1998 in Japan.

Sales of SUSTIVA, an antiretroviral agent for the treatment of human immunodeficiency virus/auto-immune immunodeficiency virus (HIV/AIDS), increased 20%, including a 7% favorable foreign exchange impact, to \$544 million in 2003 from \$455 million in the prior year. International sales of SUSTIVA increased 31%, including an 18% favorable foreign exchange impact, to \$210 million in 2003. SUSTIVA was acquired from DuPont Pharmaceuticals in October 2001 and recorded sales were \$68 million for that year. 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.

MONOPRIL, a second-generation angiotensin converting enzyme (ACE) inhibitor for the treatment of hypertension, had increased sales of 10%, including a 5% favorable foreign exchange impact, reaching \$470 million in 2003. MONOPRIL sales increased 3% to \$426 million in 2002 from \$413 million in 2001. Market exclusivity protection for MONOPRIL expired in 2003 in the U.S. and is expired or expected to expire between 2001 and 2008 in countries in the EU; MONOPRIL is not currently marketed in Japan.

GLUCOPHAGE\* franchise sales increased 22% to \$948 million in 2003, compared to a 67% decrease to \$778 million in 2002 from \$2,337 million in 2001. GLUCOPHAGE\* IR, an oral medication for treatment of non-insulin dependent (type 2) diabetes, saw 2003 sales decrease 46% to \$118 million. The decline in GLUCOPHAGE\* IR was due to the introduction of generic metformin in the United States in early 2002. GLUCOPHAGE\* IR sales decreased 88% to \$220 million in 2002 from \$1,838 million in 2001. GLUCOVANCE\*, an oral combination drug, and GLUCOPHAGE\* XR (Extended Release) tablets had sales in 2003 of \$424 million and \$395 million, respectively, compared with sales in 2002 of \$246 million and \$297 million, respectively, and sales in 2001 of \$269 million and \$230 million, respectively. Market exclusivity protection for GLUCOVANCE\* expired in January 2004. The Company does not (but others do) market these products in the EU and Japan.

Sales of ZERIT/ZERIT ER, an antiretroviral agent used in the treatment of HIV/AIDS, decreased 20%, including a 5% favorable foreign exchange impact, to \$354 million in 2003, primarily as a result of decreased demand due to potential adverse side effects. ZERIT/ZERIT ER sales decreased 14% to \$443 million in 2002 from \$515 million in 2001. 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.

Sales of VIDEX/VIDEX EC, an antiretroviral agent used in the treatment of HIV/AIDS, increased 2%, including an 8% favorable foreign exchange impact, to \$267 million in 2003. VIDEX/VIDEX EC sales increased 9% to \$262 million in 2002 from \$240 million in 2001. 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.



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Sales of SERZONE, a treatment for depression, decreased 56% to \$98 million in 2003 as a result of loss of exclusivity and a labeling change indicating a potential serious side effect of the product. SERZONE sales decreased 34% to \$221 million in 2002 from \$334 million in 2001. Market exclusivity protection for SERZONE expired in 2003 in the U.S. and SERZONE is not currently marketed in the EU and 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.

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.

	2003		2002		2001	
	% Change in U.S. Net Sales <sup>(a)</sup>	% Change in U.S. Total Prescriptions <sup>(b)</sup>	Restated % Change in U.S. Net Sales <sup>(a)</sup>	% Change in U.S. Total Prescriptions <sup>(b)</sup>	Restated % Change in U.S. Net Sales <sup>(a)</sup>	% Change in U.S. Total Prescriptions <sup>(b)</sup>
PRAVACHOL	22	2	1	5	20	9
PLAVIX*	27	29	63	35	28	35
AVAPRO*/AVALIDE*	24	15	16	13	33	20
SUSTIVA	13	17	**	16		N/A
MONOPRIL	16	(16)	2	(8)	3	(1)
GLUCOVANCE*	72	3	(9)	48	**	**
GLUCOPHAGE*XR	33	(3)	29	81	**	**
ZERIT	(29)	(25)	(13)	(11)	(12)	(8)
CEFZIL	14	(4)	(7)	(14)	(9)	(11)
COUMADIN	1	(15)	**	(16)		N/A
VIDEX/VIDEX EC	(11)	3	15	13	22	13

\*\* In excess of 200%.

(a) Reflects change in net sales in dollar terms, including change in average selling prices and wholesaler buying patterns.

(b) Reflects change in total prescriptions in unit terms, based on third-party data.

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Earnings before minority interest and income taxes of \$4,369 million in 2003 increased from \$3,185 million in 2002 primarily due to increased sales, which were partially offset by increased advertising and product spending on new and existing in-line products. Earnings before minority interest and income taxes in 2002 and 2001 were \$3,185 million and \$1,857 million, respectively. The increase in 2002 is mainly due to lower earnings in 2001 as a result of the write-off of \$2,772 million of acquired in-process research and development. Earnings in 2002 were unfavorably affected by higher sales of lower margin products, and the full year impact of generic competition on GLUCOPHAGE\* IR, TAXOL® and BUSPAR in the United States.

### *Oncology Therapeutics Network*

In 2003, OTN sales were \$2,241 million, an increase of 18% over the prior year due to volume growth and manufacturers price changes. In 2002, sales increased 33% to \$1,900 million from \$1,433 million in 2001. OTN sales accounted for 11%, 10%, and 8% of the Company's net sales in 2003, 2002 and 2001, respectively.

Earnings before minority interest and income taxes of \$14 million in 2003 decreased slightly from \$15 million in 2002 and \$16 million in 2001 due to margin erosion and investments in system infrastructure.



**Table of Contents***Nutritionals*

In 2003, Nutritionals sales were \$2,023 million, an increase of 11% over 2002. This increase was due to a 7% increase in volume and a 5% price increase, partially offset by a 1% decrease due to foreign exchange. International sales increased 9%, including a 2% unfavorable foreign exchange impact, to \$938 million from \$862 million in 2002. Domestic sales increased 13% to \$1,085 million from \$959 million in 2002. Worldwide children's nutritionals sales increased 10%, including a 5% unfavorable foreign exchange impact, to \$421 million in 2003 from \$383 million in 2002, as a result of a 29% increase in sales of ENFAGROW, primarily throughout the Pacific region, to \$156 million in 2003. Worldwide infant formula sales increased 10% to \$1,284 million in 2003 (with no significant foreign exchange impact), primarily due to increased sales of ENFAMIL, the Company's largest-selling infant formula. International sales of ENFAMIL increased 5% to \$239 million in 2003 from \$228 million in 2002 (with no significant foreign exchange impact) and domestic sales of ENFAMIL increased 10% to \$569 million in 2003 from \$518 million in 2002. Mead Johnson Nutritionals (Mead Johnson) continues to be the leader in the U.S. infant formula market. In 2002, Nutritionals sales remained consistent with 2001 sales at \$1.8 billion, reflecting a 2% increase due to price, offset by a 1% decrease due to volume and a 1% decrease due to foreign exchange. Worldwide infant formula sales decreased 4% to \$1,172 million, primarily in the specialty infant formula business. In 2002, worldwide sales of ENFAMIL decreased 1% to \$746 million from \$753 million in 2001. Worldwide children's nutritional sales increased 24%, including a 2% unfavorable foreign exchange impact, to \$383 million in 2002 from \$308 million in 2001, as a result of a 53% increase in sales of ENFAGROW, primarily across the Pacific region, to \$121 million in 2002.

Earnings before minority interest and income taxes in the Nutritionals segment increased to \$542 million in 2003 from \$486 million in 2002. This increase is primarily due to increased sales of ENFAMIL in the United States. In 2002, earnings before minority interest and income taxes in the Nutritionals segment decreased to \$486 million from \$517 million in 2001 as a result of increased promotional spending and sales force expenses related to the ENFAMIL product line.

*Other Healthcare*

The Other Healthcare segment includes ConvaTec, the Medical Imaging business and Consumer Medicines in the United States and Japan.

Sales in the Other Healthcare segment increased 8% to \$1,705 million in 2003 from \$1,573 million in 2002. In 2003, the Other Healthcare sales increase was a result of a 2% increase due to volume, a 1% increase from changes in selling prices and a 5% increase due to foreign exchange. In 2002, sales in this segment increased 28% to \$1,573 million, including \$462 million of sales from Medical Imaging, which was purchased in October 2001 as part of the DuPont Pharmaceuticals acquisition. The Other Healthcare sales increase in 2002 was a result of a 25% increase due to volume, a 2% increase from changes in selling prices and a 1% favorable foreign exchange impact. Other Healthcare sales by business were as follows:

		Restated	Restated	% Change	
	2003	2002	2001	2003 to 2002	2002 to 2001
	(dollars in millions)				
ConvaTec	\$ 843	\$ 734	\$ 710	15%	3%
Medical Imaging	508	462	98	10%	**
Consumer Medicines	354	377	424	(6)%	(11)%
<b>Total Other Healthcare</b>	<b>\$ 1,705</b>	<b>\$ 1,573</b>	<b>\$ 1,232</b>	<b>8%</b>	<b>28%</b>

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\*\* In excess of 200%.

In 2003, the increase in ConvaTec sales was due to a 13% increase, including an 9% favorable foreign exchange impact, in worldwide sales of ostomy products to \$512 million and strong growth of worldwide wound care products, which increased 17%, including a 9% favorable foreign exchange impact, to \$319 million. Foreign exchange in 2003 had a 9% favorable effect on sales. In 2002, the increase in ConvaTec sales was due to a 1% increase in worldwide sales of ostomy products to \$453 million and strong growth of worldwide wound care products, which increased 10% to \$273 million. Foreign exchange contributed 1% to the sales increase in 2002.

In 2003, the increase in Medical Imaging sales was from a 4% increase in volume, a 4% increase from changes in selling prices and a 2% increase due to foreign exchange. Worldwide sales of CARDIOLITE increased 8% to \$324 million from \$299 million in 2002. The Medical Imaging business was purchased in October 2001 as part of the DuPont Pharmaceuticals acquisition.

The steady decline in sales of Consumer Medicines, from \$424 million in 2001 to \$377 million in 2002 to \$354 million in 2003, is in part due to distributors reducing inventory levels to more desirable levels. Consumption of EXCEDRIN and other consumer brands remain flat.

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Earnings before minority interest and income taxes in the Other Healthcare segment decreased to \$408 million in 2003 from \$427 million in 2002, primarily as a result of unfavorable product mix and inventory write-offs for EXCEDRIN QUICKTABS in the Consumer Medicines business. In 2002, earnings before minority interest and income taxes in this segment increased to \$427 million from \$328 million in 2001, primarily due to the strong growth in the ConvaTec business and the addition of the Medical Imaging business in October 2001.

## **Geographic Areas**

The Company's products are available in virtually every country in the world. The largest markets are in the United States, France, Japan, Germany, Spain, Italy and Canada.

Sales in the United States increased 14% in 2003, primarily due to increased sales of PLAVIX\*, the OTN segment, the PRAVACHOL franchise, ABILIFY\* (total revenue), GLUCOVANCE\* and PARAPLATIN. These sales increases were partially offset by the continued impact of generic competition in the United States on GLUCOPHAGE\* IR and TAXOL® and the result of loss of exclusivity and a label change indicating a potential serious side effect of SERZONE. In 2002, sales in the United States decreased 4%, primarily due to the impact of generic competition in the United States on GLUCOPHAGE\* IR, TAXOL® and BUSPAR and, to a lesser extent, the buildup in the prior period of inventory levels at those U.S. wholesalers not accounted for under the consignment model and the subsequent workdown in 2002. This decrease was partially offset by an increase in PLAVIX\* sales and the addition of the products acquired from DuPont.

DuPont Pharmaceuticals U.S. pharmaceutical sales in 2002 were \$603 million. The Company's acquisition of DuPont Pharmaceuticals was completed on October 1, 2001. For information on U.S. pharmaceutical prescriber demand, refer to the table within Item 1. Business Segments Pharmaceutical Segment, 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.

Sales in Europe, Middle East and Africa increased 23%, including a 16% increase from foreign exchange, as a result of sales growth of PRAVACHOL in France, TAXOL® in France, Germany, Spain and Italy, analgesics in France, PLAVIX\* in Germany and Spain, AVAPRO\*/AVALIDE\* in Italy and SUSTIVA in Spain. The favorable impact of foreign exchange was primarily due to the euro. In 2002, sales in Europe, Middle East and Africa increased 12%, including a 4% increase from foreign exchange, as a result of the strong growth of PRAVACHOL in France and the United Kingdom, PLAVIX\* in Spain, and the addition of the DuPont Pharmaceuticals products in several markets in the region. DuPont Pharmaceuticals sales in the region were \$309 million in 2002.

Sales in the Other Western Hemisphere countries increased 10%, including a 5% decrease from foreign exchange, primarily due to increased sales of PLAVIX\* in Canada. The unfavorable impact of foreign exchange was primarily in Mexico, Brazil and Venezuela. In 2002, sales in Other Western Hemisphere countries decreased 6%, including an 8% decrease from foreign exchange. The unfavorable impact of foreign exchange was primarily in Brazil and Argentina. The underlying sales growth was primarily due to increased sales of PLAVIX\* in Canada and of nutritional products in Mexico.

Pacific region sales increased 12%, including a 6% increase from foreign exchange in 2003, as a result of increased sales of TAXOL® in Japan and increased sales of ENFAGROW throughout the region. In 2002, sales in the Pacific region increased 12%, including a 2% decrease from foreign exchange. Products with strong growth included TAXOL® and PARAPLATIN in Japan and nutritional products in China and Indonesia.

## Developments

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 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 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.

In January 2004, the Company announced that it has agreed to acquire Acordis Specialty Fibres (Acordis), a privately held company based in the United Kingdom that licenses patent rights and supplies materials to ConvaTec for its Wound Therapeutics line. The transaction is subject to regulatory approval which has not been received. If the transaction is completed, the Company expects to record an in-process research and development charge between \$50 million to \$70 million.

In December 2003, the Company confirmed that Mead Johnson, a wholly owned subsidiary of the Company, had reached an agreement with Novartis AG to sell to Novartis its Adult Nutritional business, brands, trademarks, patents and intellectual property rights for \$385 million, including \$20 million contingent on a product conversion and a \$22 million upfront payment for a supply agreement. The transaction closed in February 2004 and a pre-tax gain of approximately \$290 million is expected to be recorded in the first quarter of 2004. In 2003, Adult Nutritional products recorded sales of over \$200 million.

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In December 2003, the Company and Lexicon Genetics Incorporated (Lexicon) formed a broad alliance for drug discovery, development and commercialization in the neuroscience field. The alliance is designed to accelerate the discovery and development of breakthrough therapies to address significant, unmet medical needs in psychiatry and neurology. The Company made and expensed an initial payment of \$36 million in 2003.

In October 2003, the Company and Corgentech Inc., a biopharmaceutical company, entered into an agreement to jointly develop and commercialize Corgentech's E2F Decoy (edifoligide sodium), a novel treatment for the prevention of vein graft failure following coronary artery bypass graft and peripheral artery bypass graft surgery. The product is currently in Phase III clinical trials and the FDA has granted fast track status for both indications. The Company made and expensed an initial payment of \$45 million in 2003. Further, there are potential clinical and regulatory milestone payments of \$205 million, and arrangements for profit sharing.

In August 2003, PRAVIGARD PAC (Buffered Aspirin and Pravastatin Sodium) tablets were launched in the United States.

In July 2003, REYATAZ, a protease inhibitor for the treatment of HIV/AIDS, was launched in the United States. On March 2, 2004, the Company received marketing approval for REYATAZ in the EU.

In August 2003, the Company entered into a licensing and commercialization agreement with Flamel Technologies S.A. to develop and market BASULIN, the first controlled release, unmodified human insulin to be developed as a once-daily injection for patients with type 1 or type 2 diabetes. BASULIN is now entering Phase II clinical development. Under the agreement, the Company will lead and assume the cost of future development and manufacturing efforts for BASULIN and will have exclusive worldwide rights to the product. The Company made and expensed an initial payment of \$20 million in October 2003, with the potential for an additional \$145 million in clinical and regulatory milestone payments over time, and royalty payments on product sales.

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

Cash, cash equivalents and marketable securities totaled approximately \$5.5 billion at December 31, 2003, compared with \$4.0 billion at December 31, 2002. Approximately \$5.4 billion of such cash, cash equivalents and marketable securities was held by the Company's foreign subsidiaries, 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. For a further discussion of this matter, see **Critical Accounting Policies** **Income Taxes** below. Working capital increased to \$4.4 billion at December 31, 2003, from \$1.6 billion at December 31, 2002, primarily as a result of an increase in marketable securities, and a decrease in commercial paper outstanding, partially offset by increased accrued expenses. Cash and cash equivalents, marketable securities, the conversion of other working-capital items and borrowings are expected to fund near-term operations.

Cash and cash equivalents at December 31, 2003 primarily consisted of U.S. dollar denominated bank deposits with an original maturity of three months or less. Marketable securities at December 31, 2003 primarily consisted of U.S. dollar denominated floating rate instruments with a 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. The average interest yield on cash and cash equivalents was 1.2% and 1.4% at December 31, 2003 and 2002, respectively, while interest yields on marketable securities averaged 1.3% and 1.6%, respectively.

Long-term debt at December 31, 2003, was denominated primarily in U.S. dollars but also included Japanese yen long-term debt of \$293 million. Long-term debt increased to \$8.5 billion at December 31, 2003 from \$6.3 billion at December 31, 2002 primarily due to the \$1.0 billion of fixed rate notes and \$1.2 billion of floating rate convertible debentures issued in August 2003 and October 2003, respectively. The proceeds from these issuances were used to repay short-term borrowings and fund the cash needs of the U.S. operations. The convertible debentures mature in 2023, callable at par at any time on or after September 21, 2008 by the issuer, and are convertible into Company common stock at 24.2248 shares per \$1,000 debenture (\$41.28 per share), subject to increases up to a maximum of 38.7597 shares per \$1,000 debenture based on increases in the market price of the stock above \$41.28 per share, plus anti-dilution and certain other adjustments. Interest is payable quarterly at an annual rate equal to 3-month LIBOR, reset quarterly, minus 0.50%. A majority of the Company's debt is fixed rate. The Company, however, has entered into fixed to floating interest rate swaps for \$5.5 billion of its long-term debt. Interest expense in 2003, 2002 and 2001 was \$488 million, \$410 million, and \$182 million, respectively. There was no U.S. commercial paper outstanding at December 31, 2003. U.S. commercial paper outstanding at December 31, 2002 was \$1,158 million with an average interest rate of 1.40%. The average interest rate for the year ended December 31, 2003 and 2002, on international short-term borrowings were 8.04% and 9.58%, respectively, and on current installments of long-term debt were 1.33% and 2.56%, respectively.

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As of December 31, 2003, the Company had two revolving credit facilities, totaling \$1.0 billion in aggregate, as support for its domestic commercial paper program. These facilities were established in September 2001 and August 2003, respectively, with a syndicate of lenders, and are extendable at each anniversary date with the consent of the lenders. One of the revolving credit facilities has certain financial covenants, of which the Company is in compliance with as of December 31, 2003. There were no borrowings outstanding under the revolving credit facilities at December 31, 2003 and 2002. The Company had unused short-term lines of credit with foreign banks of \$363 million and \$321 million at December 31, 2003 and 2002, respectively.

In July 2003, Standard & Poor's lowered its long-term credit rating on the Company from AA to AA-. In addition, Standard & Poor's affirmed its A-1+ short-term rating. In April 2003, Moody's Investors Service lowered the Company's long-term credit rating from Aa2 to A1. In March 2003, Moody's affirmed the Prime-1 short-term credit rating for the Company. On March 10, 2004, Standard & Poor's placed both long-term and short-term ratings of the Company on watch with negative implications. Moody's long-term credit rating remains on negative outlook.

Net cash provided by operating activities was approximately \$3.5 billion in 2003, \$0.9 billion in 2002 and \$5.4 billion in 2001. The increase in 2003 is attributable to higher net earnings and income tax payments in 2002 primarily related to the gain arising from the sale of the Clairol business. Cash flow from operations also included pension contributions of \$332 million, \$554 million and \$300 million in 2003, 2002 and 2001, respectively.

Cash provided from operations and borrowings were primarily used over the past three years to pay dividends of \$6.5 billion and to repurchase 32 million shares at a cost of \$1.8 billion in 2002 and 2001. The Company has also invested \$2.9 billion over the past three years in capital expansion to improve plant efficiency and maintain superior research facilities.

During 2003, the Company did not purchase any of its common stock. The Company repurchased 5 million and 27 million shares of common stock at a cost of \$164 million and \$1,589 million in 2002 and 2001, respectively, bringing the total shares acquired since the share repurchase program's inception to 372 million shares. The share repurchase program authorizes the Company to purchase common stock from time to time in the open market or through private transactions as market conditions permit. This program is intended to reduce the increase in shares outstanding from option exercises and to obtain shares for general corporate purposes.

Employment levels of 44,000 at December 2003 remained constant compared to prior-year levels.

Dividends declared per common share in each of the years 2003 and 2002 were \$1.12 and in 2001 were \$1.11. In December 2003, the Company declared a quarterly dividend of \$.28 per common share and an indicated dividend for the full year 2004 of \$1.12 per share.

The Company's financial condition and liquidity could be affected by obligations to make milestone or other one-time payments and by the outcome of pending litigations and investigations, including the challenge to the PLAVIX\* patent. For more information, see Item 8. Financial Statements Note 3. Alliances and Investments and Note 22. Legal Proceedings and Contingencies.

## **Contractual Obligations**

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Payments due by period for the Company's contractual obligations at December 31, 2003, are as follows:

	Obligations Expiring by Period						
	Total	2004	2005	2006	2007	2008	Later Years
	(dollars in millions)						
Short-term borrowings	\$ 114	\$ 114	\$	\$	\$	\$	\$
Long-term debt <sup>(1)</sup>	8,522	13	116	2,500		545	5,348
Capital leases	13		4	2	2	1	4
Operating leases	456	98	95	77	65	46	75
Purchase Obligations	528	227	187	72	30	12	
ImClone milestone payment	250	250					
Stand-by letters of credit	61	60	1				
Other long-term liabilities	1,177	342	374	303	34	30	94
<b>Total</b>	<b>\$ 11,121</b>	<b>\$ 1,104</b>	<b>\$ 777</b>	<b>\$ 2,954</b>	<b>\$ 131</b>	<b>\$ 634</b>	<b>\$ 5,521</b>

(1) 2004 obligations are included in short-term borrowings on the Company's consolidated balance sheet at December 31, 2003 and all balances represent the outstanding nominal long-term debt values.

In addition to the above, the Company has committed to make potential future milestone payments to third-parties as part of in-licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on the Company's consolidated balance sheet.



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For a discussion of contractual obligations, reference is made to Item 8. Financial Statements Note 16. Short-Term Borrowings and Long-Term Debt, Note 18. Financial Instruments, Note 20. Leases, and Note 21. Pension and Other Postretirement Benefit Plans.

### **Off-Balance Sheet Arrangements**

On March 5, 2002, the Company and ImClone revised their agreement, reducing the total payment to \$900 million from \$1.0 billion. Pursuant to this agreement, the Company paid ImClone \$200 million in 2001, \$140 million in 2002 and \$60 million in 2003. 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 and will pay an additional \$250 million if ERBITUX\* is approved for use in a second tumor type. For a discussion of the Company's agreement with ImClone, see Item 8. Financial Statements Note 3. Alliances and Investments.

### **Recently Issued Accounting Standards**

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, *Employer's Accounting for Pensions*, No. 88, *Employer's Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and Termination Benefits*, and No. 106, *Employer's Disclosures about Post-retirements Plans 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 8. Financial Statements Note 21. Pension and Other Postretirement Benefit Plans and Note 22. Legal Proceedings and Contingencies).

In December 2003, the FASB revised Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN 46). FIN 46, requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN 46 also requires disclosures about variable interest entities that a company is not required to consolidate but in which it has a significant variable interest. The consolidation requirements of FIN 46 (as revised) apply immediately to variable interest entities created after January 31, 2003 and to existing entities in the first fiscal year or interim

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period beginning after March 15, 2004. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The initial adoption of this accounting pronouncement did not have a material effect on the consolidated financial statements.

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 initial adoption of this accounting pronouncement did not affect the consolidated financial statements.

In May 2003, the Emerging Issues Task Force 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. 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.

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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, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45) (discussed below) and amends certain other existing pronouncements. The initial adoption of this accounting pronouncement did not have a material effect on the consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. SFAS in 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 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.

## **Retirement Benefits**

### *Plan Description*

The Company and certain of its subsidiaries have defined benefit pension plans and defined contribution plans for regular full-time employees. The principal defined benefit pension plan is the Bristol-Myers Squibb Retirement Income Plan and the principal defined contribution plan is the Bristol-Myers Squibb Savings and Investment Program.

Approximately 80-85% of total Company defined benefit pension plan assets and liabilities are held in U.S. plans. The assets for the U.S. plans are held in a single trust with a common asset allocation. Unless specified otherwise, the references in this section are to total Company plans (U.S. plans together with international plans).

Benefits under the Company's defined benefit pension plans are based primarily on years of credited service and on participants' compensation. Assets under the Company's defined benefit plans consist primarily of equity and fixed-income securities. At December 31, 2003, the fair market value of plan assets for the Company's defined benefit plans increased to \$4,085 million from \$3,318 million at December 31, 2002. For the U.S. plans, assets were allocated 71% to equity securities (compared to 67% at the end of 2002), 23% to fixed income securities (compared to 26% at the end of 2002) and 6% to private equity and other investments (compared to 7% at the end of 2002). Bristol-Myers Squibb common stock represented less than 1% of assets for the U.S. plans at the end of 2003 and 2002.

The Company provides comprehensive medical and group life benefits for substantially all U.S. retirees who elect to participate in the Company's comprehensive medical and group life plans. The asset allocation for these postretirement plans is identical to the asset allocation described above for the U.S. defined benefit pension plans.

*Accrual Accounting and Significant Assumptions*

Consistent with the requirements of SFAS No. 87, *Employers' Accounting for Pensions*, the Company accounts for pension benefits using the accrual method, recognizing pension expense before the payment of benefits to retirees. The accrual method of accounting for pension benefits necessarily requires actuarial assumptions concerning future events that will determine the amount and timing of the benefit payments.

The Company's key assumptions used in calculating its cost of pension benefits are the discount rate, the rate of compensation increase and the expected long-term rate of return on plan assets. The Company, in consultation with its actuaries, evaluates the key actuarial assumptions and other assumptions used in calculating its cost of pension benefits, such as retirement, turnover and mortality rates, based on expectations or actual experience, as appropriate, and determines such assumptions on December 31 of each year to calculate liability information as of that date and pension expense for the following year. Depending on the assumptions used, the pension expense could vary within a range of outcomes and have a material effect on reported earnings. In addition, the assumptions can materially affect accumulated benefit obligations and future cash funding. Actual results in any given year may differ from those estimated because of economic and other factors.

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The assumed discount rate used by the Company for determining future pension obligations under the U.S. plans is based on indices of AA and AAA-rated corporate bonds. The indices of high quality corporate bonds selected reflect the weighted-average remaining period of benefit payments. The assumed rate of compensation increase used by the Company for determining future pension obligations reflects an estimate of the change in actual future compensation levels due to general price levels, productivity, seniority and other factors.

In 2003, net pension expense for the Company's defined benefit pension plans included in earnings before minority interest and income taxes was \$136 million compared to \$34 million in 2002.

The U.S. plans pension expense for 2003 was determined using a 6.75% assumed discount rate and a 3.25% assumed rate of compensation increase. The present value of benefit obligations at December 31, 2003 for the U.S. plans was determined using a 6.25% assumed discount rate. If the assumed discount rate used in determining the U.S. plans pension expense for 2003 had been reduced by 0.5%, such expense would have increased by approximately \$30.4 million. If the assumed rate of compensation increase used in determining the U.S. plans pension expense for 2003 had been reduced by 0.25%, such expense would have decreased by approximately \$6.8 million. If the assumed discount rate used in determining the accumulated benefit obligation at December 31, 2003 had been reduced by 0.5%, the accumulated benefit obligation would have increased by \$235.6 million.

The U.S. plans pension expense for 2003 was determined using a 9% expected long-term rate of return on plan assets. If the expected long-term rate of return on plan assets used in determining the U.S. plans pension expense for 2003 had been reduced by 1%, such expense would have increased by \$34 million.

Actual rates of return earned on U.S. plan assets for each of the last ten years were as follows:

<u>Year</u>	<u>Return</u>	<u>Year</u>	<u>Return</u>
2003	25.0%	1998	13.3%
2002	(13.4)%	1997	22.2%
2001	(6.1)%	1996	17.0%
2000	3.5%	1995	23.0%
1999	18.2%	1994	0.0%

As discussed below, GAAP provides that differences between expected and actual returns are recognized over the average future service of employees.

At December 31, 2003, the Company further lowered its assumed discount rate for U.S. plans from 6.75% to 6.25%. Its assumed rate of compensation increase was raised from 3.25% to 3.56% following a review of recent experience. Compensation is assumed to increase on a scale with different rates for different ages. The 3.56% rate disclosed at December 31, 2003 is the single rate which, if used at each age, would produce the same present value of benefit obligations. The same methodology for disclosure was used in calculating the 3.54% rate at December 31, 2001 and the 3.25% rate at December 31, 2002. The reduction in the discount rate and increase in the assumed rate of compensation increase had the effect of increasing the present value of benefit obligations and, accordingly, will have the effect of increasing pension expense for 2004. In addition, the Company revised, based upon a review of experience, its assumption for active mortality. This revision had the effect of increasing the present value of benefit obligations and, accordingly, will have the effect of increasing pension expense for 2004.

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At December 31, 2002, the Company lowered its assumed discount rate for U.S. plans from 7.25% to 6.75%, to reflect a decline in yields on high quality corporate bonds, and a decline in its assumed rate of compensation increase from 3.54% to 3.25%, to reflect expectations of lower inflation in the future and consistent with the reduction in the assumed discount rate. The reduction in the assumed discount rate increased the present value of future benefit obligations and, accordingly, had the effect of increasing U.S. plans pension expense for 2003. In contrast, the reduction in the assumed rate of compensation increase decreased the present value of benefit obligations and, accordingly, had the effect of decreasing U.S. plans pension expense for 2003. In addition, the Company revised, based on a change in its expectations of future terminations and retirements, its retirement and turnover assumptions. This revision decreased the present value of benefit obligations and 2003 pension expense.

Following many years of strong performance, the global equity market fell sharply in 2000-2002 (the S&P 500 declined by a cumulative 37.6%). This was reversed in 2003 (the S&P 500 rose by 28.7%). The Company reduced the expected rate of return on U.S. plan assets at December 31, 2002 from 10% to 9% and maintained the 9% throughout 2003 and into 2004.

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The Company expects that the net pension expense for its defined benefit pension plans included in earnings before minority interest and income taxes will be approximately \$120 million higher in 2004 than the \$136 million in 2003, reflecting, among other things, the decrease in the assumed discount rate, the increase in the assumed rate of compensation increase and a decrease in the market-related value of the assets in the Company's defined benefit pension plans. The rise in the global equity markets in 2003 has improved the funded status of the plans after three difficult years in 2000-2002. Since investment gains and losses are recognized in market-related value of assets over a period of years, however, the negative impact of the 2000-2002 period will be felt in 2004 and following, putting upward pressure on pension expense.

The Company has used the same assumed discount rates and expected long-term rates of return on plan assets in calculating its cost of pension benefits and its cost of other postretirement benefits except in the case of the discount rate at December 31, 2003. A rate of 6.25% was used for pension benefits versus 6.00% for other postretirement benefits to reflect the shorter duration of the other postretirement liabilities.

U.S. health care costs for the retiree population are assumed to increase 10.0% in 2004 and then trend down to an expected increase of 4.5% per year by 2010. If actual costs are higher than those assumed, this will likely put significant upward pressure on the Company's expense for retiree health care.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Following the guidance in FASB Staff Position FAS 106-1, the Company has elected to defer recognition of the effect of the Act, so the accumulated postretirement benefit obligation and net periodic postretirement benefit cost do not reflect the effect of the Act on the 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.

*Delayed Recognition of Actuarial Gains and Losses*

At December 31, 2003 and 2002, unrecognized net actuarial losses for the Company's defined benefit plans were \$1,676 million and \$1,657 million, respectively, based on the fair market value of plan assets. These unrecognized net actuarial losses reflect in part a decline in the fair market value of plan assets and a reduction of the weighted-average discount rate in 2003 and 2002.

SFAS No. 87 provides for delayed recognition of actuarial gains and losses, including amounts arising from changes in the estimated plan benefit obligations due to changes in the assumed discount rate, differences between the actual and expected returns on plan assets, and other assumption changes. SFAS No. 87 requires that unrecognized net actuarial gain or loss, determined based on the market-related value of plan assets (which differs from fair market value and is a calculated value that recognizes changes in fair value in a systematic and rational manner over not more than five years), be amortized in pension income or expense for the year to the extent that such unrecognized net actuarial loss or gain exceeds 10% of the greater of the projected benefit obligation or the market-related value of plan assets at the beginning of the year. These net gains and losses are recognized as pension income or expense prospectively over a period that approximates the average remaining service period of active employees expected to receive benefits under the plans (approximately 10 years) to the extent that they are not offset by losses and gains in subsequent years.

At December 31, 2002, the unrecognized net actuarial loss, determined based on the market-related value of plan assets, was \$994 million. This amount exceeded 10% of the greater of the projected benefit obligation or the market related value of plan assets by \$577 million. At December 31, 2003, the unrecognized net actuarial loss, determined based on the market-related value of plan assets, was \$1,717 million. This amount exceeded 10% of the greater of the projected benefit obligation or the market related value of plan assets by \$1,241 million. Unless offset by future unrecognized gains from higher discount rates or higher than expected returns on plan assets, amortization of this \$1,241 million

unrecognized loss is expected to increase pension expense for each of the following ten years by approximately \$124 million per year, which amount is reflected in the higher expense expected in 2004.

In the event the fair market value of pension plan assets of a particular plan is less than the accumulated benefit obligation for such plan at year-end, GAAP may require an additional minimum liability and, in such circumstances, a reduction in stockholders' equity or an establishment of an intangible asset. At December 31, 2003, fair market value of the Company's defined benefit pension plan assets was \$4,085 million and the related accumulated benefit obligation was \$4,154 million. The Company recognized an additional minimum liability of \$53 million (cumulative \$203 million) at December 31, 2003, which was offset by the \$53 million charge in other comprehensive income included in stockholders' equity. At December 31, 2002, fair market value of the Company's defined benefit pension plan assets was \$3,318 million, and the related accumulated benefit obligation was \$3,604 million. The Company recognized an additional minimum liability of \$142 million (cumulative \$150 million) at December 31, 2002, which was offset by the creation of a \$10 million intangible asset and \$132 million charge in other comprehensive income included in stockholders' equity.

#### *Plan Funding*

The Company's funding policy for defined benefit plans is to contribute amounts to provide for current service and to fund past service liability. The Company contributed to the defined benefit plans \$332 million and \$554 million in 2003 and 2002, respectively.



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### **Critical Accounting Policies**

The Company prepares its financial statements in conformity with accounting principles generally accepted in the United States. 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, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company's critical accounting policies are those that are both most important to the Company's financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may vary from these estimates.

The Company believes that the following represent its critical accounting policies. For a summary of all of the Company's significant accounting policies, including the critical accounting policies discussed below, see Item 8. Financial Statements Note 1. Accounting Policies. Management and the Company's independent accountants have discussed the Company's critical accounting policies with the Audit Committee of the Board of Directors.

#### *Revenue Recognition*

The Company's accounting policy for revenue recognition has a substantial impact on its reported results and relies on certain estimates that require the most difficult, subjective and complex judgments on the part of management. The Company recognizes revenue for sales when substantially all the risks and rewards of ownership have transferred to the customer, except in the case of certain transactions with its U.S. pharmaceutical wholesalers, which are accounted for using the consignment model. Under GAAP, revenue is recognized when substantially all the risks and rewards of ownership have transferred. 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 should be 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 wholesalers as consignment inventory at the Company's cost of such inventory. The Company recognizes revenue (net of discounts, rebates, sales allowances and accruals for returns, all of which involve significant estimates and judgments) when the consignment inventory is no longer subject to incentive arrangements but not later than when such inventory is sold through to the wholesalers' customers, on a FIFO basis.

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.

#### *Acquired In-Process Research and Development*

The fair value of in-process research and development acquired in a business combination is determined by independent appraisal based on the present value of each research project's projected cash flows. An income approach is utilized that is consistent with guidance in the practice aid issued by the American Institute of Certified Public Accountants entitled, *Assets Acquired in a Business Combination to Be Used in Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries*. Future cash flows are predominately based on the net income forecast of each project consistent with historical pricing, margins and expense levels of similar products. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and the life of each research project's underlying patent. In determining the fair value of each research project, expected revenues are first adjusted for technical risk of completion. The resulting cash flows are then discounted at a rate approximating the Company's weighted average cost of capital.

#### *Impairment of Long-Lived Assets*

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An

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estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its estimated net realizable value.

Goodwill is evaluated at least annually for impairment in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires that goodwill be tested for impairment using a two-step process. The first step is to identify a potential impairment, and the second step measures the amount of the impairment loss, if any. Goodwill is deemed to be impaired if the carrying amount of a reporting unit's goodwill exceeds its estimated fair value. SFAS No. 142 requires that indefinite-lived intangible assets be tested for impairment using a one-step process, which consists of a comparison of the fair value to the carrying value of the intangible asset. Such intangible assets are deemed to be impaired if their net book value exceeds their estimated fair value.

The estimates of future cash flows, based on reasonable and supportable assumptions and projections, require management's judgment. Any changes in key assumptions about the Company's businesses and their prospects, or changes in market conditions, could result in an impairment charge.

### *Equity Investments*

The Company reviews its equity investments for impairment based on its determination of whether the decline in market value of the investment below the Company's carrying value is other than temporary. In making this determination, the Company considers Accounting Principles Board Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*, which sets forth factors to be evaluated in determining whether a loss in value should be recognized, including the Company's ability to hold its investment, the market price and market price fluctuations of the investment's publicly traded shares and inability of the investee to sustain an earnings capacity, which would justify the carrying amount of the investment. The Company's investment in ImClone is subject to this accounting. See Item 8. Financial Statements Note 3. Alliances and Investments for a discussion of the Company's investment in ImClone.

### *Retirement Benefits*

The Company's pension plans and postretirement benefit plans are accounted for using actuarial valuations required by SFAS No. 87, *Employers' Accounting for Pensions*, and SFAS No. 106, *Employers' Accounting for Postretirement Benefits Other Than Pensions*. The Company considers accounting for retirement plans critical because management is required to make significant subjective judgments about a number of actuarial assumptions, including discount rates, salary growth, long-term return on plan assets, retirement, turnover, health care cost trend rates and mortality rates. Depending on the assumptions and estimates used, the pension and postretirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. In addition, the assumptions can materially affect accumulated benefit obligations and future cash funding. For a detailed discussion of the Company's retirement benefits, see Retirement Benefits above and Item 8. Financial Statements Note 21. Pension and Other Postretirement Benefit Plans.

### *Restructuring*

To downsize and streamline operations and rationalize manufacturing facilities, the Company has periodically recorded restructuring charges. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to

be incurred when the restructuring actions take place. Actual results could vary from these estimates, resulting in an adjustment to earnings.

### *Contingencies*

In the normal course of business, the Company is subject to contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including government investigations, shareholders suits, product liability, environmental liability and tax matters. 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. For a discussion of contingencies, see Item 8. Financial Statements Note 9. Income Taxes and Note 22. Legal Proceedings and Contingencies.

### *Income Taxes*

As of December 31, 2003, taxes were not provided on approximately \$12.6 billion of undistributed earnings of foreign subsidiaries, as the Company has invested or expects to invest the undistributed earnings indefinitely. If in the future these earnings are repatriated to the United States, or if the Company determines such earnings will be remitted in the foreseeable future, additional tax provisions would be required. Due to complexities in the tax laws and the assumptions that would have to be made, it is not practicable to estimate the amounts of income taxes that would have to be provided.

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The Company evaluates the need for a deferred tax asset valuation allowance by assessing whether it is more likely than not that it will realize its deferred tax assets in the future. The assessment of whether or not a valuation allowance is required often requires significant judgment including the forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowance are made to earnings in the period when such assessment is made.

In addition, the Company has operations in tax jurisdictions located in most areas of the world and is subject to audit in these jurisdictions. Tax audits by their nature are often complex and can require several years to resolve. Accruals for tax contingencies require management to make estimates and judgments with respect to the ultimate outcome of a tax audit. Actual results could vary from these estimates.

**Outlook for 2004**

The Company expects to have both growth opportunities and exclusivity challenges over the next several years. For 2004, it estimates reductions of net sales 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 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. Sales rose in 2003, resulting in a higher base, and generic competition did not develop in 2003 as expected, thereby increasing the expected level of exclusivity losses in 2004. In addition, the impact of exclusivity losses for PARAPLATIN anticipated to occur primarily in 2005 will be accelerated into 2004 if an anticipated six-month extension of exclusivity protection based on pediatric studies is not obtained by April 2004. The 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. Subject to these uncertainties, the Company estimates that there will be incremental exclusivity losses in each of the next several years, as measured against the net sales levels at the time exclusivity will be lost, of between \$1 billion and \$1.3 billion in each of the years 2005, 2006 and 2007, resulting, together with the estimated reductions in net sales for 2004 described above, in total estimated exclusivity losses of \$2.2 to \$2.6 billion in 2005, \$3.2 to \$3.9 billion in 2006 and \$4.2 to \$5.2 billion in 2007.

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 of 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 reduces 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 to standard statin therapy with PRAVACHOL in the reduction of the risk of later major cardiovascular events.

The Company believes this revenue loss will be more or less offset by growth of revenues resulting from growth of the Company's in-line products, including PLAVIX\*, AVAPRO\*/AVALIDE\* and SUSTIVA, the growth of recently launched exclusive products, ABILIFY\* and REYATAZ, the growth of the recently FDA approved product ERBITUX\*, and by the introduction of late-stage pipeline products such as ABATACEPT (CTLA4Ig), entecavir and muraglitazar that may be approved within the next thirty-six months and begin to contribute significantly by 2007. Additionally, OTN sales growth is expected to continue. This belief is subject to any adverse determination that may occur with respect to the PLAVIX\* patent litigation. See Item 1. Business Competition and Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies. In addition, there can be no assurance as to when or if the Company will obtain the required regulatory approvals for its late-stage pipeline products. The Company expects the resulting product mix to pressure Company margins because the products losing exclusivity protection carry higher margins than products expected to grow sales.

The Company has historically reviewed and will continue to review its cost base. Decisions that may be taken as a result of 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, as reflected in earnings guidance. External development and licensing will remain important elements of the Company's strategy, but the potential cost and impact of any transactions that may be entered into in the future are not built into the Company's plans or guidance with respect to 2004 earnings.

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 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

The Company's expectations for future sales growth described above include substantial expected increases in sales of PLAVIX\*, which had net sales of approximately \$2.5 billion in 2003. The composition of matter patent for PLAVIX\*, which expires in 2011, is currently the subject of litigation in the United States. Similar proceedings involving PLAVIX\* also have been instituted outside the United States. The Company continues to believe that the patent is valid and that it is infringed, and with its alliance partner and patent-holder Sanofi, is vigorously pursuing these cases. It is not possible at this time reasonably to assess the outcome of these litigations, or if there were an adverse determination in these litigations, the timing of potential generic competition for

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PLAVIX\*. However, if generic competition were to occur, the Company believes it is very unlikely to occur before sometime in 2005. Loss of market exclusivity for 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.

Actual results may differ materially from the experience described above. Some of the factors that could affect these expectations are described under "Cautionary Factors That May Affect Future Results" below.

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

This annual report on Form 10-K (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 of similar meaning 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.

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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.



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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.

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 American Institute of Certified Public Accountants, 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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

The Company is exposed to market risk due to changes in currency exchange rates and interest rates. To reduce that risk, the Company enters into certain derivative financial instruments, when available on a cost-effective basis, to hedge its underlying economic exposure. These instruments are managed on a consolidated basis to efficiently net exposures and thus take advantage of any natural offsets. Derivative financial

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instruments are not used for speculative purposes. Gains and losses on hedging transactions are offset by gains and losses on the underlying exposures being hedged. Any ineffective portion of hedges is reported in earnings as it occurs.

Foreign exchange option contracts and forward contracts are used to hedge anticipated transactions. The Company's primary foreign currency exposures in relation to the U.S. dollar are the euro, Japanese yen, Canadian dollar, and Mexican peso.

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The table below summarizes the Company's outstanding foreign exchange contracts as of December 31, 2003. The fair value of all foreign exchange contracts is based on year-end currency rates (and the Black-Scholes model in the case of option contracts). The fair value of option contracts and forward contracts should be viewed in relation to the fair value of the underlying hedged transactions and the overall reduction in exposure to adverse fluctuations in foreign currency exchange rates.

	<b>Weighted Average Strike Price</b>	<b>Notional Amount</b>	<b>Fair Value</b>	<b>Maturity</b>
(dollars in millions, except currency rates)				
<b>Foreign Exchange Forwards:</b>				
Australian Dollar	0.64	\$ 157	\$ (22)	2004/2005
Brazilian Real	3.31	12	(1)	2004
British Pound	1.67	158	(8)	2004
Canadian Dollar	1.44	277	(28)	2004/2005
Euro	1.14	2,058	(200)	2004/2005
Japanese Yen	111.82	(285)	5	2004
South African Rand	8.30	14	(3)	2004
Swedish Krona	8.03	53	(6)	2004
Swiss Franc	1.28	44	(2)	2004
<b>Total Contracts</b>		<b>\$ 2,488</b>	<b>\$ (265)</b>	

At December 31, 2002, the Company held option contracts with an aggregate notional amount and fair value of \$754 million and \$12 million, respectively. These contracts granted the right to sell euros, Canadian and Australian dollars. The Company also held forward contracts with an aggregate notional amount of \$1,021 million and fair value was a liability of \$37 million. These contracts primarily related to exposures in the euro.

The Company uses derivative instruments as part of its interest rate risk management policy. The derivative instruments used include interest rate swaps, which are subject to fair-value hedge accounting treatment. During 2003 and 2002, the Company executed several fixed to floating interest rate swaps to convert \$5.5 billion of the Company's fixed rate debt to be paid in 2006, 2008, 2011 and 2013 to variable rate debt. For the year ended December 31, 2003, the Company recognized a net reduction in interest expense of \$116 million that reflects the benefit of the lower floating rate obtained in the swap agreement. SFAS No. 133 requires the revaluation, at fair value, of the swap contracts as well as the underlying debt being hedged. As such, the swap contracts and the underlying debt have been revalued resulting in an increase in the current assets and long-term debt of \$40 million. Swap contracts are generally held to maturity and are not used for speculative purposes. The following table summarizes the interest rate swaps outstanding as of December 31, 2003 (dollars in millions):

<b>Interest Rate Contracts</b>	<b>Notional Amount of</b>		<b>Maturity</b>	<b>Fair Value</b>
	<b>Underlying Debt</b>	<b>Variable Rate Received</b>		
Swaps associated with				
4.75% Notes due 2006	\$ 2,000	1 month U.S.\$ LIBOR +1.04%	2006	\$ 54
Swaps associated with	400	1 month U.S.\$ LIBOR +0.35%	2008	1

4.00% Notes due 2008

Swaps associated with

5.75% Notes due 2011	2,500	1 month U.S.\$ LIBOR +1.50%	2011	(23)
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Swaps associated with

5.25% Notes due 2013	600	1 month U.S.\$ LIBOR +0.42%	2013	8
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	<u>5,500</u>			<u>40</u>
	<u>\$</u>			<u>\$</u>

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The following table summarizes the interest rate swaps outstanding as of December 31, 2002 (dollars in millions):

<u>Interest Rate Contracts</u>	<u>Notional Amount of Underlying Debt</u>	<u>Variable Rate Received</u>	<u>Maturity</u>	<u>Fair Value</u>
Swaps associated with				
4.75% Notes due 2006	\$ 1,500	1 month U.S.\$ LIBOR +.54%	2006	\$ 83
Swaps associated with				
5.75% Notes due 2011	1,500	1 month U.S.\$ LIBOR +1.31%	2011	50
	<u>\$ 3,000</u>			<u>\$ 133</u>

It is estimated that a 10% change in interest rate structure would not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

The Company also has outstanding several interest rate and foreign currency swaps related to Japanese yen notes due through 2005. The aggregate fair value of these instruments as of December 31, 2003 and 2002 was \$0.2 million and \$1 million, respectively.

The Company had \$8,522 million and \$6,261 million of long-term debt outstanding at December 31, 2003 and 2002, respectively. See Item 8. Financial Statements Note 16. Short-Term Borrowings and Long-Term Debt and Note 18. Financial Instruments for additional information.

The Company maintains cash, cash equivalents and marketable securities with various financial institutions, in order to limit exposure to any one financial institution. These financial institutions are headquartered primarily in North America and Europe.

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**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENT OF EARNINGS**

(in millions, except per share data)

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

	Year Ended December 31,		
	2003	Restated 2002	Restated 2001
<b>EARNINGS</b>			
Net Sales	\$ 20,894	\$ 18,106	\$ 18,044
Cost of products sold	7,592	6,532	5,515
Marketing, selling and administrative	4,660	4,124	4,058
Advertising and product promotion	1,416	1,143	1,201
Research and development	2,279	2,206	2,157
Acquired in-process research and development		169	2,772
Provision for restructuring and other items	26	14	456
Litigation charges, net	199	659	77
Gain on sales of businesses/product lines		(30)	(475)
Asset impairment charge for investment in ImClone		379	
Equity in net income of affiliates	(151)	(80)	(78)
Other expense, net	179	229	98
Total expenses	16,200	15,345	15,781
Earnings from Continuing Operations Before Minority Interest and Income Taxes	4,694	2,761	2,263
Provision for income taxes	1,215	391	213
Minority interest, net of taxes	373	303	179
Earnings from Continuing Operations	3,106	2,067	1,871
Discontinued Operations			
Net earnings		32	226
Net gain on disposal		38	2,565
		70	2,791
Net Earnings	\$ 3,106	\$ 2,137	\$ 4,662
Earnings per Common Share			
Basic			
Earnings from Continuing Operations	\$ 1.60	\$ 1.07	\$ 96
Discontinued Operations			

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Net earnings		.02	.12
Net gain on disposal		.02	1.32
		<u>          </u>	<u>          </u>
		.04	1.44
		<u>          </u>	<u>          </u>
Net Earnings	\$ 1.60	\$ 1.11	\$ 2.40
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Diluted</b>			
Earnings from Continuing Operations	\$ 1.59	\$ 1.06	\$ .95
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Discontinued Operations</b>			
Net earnings		.02	.11
Net gain on disposal		.02	1.31
		<u>          </u>	<u>          </u>
		.04	1.42
		<u>          </u>	<u>          </u>
Net Earnings	\$ 1.59	\$ 1.10	\$ 2.37
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Average Common Shares Outstanding</b>			
Basic	1,937	1,936	1,940
Diluted	1,950	1,942	1,965
Dividends declared per common share	\$ 1.12	\$ 1.12	\$ 1.11

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

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

(dollars in millions)

	<u>2003</u>	<u>Restated 2002</u>	<u>Restated 2001</u>
<b>COMPREHENSIVE INCOME</b>			
Net Earnings	\$ 3,106	\$ 2,137	\$ 4,662
Other Comprehensive Income:			
Foreign currency translation, net of tax benefit of \$25 in 2003, \$53 in 2002 and \$40 in 2001	233	161	160
Deferred (losses) on derivatives qualifying as hedges, net of tax benefit of \$65 in 2003, \$19 in 2002 and \$37 in 2001	(171)	(25)	(62)
Minimum pension liability adjustment, net of tax benefit of \$17 in 2003, \$43 in 2002 and \$3 in 2001	(36)	(89)	(5)
Available for sale securities, net of taxes of \$13 in 2003	23	1	
Total Other Comprehensive Income	49	48	93
Comprehensive Income	\$ 3,155	\$ 2,185	\$ 4,755
<b>RETAINED EARNINGS</b>			
Retained Earnings, January 1	\$ 18,503	\$ 18,530	\$ 16,166
Net earnings	3,106	2,137	4,662
	21,609	20,667	20,828
Cash dividends declared	(2,170)	(2,168)	