

BRISTOL MYERS SQUIBB CO  
Form 10-K  
February 22, 2008  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2007

Commission File Number 1-1136

**BRISTOL-MYERS SQUIBB COMPANY**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction)

22-0790350  
(IRS Employer)

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of incorporation or organization)

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

Identification No.)

(Address of principal executive offices)

Telephone: (212) 546-4000

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

Title of each class	Name of each exchange on which registered
Common Stock, \$0.10 Par Value	New York Stock Exchange
\$2 Convertible Preferred Stock, \$1 Par Value	New York Stock Exchange

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of accelerated filer, large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the 1,978,987,106 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, 2007) was approximately \$62,456,833,065. Bristol-Myers Squibb has no non-voting common equity. At February 12, 2008, there were 1,979,387,706 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the Proxy Statement for the registrant's Annual Meeting of Stockholders to be held May 6, 2008 are incorporated by reference into Part III of this Annual Report on Form 10-K.



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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 health care related products.

**Acquisitions and Divestitures**

In July 2007, the Company completed the sale of the BUFFERIN\* and EXCEDRIN\* brands in Japan, Asia (excluding China and Taiwan) and certain Oceanic countries to Lion Corporation (Japan) for \$247 million in cash. As a result of this transaction, the Company recognized a pre-tax gain of \$247 million (\$144 million net of tax) in the third quarter of 2007.

In October 2007, the Company completed the acquisition of Adnexus Therapeutics, Inc. (Adnexus), developer of a new therapeutic class of biologics called ADNECTINS, for a net purchase price of \$415 million. In addition, in the event that certain future development and regulatory milestones are achieved, the Company is obligated under the terms of the agreement to pay the former stockholders of Adnexus up to an additional \$74 million.

In December 2007, the Company entered into a definitive agreement with Avista Capital Partners L.P. (Avista) for the sale of its Medical Imaging business for a purchase price of approximately \$525 million in cash, subject to customary post-closing adjustments. The closing of the transaction was completed on January 7, 2008. As a result of this transaction, the Company expects to recognize a pre-tax gain of approximately \$20 million to \$40 million (\$30 million to \$50 million loss net of tax) in the first quarter of 2008, subject to the post-closing adjustments.

**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 U.S. Securities and Exchange Commission (SEC).

Information relating to corporate governance at Bristol-Myers Squibb, including the Company's Standards of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers, Code of Business Conduct and Ethics for Directors, (collectively, the Codes), Corporate Governance Guidelines, and information concerning the Company's Executive Committee, Board of Directors, including Board Committees and Committee charters, and transactions in Bristol-Myers Squibb securities by Directors and executive officers, is available on the Company's website at [www.bms.com](http://www.bms.com) under the Investors Corporate Governance caption and in print to any stockholder upon request. Any waivers to the Codes by directors or executive officers and any material amendment to the Code of Business Conduct and Ethics for Directors and Code of Ethics for Senior Financial Officers 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 2008 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 2008 Annual Meeting of Stockholders and 2007 Annual Report will be available on the Company's website ([www.bms.com](http://www.bms.com)) under the Investors SEC Filings caption on or after March 21, 2008.

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**Business Segments**

The Company has three reportable segments—Pharmaceuticals, Nutritionals and ConvaTec (previously a component of the Other Health Care operating segment). In January 2008, the Company completed the sale of its Medical Imaging business to Avista. The results of the Medical Imaging business previously included in the former Other Health Care operating segment, are presented as part of the Company’s results from discontinued operations.

The Pharmaceuticals segment is made up of the global pharmaceutical and international consumer medicines business. The Pharmaceuticals segment accounted for 81% of the Company’s sales in 2007, 80% of the Company’s sales in 2006, and 83% of the Company’s sales in 2005. U.S. Pharmaceuticals sales accounted for 58%, 54% and 54% of total Pharmaceutical sales in 2007, 2006 and 2005, respectively, while international Pharmaceutical sales accounted for 42%, 46% and 46% of total Pharmaceutical sales in 2007, 2006 and 2005, respectively.

The other two segments—Nutritionals and ConvaTec—comprise the Company’s Health Care Group. The Nutritionals segment consists of Mead Johnson Nutritionals (Mead Johnson), primarily an infant formula and children’s nutritionals business. The ConvaTec segment consists of the ostomy, wound and skin care business. Health Care Group sales accounted for 19% of the Company’s sales in 2007, 20% of the Company’s sales in 2006, and 17% of the Company’s sales in 2005. U.S. Health Care Group sales accounted for 40%, 42% and 43% of total Health Care Group sales in 2007, 2006 and 2005, respectively, while international Health Care Group sales accounted for 60%, 58% and 57% of total Health Care Group sales in 2007, 2006 and 2005, respectively.

For additional information about these segments, see Item 8. Financial Statements—Note 19. Segment Information.

*Pharmaceuticals Segment*

The Pharmaceuticals segment competes with other worldwide research-based drug companies, smaller research companies and generic drug manufacturers. These products are sold worldwide, primarily to wholesalers, retail pharmacies, hospitals, government entities and the medical profession. The Company manufactures these products in the U.S. and Puerto Rico and in 14 foreign countries. U.S. Pharmaceuticals net sales accounted for 58%, 54% and 54% of total Pharmaceuticals net sales in 2007, 2006 and 2005, respectively, while Pharmaceuticals net sales in Europe, Middle East and Africa accounted for 25%, 28% and 29% of total Pharmaceuticals net sales in 2007, 2006 and 2005, respectively. Pharmaceuticals net sales in Japan accounted for 4% of total Pharmaceuticals net sales in each of 2007, 2006 and 2005.

The Company’s key products include PLAVIX\* (clopidogrel bisulfate), AVAPRO/AVALIDE\* (irbesartan/irbesartan hydrochlorothiazide), REYATAZ (atazanavir sulfate), ABILIFY\* (aripiprazole), ERBITUX\* (cetuximab), SPRYCEL (dasatinib), BARACLUDGE (entecavir), ORENCIA (abatacept), the SUSTIVA Franchise (efavirenz) and IXEMPRA (ixabepilone).

The composition of matter patent for PLAVIX\*, which expires in 2011, is currently the subject of patent litigation in the U.S. with Apotex Inc. and Apotex Corp. (Apotex) and other generic companies as well as in other less significant jurisdictions. As previously disclosed, on August 8, 2006, Apotex launched a generic clopidogrel bisulfate product that competes with PLAVIX\*. The generic launch had a significant adverse impact on PLAVIX\* sales, which the Company estimates to be in a range of \$250 million to \$350 million in 2007 and \$1.2 billion to \$1.4 billion in 2006. Estimated total U.S. prescription demand for clopidogrel bisulfate (branded and generic) increased 8% in 2007 compared to 2006, while estimated total U.S. prescription demand for branded PLAVIX\* increased 34% in the same period. The Company believes that the supply of generic clopidogrel bisulfate that was sold into distribution channels following the Apotex at-risk launch in August 2006 has been substantially depleted. In June 2007, the U.S. District Court for the Southern District of New York (District Court) upheld the composition of matter patent for PLAVIX\* and enjoined Apotex from engaging in any activity that infringes the patent, including marketing its generic product in the U.S. until after the patent expires. Apotex has appealed the District Court’s decision. The Apotex appeal date has been set for March 2008. The damages phase of the trial is on-going. For more information about the pending PLAVIX\* litigation, as well as the generic launch by Apotex, see Item 8. Financial Statements—Note 22. Legal Proceedings and Contingencies.

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### ***Products***

Most of the Company's pharmaceutical revenues come from products in the following therapeutic classes: cardiovascular; virology, including human immunodeficiency virus (HIV) infection; oncology; affective and other (psychiatric) disorders; and immunoscience.

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. In the U.S. and some other countries, 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.

An increasing portion of the Company's innovative pharmaceutical products are biological products, or biologics. Currently, generic versions of biological products cannot be approved under U.S. law. However, the law could change in the future. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics. Competitors seeking approval of biological products must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex processes and are more costly than those of traditional pharmaceutical operations.

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 currently estimated to occur in the U.S., 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 U.S., the EU and Japan. In many 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 prior to the expiration of data exclusivity.

The Company estimates the market exclusivity period for each of its products on a case-by-case basis for the purposes of business planning only. The length of market exclusivity for any of the Company's products is impossible to predict with certainty because of the complex interaction between patent and regulatory forms of exclusivity and the inherent uncertainties regarding patent litigation. Although the Company provides these estimates for business planning purposes, these are not intended as an indication of how the Company's patents might fare in any particular patent litigation brought against potential infringers. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that appears in the estimate or that the exclusivity will be limited to the estimate.

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Pharmaceutical Products Dollars in Millions	2007	2006	2005	Past or Currently Estimated Year of U.S. Basic Exclusivity Loss	Past or Currently Estimated Year of EU Basic Exclusivity Loss (a)	Past or Currently Estimated Year of Japanese Basic Exclusivity Loss
<b>Cardiovascular</b>						
PLAVIX*	\$ 4,755	\$ 3,257	\$ 3,823	2011	2008-2013	++
AVAPRO*/AVALIDE*	1,204	1,097	982	2012	2007-2013	++
PRAVACHOL	443	1,197	2,256	2006	2002-2008	++
COUMADIN	201	220	212	(b)	(b)	++
<b>Virology</b>						
REYATAZ	1,124	931	696	2017	2017	2017
SUSTIVA Franchise (total revenue)	956	791	680	2013 <sup>(c)</sup>	2013 <sup>(c)</sup>	++
BARACLUDE	275	83	12	2015	2011-2016	2016
<b>Oncology</b>						
ERBITUX*	692	652	413	2017 <sup>(d)</sup>	++	++
TAXOL® (paclitaxel)	422	563	747	2000	2003	2006
SPRYCEL	158	25		2020	2020 <sup>(e)</sup>	++
IXEMPRA	15			2018	2018	++
<b>Affective (Psychiatric) Disorders</b>						
ABILIFY* (total revenue)	1,660	1,282	912	2014 <sup>(f)</sup>	2014 <sup>(g)</sup>	++
<b>Immunoscience</b>						
ORENCIA	231	89		2016 <sup>(d)</sup>	2012 <sup>(h)</sup>	++
<b>Other Pharmaceuticals</b>						
EFFERALGAN	308	266	283	++	N/A	++

Note: The currently estimated 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 manufacturing or methods of using the drug. Such patents may sometimes result in a favorable market position for the Company's product, but product exclusivity cannot be predicted or assured. Note also that, for products filed under a Biologics License Application (BLA) in the U.S., the year of exclusivity is listed as the year of patent expiration even though there is currently not a regulatory pathway for the approval of follow-on biologic products, as described in more detail in Intellectual Property and Product Exclusivity below.

\* Indicates brand names of products which are registered trademarks not owned by the Company or its subsidiaries. Specific trademark ownership information can be found on page 152.

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

(a) References to the EU throughout this Form 10-K include the following current 27 member states: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom (UK). Basic patent applications have not been filed in all 27 current member states for all of the listed products. 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) Basic exclusivity expired before BMS acquired the product.

(c) Exclusivity period relates to SUSTIVA brand only.

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- (d) Biologic product approved under a BLA. In the U.S., there is currently no regulatory approval path for generic biologics.
- (e) Pending application. EU patent application was not filed in Estonia, Latvia, Lithuania, Malta, Slovakia and Slovenia.
- (f) The Company's rights to commercialize aripiprazole in the U.S. terminate in 2012.
- (g) The Company's rights to commercialize aripiprazole in the EU terminate in 2014.
- (h) Data exclusivity in the EU expires in 2017.



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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 U.S. and, where applicable, the EU and Japan.

**Cardiovascular**

**PLAVIX\***

Clopidogrel bisulfate 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 bisulfate was codeveloped and is jointly marketed with Sanofi-Aventis (Sanofi). The worldwide alliance operates under the framework of two geographic territories: one in the Americas and Australia (the Company's primary territory) and the other in Europe and Asia (Sanofi's primary territory).

The composition of matter patent in the U.S. expires in 2011 (which includes a statutory patent term extension), and is currently the subject of patent litigation in the U.S. with Apotex and other generic companies, as well as in other less significant jurisdictions. The District Court has upheld the validity and enforceability of the composition of matter patent and Apotex has appealed that decision. The oral argument on the Apotex appeal date has been set for March 2008. It is not possible at this time reasonably to assess the outcome of the appeal by Apotex and/or the timing of any renewed generic competition from Apotex or potential additional generic competition from other generic pharmaceutical companies. However, if Apotex were to prevail in its appeal, the Company would expect renewed generic competition promptly thereafter. For more information about these litigation matters, as well as the generic launch by Apotex, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

In the EU, regulatory data exclusivity expires in July 2008 in all the EU member countries and the key composition of matter patent expires in 2013 in the majority of the EU member countries.

The Company obtains its bulk requirements for clopidogrel bisulfate from Sanofi and a third party. Both the Company and Sanofi finish the product in their own facilities. For more information about the Company's arrangements with Sanofi, see Strategic Alliances below and Item 8. Financial Statements Note 2. Alliances and Investments.

**AVAPRO\*/AVALIDE\***

Irbesartan/irbesartan-hydrochlorothiazide 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 worldwide alliance operates under the framework of two geographic territories: one in the Americas and Australia (the Company's primary territory) and the other in Europe and Asia (Sanofi's primary territory). In September 2006, the Company elected to terminate its copromotion of this product with Sanofi in Ireland, Sweden, Norway, Finland and Denmark.

The basic composition of matter patent in the U.S. expires in 2012 (including pediatric extension) and in the EU in 2013. Data exclusivity in the EU expires in August 2007 for AVAPRO\* and in October 2008 for AVALIDE\*.

Irbesartan is manufactured by both the Company and Sanofi. The Company manufactures its bulk requirements for irbesartan and finishes AVAPRO\*/AVALIDE\* in its own facilities. For AVALIDE\*, the Company purchases bulk requirements for hydrochlorothiazide from a third party.

For more information about the Company's arrangements with Sanofi, see Strategic Alliances below and Item 8. Financial Statements Note 2. Alliances and Investments.

**PRAVACHOL**

Pravastatin sodium is an HMG Co-A reductase inhibitor indicated as an adjunct to diet and exercise 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.

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The Company has licensed a patent covering pravastatin, marketed by the Company in the U.S. as PRAVACHOL, from Sankyo Company, Ltd. (Sankyo) of Japan, with key provisions of the agreement expiring as exclusivity expires on a market-by-market basis. Exclusivity in the U.S. under the patent (including pediatric extension) expired in April 2006. The Company entered into a distribution agreement with Watson Pharmaceutical (Watson) in November 2005 authorizing Watson to distribute generic pravastatin sodium tablets in the U.S.

In December 2006, LEK D.D. (LEK), a Slovenian generic company that is wholly-owned by Novartis AG (Novartis), filed suit against the Company and Watson in the U.S. District court for the Eastern District of Texas in Marshall, Texas. LEK's complaint alleges that the Company's sale of PRAVACHOL and Watson's sale of an authorized generic of PRAVACHOL infringe two patents of LEK. For more information about this litigation matter, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

The composition of matter patent has expired in all countries in the EU.

The Company obtains its bulk requirements for pravastatin from Sankyo and finishes the product in its own facilities.

**COUMADIN**

Warfarin sodium is an oral anticoagulant used predominantly in patients with atrial fibrillation or deep venous thrombosis/pulmonary embolism.

Market exclusivity expired in the U.S. in 1997. Basic patent protection and regulatory data protection had expired before the Company acquired COUMADIN in 2001.

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

**Virology**

**REYATAZ**

Atazanavir sulfate is a protease inhibitor for the treatment of HIV. REYATAZ was launched in the U.S. 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 Company is entitled to promote REYATAZ for use in combination with NORVIR\* (ritonavir) under a Non-Exclusive License Agreement between Abbott Laboratories and the Company dated July 30, 2003, as amended, for which it pays a royalty based on a percentage of net sales.

Market exclusivity for REYATAZ is expected to expire in 2017 in the U.S., in the major EU member countries and Japan. Data exclusivity in the EU expires in 2014.

The Company manufactures its bulk requirements for atazanavir and finishes the product in its own facilities.

**SUSTIVA Franchise**

Efavirenz, the active ingredient in SUSTIVA, is a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of HIV. The SUSTIVA Franchise includes SUSTIVA, an antiretroviral drug used in the treatment of HIV, and as well as bulk efavirenz included in the combination therapy, ATRIPLA\*, which is sold through a joint venture with Gilead Sciences, Inc. (Gilead). The Company and Gilead share responsibility for commercializing ATRIPLA\* in the U.S. Gilead records 100% of ATRIPLA\* revenues and consolidates the results of the joint venture in its operating results. The Company records revenue for the bulk efavirenz component of ATRIPLA\* upon sales of that product by the Gilead joint venture to third-party customers. The Company's revenue for the efavirenz component is determined by applying a percentage to ATRIPLA\* revenue, which approximates revenue for the SUSTIVA brand. In Europe, the Company and Gilead share responsibility for commercializing ATRIPLA\* throughout the EU and certain other European countries. Gilead will record revenues from future net sales of ATRIPLA\* in most countries in Europe and the Company will record revenues at a percentage relative to the contribution represented by SUSTIVA. In December 2007, the European Commission granted marketing authorization for ATRIPLA\*. For more information about the Company's arrangement with Gilead, see Strategic Alliances below and Item 8. Financial Statements Note 2. Alliances and Investments.

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Rights to market efavirenz in the U.S., Canada, the UK, France, Germany, Ireland, Italy and Spain are licensed from Merck & Co., Inc. for a royalty based on a percentage of net sales.

Market exclusivity for SUSTIVA is expected to expire in 2013 in the U.S. and in countries in the EU; the Company does not, but another company does, market efavirenz in Japan.

The Company obtains its bulk requirements for efavirenz from third parties and produces finished goods in its own facilities. The Company provides bulk efavirenz to Gilead, who is responsible for producing ATRIPLA\* finished goods.

**BARACLUDE**

Entecavir is a potent and selective inhibitor of hepatitis B virus that was approved by the FDA in March 2005 for the treatment of chronic hepatitis B infection. BARACLUDE was discovered and developed internally. It has also been approved and marketed in over 50 countries outside of the U.S. including China, Japan and the EU. The Company has learned that in China several companies have filed for clinical trial permission since the Company received approval. The Company is not aware that any of the applications for clinical trial permission in China have been approved. Due to uncertainty about China's exclusivity laws, it is possible that one or more of these companies could receive marketing authorization from China's health authority by 2010.

The Company has a composition of matter patent that expires in the U.S. in 2010. An application for a patent term extension has been approved in the U.S., which extends the patent expiration to 2015. The composition of matter patent expires in the EU between 2011 and 2016 and in Japan in 2016. A patent term extension has been approved in Japan which extends the patent expiration to 2016. Supplementary protection certificates have been requested in the EU and approved in some EU countries, extending the exclusivity for the approved product to 2016.

The Company manufactures its bulk requirements for entecavir and finishes the product in its own facilities.

**Oncology**

**ERBITUX\***

ERBITUX\* (cetuximab) 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\*, a biological product, is approved for the treatment in combination with irinotecan of patients with EGFR-expressing metastatic colorectal cancer (mCRC) who had failed an irinotecan-based regimen and as monotherapy for patients who are intolerant of irinotecan. In March 2006, the FDA approved ERBITUX\* for use in the treatment of squamous cell carcinoma of the head and neck. Specifically, ERBITUX\* was approved for use in combination with radiation therapy, for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck and, as a single agent, for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed.

Also, in October 2007, the Company received FDA approval for a supplemental Biologics License Application (sBLA) filing to update the ERBITUX\* product labeling to include overall survival data as a single agent in EGFR-expressing mCRC patients after failure of both irinotecan-based and oxaliplatin-based regimens.

ERBITUX\* is marketed in North America by the Company under a distribution and copromotion agreement with ImClone Systems Incorporated (ImClone). The Company shares copromotion rights to ERBITUX\* with Merck KGaA in Japan under a codevelopment and cocommercialization agreement signed in October 2007 among the Company, ImClone, Merck KGaA and Merck Japan. ERBITUX\* is not yet marketed in Japan, although an application has been submitted with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for the use of ERBITUX\* in treating patients with advanced colorectal cancer. For a description of the Company's alliance with ImClone, see Strategic Alliances below and Item 8. Financial Statements Note 2. Alliances and Investments.

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In July 2007, the Company and ImClone amended the terms of their agreement for the codevelopment and copromotion of ERBITUX\* in North America. Under this amendment, the companies have jointly agreed to expand the investment in the ongoing clinical development plan for ERBITUX\* by up to several hundred million dollars. Development costs, up to a threshold value, will be the sole responsibility of the Company; costs in excess of this threshold will be shared by both companies according to a predetermined ratio.

There is no composition of matter patent that specifically claims ERBITUX\*. ERBITUX\* has been approved by the FDA and other health authorities for monotherapy, for which there is no use patent. The use of ERBITUX\* in combination with an anti-neoplastic agent is approved by the FDA. Such combination use is claimed in a granted U.S. patent that expires in 2017. The inventorship of this use patent has been challenged by three researchers from Yeda Research and Development Company Ltd. (Yeda). In September 2006, the court granted Yeda the complete ownership of that patent. ImClone appealed the court's decision and also filed a declaratory judgment action alleging that if the Yeda researchers remain sole inventors of the patent, the patent is invalid.

Pursuant to a settlement agreement executed and announced in December 2007 by ImClone, Sanofi and Yeda to end worldwide litigation related to the use patent, Sanofi and Yeda granted ImClone a worldwide license under the use patent. The settlement agreement does not change ImClone's worldwide royalty rate for ERBITUX\* sales. Under its commercial agreement with ImClone, the Company pays a royalty to ImClone on sales of ERBITUX\* that is not impacted by the settlement agreement.

Yeda also has the right to license the use patent to others. Yeda's license of the patent to third parties could result in product competition for ERBITUX\* that might not otherwise occur. It is too early to assess whether and to what extent any such competitive impact will occur or to quantify any such impact. However, Yeda has also granted Amgen Inc. (Amgen) a license under the use patent. Amgen received FDA approval to market an EGFR-product that competes with ERBITUX\*.

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. For more information about biologics patents, see Intellectual Property and Product Exclusivity below.

The Company obtains its finished goods requirements for cetuximab for use in North America from ImClone. ImClone manufactures bulk requirements for cetuximab in its own facilities and finishing is performed by a third party for ImClone. For a description of the Company's supply agreement with ImClone, see Manufacturing and Quality Assurance below.

**TAXOL® (paclitaxel)**

Paclitaxel is used in the treatment of refractory ovarian cancer, first-line treatment of ovarian cancer in combination with cisplatin, second-line treatment of acquired immunodeficiency syndrome (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.

The active ingredient in TAXOL® (paclitaxel) did not have patent protection in the U.S., the EU or Japan, but did have regulatory protection in the form of data exclusivity. Data exclusivity in the U.S. expired in 1997. An initial approval for a U.S. generic version of paclitaxel was granted in 2000, revoked by the FDA in 2001 and then reinstated in 2002. Data exclusivity in the EU expired in 2003. Data exclusivity for TAXOL® (paclitaxel) in Japan expired in 2003. A patent claiming the approved dosing and administration schedule expires in Japan in 2013. A nullity action filed in 2004 in the Japanese Patent Office invalidated this patent and the Company appealed the decision, but the invalidation decision was affirmed. Meanwhile, a generic paclitaxel was launched in Japan in 2006.

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® (paclitaxel) data.

The Company manufactures its bulk requirements for paclitaxel and finishes the product in its own facilities.

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**SPRYCEL**

Dasatinib is a multi-targeted tyrosine kinase inhibitor that was approved by the FDA in June 2006 for treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib, and for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. Dasatinib was approved in the EU in November 2006. SPRYCEL was discovered and developed internally.

The basic composition of matter patent protecting dasatinib in the U.S. is due to expire in April 2020, and a patent term extension has been requested, which, upon grant, would extend the patent term until June 2020. In several EU countries, the patent is pending and upon grant, would expire in April 2020 (excluding term extensions). An EU patent application was not filed in Cyprus, Estonia, Latvia, Lithuania, Malta, Netherlands, Slovakia or Slovenia. In the U.S., New Chemical Entity Protection expires in 2011, and Orphan Drug Exclusivity expires in 2013, which protects the product from generic applications for the currently approved orphan indications only.

The Company manufactures its bulk requirements for dasatinib and finishes the product in its own facilities.

**IXEMPRA**

IXEMPRA (ixabepilone) is a microtubule inhibitor belonging to a class of antineoplastic agents, the epothilones and their analogs. In October 2007, the FDA approved ixabepilone in combination with capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated, and in monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine. Marketing authorization is currently being sought in EU and other countries.

The basic composition of matter patent protecting ixabepilone in the U.S. is due to expire in May 2018, and a patent term extension has been requested which, upon grant, would extend the patent term until September 2020. A corresponding patent also has been granted in EU countries which is due to expire in June 2018 (excluding term extensions). An EU patent application was not filed in Malta. In the U.S., New Chemical Entity Protection expires in 2012.

Ixabepilone was developed by the Company, but is subject to a license agreement with Helmholtz Zentrum für Infektionsforschung GmbH (HZI), relating to epothilone technologies. Under the Agreement, HZI is entitled to royalties of 0.5% of net sales in all countries in which the product is sold.

The Company manufactures its bulk requirements for ixabepilone in its own facilities including manufacture of the active ingredient. The drug product which comprises a pharmaceutical kit is finished by Baxter Oncology GmbH.

**Affective (Psychiatric) Disorders**

**ABILIFY\***

Aripiprazole is an atypical antipsychotic agent for patients with schizophrenia, acute bipolar mania and Bipolar I Disorder.

Aripiprazole is copromoted in the U.S. by the Company and Otsuka Pharmaceutical Co., Ltd. (Otsuka). The Company's rights to commercialize aripiprazole in the U.S. terminate in 2012. Thereafter, Otsuka has the sole right to commercialize aripiprazole in the U.S. In Germany and Spain, the Company copromotes with an Otsuka affiliate. In the UK and France, the Company currently acts as distributor for the product and copromotes with an Otsuka affiliate. In all other European markets, the Company acts as exclusive distributor. The Company is the exclusive licensee for the product in the rest of the world, excluding Japan and certain other countries. In the U.S., Spain and Germany, the Company records alliance revenue for its contractual share of the net sales and records all expenses related to the product. Alliance revenue is recorded by the Company as net sales based upon 65% of third-party customer net sales in the copromotion countries. The Company recognizes this alliance revenue when ABILIFY\* is shipped and all risks and rewards of ownership have transferred to third-party customers. In the UK, France and Italy, the Company currently records 100% of the net sales and related cost of products sold. In countries where the Company has an exclusive right to sell ABILIFY\*, the Company also records 100% of the net sales and related cost of products sold. For more information about the Company's arrangement with Otsuka, see Strategic Alliances below and Item 8. Financial Statements Note 2. Alliances and Investments.

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The basic U.S. composition of matter patent for ABILIFY\* expires in 2014 (including the granted patent term extension). In 2004, Otsuka filed with the U.S. Patent and Trademark Office (USPTO) a Request for Reexamination of a U.S. composition of matter patent, U.S. Patent No. 5,006,528 (the 528 Patent), covering ABILIFY\*. In June 2006, the USPTO issued an Ex Parte Reexamination Certificate for the 528 Patent confirming the patentability of the original claims and approving additional new claims.

Otsuka has received formal notices from each of Teva Pharmaceuticals USA (Teva), Barr Pharmaceuticals, Inc. (Barr), Sandoz Inc. (Sandoz), Synthron Laboratories, Inc. (Synthron), Sun Pharmaceuticals Ltd. (Sun) and Apotex stating that each has filed an Abbreviated New Drug Application (aNDA) with the FDA for various dosage forms of aripiprazole, which the Company and Otsuka comarket in the U.S. as ABILIFY\*. Each of the notices further states that its aNDA contains a p(IV) certification directed to 528 Patent, which covers aripiprazole and expires in October 2014. In addition, each of the notices purports to provide Otsuka with the respective p(IV) certification. These certifications contain various allegations regarding the enforceability of the 528 Patent and/or the validity and/or infringement of some or all of the claims therein. Otsuka has filed patent infringement actions based on the 528 Patent against Teva, Barr, Sandoz, Sun and Apotex in the U.S. District Court of New Jersey and against Synthron in the U.S. District Court for the Middle District of North Carolina. Otsuka has sole rights to enforce the 528 Patent.

A composition of matter patent is in force in Germany, the UK, France, Italy, the Netherlands, Romania, Sweden, Switzerland, Spain and Denmark. The original expiration date of 2009 has been extended to 2014 by grant of a supplemental protection certificate in all of the above countries except Romania and Denmark. Data exclusivity in the EU expires in 2014. There is no composition of matter patent in Austria, Belgium, Finland, Greece, Ireland, Luxembourg, Portugal, Latvia, Hungary, Cyprus, Czech Republic, Slovenia, Slovakia, Poland, Malta, Lithuania, Bulgaria and Estonia.

The Company obtains its bulk requirements for aripiprazole from Otsuka. Both Otsuka and the Company finish the product in their own facilities.

**Immunoscience**

**ORENCIA**

Abatacept, a biological product, is a fusion protein with novel immunosuppressive activity targeted initially at adult patients with moderate to severe rheumatoid arthritis, who have had an inadequate response to certain currently available treatments. Abatacept was approved by the FDA in December 2005 and made commercially available in the U.S. in February 2006.

ORENCIA was discovered and developed internally.

The Company has a series of patents covering abatacept and its method of use. The latest of the composition of matter patents expires in the U.S. in 2016. The Company has submitted its request for patent term extension for one of the composition of matter patents that expires in 2015, which could possibly extend the term of the patent. In the majority of the EU countries, the Company has a patent covering abatacept that expires in 2012. Data exclusivity in the EU expires in 2017. In January 2006, Repligen Corporation and the Regents of the University of Michigan filed a complaint against the Company in the U.S. District Court for the Eastern District of Texas, Marshall Division alleging that the Company's then-anticipated sales of ORENCIA will infringe U.S. Patent No. 6,685,941. In August 2006, Zymogenetics Inc. filed a complaint against the Company in the U.S. District Court for the District of Delaware. The complaint alleges that the Company's manufacture and sales of ORENCIA infringe U.S. Patents No. 5,843,725 and 6,018,026. For more information about these litigations, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

The Company obtains bulk abatacept from a third party and from its own manufacturing facilities. The Company finishes the product in its own facilities.

**Other Pharmaceuticals**

**EFFERALGAN**

EFFERALGAN is a formulation of acetaminophen first introduced in 1972 and distributed as an effervescent tablet. It is indicated for the treatment of fever or mild to moderate pain for adults and children, and marketed primarily in Europe. There is no composition of matter patent in Europe for EFFERALGAN.

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In addition to the products discussed above, the Company's Pharmaceuticals segment also includes the Company's wholly-owned UPSA Consumer Medicines business in Europe, which includes EFFERALGAN, described above, as well as ASPIRINE UPSA, DAFALGAN and FERVEX in Europe and other overseas markets.

### **Strategic Alliances and Arrangements**

The Company enters into strategic alliances and arrangements 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. The Company also enters into strategic alliances and arrangements with third parties, which give such third parties the rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are owned by the Company. These alliances and arrangements can take many forms, including licensing arrangements, codevelopment and comarketing agreements, copromotion arrangements and joint ventures. Such alliances and arrangements reduce the risk of incurring all 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 that are not partnered 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 and arrangements for the Company's products are those with Sanofi for PLAVIX\* and AVAPRO\*/AVALIDE\*, Otsuka for ABILIFY\*, ImClone for ERBITUX\* and Gilead for ATRIPLA\*. The Company's most significant alliances and arrangements for investigational compounds under development are with Medarex, Inc. (Medarex) for ipilimumab, a monoclonal antibody being investigated as an anticancer treatment, the rights to which are owned by Medarex; with AstraZeneca PLC (AstraZeneca) for saxagliptin, an oral compound discovered by the Company for the potential treatment of diabetes that is a DPP-IV inhibitor, and dapagliflozin, an oral compound discovered by the Company for the potential treatment of diabetes that is a sodium-glucose cotransporter-2 (SGLT2) inhibitor; and with Pfizer, Inc. (Pfizer) for apixaban, an anticoagulant discovered by the Company being studied for the prevention and treatment of a broad range of venous and arterial thrombotic conditions. Each of these significant alliances and arrangements are discussed in more detail below. Additionally, the Company has licensing arrangements with Novartis for REYATAZ and with HZI for IXEMPRA, a novel microtubule-stabilizing agent for the treatment of breast cancer.

In general, the Company's strategic alliances and arrangements are for periods co-extensive with the periods of market exclusivity protection on a country-by-country basis. Based on the Company's current expectations with respect to the expiration of market exclusivity in the Company's significant markets, the licensing arrangements with Novartis for REYATAZ are expected to expire in 2017 in the U.S., the EU and Japan; and HZI for IXEMPRA are expected to expire in 2017 in the U.S., and on the 10th anniversary of the first commercial sale in the EU and Japan. 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](#) above and [Intellectual Property and Product Exclusivity](#) below.

Each of the Company's strategic alliances and arrangements with third parties who own the rights to manufacture, market and/or sell pharmaceutical products 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 or if a material safety issue arises with a product such that the medical risk/benefit is incompatible with the welfare of patients to continue to develop or commercialize this product. Termination upon 30 to 90 days notice is generally available where an involuntary bankruptcy petition has been filed (and has 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 and arrangements typically do not otherwise contain 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 and arrangement 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 terms of the Company's strategic alliances and arrangements generally are co-extensive with the exclusivity period, which is discussed above, and may vary on a country-by-country basis.

As discussed below, the Company's strategic alliance with Otsuka expires in November 2012 in the U.S. and Puerto Rico, which is prior to the expected expiration of market exclusivity protection for ABILIFY\* in 2014 in the U.S. (including a granted patent term extension).





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### **Current Marketed Products**

**Sanofi** The Company has agreements for the codevelopment and cocommercialization of AVAPRO\*/AVALIDE\*, 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\*/COAPROVEL\* and comarketed in certain countries outside the U.S. by the Company under the tradename KARVEA\*/KARVEZIDE\*; and PLAVIX\*, 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 two geographic regions, one covering certain European and Asian countries, defined as Territory A, and one covering the U.S., Puerto Rico, Canada, Australia and certain Latin American countries, defined as Territory B. The region covering the U.S., Puerto Rico, Canada, Australia, and certain Latin American countries is managed by two separate territory agreements, one for U.S. and Puerto Rico AVAPRO\*/AVALIDE\* only, and a second agreement for U.S. and Puerto Rico PLAVIX\* only, plus Canada, Australia, Mexico, Brazil, Colombia and Argentina for both products. Within each of Territory A and B, a Territory Partnership exists to supply product to the countries within each territory and to manage certain central expenses such as marketing, research and development and royalties. Countries within Territory A and B are structured so that the Company's local affiliate and Sanofi either comarket separate brands (e.g., each affiliate operates independently and sells a competing brand), or copromote a single brand.

Within Territory A, the comarketing countries include Germany, Spain, Italy (irbesartan only), Greece and China (clopidogrel bisulfate only). The Company sells ISCOVER\* and KARVEA\*/KARVEZIDE\* and Sanofi sells PLAVIX\* and APROVEL\*/COAPROVEL\* in these countries, except China, where the Company retains the right to, but does not currently comarket ISCOVER\*. The Company and Sanofi copromote PLAVIX\* and APROVEL\*/COAPROVEL\* in France, the UK, Belgium, Netherlands, Switzerland and Portugal. In addition, the Company and Sanofi copromote PLAVIX\* in Austria, Italy, Ireland, Denmark, Finland, Norway, Sweden, Turkey, Taiwan, Korea, Singapore, Malaysia and Hong Kong, and APROVEL\*/COAPROVEL\* in certain French export countries. Sanofi acts as the operating partner for Territory A and owns a 50.1% majority financial controlling interest in this territory. The Company's ownership interest in this territory is 49.9%. The Company accounts for the investment in partnership entities in this territory under the equity method and records its share of the results in equity in net income of affiliates in the consolidated statement of earnings. The Company's share of net income from these partnership entities before taxes was \$526 million in 2007, \$439 million in 2006 and \$345 million in 2005.

Within Territory B, the Company and Sanofi copromote PLAVIX\* in the U.S., Canada and Puerto Rico and AVAPRO\*/AVALIDE\* in Canada. The other Territory B countries, Australia, Mexico, Brazil, Colombia (clopidogrel bisulfate only) and Argentina are comarketing countries. In 2001, the Company and Sanofi modified their previous exclusive license to the Company for AVAPRO\*/AVALIDE\* in the U.S. and Puerto Rico 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 \$200 million in 2001 and \$150 million in 2002. The Company accounts for these payments as a sale of an interest in a license and defers and amortizes the total amount of \$350 million into other income over the expected useful life of the license, which is approximately 11 years from the date of the formation of the copromotion joint venture. The Company acts as the operating partner for Territory B and the U.S./Puerto Rico AVAPRO\*/AVALIDE\* Territory and owns a 50.1% majority controlling interest in these territories. As such, the Company consolidates all partnership results in these territories and records Sanofi's share of the results as a minority interest expense, net of taxes, which was \$746 million in 2007, \$428 million in 2006 and \$578 million in 2005.

The Company recorded sales in Territory B, the U.S./Puerto Rico AVAPRO\*/AVALIDE\* Territory and Territory A comarketing countries of \$5,958 million in 2007, \$4,355 million in 2006 and \$4,805 million in 2005.

In September 2006, the Company opted out of its copromotion rights with Sanofi for APROVEL\*/COAPROVEL\* in Ireland, Sweden, Denmark, Finland and Norway. The Company has also opted out of its comarketing or copromotion arrangements in a number of other countries prior to 2006. The Company receives a royalty payment from Sanofi based on a percentage of Sanofi's net sales in the opt-out countries.

The territory partnerships are governed by a series of committees with enumerated functions, powers and responsibilities. Each territory has two senior committees (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 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



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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; (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.

For further discussion of the Company's strategic alliance with Sanofi, see Item 8. Financial Statements Note 2. Alliances and Investments.

**Otsuka** In 1999, the Company entered into a worldwide commercialization agreement with Otsuka, to codevelop and copromote ABILIFY\* for the treatment of schizophrenia and related psychiatric disorders, except in Japan, China, Taiwan, North Korea, South Korea, the Philippines, Thailand, Indonesia, Pakistan and Egypt. The Company began copromoting the product with Otsuka in the U.S. and Puerto Rico in November 2002. In June 2004, the Company received marketing approval from the European Commission. The product is currently copromoted with Otsuka in the UK, Germany, France and Spain. In the U.S., Germany and Spain, where the product is invoiced to third-party customers by the Company on behalf of Otsuka, the Company records alliance revenue for its 65% contractual share of third-party net sales and records all expenses related to the product. The Company recognizes this alliance revenue when ABILIFY\* is shipped and all risks and rewards of ownership have transferred to third-party customers. In the UK, France and Italy, where the Company is presently the exclusive distributor for the product, the Company records 100% of the net sales and related cost of products sold and expenses. The Company also has an exclusive right to sell ABILIFY\* in other countries in Europe, the Americas and a number of countries in Asia. In these countries the Company records 100% of the net sales and related cost of products sold.

Under the terms of the agreement, the Company purchases the product from Otsuka and performs finish manufacturing for sale by the Company or Otsuka to third-party customers. The agreement expires in November 2012 in the U.S. For the entire EU, the agreement expires in June 2014. In each other country where the Company has the exclusive right to sell ABILIFY\*, the agreement expires on the later of the 10th anniversary of the first commercial sale in such country or expiration of the applicable patent 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 within 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, or (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 total revenue for ABILIFY\* of \$1,660 million in 2007, \$1,282 million in 2006 and \$912 million in 2005. Total milestone payments made to Otsuka under the agreement through 2007 were \$217 million, of which \$157 million was expensed as acquired in-process research and development in 1999. The remaining \$60 million was capitalized in other intangible assets and is amortized into cost of products sold over the remaining life of the agreement in the U.S., ranging from 8 to 11 years. The Company amortized in cost of products sold \$6 million in each of 2007, 2006 and 2005. The unamortized capitalized payment balance was \$29 million and \$35 million as of December 31, 2007 and 2006, respectively.

For further discussion of the Company's strategic alliance with Otsuka, see Item 8. Financial Statements Note 2. Alliances and Investments.

**ImClone** In 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 a commercialization arrangement expiring in September 2018 for the codevelopment and copromotion of ERBITUX\*, for a series of payments originally totaling \$1 billion. The Company



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paid ImClone a milestone payment of \$200 million in 2001. In 2002, the agreement with ImClone was revised to reduce the total payments to \$900 million from \$1 billion. In accordance with the agreement, the Company paid ImClone \$140 million in 2002, \$60 million in 2003, \$250 million in 2004 and \$250 million in the first quarter of 2006. The 2004 payment was made upon the approval by the FDA of the BLA for ERBITUX\* for use in combination with irinotecan in the treatment of patients with EGFR-expressing, mCRC who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, mCRC who are intolerant to irinotecan-based chemotherapy. The 2006 milestone payment was made upon FDA approval of ERBITUX\* for use in the treatment of squamous cell carcinoma of the head and neck in combination with radiation or as monotherapy. The Company also has codevelopment and copromotion rights in Canada and Japan to the extent the product is commercialized in such countries. Under the agreement, covering North America, ImClone receives a distribution fee based on a flat rate of 39% of net sales in North America. The Company purchases all of its commercial requirements for bulk ERBITUX\* from ImClone at a price equal to ImClone's manufacturing cost plus 10%.

In July 2007, the Company and ImClone amended the terms of their agreement for the codevelopment and copromotion of ERBITUX\* in North America. Under this amendment, the companies have jointly agreed to expand the investment in the ongoing clinical development plan for ERBITUX\* by up to several hundred million dollars. Development costs, up to a threshold value, will be the sole responsibility of the Company; costs in excess of this threshold will be shared by both companies according to a predetermined ratio.

The Company shares copromotion rights to ERBITUX\* with Merck KGaA in Japan under a codevelopment and cocommercialization agreement signed in October 2007 among BMS, BMKK, E.R. Squibb & Sons, LLC, ImClone, Merck KGaA and Merck Japan. ERBITUX\* is not yet marketed in Japan, although the Company and ImClone submitted in February 2007 an application to the PMDA for the use of ERBITUX\* in treating patients with advanced colorectal cancer.

The Company accounts for the \$500 million total approval milestones paid in 2004 and 2006 as license acquisitions, and amortizes the payments into the cost of products sold over the remaining term of the agreement, which ends in 2018. The Company amortized into cost of products sold \$38 million, \$34 million and \$17 million for 2007, 2006 and 2005, respectively. The unamortized portion of the approval payments is recorded in other intangible assets, net, in the consolidated balance sheet and was \$397 million and \$435 million as of December 31, 2007 and 2006, respectively.

The Company determines its equity share in ImClone's net income or loss by eliminating from ImClone's results the milestone revenue ImClone recognized for the \$400 million in pre-approval milestone payments made by the Company from 2001 through 2003. The Company recorded net income of \$7 million and \$43 million in 2007 and 2006, respectively, and net loss of \$5 million in 2005 for its share of ImClone's results of operations. The Company records its share of the results in equity in net income of affiliates in the consolidated statement of earnings. The Company recorded net sales for ERBITUX\* of \$692 million in 2007, \$652 million in 2006 and \$413 million in 2005.

The Company's recorded investment and the market value of its holdings in ImClone common stock was \$114 million and approximately \$619 million as of December 31, 2007, respectively, and \$109 million and approximately \$385 million as of December 31, 2006, respectively. The Company holds 14.4 million shares of ImClone stock, representing approximately 17% of ImClone's shares outstanding at December 31, 2007 and 2006. On a per share basis, the carrying value of the ImClone investment and the closing market price of the ImClone shares as of December 31, 2007 were \$7.92 and \$43.00, respectively, compared to \$7.59 and \$26.76, respectively, as of December 31, 2006.

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), or upon six months notice from the Company if there exists a significant concern regarding a regulatory or patient safety issue that would seriously impact the long-term viability of the product. Upon termination or expiration of the alliance, the Company does not retain any rights to ERBITUX\*.

During 2004 and through May 2005, McKesson Corporation (McKesson), one of the Company's wholesalers, provided warehousing, packing and shipping services for ERBITUX\*. McKesson held ERBITUX\* inventory on consignment and, under the Company's revenue recognition policy, the Company recognized revenue when such inventory was shipped by McKesson to the end-users. McKesson also held inventories of ERBITUX\* for its own account. Upon the divestiture of Oncology Therapeutics Network in May 2005, the Company discontinued the consignment arrangement with McKesson and McKesson no longer held inventories for its own account. Thereafter, the Company sold ERBITUX\* to intermediaries (such as wholesalers and specialty oncology distributors) and shipped ERBITUX\* directly to the end-users of the product who are the customers of those intermediaries. Beginning in the third quarter of 2006, the Company began expanding its distribution model to include wholesalers and distributors who hold ERBITUX\* inventory. The Company recognizes revenue upon such shipment consistent with its revenue recognition policy.

For further discussion of the Company's strategic alliance with ImClone, see Item 8. Financial Statements Note 2. Alliances and Investments.



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**Gilead** In 2004, the Company and Gilead entered into a joint venture to develop and commercialize a fixed-dose combination of the Company's SUSTIVA and Gilead's TRUVADA\* (emtricitabine and tenofovir disoproxil fumarate) in the U.S. In July 2006, the FDA granted approval of ATRIPLA\*, which is the first complete Highly Active Antiretroviral Therapy treatment product for HIV available in the U.S. in a fixed-dose combination taken once daily. Fixed-dose combinations contain multiple medicines formulated together and may help simplify HIV therapy for patients and providers. Guidelines issued by the U.S. Department of Health and Human Services list the combination of emtricitabine, tenofovir disoproxil fumarate and efavirenz as one of the preferred non-NNRTI-based treatments for use in appropriate patients that have never taken anti-HIV medicines before. In September 2006, the companies amended their agreements to commercialize ATRIPLA\* in Canada. ATRIPLA\* was approved by Health Canada in October 2007 and by the European Commission in December 2007 for commercialization in the 27 countries of the EU, as well as Norway and Iceland.

The Company and Gilead share responsibility for commercializing ATRIPLA\* in the U.S., Canada, throughout the EU and certain other European countries, and both provide funding and field-based sales representatives in support of promotional efforts for ATRIPLA\*. Gilead records 100% of ATRIPLA\* revenues in the U.S., Canada and most countries in Europe. The Company records revenue for the bulk efavirenz component of ATRIPLA\* upon sales of that product by the joint venture with Gilead to third-party customers. The Company's revenue for the efavirenz component is determined by applying a percentage to ATRIPLA\* revenue, which approximates revenue for the SUSTIVA brand. The Company recorded efavirenz revenues of \$335 million in 2007 and \$76 million in 2006 related to ATRIPLA\* sales.

Gilead consolidates the results of the joint venture in their operating results and the Company accounts for its participation in the joint venture under the equity method of accounting and records its share of the joint venture results in equity in net income of affiliates in the consolidated statement of earnings. The Company recorded an equity loss on the joint venture with Gilead of \$9 million in 2007, \$6 million in 2006 and \$4 million in 2005.

The joint venture between the Company and Gilead will continue until terminated by mutual agreement of the parties or otherwise as described below. In the event of a material breach by one party, the non-breaching party may terminate the joint venture only if both parties agree that it is both desirable and practicable to withdraw the combination product from the markets where it is commercialized. At such time as one or more generic versions of SUSTIVA appear on the market in the U.S., Gilead will have the right to terminate the joint venture and thereby acquire all the rights to the combination product, both in the U.S. and Canada; however, the Company will continue for three years to receive a percentage of the net sales based on the contribution of bulk efavirenz to ATRIPLA\*, and otherwise retains all rights to SUSTIVA.

For further discussion of the Company's strategic alliance with Gilead, see Item 8. Financial Statements Note 2. Alliances and Investments.

### **Investigational Compounds Under Development**

**Medarex** In 2004, the Company entered into a worldwide collaboration and share purchase agreement with Medarex to codevelop and copromote ipilimumab, a fully human antibody currently in Phase III development for the treatment of metastatic melanoma. The agreement became effective in January 2005 after the companies received certain governmental clearances and approvals, and the receipt of consent from the U.S. Public Health Service of the sublicense to the Company of Medarex's rights to MDX-1379 (gp100), a vaccine that is being developed in combination with ipilimumab. The FDA has granted Fast Track status to ipilimumab in combination with MDX-1379 for treatment of patients with late stage unresectable metastatic melanoma who have failed or are intolerant to first-line therapy.

In January 2005, under the terms of the agreement, the Company made a cash payment of \$25 million to Medarex, which was expensed as research and development, and an additional \$25 million equity investment in Medarex. Further milestone payments are expected to be made upon the successful achievement of various regulatory and sales-related stages. The Company and Medarex will also share in future development and commercialization costs. Medarex could receive up to \$205 million if all regulatory milestones are met, and up to \$275 million in sales-related milestones. Medarex will have an option to copromote and receive up to 45% of the profits with the Company in the U.S. The Company will receive an exclusive license outside of the U.S. and pay royalties to Medarex.

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The agreement with Medarex does not expire unless and until one of the following events occurs: (1) the Company voluntarily terminates the agreement in its entirety or on a country-by-country basis by providing Medarex with six months prior written notice; (2) the Company voluntarily terminates the agreement on a product-by-product basis (but only if a second product is then in GLP toxicology studies or later) or a country-by-country basis by providing Medarex with six months prior written notice depending on the circumstances; (3) the Company terminates Medarex's copromotion option and rights in the U.S. on 60 days written notice after the end of the second calendar year in the event Medarex provides less than 60 percent of certain performance obligations in any two out of three consecutive calendar years (such termination right to be exercised only with respect to those indications as to which Medarex failed to meet such performance obligation). Upon any such termination by the Company via any of the scenarios in (1)–(3) above, Medarex will no longer have a right to share in the profits and losses of the product for the terminated indication(s) and, instead the Company will pay Medarex royalties on net sales of the product; or (4) Medarex terminates the agreement with respect to all products on 60 days written notice if the Company provides less than 60 percent of certain performance obligations in any two out of three consecutive calendar years. Generally, upon termination in (4), the Company will assign all rights to the product to Medarex and receive a royalty thereafter on intellectual property licensed by the Company to Medarex. Medarex may also elect not to copromote a product for one or more indications in the U.S., in which event it will receive a royalty on sales of the product for such indication. If there is a material breach as to manufacturing by a party, then the other party shall be limited to termination of such party's manufacturing rights only.



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**AstraZeneca** In January 2007, the Company entered into two worldwide (except for Japan) codevelopment and cocommercialization agreements with AstraZeneca, one for the codevelopment and cocommercialization of saxagliptin, a DPP-IV inhibitor (Saxagliptin Agreement), and one for the codevelopment and cocommercialization of dapagliflozin, a SGLT2 inhibitor (SGLT2 Agreement). Both compounds are being studied for the treatment of diabetes and were discovered by the Company. Under the terms of the agreements, the Company received from AstraZeneca an upfront payment of \$100 million in January 2007, which was deferred and is being recognized over the life of the agreements into other income. The Company amortized into other income \$7 million in 2007. The unamortized portion of the upfront payment was \$93 million as of December 31, 2007. Milestone payments are expected to be received by the Company upon the successful achievement of various development and regulatory events, as well as sales-related milestones. Under the Saxagliptin Agreement, the Company could receive up to \$300 million if all development and regulatory milestones are met and up to an additional \$300 million if all sales-based milestones are met. Under the SGLT2 Agreement, the Company could receive up to \$350 million if all development and regulatory milestones are met and up to an additional \$300 million if all sales-based milestones are met. Under each agreement, the Company and AstraZeneca also share in future development and commercialization costs. The majority of development costs under the initial development plans through 2009 will be paid by AstraZeneca and any additional development costs will generally be shared equally. The Company records in research and development expenses saxagliptin and dapagliflozin development costs net of its alliance partner's share. Under each agreement, the two companies will jointly develop the clinical and marketing strategy and share commercialization expenses and profits/losses equally on a global basis, excluding Japan, and the Company will manufacture both products and, with certain limited exceptions, record net sales.

**Pfizer** In April 2007, the Company and Pfizer entered into a worldwide codevelopment and cocommercialization agreement for apixaban, an anticoagulant discovered by the Company being studied for the prevention and treatment of a broad range of venous and arterial thrombotic conditions. In accordance with the terms of the agreement, Pfizer made an upfront payment of \$250 million to the Company in May 2007, which was deferred and is being recognized over the life of the agreement into other income. In December 2007, the Company and Pfizer agreed to include Japan in the worldwide agreement. Pfizer made an upfront payment of \$40 million in December 2007, which was deferred and is being recognized over the life of the agreement into other income. The Company amortized into other income \$11 million in 2007. The unamortized portion of the upfront payments was \$279 million as of December 31, 2007. Pfizer will fund 60% of all development costs effective January 1, 2007 going forward, and the Company will fund 40%. The Company records in research and development expenses apixaban development costs net of its alliance partner's share. The Company may also receive additional payments of up to \$780 million from Pfizer based on development and regulatory milestones. The companies will jointly develop the clinical and marketing strategy of apixaban, and will share commercialization expenses and profits/losses equally on a global basis.

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

**HEALTH CARE GROUP***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. The ENFAMIL LIPIL product is the first infant formula in the U.S. to contain the nutrients docosahexaenoic acid (DHA) and arachidonic acid (ARA). 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 worldwide license and supply agreement. The supply agreement, in force until at least 2011, provides no firm guarantee of supply and pricing is subject to change pursuant to a pricing formula. The license expires beginning in 2024 on a country-by-country basis 25 years after the Company commenced sales in a country.

The Company's Nutritionals products are generally sold by wholesalers and retailers and are promoted primarily to health care professionals. The Company also promotes Nutritionals products directly to consumers worldwide through advertising. The Company manufactures these products in the U.S. and in five foreign countries. Nutritionals sales accounted for 13% of the Company's sales in 2007, 14% of the Company's sales in 2006 and 12% of the Company's sales in 2005. U.S. Nutritionals sales accounted for 44%, 46% and 49% of total Nutritionals sales in 2007, 2006 and 2005, respectively, while international Nutritionals sales accounted for 56%, 54% and 51% of total Nutritionals sales in 2007, 2006 and 2005, respectively. Approximately one-half of U.S. gross 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 program sales.

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Key Nutritionals product lines and their sales are as follows:

Dollars in Millions	2007	2006	2005
Infant Formulas	\$ 1,786	\$ 1,637	\$ 1,576
ENFAMIL	1,082	1,007	992
Toddler/Children's Nutritionals	693	606	529
ENFAGROW	295	262	206

*ConvaTec Segment*

The ConvaTec segment manufactures, distributes and sells ostomy and modern wound and skin care products. Principal brands of ConvaTec include NATURA, SUR-FIT, ESTEEM, AQUACEL, DUODERM and FLEXI-SEAL. These products are marketed worldwide, primarily to hospitals, medical professions 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 U.S., the UK and the Dominican Republic.

ConvaTec sales accounted for approximately 6% of the Company's sales in 2007, 6% of the Company's sales in 2006 and 5% of the Company's sales in 2005. U.S. ConvaTec sales accounted for 32%, 33% and 31% of total ConvaTec sales in 2007, 2006 and 2005, respectively, while international ConvaTec sales accounted for 68%, 67% and 69% of total ConvaTec sales in 2007, 2006 and 2005, respectively.

ConvaTec sales by business and key products are as follows:

Dollars in Millions	2007	2006	2005
ConvaTec	\$ 1,155	\$ 1,048	\$ 992
Ostomy	594	554	550
Wound Therapeutics	488	441	416

**Productivity Transformation Initiative**

The Company undertook a broad range of actions in the fourth quarter of 2007 as part of the previously announced three-year Productivity Transformation Initiative (PTI), which is reducing costs, streamlining operations and rationalizing global manufacturing. The initiative, which is on track to achieve \$1.5 billion in annual cost savings and cost avoidance on a pre-tax basis by 2010, is central to the Company's strategy to become a more nimble and flexible next generation biopharmaceutical enterprise.

Key productivity initiatives include reducing general and administrative operations by simplifying, standardizing and outsourcing, where appropriate, processes and services, rationalizing the Company's mature brands portfolio, consolidating its global manufacturing network while eliminating complexity and enhancing profitability, simplifying its geographic footprint and implementing a more efficient go-to-market model. Specific productivity goals include reducing the number of brands in the Company's mature products portfolio by 60 percent between 2007 and 2011, reducing the number of manufacturing facilities by more than 50 percent by the end of 2010, and reducing total headcount by approximately 10 percent between 2007 and 2010. Some positions have been eliminated in 2007, although the substantial majority of positions will be eliminated in 2008 and 2009. The Company has announced the impending closure of several manufacturing facilities, including Barceloneta, Puerto Rico and Mayaguez, Puerto Rico.

Costs associated with the implementation of the PTI are estimated to be between \$0.9 billion to \$1.1 billion on a pre-tax basis, with \$292 million incurred in 2007 and approximately \$500 million expected to be incurred in 2008. The ultimate timing of the recording of the charges cannot be predicted with certainty and will be affected by the occurrence of triggering events for expense recognition under U.S. Generally Accepted Accounting Principles (GAAP), among other factors.

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

In general, the Company purchases its raw materials, medical devices and supplies required for the production of the Company's products in the open market. For some products, the Company purchases its raw materials, medical devices and supplies from a single source, which in certain circumstances is specified in the Company's product registrations, thereby requiring the Company to obtain such raw materials and supplies from that particular source. The Company attempts, if possible, to mitigate raw material supply risks to the Company, through inventory management and alternative sourcing strategies. For further discussion of sourcing, see [Manufacturing and Quality Assurance](#) below and discussions of particular products.

### **Manufacturing and Quality Assurance**

To meet all expected product demand, the Company operates and manages its manufacturing network, including its third-party contract manufacturers, and the inventory related thereto, in a manner that permits the Company to improve efficiency while maintaining flexibility in its ability to reallocate manufacturing capacity. Pharmaceutical production processes are complex, highly regulated and vary widely from product to product. Given that shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital and out-of-pocket expenditures and regulatory approvals, the Company maintains and operates its flexible manufacturing network, consisting of internal and external resources, that minimizes unnecessary product transfers and inefficient uses of manufacturing capacity. 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 compliance with increasing regulatory requirements. In addition, as the Company adds to its product line and realigns its focus over the next several years, the Company expects to modify its existing manufacturing network to meet complex processing standards that may be required for newly introduced products, including 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 is limited. As biologics become more important to the Company's product portfolio, the Company may continue to make arrangements with third-party manufacturers, and in addition expects to make substantial investments to increase its internal capacity to produce biologics on a commercial scale. During 2006, the Board of Directors approved capital expenditures of approximately \$750 million for a bulk biologics manufacturing facility in the U.S. In February 2007, the Company completed the land purchase of an 89-acre site to locate its large scale multi-product bulk biologics manufacturing facility in Devens, Massachusetts. Construction of the Devens, Massachusetts facility began in early 2007, and the facility is projected to be operationally complete by 2009. The Company expects to submit the site for regulatory approval in 2010. Commercial production of biologic compounds is anticipated to begin by 2011.

The Company relies on third parties to manufacture, or to supply it with active ingredients necessary for it to manufacture certain products, including PLAVIX\*, ABILIFY\*, ERBITUX\*, the SUSTIVA Franchise, ORENCIA\*, PRAVACHOL, COUMADIN and TAXOL® (paclitaxel). To maintain a stable supply of these products, the Company takes a variety of actions designed to provide that there is a reasonable level of these ingredients held by the third-party supplier, the Company 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. For example, the Company will rely on the combined capacity of its Devens, Massachusetts, Syracuse, New York, and Manati, Puerto Rico, facilities, and the capacity available at its third-party contract manufacturers to manufacture ORENCIA\* and the commercial quantities of the Company's other investigational compounds in late-stage development should those compounds receive regulatory approval.

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.

In connection with divestitures, licensing arrangements or distribution agreements of certain of the Company's products, 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 technical information and production processes.

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Control of production processes involves detailed 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 ensure 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 licenses a number of patents in the U.S. and foreign countries primarily covering its 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. In the U.S. and some other countries, 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 U.S., 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 prior to the expiration of regulatory data exclusivity 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 estimates 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 concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that the Company currently estimates or that the exclusivity will be limited to the estimate. For a discussion on market exclusivity, see "Pharmaceuticals Segment" above.

In addition to patents and regulatory forms of exclusivity, the Company also holds intellectual property in the form of trademarks on products such as ENFAMIL. 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*

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A company seeking to market an innovative pharmaceutical in the U.S. 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 New Drug Application (NDA). If the medicine is a biological product, a BLA is filed. The type of application filed affects regulatory exclusivity rights.

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A competitor seeking to launch a generic substitute of a chemical innovative drug in the U.S. must file an 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 a 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 in the U.S., 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 a 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, a 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 U.S., 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 date of that patent. There are two limits to these extensions. First, the maximum term a patent can be extended is five 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 most forms of exclusivity (patent and regulatory) that are listed with the FDA at the time the studies are completed and submitted to the FDA, but not against products already finally approved.

Currently, generic versions of biological products cannot be approved under U.S. law. However, the law could change in the future. Even in the absence of new legislation, the FDA is taking steps toward allowing generic versions of certain biologics. Competitors seeking approval of biological products must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex processes and are more costly than those of traditional pharmaceutical operations.

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

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 decide whether to file a patent infringement suit against the generic manufacturer. 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 (or first filers if more than one generic qualifies) may be entitled to a 180-day period of market exclusivity 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.

In the U.S., the increased likelihood of generic challenges to innovators' intellectual property has 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, and Other Intellectual Property Litigation. Second, statutory and regulatory provisions in the U.S. 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 ways to expand the use of a regulatory mechanism that allows for regulatory approval of drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required for a full NDA. 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.

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### *European Union*

Recent pharmaceutical legislation in the EU has 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 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 10 or 11 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 these provisions will apply as new marketing authorization applications are submitted under the new legislation. For those products that continue to be covered under the old law, there is a 10-year period of data protection under the centralized procedures and a period of either six or 10 years under the mutual recognition procedure (depending on the member state). Regardless of the procedure used to obtain marketing authorization approval, 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.

Patents on pharmaceutical products are generally enforceable in the EU. However, in contrast to the U.S., 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 U.S., 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. The European Medicines Evaluation Agency (EMA) has issued a guideline that outlines what additional information has to be provided for biosimilar products, also known as generic biologics, in order for the EMA to review an application for marketing approval.

### *Japan*

In Japan, medicines of new chemical entities are generally afforded eight years (previously six years before 2007) of data exclusivity for approved indications and dosage. Patents on pharmaceutical products are enforceable. Generic copies can receive regulatory approval after data exclusivity and patent expirations. As in the U.S., 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 U.S., 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 U.S. (e.g., Canada) or the EU (e.g., Switzerland). Among developing countries, some have adopted patent laws and/or regulatory exclusivity laws, while others have not. Some developing countries 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 developing countries, the Company takes into account not only formal legal rights but political and other factors as well.

## **Marketing, Distribution and Customers**

The Company promotes its products in medical journals and directly to health care providers such as doctors, nurse practitioners, physician assistants, pharmacists, technologists, hospitals, Pharmacy Benefit Managers (PBMs), Managed Care Organizations (MCOs) and government agencies. The Company also markets directly to consumers in the U.S. 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), including Medicare Part D plans and reimbursement lists by demonstrating

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the qualities and treatment benefits of its products. 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 unsolicited 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 marketing and sales organizations. Each organization markets a distinct group of products supported by a sales force and is typically based on particular therapeutic areas or physician groups. These sales forces often focus on selling new products when they are introduced, and promotion 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 distributors, retailers, hospitals, clinics, government agencies and pharmacies. In 2007, sales to three pharmaceutical wholesalers in the U.S., McKesson, Cardinal Health, Inc. (Cardinal) and AmerisourceBergen Corporation (AmerisourceBergen), accounted for approximately 19%, 16% and 12%, respectively, of the Company's total net sales. In 2006, sales to McKesson, Cardinal and AmerisourceBergen accounted for approximately 19%, 16% and 11%, respectively, of the Company's total net sales. In 2005, sales to McKesson, Cardinal and AmerisourceBergen accounted for approximately 21%, 18% and 12%, respectively, of the Company's total net sales. Sales to these U.S. wholesalers were concentrated in the Pharmaceuticals segment.

The Company's U.S. Pharmaceuticals business, through the Inventory Management Agreements (IMAs), has arrangements with substantially all of its direct wholesaler and distributor customers that allow the Company to monitor U.S. wholesaler inventory levels and require those wholesalers to maintain inventory levels that are no more than one month of their demand. The IMAs have a two-year term, through December 31, 2009, subject to certain termination provisions.

The Company sells ERBITUX\* to intermediaries (such as wholesalers and specialty oncology distributors) and ships ERBITUX\* directly to the end users of the product who are the customers of those intermediaries. The Company also sells ERBITUX\* in the U.S. to other wholesalers and distributors who then hold ERBITUX\* inventory. The Company recognizes revenue upon such shipment consistent with its revenue recognition policy.

For information on sales and marketing of Nutritionals and ConvaTec products, see [Nutritionals Segment](#) and [ConvaTec Segment](#) above.

## **Competition**

The markets in which the Company 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 relating to 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.

To successfully compete for business with MCOs and PBMs, 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 U.S., patent protection is weak or nonexistent and the Company must compete with generic versions shortly after it launches its innovative product. In addition, generic pharmaceutical companies may introduce a generic product before exclusivity has expired, and before the resolution of any related patent litigation. For a discussion of the generic launch of a clopidogrel bisulfate product that competes with PLAVIX\*, see [Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies PLAVIX\\*](#)

Litigation.

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Many other companies, large and small, manufacture and sell one or more products that are similar to those marketed by the Company's Nutritional and ConvaTec segments. Sources of competitive advantage include patents and trademarks, 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 need, 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 U.S. has been a major factor in the competitive make-up of the health care 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, Medicare Part D formularies, 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.

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 U.S. and, to a lesser extent, 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 U.S., 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 innovator 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 developing 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 U.S. generally allow, and in many 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 many of the sales and marketing costs, which innovators must incur.

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### Research and Development

The Company invests heavily in research and development because it believes it is critical to its long-term competitiveness. Bristol-Myers Squibb Pharmaceutical Research and Development 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 U.S. and in Belgium, Canada, the UK and India. Management continues to emphasize leadership, innovation, productivity and quality as strategies for success in Bristol-Myers Squibb Pharmaceutical Research and Development.

The Company spent \$3,282 million in 2007, \$2,991 million in 2006 and \$2,678 million in 2005 on Company-sponsored research and development activities. The Company-sponsored pharmaceutical research and development spending includes certain payments under third-party collaborations and contracts. At the end of 2007, the Company employed approximately 8,200 people in research and development throughout the Company, 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 disease areas with significant unmet medical need: 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 may selectively pursue promising leads in other areas. In addition to discovering and developing new molecular entities, the Company looks for ways to expand the value of existing products through new uses and formulations that can provide additional benefits to patients.

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 contracts with others for the performance of research in their facilities. The Company'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. In drug development, the Company engages 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.

Drug development is time consuming, expensive and risky. In the development of human health products, industry practice and government regulations, in the U.S. and most foreign countries, provide for the determination of effectiveness and safety of new molecular entities through preclinical tests and controlled clinical evaluation. Before a new drug may be marketed in the U.S., recorded data on preclinical and clinical experience are included in the NDA or the BLA 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 U.S. and many foreign countries. There can be no assurance that a compound developed as a result of any program will obtain the regulatory approvals necessary for it to be marketed for any particular disease indication.

On average, only about one in 10,000 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 10 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.

Listed below are several investigational compounds that the Company has in the later stages of development. All of these compounds are in 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, among other factors. 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 patent term extensions.

Apixaban	Apixaban is an oral Factor Xa inhibitor, which is being developed internally and has recently entered Phase III clinical trials for the prevention of thromboembolic disorders. In April 2007, the Company entered into a worldwide agreement with Pfizer for the codevelopment and cocommercialization of apixaban. The Company owns an issued U.S. patent covering composition of matter and method of use of apixaban that expires in September 2022 (extended to February 2023 via patent term adjustment).
Saxagliptin	Saxagliptin is an oral compound for the potential treatment of diabetes, which was discovered internally and is currently in Phase III clinical trials. In January 2007, the Company entered into the Saxagliptin Agreement with AstraZeneca for the

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codevelopment and cocommercialization of saxagliptin. A patent application covering the composition of matter has been issued and will expire in 2021 in the U.S.

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Ipilimumab	Ipilimumab, which is being codeveloped with Medarex and is currently in Phase III clinical trials, is a monoclonal antibody being investigated as an anticancer treatment. It is in a novel class of agents intended to potentiate elements of the immunologic response. The Company owns a composition of matter patent that expires in the U.S. in 2016 and has rights to method of use patents owned by Medarex that expire in the U.S. in 2015. The Company also has rights to a Medarex composition of matter patent that expires in 2020 (extended to 2022 via patent term adjustment) and pending Medarex patent applications covering composition of matter and method of use of ipilimumab.
Belatacept	Belatacept, a biological product, which is being developed internally and is in Phase III clinical trials, is a fusion protein with novel immunosuppressive activity targeted at prevention of solid organ transplant rejection. The Company has a composition of matter patent that expires in the U.S. in 2021.
Dapagliflozin	Dapagliflozin is an oral compound for the potential treatment of diabetes, which was discovered internally and is currently in Phase III clinical trials. In January 2007, the Company entered into the SGLT2 Agreement with AstraZeneca for the codevelopment and cocommercialization of dapagliflozin. A patent application covering the composition of matter has been issued and will expire in 2020 in the U.S.

In November 2007, the Company and Pierre Fabre Medicament S.A. announced the termination of the license agreement for the development of vinflunine, a chemotherapy agent under investigation for the treatment of advanced or metastatic bladder cancer and other tumor types.

The Company sometimes enters into agreements with respect to its own investigational compounds in order to share the costs and risks of development, and in some cases, facilitate their commercialization. These agreements can take many forms, including codevelopment, comarketing, copromotion and/or joint venture arrangements.

The Company's competitors also devote substantial funds and resources to research and development. In addition, the consolidation that has occurred in the pharmaceutical 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 (FDC Act), 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 U.S. 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-marketing surveillance of the Company's pharmaceutical products. The FDA also regulates most of the Company's Nutritionals and ConvaTec products. In many cases, the FDA's requirements have increased the amount of time and money necessary to develop new products and bring them to market in the U.S.

The Company's pharmaceutical products, as well as the medical device products it sells through its ConvaTec business, are subject to pre-market approval requirements in the U.S. 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 (PHS Act), and related regulations. Biological drugs are licensed under the PHS Act. Medical devices are subject to the FDC Act including Medical Device Amendments. The Company's Nutritionals products are regulated by the FDA, primarily under the Infant Formula Act of 1980 and its amendments.



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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.

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The Federal government has extensive enforcement powers over the activities of pharmaceutical and medical device 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 and cash flows. The Federal government has similar powers with respect to the manufacturing operations of the Nutritionals business.

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 (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 recordkeeping, packaging, quantity, labeling, product handling and facility storage and security requirements intended to prevent the sale of pharmaceutical product samples or other diversions. For discussion of recent settlement of certain investigations of drug pricing and sales and marketing activities, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

The FDA Amendments Act of 2007 imposed additional obligations on pharmaceutical companies and delegated more enforcement authority to the FDA in the area of drug safety. Key elements of this legislation give the FDA new authority to (1) require that companies conduct post-marketing safety studies of drugs, (2) impose certain drug labeling changes relating to safety, (3) mandate risk mitigation measures such as the education of healthcare providers and the restricted distribution of medicines, (4) require companies to publicly disclose data from clinical trials and (5) pre-review television advertisements.

The marketing practices of all U.S. pharmaceutical manufacturers are subject to Federal and state health care laws that are used to protect the integrity of government health care programs. The Office of Inspector General of the U.S. Department of Health and Human Services (OIG) oversees compliance with applicable Federal laws, in connection with the payment for products by government funded programs (primarily Medicaid and Medicare). These laws include the Federal anti-kickback statute, which criminalizes the offering of something of value to induce the recommendation, order or purchase of products or services reimbursed under a government health care program. The OIG has issued a series of Guidances to segments of the health care industry, including the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers (the OIG Guidance), which includes a recommendation that pharmaceutical manufacturers, at a minimum, adhere to the PhRMA Code, a voluntary industry code of marketing practices. The Company subscribes to the PhRMA Code, and has implemented a compliance program to address the requirements set forth in the OIG Guidance and the Company's compliance with the health care laws. Failure to comply with these health care laws could subject the Company to administrative and legal proceedings, including actions by the state and Federal government agencies. Such actions could result in the imposition of civil and criminal sanctions, which may include fines, penalties and injunctive remedies, the impact of which could materially adversely affect the Company's business, financial condition and results of operations and cash flows.

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, the Department of Justice and the Department of Health and Human Services in the U.S. 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.

The Company's activities outside the U.S. 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. 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.

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Whether or not FDA approval or approval of the EMEA has been obtained for a product, approval of the product by comparable regulatory authorities of countries outside of the U.S. or the EU, as the case may be, 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 U.S. Approval in one country does not assure that such product will be approved in another country.

In many markets outside the U.S., 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. Most European countries do not provide market pricing for new medicines, except the UK and Germany. Pricing freedom is limited in the UK by the operation of a profit control plan and in Germany by the operation of a reference price system. Companies also face significant delays, mainly in France, Spain, Italy and Belgium, 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 cost containment issues exist in many foreign countries where the Company does business.

Federal and state governments also have pursued direct methods to reduce the cost of drugs for which they pay. The Company participates in state government-managed Medicaid programs, as well as certain other qualifying Federal and state government programs whereby discounts and rebates are provided to participating state and local government entities. Rebates under Medicaid and related state programs reduced revenues by \$169 million in 2007, \$174 million in 2006 and \$595 million in 2005. The decrease in 2006 as compared to 2005 was primarily due to the exclusivity loss of PRAVACHOL and lower PLAVIX\* sales. The shift in patient enrollment from Medicaid to Medicare under Medicare Part D also resulted in a decrease in Medicaid rebates, which was partially offset by a corresponding increase in the Company's managed health care rebates. The Company also participates in prime vendor programs with government entities, the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs. These entities receive minimum discounts based off a defined non-federal average manufacturer price for purchases. Other prime vendor programs in which the Company participates provide discounts for outpatient medicines purchased by certain Public Health Service entities and other hospitals meeting certain criteria. The Company recorded discounts related to the prime vendor programs of \$662 million in 2007, \$703 million in 2006 and \$1,090 million in 2005.

In the U.S., governmental cost containment efforts have extended to the federally funded Special Supplemental Nutrition Program for WIC. All states participate in the WIC program 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 a WIC customer. States participating in the WIC program are required to engage in competitive bidding or to use other cost containment measures that yield savings equal to or greater than the savings generated by a competitive bidding system. Mead Johnson participates in this program and approximately half of its gross U.S. sales are subject to rebates under the WIC program. Rebates under the WIC program reduced revenues by \$848 million in 2007, \$872 million in 2006 and \$843 million in 2005.

For further discussion of these rebates and programs, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations.

## **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.

An environment, health and safety group within the Company 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 \$38 million, \$50 million and \$45 million on capital environmental projects undertaken specifically to meet environmental requirements in 2005, 2006 and 2007, respectively, and expects to spend approximately \$46 million in 2008. Although the Company believes that it is in



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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 Federal, state and foreign environmental laws, including the U.S. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). 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, and in some cases to provide compensation and/or restoration for damages to natural resources. Currently, the Company is involved in investigation and remediation at 13 current or former Company facilities. The Company has also been identified as a potentially responsible party (PRP) under applicable laws for environmental conditions at approximately 30 former waste disposal or reprocessing facilities operated by third parties at which investigation and/or remediation activities are ongoing.

The Company may face liability under CERCLA and other Federal, state and foreign laws for the entire cost of investigation or remediation of contaminated sites, or for natural resource damages, regardless of fault or ownership at the time of the disposal or release. In addition, at certain sites the Company bears remediation responsibility pursuant to contract obligations. Generally, at third-party operator sites involving multiple PRPs, liability has been or is expected to be apportioned based on the nature and amount of hazardous substances disposed of by each party at the site and the number of financially viable PRPs. For additional information about these matters, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

## **Employees**

The Company employed approximately 42,000 people at December 31, 2007.

In late 2007, the Company undertook a broad range of actions, as part of the previously announced three-year PTI. As part of this multi-year PTI, the Company is implementing a comprehensive cost reduction program that includes workforce reductions in some areas and the rationalization of some facilities. Specific productivity goals include reducing total headcount by approximately 10 percent between 2007 and 2010.

Some positions have been eliminated in 2007, although the substantial majority of positions will be eliminated in 2008 and 2009. During 2007, the Company recorded pre-tax charges of \$189 million, relating to the termination benefits and other related costs for workforce reductions of approximately 2,800 manufacturing, selling and administrative personnel, across all geographic regions.

For further discussion of this initiative and 2007 restructuring activities, see Productivity Transformation Initiative above and Item 8. Financial Statements Note 3. Restructuring.

## **Foreign Operations**

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

Revenues from operations outside the U.S. of \$8.5 billion accounted for 44% of the Company's total revenues in 2007. In 2007, revenues exceeded \$500 million in each of France, Canada, Spain, Japan, Italy, Mexico and Germany. In 2006, revenues exceeded \$500 million in each of France, Japan, Canada, Spain, Italy and Mexico. In 2005, revenues exceeded \$500 million in each of France, Japan, Spain, Canada, Italy and Germany. No single country outside the U.S. contributed more than 10% of the Company's total revenues in 2007, 2006 or 2005. For a geographic breakdown of net sales, see the table captioned Geographic Areas 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.

International operations are subject to certain risks, which are inherent in conducting business abroad, including, but not limited to, currency fluctuations, possible nationalization or expropriation, price and exchange controls, counterfeit, 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.

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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 2007, the change in foreign exchange rates had a net favorable impact on the growth rate of 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 discussions under Item 7A. Quantitative and Qualitative Disclosures About Market Risk and Item 8. Financial Statements Note 18. Financial Instruments.

**Table of Contents****Item 1A. RISK FACTORS.**

Any of the factors described below could significantly and negatively affect the Company's business, prospects, financial condition, operating results, or credit ratings, which could cause the trading price of the Company's common stock to decline. Additional risks and uncertainties not presently known to the Company, or risks that the Company currently considers immaterial, may also impair the Company's operations.

***The Company faces competition from other pharmaceutical manufacturers, including from lower-priced generic products, and it is possible that the Company may lose market exclusivity of a product earlier than expected.***

*Competition from manufacturers of competing products, including lower-priced generic versions of the Company's products is a major challenge, both within the United States (U.S.) and internationally. Such competition may include (i) new products developed by competitors that have lower prices or superior performance features or that are otherwise competitive with the Company's current products; (ii) technological advances and patents attained by competitors; (iii) results of clinical studies related to the Company's products or a competitor's products; (iv) problems with licensors, suppliers and distributors; and (v) business combinations among the Company's competitors and major customers.*

*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. In the U.S. and some other countries, 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.*

*Market exclusivity for the Company's products is based upon patent rights and/or certain regulatory forms of exclusivity. The scope of the Company's patent rights may vary from country to country. In some countries, including in certain European Union member states, basic patent protection for the Company's products may not exist because historically certain countries did not offer the right to obtain certain types of patents and/or the Company (or its licensors) did not file in those markets. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions of the product can be approved and marketed. In addition, prior to the expiration of data exclusivity, a competitor could seek regulatory approval by submitting its own clinical trial data to obtain marketing approval. Manufacturers of generic products are also increasingly seeking to challenge patents before they expire, and may in some cases launch a generic product before the expiration of the applicable patent(s) and/or before the final resolution of patent litigation. The length of market exclusivity for any of the Company's products is impossible to predict with certainty and there can be no assurance that a particular product will enjoy market exclusivity for the full period of time that appears in the estimates disclosed in this Form 10-K.*

*For a discussion of how generic versions of a product can impact that product's sales, see Item 1. Business Competition Generic Competition above. For more information about market exclusivity, see Item 1. Business Products and Item 1. Business Intellectual Property and Product Exclusivity above.*

***The patent infringement lawsuit with Apotex Inc. and Apotex Corp. (Apotex) involving PLAVIX\* is ongoing, and there is a risk of generic competition from Apotex and from other generic pharmaceutical companies.***

*Although, as previously disclosed, the U.S. District Court for the Southern District of New York (District court) issued an opinion and order upholding the validity and enforceability of the U.S. Patent No. 4,847,265 relating to PLAVIX\*, ruled that Apotex's generic clopidogrel bisulfate product infringed the patent and enjoined Apotex from engaging in any activity that infringes that patent, the PLAVIX\* patent infringement lawsuit is still ongoing and there is a risk that the Company could face generic competition from Apotex and from other generic pharmaceutical companies. Apotex has filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. If Apotex were to prevail in its appeal of the District court's decision, the Company could face renewed generic competition for PLAVIX\* from Apotex promptly thereafter. Loss of market exclusivity for PLAVIX\* and/or sustained generic competition would be material to the Company's results of operations and cash flows and could be material to its financial condition and liquidity. It is not possible at this time reasonably to assess the outcomes of the appeal by Apotex of the District court's decision, or the other PLAVIX\* patent litigations or the timing of any renewed generic competition for PLAVIX\* from Apotex or additional generic competition for PLAVIX\* from other third-party generic pharmaceutical companies.*

*The Company has recorded deferred tax assets related to the U.S. foreign tax credit, research tax credit and charitable contribution carryforwards. The charitable contribution carryforwards expire in varying amounts beginning in 2009, while the foreign tax credit and research tax credit carryforwards expire in varying amounts beginning in 2012. Realization of the foreign tax credit, research tax credit and charitable contribution carryforwards is dependent on generating sufficient domestic taxable income prior to their expiration. Although realization is not assured, management believes it is more likely than not that these deferred tax assets will be realized. The amount of foreign tax credit, research tax credit and charitable contribution carryforwards considered realizable, however, could be reduced in the near term if PLAVIX\* is subject to either renewed or additional generic competition. If such events occur, the Company may need to record additional*

valuation allowances against these U.S. federal deferred tax assets. For a discussion of PLAVIX\* related matters, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

***The Company may be adversely impacted by economic factors beyond its control and may incur additional impairment charges to its investment portfolio.***

*As of December 31, 2007, the Company had \$811 million of principal invested in auction rate securities (ARS), representing interests in collateralized debt obligations supported by pools of residential and commercial mortgages or credit cards, insurance securitizations and other structured credits, including corporate bonds. Some of the underlying collateral for the ARS held by the Company consists of sub-prime mortgages. The estimated market value of the Company's ARS holdings at December 31, 2007 was \$419 million, which reflects a \$392 million adjustment to the principal value of \$811 million. Although the ARS continue to pay interest according to their stated terms, based on valuation models and an analysis of other-than-temporary impairment factors, the Company has recorded an impairment charge of \$275 million in the fourth quarter, reflecting the portion of ARS holdings that the Company has concluded have an other-than-temporary decline in value. In addition, the Company recorded an unrealized pre-tax loss of \$142 million in other comprehensive income as a reduction in shareholders equity, reflecting \$117 million of adjustments to ARS holdings and \$25 million of other marketable securities that the Company has concluded have a temporary decline in value.*

*The credit and capital markets have continued to deteriorate in 2008. If uncertainties in these markets continue, these markets deteriorate further or the Company experiences any additional ratings downgrades on any investments in its portfolio (including on ARS), the Company may incur additional impairments to its investment portfolio, which could negatively affect the Company's financial condition, cash flow and reported earnings.*



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*The Company also has significant operations outside of the U.S. Revenue from operations outside of the U.S. accounted for 44% of the Company's revenues in 2007. As such, the Company is exposed to changes in fluctuation of foreign currency exchange rates. For more information on the Company's foreign currency exchange exposure, see Item 7A. Quantitative and Qualitative Disclosures About Market Risk. The Company also has significant borrowings which are exposed to changes in interest rates. At December 31, 2007, the Company had short-term borrowings and long-term debt of \$6.3 billion. For more information on the Company's interest rate exposure, see Item 7A. Quantitative and Qualitative Disclosures About Market Risk. The Company is also exposed to other economic factors over which the Company has no control.*

***The Company may experience difficulties and delays in the manufacturing and sale of its products.***

*The Company may experience difficulties and delays inherent in manufacturing and sale, such as (i) seizure or recalls of pharmaceutical products or forced closings of manufacturing plants; (ii) the failure to obtain, the imposition of limitations on the use of, or loss of patent and other intellectual property rights; (iii) 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; (iv) construction delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's biologics products; and (v) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, such as biologics, or physical limitations that could impact continuous supply.*

***The Company may experience difficulties or delays in the development and commercialization of new products.***

*The Company may experience difficulties and delays in the development and commercialization of new products, including the inherent risks and uncertainties associated with product development, such as (i) compounds or products that may appear promising in development but fail to reach market within the expected or optimal timeframe, or fail ever to reach market, or to be approved for additional indications for any number of reasons, including efficacy or safety concerns, the delay or denial of necessary regulatory approvals and the difficulty or excessive cost to manufacture; (ii) failure to enter into or successfully implement optimal alliances where appropriate for the discovery and/or commercialization of products, or otherwise to maintain a consistent scope and variety of promising late-stage products; (iii) failure of one or more of the Company's products to achieve or maintain commercial viability.*

***There are legal matters in which adverse outcomes could negatively affect the Company's business.***

*The Company is currently involved in various lawsuits, claims, proceedings and government 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) sales and marketing practices in the U.S. and internationally; (iii) adverse decisions in litigation, including product liability and commercial cases; (iv) recalls or withdrawals of pharmaceutical products or forced closings of manufacturing plants; (v) the failure to fulfill obligations under supply contracts with the government and other customers which may result in liability; (vi) product pricing and promotion matters; (vii) lawsuits and claims asserting violations of securities, antitrust, federal and state pricing and other laws; (viii) environmental, health and safety matters; and (ix) tax liabilities. There can be no assurance that there will not be an increase in scope of these matters or there will not be additional lawsuits, claims, proceedings or investigations in the future; nor is there any assurance that these matters will not have a material adverse impact on the Company.*

***U.S. and foreign regulations may negatively affect the Company's sales and profit margins.***

*The Company could become subject to new government laws and regulations, such as (i) health care reform initiatives in the U.S. at the state and Federal level and in other countries; (ii) changes in the U.S. Food and Drug Administration (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 U.S. and certain foreign countries; (iv) new laws, regulations and judicial or other governmental decisions affecting pricing or marketing within or across jurisdictions; (v) changes in intellectual property law; and (vi) other matters such as compulsory licenses that could alter the protections afforded one or more of its products.*

***The Company faces increased pricing pressure in the U.S. and abroad from managed care organizations, institutional purchasers, and government agencies and programs that could negatively affect the Company's sales and profit margins.***

*Pharmaceutical products are subject to increasing price pressures and other restrictions in the U.S. and worldwide, including (i) rules and practices of managed care groups and institutional and governmental purchasers, (ii) judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,*

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*(iii) the potential impact of importation restrictions, legislative and/or regulatory changes, pharmaceutical reimbursement, Medicare Part D Formularies and product pricing in general, and (iv) other developments in technology and/or industry practices that could directly or indirectly impact the reimbursement policies and practices of third-party payers.*

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### ***The Company relies on third parties to meet their contractual, regulatory, and other obligations.***

*The Company relies on vendors, partners, including alliances with other pharmaceutical companies for the development and commercialization of products, and other third parties to meet their contractual, regulatory, and other obligations in relation to their arrangements with the Company. The failure of these parties to meet their obligations, and/or the development of significant disagreements or other factors that materially disrupt the ongoing commercial relationship and prevent optimal alignment between the partners and their activities, could have a material adverse impact on the Company.*

### ***Failure to execute the Company's business strategy could adversely impact its growth and profitability.***

*As part of its strategy, the Company currently is implementing a comprehensive cost reduction program that includes workforce reductions in some areas and the rationalization of some facilities. The Company expects to incur restructuring and other charges in connection with this program in the range of \$0.9 billion to \$1.1 billion on a pre-tax basis over the next three years, with \$292 million of those charges having been incurred in the fourth quarter of 2007 and approximately \$500 million in charges expected to be incurred in 2008.*

*The Company may not be able to fully execute the strategic transformation of its business to attain a new period of sustainable revenue and earnings growth. The Company continues to invest in its key products and pipeline as part of a focus on addressing areas of significant unmet medical need. Failure to realize the expected cost savings in 2008, to achieve and maintain a competitive cost base, or to successfully transition the product portfolio, however, could materially and adversely affect the Company's results of operations. In addition, the Company's failure to hire and retain personnel with the right expertise and experience in operations that are critical to its business functions could adversely impact the execution of its business strategy. Changes in the Company's structure, operations, revenues, costs, or efficiency resulting from acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives, could result in greater than expected costs and other difficulties, including the need for regulatory approvals, as appropriate.*

### ***The Company is increasingly dependent on its information technology and outsourcing arrangements.***

*The Company is increasingly dependent on information technology systems and any significant breakdown, invasion, destruction or interruption of these systems could negatively impact operations. The Company is also increasing its dependence on third-party providers for certain services, including information technology systems. The failure of these service providers to meet their obligations and/or the development of significant disagreements or other factors that materially disrupt the Company's ongoing relationship with these providers could negatively affect operations.*

**Table of Contents****Item 1B. UNRESOLVED STAFF COMMENTS.**

None.

**Item 2. PROPERTIES.**

The Company's world headquarters is located at 345 Park Avenue, New York, NY, where it leases approximately 375,000 square feet of floor space, approximately 215,000 square feet of which is sublet to others.

The Company manufactures products at 36 major worldwide locations with an aggregate floor space of approximately 11.7 million square feet. All facilities are owned by the Company. The following table illustrates the geographic location of the Company's significant manufacturing facilities by business segment.

	Total Company	Pharmaceuticals	Nutritionals	ConvaTec
United States	8	5	2	1
Europe, Middle East and Africa	14	11	1	2
Other Western Hemisphere	7	5	1	1
Pacific	7	4	3	
<b>Total</b>	<b>36</b>	<b>25</b>	<b>7</b>	<b>4</b>

Portions of these facilities and other facilities owned or leased by the Company in the U.S. 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, 2007.

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

Listed below is information on executive officers of the Company as of February 21, 2008. 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>Name and Current Position</b>	<b>Age</b>	<b>Employment History for the Past 5 Years</b>
James M. Cornelius <i>Chairman of the Board and Chief Executive Officer</i> <i>Member of the Management Council</i>	64	2000 to 2005 Chief Executive Officer and Chairman of the Board, Guidant Corporation.  2005 to 2006 Interim Chief Executive Officer and Chairman of the Board, Guidant Corporation.  2006 to 2007 Interim Chief Executive Officer and Director of the Company.  2007 to 2008 Chief Executive Officer and Director of the Company.  2008 to present Chairman of the Board and Chief Executive Officer of the Company.
Lamberto Andreotti <i>Executive Vice President and President,</i> <i>Worldwide Pharmaceuticals</i> <i>Member of the Management Council</i>	57	2002 to 2005 Senior Vice President and President International, Worldwide Medicines Group, a division of the Company.  2005 to present Executive Vice President and President, Worldwide Pharmaceuticals, a division of the Company.
Stephen E. Bear <i>Senior Vice President, Human Resources,</i> <i>Corporate Staff</i> <i>Member of the Management Council</i>	57	2001 to present Senior Vice President, Human Resources, Corporate Staff of the Company.
Andrew R. J. Bonfield <i>Executive Vice President and Chief Financial Officer,</i> <i>Corporate Staff</i> <i>Member of the Management Council</i>	45	2002 to present Chief Financial Officer, Corporate Staff of the Company.
Joseph C. Caldarella <i>Vice President and Corporate Controller,</i> <i>Corporate Staff</i>	52	1998 to 2005 Vice President, Finance, Pharmaceutical Research Institute, a division of the Company.  2005 to present Vice President and Corporate Controller, Corporate Staff of the Company.

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John E. Celentano	48	2002 to 2005	President, Latin America and Canada, Worldwide Medicines Group, a division of the Company.
<i>President, Health Care Group</i>		2005 to present	President, Health Care Group, a division of the Company.
<i>Member of the Management Council</i>			
Anthony C. Hooper	53	2002 to 2004	President, Europe, Middle East & Africa, Worldwide Medicines Group, a division of the Company.
<i>President, U.S. Pharmaceuticals</i>		2004 to present	President, U.S. Pharmaceuticals, Worldwide Medicines Group, a division of the Company.
<i>Member of the Management Council</i>			
Sandra Leung	47	2002 to 2006	Vice President and Corporate Secretary, Corporate Staff of the Company.
<i>Senior Vice President and General Counsel</i>		2006 to 2007	Vice President, Corporate Secretary and Acting General Counsel, Corporate Staff of the Company.
<i>Corporate Staff</i>		2007 to present	Senior Vice President and General Counsel, Corporate Staff of the Company.
<i>Member of the Management Council</i>			

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Elliott Sigal, M.D., Ph.D. <i>Executive Vice President, Chief Scientific Officer and President, Pharmaceutical Research and Development Member of the Management Council</i>	56	2002 to 2004 Senior Vice President, Global Clinical and Pharmaceutical Development, Pharmaceutical Research Institute, a division of the Company.  2004 to present Chief Scientific Officer and President, Pharmaceutical Research and Development, a division of the Company.
Robert T. Zito <i>Senior Vice President, Corporate and Business Communications and Chief Communications Officer Member of the Management Council</i>	54	1999 to 2004 Executive Vice President, Communications, New York Stock Exchange.  2004 to present Senior Vice President, Corporate Affairs, Corporate Staff of the Company.

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

Bristol-Myers Squibb common and preferred stocks are traded on the New York Stock Exchange (NYSE) and were traded on the NYSE Arca, Inc, formerly the Pacific Exchange, Inc. (symbols: BMY; BMYPR). On December 1, 2006, the Company voluntarily withdrew its securities from listing on the NYSE Arca, Inc. A quarterly summary of the high and low market prices is presented below:

Common:

	2007		2006	
	High	Low	High	Low
First Quarter	\$ 29.39	\$ 25.73	\$ 25.95	\$ 21.21
Second Quarter	32.25	27.00	25.97	23.21
Third Quarter	32.35	26.38	26.14	20.08
Fourth Quarter	30.35	26.52	26.41	23.93

Preferred:

	2007		2006	
	High	Low	High	Low
First Quarter	\$ 600.00	\$ 460.00	\$ 360.00	\$ 355.00
Second Quarter	500.00	500.00	*	*
Third Quarter	503.00	475.00	420.00	318.00
Fourth Quarter	475.37	450.00	430.00	400.00

\* During the second quarter of 2006, 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, 2007 was 69,254.

The number of record holders is based upon the actual number of holders registered on the books of the Company 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 2008 Proxy Statement to be filed on or about March 21, 2008 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.



**Table of Contents****Dividends**

The Board of Directors of the Company declared the following dividends per share, which were paid in 2007 and 2006 in the quarters indicated below:

	Common		Preferred	
	2007	2006	2007	2006
First Quarter	\$ .28	\$ .28	\$ .50	\$ .50
Second Quarter	.28	.28	.50	.50
Third Quarter	.28	.28	.50	.50
Fourth Quarter	.28	.28	.50	.50
	\$ 1.12	\$ 1.12	\$ 2.00	\$ 2.00

In December 2007, the Board of Directors of the Company declared a quarterly dividend of \$.31 per share on the common stock of the Company and of \$.50 per share on the preferred stock of the Company, which was paid on February 1, 2008 to shareholders of record as of January 4, 2008.

**Unregistered Sales of Equity Securities and Use of Proceeds**

The following table summarizes the surrenders of the Company's equity securities in connection with stock option and restricted stock programs during the 12-month period ended December 31, 2007:

Period	Total Number of Shares Purchased <sup>(a)</sup>	Average Price Paid per Share <sup>(a)</sup>	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(b)</sup>	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(b)</sup>
Dollars in Millions, except per share data				
January 1 to 31, 2007	11,191	\$ 26.10		\$2,220
February 1 to 28, 2007	8,819	\$ 28.13		\$2,220
March 1 to 31, 2007	290,683	\$ 26.91		\$2,220
Three months ended March 31, 2007	310,693			
April 1 to 30, 2007	11,307	\$ 27.33		\$2,220
May 1 to 31, 2007	203,148	\$ 30.16		\$2,220
June 1 to 30, 2007	7,448	\$ 30.91		\$2,220
Three months ended June 30, 2007	221,903			
July 1 to 31, 2007	28,362	\$ 31.56		\$2,220
August 1 to 31, 2007	6,956	\$ 29.42		\$2,220
September 1 to 30, 2007	31,477	\$ 28.27		\$2,220
Three months ended September 30, 2007	66,795			
October 1 to 31, 2007	26,955	\$ 29.02		\$2,220
November 1 to 30, 2007	12,955	\$ 29.01		\$2,220
December 1 to 31, 2007	4,242	\$ 29.38		\$2,220

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Three months ended December 31, 2007 44,152

Twelve months ended December 31, 2007 643,543

- (a) Reflects the following transactions during the 12 months ended December 31, 2007: (i) the surrender to the Company of 166,630 shares of Common Stock to pay the exercise price and to satisfy tax withholding obligations in connection with the exercise of employee stock options, and (ii) the surrender to the Company of 476,913 shares of Common Stock to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees.
- (b) In June 2001, the Company announced that the Board of Directors authorized the purchase of up to \$14 billion of Company common stock. During the 12 months ended December 31, 2007, no shares were repurchased pursuant to this program and no purchases of any shares under this program are expected in 2008.

**Table of Contents****Performance Graph**

The following performance graph compares the performance of Bristol-Myers Squibb for the periods indicated with the performance of the Standard & Poor's 500 Stock Index (S&P 500) and the average performance of a group consisting of our peer corporations on a line-of-business basis. The corporations making up our peer companies group are Abbott Laboratories, AstraZeneca PLC, Eli Lilly and Company, GlaxoSmithKline plc, Johnson & Johnson, Merck & Co., Inc., Novartis AG, Pfizer, Inc., Sanofi-Aventis (including the performance of Aventis prior to its merger with Sanofi), Schering-Plough Corporation and Wyeth.

Total return indices reflect reinvested dividends and are weighted using beginning-period market capitalization for each of the reported time periods. We measured our performance against this same group in the 2007 Proxy Statement.

**Comparison of Five-Year Cumulative Total Return**

	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07
Bristol-Myers Squibb	\$ 100	\$ 129	\$ 120	\$ 112	\$ 135	\$ 141
S&P 500 Index	\$ 100	\$ 129	\$ 143	\$ 150	\$ 173	\$ 183
Peer Group	\$ 100	\$ 113	\$ 111	\$ 114	\$ 129	\$ 131

Assumes \$100 invested on 12/31/02 in Bristol-Myers Squibb Common Stock, S&P 500 Index and Peer Companies Group Index. Values are as of December 31 of specified year assuming dividends are reinvested.

**Table of Contents****Item 6. SELECTED FINANCIAL DATA.****Five-Year Financial Summary**

Amounts in Millions, except per share data	2007	2006	2005	2004	2003
<b>Income Statement Data:</b> <sup>(1)(2)</sup>					
Net Sales	\$ 19,348	\$ 17,256	\$ 18,605	\$ 18,791	\$ 18,145
Earning from Continuing Operations Before Minority Interest and Income Taxes	3,534	2,400	4,304	4,210	4,529
Net Earnings from Continuing Operations	1,968	1,422	2,842	2,213	2,978
<b>Net Earnings from Continuing Operations per Common Share:</b>					
Basic	\$ 1.00	\$ 0.73	\$ 1.45	\$ 1.14	\$ 1.54
Diluted <sup>(3)</sup>	\$ 0.99	\$ 0.73	\$ 1.44	\$ 1.12	\$ 1.53
<b>Average common shares outstanding:</b>					
Basic	1,970	1,960	1,952	1,942	1,937
Diluted <sup>(3)</sup>	1,980	1,963	1,983	1,976	1,950
Dividends paid on common and preferred stock	\$ 2,213	\$ 2,199	\$ 2,186	\$ 2,174	\$ 2,169
Dividends declared per Common Share	\$ 1.15	\$ 1.12	\$ 1.12	\$ 1.12	\$ 1.12
<b>Financial Position Data at December 31:</b>					
Total Assets <sup>(4)(5)</sup>	\$ 26,172	\$ 25,575	\$ 28,138	\$ 30,435	\$ 27,448
Cash and cash equivalents	1,801	2,018	3,050	3,680	2,549
Marketable securities	424	1,995	2,749	3,794	3,013
Long-term debt	4,381	7,248	8,364	8,463	8,522
Stockholders' Equity	10,562	9,991	11,208	10,202	9,786

(1) The Company recorded items that affected the comparability of results. For a discussion of these items for the years 2007, 2006 and 2005, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Expenses; Item 8. Financial Statements Note 2. Alliances and Investments; Note 3. Restructuring; Note 4. Acquisitions and Divestitures; Note 5. Discontinued Operations and Assets Held for Sale; Note 9. Cash, Cash Equivalents and Marketable Securities; Note 15. Short-Term Borrowings and Long-Term Debt; and Note 22. Legal Proceedings and Contingencies.

(2) Excludes discontinued operations of Medical Imaging for years 2003 through 2007 and Oncology Therapeutics Network for years 2003 through 2005.

(3) In 2007 and 2006, the 29 million weighted-average shares issuable, as well as \$38 million and \$35 million, respectively, of interest expense, net of tax, on the assumed conversion of convertible debt were not included in the diluted earnings per share calculation because they were anti-dilutive.

(4) In 2006, includes the impact of the adoption of Statement of Financial Accounting Standard (SFAS) No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* an amendment of FASB Statements No. 87, 88, 106, and 132(R). For further discussion on SFAS No. 158, see Item 8. Financial Statements Note 21. Pension and Other Postretirement Benefits.

(5) In 2007, includes Medical Imaging and other assets classified as held for sale.

**Table of Contents****Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS. EXECUTIVE SUMMARY****About the Company**

Bristol-Myers Squibb Company (BMS, the Company or Bristol-Myers Squibb) is a global biopharmaceutical and related health care products company whose mission is to extend and enhance human life by providing the highest quality pharmaceutical and related health care products. The Company is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceuticals and related health care products.

The Company has three reportable segments: Pharmaceuticals, Nutritionals and ConvaTec. The Pharmaceuticals segment consists of the global pharmaceutical/biotechnology and international consumer medicines business, which accounted for approximately 81% of the Company's 2007 net sales. The Nutritionals segment consists of Mead Johnson Nutritionals (Mead Johnson), primarily an infant formula and children's nutritionals business, which accounted for approximately 13% of the Company's 2007 net sales. The ConvaTec segment consists of ostomy, wound and skin care business, which accounted for approximately 6% of the Company's 2007 net sales and was previously included in the Other Health Care operating segment. In January 2008, the Company completed the sale of its Medical Imaging business to Avista Capital Partners L.P. (Avista). The results of the Medical Imaging business, previously included in the former Other Health Care operating segment, are presented as part of the Company's results from discontinued operations.

**2007 Financial Highlights**

Worldwide net sales from continuing operations for 2007 increased 12% to \$19.3 billion compared to 2006. PLAVIX\* (clopidogrel bisulfate) sales grew 46%, primarily reflecting the adverse impact of generic competition from August 2006 to mid-2007, as well as strong underlying sales growth. The other key products within the Company's Pharmaceuticals segment, including AVAPRO\*/AVALIDE\* (irbesartan/irbesartan-hydrochlorothiazide), REYATAZ (atazanavir sulfate), the SUSTIVA (efavirenz) Franchise and ABILIFY\* (aripiprazole) experienced double digit sales growth for the year. Sales of the Company's newer specialty and biologics medicines BARACLUDE (entecavir), ORENCIA (abatacept) and SPRYCEL (dasatinib) continue to be strong. In addition, the Company launched IXEMPRA (ixabepilone) for the treatment of metastatic or locally advanced breast cancer. Overall worldwide sales growth, however, was moderated by a significant decline in PRAVACHOL (pravastatin sodium) sales due to generic competition.

Net earnings from continuing operations were \$2.0 billion in 2007 compared with \$1.4 billion in 2006. The 2007 results include a \$230 million charge for acquired in-process research and development related to the purchase of Adnexus Therapeutics, Inc. (Adnexus), a \$292 million charge in connection with the Company's three-year Productivity Transformation Initiative (PTI) and a \$275 million impairment charge of the Company's investment in certain auction rate securities (ARS). The 2006 results include a \$353 million increase in reserves for a pricing and sales litigation settlement and \$220 million in early debt retirement costs. Additionally, the Company also recorded gains on sale of product assets and properties of \$273 million and \$200 million in 2007 and 2006, respectively.

In December 2007, the Company announced that the Board of Directors (the Board) declared an 11 percent dividend increase, the first increase since 2002. The dividend increase will result in a quarterly dividend of thirty-one cents (\$.31) per share on the Company's Common Stock for an indicative dividend for the full year of 2008 of \$1.24 per share, subject to the normal quarterly review by the Board.

**Business Environment**

The Company conducts its business primarily within the pharmaceutical/biotechnology industry, which is highly competitive and subject to numerous government regulations. Many competitive factors may significantly affect the Company's sales of its products, including product efficacy, safety, price and cost-effectiveness, marketing effectiveness, product labeling, quality control and quality assurance of its manufacturing operations, and research and development of new products. To successfully compete for business in the health care industry, the Company must demonstrate that its products offer medical benefits, as well as cost advantages. Currently, most of the Company's new product introductions compete with other products already on the market in the same therapeutic category, in addition to potential competition of new products that competitors may introduce in the future. The Company manufactures branded products, which are priced higher than generic products. Generic competition is one of the Company's leading challenges globally.

In the pharmaceutical/biotechnology industry, the majority of an innovative product's commercial value is usually realized during the period that the product has market exclusivity. When a product loses exclusivity, it is no longer protected by a patent and is



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subject to new competing products in the form of generic brands. Upon exclusivity loss, the Company can lose a major portion of that product's sales in a short period of time. Currently, generic versions of biological products cannot be approved under U.S. law. However, the law could change in the future. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics. Competitors seeking approval of biological products must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex processes and are more costly than those of traditional pharmaceutical operations.

Both in the U.S. and internationally, the health care industry is subject to various government-imposed regulations that authorize prices or price controls that have and will continue to have an impact on the Company's sales. In the U.S., 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. In addition, the Medicare Prescription Drug Improvement and Modernization Act provides outpatient prescription drug coverage to senior citizens in the U.S. This legislation has had a modest favorable impact on the Company, as a result of an increase in the number of seniors with drug coverage. There continues to be a potential negative impact on the U.S. pharmaceutical business that could result from pricing pressures or controls. In many markets outside the U.S., the Company operates in environments of government-mandated, cost-containment programs, or under other regulatory bodies or groups that can exert downward pressure on pricing. Pricing freedom is limited in the United Kingdom (UK), for instance, by the operation of a profit control plan 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 after drug approval before new medicines become available in some national markets.

The growth of Managed Care Organizations (MCOs) in the U.S. has played a large role in the competition that surrounds the health care industry. MCOs seek to reduce health care expenditures for participants by making volume purchases and entering into long-term contracts to negotiate discounts with various pharmaceutical providers. Because of the market potential created by the large pool of participants, marketing prescription drugs to MCOs has become an important part of the Company's strategy. Companies compete for inclusion in a MCO formulary and the Company has generally been successful in having its major products included. The Company believes that developments in the managed care industry, including continued consolidation, have had and will continue to have a generally downward pressure on prices.

Pharmaceutical/biotechnology production processes are complex, highly regulated and vary widely from product to product. Shifting or adding manufacturing capacity can be a lengthy process requiring significant capital expenditures and regulatory approvals. Biologics manufacturing involves more complex processes than those of traditional pharmaceutical operations. As biologics become more important to the Company's product portfolio, the Company will continue to make arrangements with third-party manufacturers, and to make substantial investments to increase its internal capacity to produce biologics on a commercial scale. One such investment is the building of a new state-of-the-art manufacturing facility for the production of biologics in Devens, Massachusetts, the construction of which began in May 2007.

The Company has maintained a competitive position in the market and strives to uphold this position, which is dependent on its success in discovering and developing innovative, cost-effective products that serve unmet medical need. Recently, several of the Company's competitors have announced cost reduction programs in an effort to reduce their respective cost bases and increase their productivity and competitiveness. The Company has also announced a three-year PTI to reduce costs, streamline operations and rationalize global manufacturing as part of its efforts to become a more productive and competitive biopharmaceutical company.

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. For additional discussion of legal matters, see Item 8. Financial Statements Note 22. Legal Proceedings and Contingencies.

### **Strategy**

In December 2007, the Company outlined its multi-year strategy designed to transform the Company into a next-generation biopharmaceutical company. The strategy encompasses all aspects and all geographies of the business and will yield substantial cost savings and cost avoidance and increase the Company's financial flexibility to take advantage of attractive market opportunities that may arise.

As the Company develops into a next-generation biopharmaceutical company, it will continue to invest in key growth products, including specialty and biologic medicines, and cardiovascular and metabolic drugs. The Company continues to execute its ongoing strategy for long-term growth through the scale back of assets in its profitable, though declining, mature brands and increased focus





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on key and new growth products, which include PLAVIX\*, ABILIFY\*, AVAPRO\*/AVALIDE\*, REYATAZ, the SUSTIVA Franchise, ERBITUX\* (cetuximab), ORENCIA, BARACLUDE, SPRYCEL and IXEMPRA. The Company experienced the last of a series of major anticipated exclusivity losses in 2006 and does not expect any significant new exclusivity losses for the next several years.

In order to support the production of specialty products in the pharmaceutical portfolio, including biologics, the Company completed a land purchase in 2007 of an 89-acre site to locate its new large-scale, expandable multi-project bulk biologics manufacturing facility in Devens, Massachusetts. The Company has committed \$750 million to fund the construction of the facility which began in May 2007. The facility is projected to be operationally complete in 2009, and the Company plans to submit the site for regulatory approval in 2010. Commercial production of biologic compounds is anticipated to begin in 2011. In addition, the Company expanded its Manati, Puerto Rico facility, with the expansion targeted for start-up in 2008.

The new state-of-the-art facility, as well as the expanded Manati, Puerto Rico facility, will support the filling and finishing of the Company's sterile products and biologic compounds, including ORENCIA, the Company's first internally discovered and developed biologic medicine, and commercial quantities of compounds currently in development should those compounds receive regulatory approval.

In keeping with its strategy, the Company invested \$3.3 billion in research and development, representing a 10% growth rate over 2006. Research and development dedicated to pharmaceutical products, including milestone payments for in-licensing and development programs, was \$3.1 billion compared to \$2.8 billion in 2006.

Consistent with the Company's objective to maximize the value of its non-pharmaceutical businesses, in January 2008, the Company completed the sale of its Medical Imaging business to Avista. The Company will continue to seek opportunities to maximize the value of its remaining Health Care Group businesses.

As it transitions into a next-generation biopharmaceutical company, the Company seeks to reallocate resources to enable strategic acquisitions, such as the acquisition of Adnexus in October 2007, as well as pursue partnerships and other collaborative arrangements, such as the worldwide alliance with AstraZeneca PLC (AstraZeneca) to discover, develop and commercialize saxagliptin and dapagliflozin and the two separate agreements with Pfizer Inc. (Pfizer) for the research, development and commercialization of a Pfizer discovery program and for the development and commercialization of apixaban.

### **Productivity Transformation Initiative**

The Company undertook a broad range of actions in the fourth quarter of 2007 as part of the previously announced three-year PTI, which is reducing costs, streamlining operations and rationalizing global manufacturing. The initiative, which is on track to achieve \$1.5 billion in annual cost savings and cost avoidance on a pre-tax basis by 2010, is central to the Company's strategy to become a more nimble and flexible next generation biopharmaceutical enterprise.

Key productivity initiatives include reducing general and administrative operations by simplifying, standardizing and outsourcing, where appropriate, processes and services, rationalizing the Company's mature brands portfolio, consolidating its global manufacturing network while eliminating complexity and enhancing profitability, simplifying its geographic footprint and implementing a more efficient go-to-market model. Specific productivity goals include reducing the number of brands in the Company's mature products portfolio by 60 percent between 2007 and 2011, reducing the number of manufacturing facilities by more than 50 percent by the end of 2010, and reducing total headcount by approximately 10 percent between 2007 and 2010. Some positions have been eliminated in 2007, although the substantial majority of positions will be eliminated in 2008 and 2009. Among the many productivity activities across the entire organization in the fourth quarter of 2007 are the impending closure of several manufacturing facilities, including Mayaguez, Puerto Rico and Barceloneta, Puerto Rico.

Costs associated with the implementation of the PTI are estimated to be between \$0.9 billion to \$1.1 billion on a pre-tax basis, with \$292 million incurred in 2007 and approximately \$500 million expected to be incurred in 2008. The ultimate timing of the recording of the charges cannot be predicted with certainty and will be affected by the occurrence of triggering events for expense recognition under U.S. Generally Accepted Accounting Principles (GAAP), among other factors.

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### **New Product and Pipeline Developments**

In December 2007, the Company and Medarex, Inc. (Medarex) announced top-line data from the three registrational trials (008, 022, 007) that constitute the monotherapy program for ipilimumab in patients with metastatic melanoma. The results from study 008, conducted under Special Protocol Assessment, did not meet the primary endpoint, which was to rule out a best objective response rate of less than 10 percent. However, the totality of data from the registrational program included a clear dose response effect observed in study 022 and best objective response rates across the three studies ranging from mid-single digits to mid-teens as determined by independent radiology review. After the receipt of additional data from ongoing clinical trials, the companies plan to meet with the FDA to discuss the regulatory pathway, with the goal of submitting a regulatory filing by the middle of 2008, if supported by the data.

In November 2007, the Company and Pierre Fabre Medicament S.A. (Pierre Fabre) announced the termination of the license agreement for the development of vinflunine, a chemotherapy agent under investigation for the treatment of advanced or metastatic bladder cancer and other tumor types.

In November 2007, ABILIFY\* was approved by the FDA as adjunctive, or add-on, treatment to antidepressant therapy in adults with major depressive disorder (MDD). ABILIFY\* is the first medication approved by the FDA as add-on treatment for MDD. The FDA also approved ABILIFY\* for the treatment of schizophrenia in adolescent patients (ages 13-17) and accepted for Priority Review the supplemental New Drug Application (sNDA) for the treatment of pediatric patients (ages 10-17) with Bipolar I Disorder.

An update to the SPRYCEL label to include a lower recommended starting dose of 100 mg once daily, from 70 mg twice daily, as a starting dose for patients with chronic-phase chronic myeloid leukemia resistant or intolerant to imatinib was approved by the FDA in November 2007 and by the European Commission in August 2007. During the first quarter of 2007, SPRYCEL received approval and/or reimbursement in additional European markets, including Ireland, Norway, Sweden and Greece, and was also approved in Canada and New Zealand.

In October 2007, ATRIPLA\* (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) was approved in Canada as the first once-daily single-tablet regimen for the treatment of human immunodeficiency virus-1 infection in adults. In December 2007, the European Commission granted marketing authorization for ATRIPLA\*, formally approving it for commercialization in the 27 countries of the European Union (EU), as well as in Norway and Iceland. ATRIPLA\* has been launched in the UK, Germany and Austria.

In October 2007, the Company launched IXEMPRA, for the treatment of patients with metastatic or locally advanced breast cancer, in the U.S. In addition, the Japanese New Drug Application for ixabepilone was submitted in December 2007, and the Marketing Authorization Application for ixabepilone is under review by the European Medicines Evaluation Agency (EMEA), following submission in September 2007.

In October 2007, the Company acquired privately-held Adnexus, developer of a new therapeutic class of biologics called ADNECTINS. ADNECTINS are a proprietary class of targeted biologics based on a naturally occurring protein found in human serum.

In October 2007, the Company and ImClone Systems Incorporated (ImClone) announced that the FDA approved an update to the ERBITUX\* product labeling to include overall survival data as a single agent in epidermal growth factor inhibitor (EGFR)-expressing metastatic colorectal cancer (mCRC) patients after the failure of both irinotecan- and oxaliplatin-based regimens. In September, the Company and ImClone announced that a Phase III study of ERBITUX\* in combination with platinum-based chemotherapy, conducted by Merck KGaA, met its primary endpoint of increasing overall survival compared with chemotherapy alone in patients with advanced non-small cell lung cancer. As previously disclosed, an earlier study conducted by ImClone and the Company evaluating the use of ERBITUX\* in combination with a different platinum-based therapy did not meet its primary endpoint of increasing progression-free survival in patients with advanced non-small cell lung cancer. Key secondary endpoints of this study, however, were statistically significant and favored the ERBITUX\*-containing arm.

In September 2007, the FDA approved a sNDA for a single 300 mg tablet of PLAVIX\*. The 300 mg loading dose has been proven effective in a broad acute coronary syndrome patient population. The 300 mg tablet of clopidogrel bisulfate was launched in the U.S. in December 2007 and is currently under EMEA review.

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In August 2007, the Company and Pfizer finalized the collaborative agreement for the research, development and commercialization of a Pfizer discovery program which includes advanced pre-clinical compounds with potential applications for the treatment of metabolic disorders, including obesity and diabetes. The Company recorded an upfront charge of \$60 million in accordance with the terms of the agreement. Pfizer will be responsible for all research and early-stage development activities for the metabolic disorders program, and the companies will jointly conduct Phase III development and commercialization activities. The companies will share all development and commercialization expenses along with profits/losses on a 60%-40% basis, with Pfizer assuming the larger share of both expenses and profits/losses.

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In August 2007, the FDA accepted, for filing and review, the supplemental Biologics License Application for ORENCIA for the treatment of pediatric patients with juvenile idiopathic arthritis. ORENCIA was approved by the European Commission in May 2007, and has received approval and/or reimbursement in several European markets, including the UK, Germany, Austria, Sweden, the Netherlands and Denmark. In April 2007, the FDA approved an update to the ORENCIA product labeling regarding the progression of structural joint damage an important measure in the treatment of rheumatoid arthritis (RA). The indication was strengthened from slowing to inhibiting the progression of structural damage in adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs, such as methotrexate or tumor necrosis factor antagonists.

In July 2007, the Company and ImClone amended the terms of their agreement for the codevelopment and copromotion of ERBITUX\* in North America. Under this amendment, the companies have jointly agreed to expand the investment in the ongoing clinical development plan for ERBITUX\*. Development costs, up to a threshold value, will be the sole responsibility of the Company; costs in excess of this threshold will be shared by both companies according to a pre-determined ratio. With this additional funding, the companies intend to further explore the use of ERBITUX\* in additional tumor types including brain, breast, bladder, gastric, lung, pancreas and prostate.

In May 2007, the Company and Isis Pharmaceuticals, Inc. (Isis) entered into a collaborative agreement to discover, develop and commercialize novel antisense drugs targeting proprotein convertase subtilisin kexin 9 for the prevention and treatment of cardiovascular disease. The Company made an upfront payment of \$15 million to Isis as part of this agreement and will provide Isis with at least \$9 million in research funding over a period of three years.

In April 2007, the Company and Pfizer entered into a worldwide collaboration to develop and commercialize apixaban, an anticoagulant discovered by the Company being studied for the prevention and treatment of a broad range of venous and arterial thrombotic conditions. In accordance with the terms of the agreement, Pfizer made upfront payments of \$250 million and \$40 million to the Company in May 2007 and December 2007, respectively. Pfizer will fund 60% of all development costs effective January 1, 2007 going forward, and the Company will fund 40%. The Company may also receive additional payments of up to \$780 million from Pfizer based on development and regulatory milestones. The companies will jointly develop the clinical and marketing strategy of apixaban, and will share commercialization expenses and profits/losses equally on a global basis.

In February 2007, BARACLUDGE was added to the American Association for the Study of Liver Disease treatment guidelines for hepatitis B as a first-line treatment option. BARACLUDGE also received approval and/or reimbursement in additional European markets, including Italy, throughout the first quarter of 2007.

In January 2007, the Company entered into two worldwide (except for Japan) codevelopment and cocommercialization agreements with AstraZeneca to develop and commercialize two investigational compounds being studied for the treatment of type 2 diabetes. The Company received upfront payments of \$100 million from AstraZeneca. In addition, the Company will receive milestone payments from AstraZeneca upon successful achievement of various regulatory and sales related stages. The companies have agreed upon initial development plans for the two compounds. From 2007 through 2009, the majority of development costs will be paid by AstraZeneca and any subsequent development costs will generally be shared equally. In July 2007, the companies decided to move the investigational compound dapagliflozin, a selective inhibitor of the sodium-glucose transporter 2 being studied for the treatment of diabetes, into Phase III testing based on results of Phase II clinical trials.

In December 2006, the Company entered into a collaboration agreement with Exelixis Pharmaceuticals, Inc. (Exelixis) to discover, develop and commercialize novel targeted therapies for the treatment of cancer. The agreement became effective in January 2007 and in accordance with the terms of the agreement, the Company made an upfront payment of \$60 million to Exelixis. In January 2008, the Company exercised an option to develop and commercialize compounds targeting one therapeutic target and paid Exelixis \$20 million in February 2008. Exelixis is also eligible to receive \$20 million for each of up to two additional investigational drug candidates selected by the Company. At the option of Exelixis, the companies will share equally all development costs along with commercial profits in the U.S.; otherwise, the Company will be responsible for development and will pay development milestones and royalties to Exelixis.

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The following discussions of the Company's results of continuing operations exclude the results related to the Medical Imaging business, which was previously presented as a component of the former Other Health Care operating segment prior to its divestiture in January 2008, and the Oncology Therapeutics Network (OTN) business, which was previously presented as a separate operating segment prior to its divestiture in 2005. These businesses have been segregated from continuing operations and reflected as discontinued operations for all periods presented. See Discontinued Operations below. The Company's results of operations were as follows:

Dollars in Millions	2007	2006	2005	% Change	
				2007 vs. 2006	2006 vs. 2005
Net Sales	\$ 19,348	\$ 17,256	\$ 18,605	12%	(7)%
Earnings from Continuing Operations Before Minority Interest and Income Taxes	\$ 3,534	\$ 2,400	\$ 4,304	47%	(44)%
<i>% of net sales</i>	<i>18.3%</i>	<i>13.9%</i>	<i>23.1%</i>		
Provision for Income Taxes	\$ 803	\$ 538	\$ 870	49%	(38)%
<i>Effective tax rate</i>	<i>22.7%</i>	<i>22.4%</i>	<i>20.2%</i>		
Net Earnings from Continuing Operations	\$ 1,968	\$ 1,422	\$ 2,842	38%	(50)%
<i>% of net sales</i>	<i>10.2%</i>	<i>8.2%</i>	<i>15.3%</i>		

Net sales from continuing operations for 2007 increased 12% to \$19.3 billion, including a 3% favorable foreign exchange impact, compared to 2006. U.S. net sales in 2007 increased 18% to \$10.8 billion compared to 2006. International net sales in 2007 increased 5% to \$8.5 billion compared to 2006, including a 7% favorable foreign exchange impact.

In 2006, net sales from continuing operations decreased 7% to \$17.3 billion, compared to 2005. U.S. net sales in 2006 decreased 8% to \$9.2 billion compared to 2005, while international net sales decreased 7% to \$8.1 billion in 2006 as compared to 2005.

The composition of the change in net sales were as follows:

	Total Change	Analysis of % Change		
		Volume	Price	Foreign Exchange
2007 vs. 2006	12%	7%	2%	3%
2006 vs. 2005	(7)%	(9)%	2%	

In general, the Company's business is not seasonal. For information on U.S. pharmaceutical 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 key pharmaceutical products and new products sold by the U.S. Pharmaceuticals business.

The Company operates in three reportable segments Pharmaceuticals, Nutritionals and ConvaTec (previously a component of the Other Health Care operating segment). In January 2008, the Company completed the sale to Avista of the Medical Imaging business, which was previously presented as a component of the Other Health Care operating segment. In May 2005, the Company completed the sale of OTN, which was previously presented as a separate operating segment. As such, the results of operations for Medical Imaging and OTN are presented as part of the Company's results from discontinued operations in accordance with Statement of Financial Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Accordingly, Medical Imaging and OTN results of operations in prior periods have been reclassified to discontinued operations to conform with current year presentations.

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The Company's net sales by segment were as follows:

Dollars in Millions	2007	Net Sales 2006	2005	% Change	
				2007 vs. 2006	2006 vs. 2005
Pharmaceuticals	\$ 15,622	\$ 13,861	\$ 15,408	13%	(10)%
<i>% of net sales</i>	<i>81%</i>	<i>80%</i>	<i>83%</i>		
Nutritionals	2,571	2,347	2,205	10%	6%
<i>% of net sales</i>	<i>13%</i>	<i>14%</i>	<i>12%</i>		
ConvaTec	1,155	1,048	992	10%	6%
<i>% of net sales</i>	<i>6%</i>	<i>6%</i>	<i>5%</i>		
Health Care Group	3,726	3,395	3,197	10%	6%
Total	\$ 19,348	\$ 17,256	\$ 18,605	12%	(7)%

The Company recognizes revenue net of various sales adjustments to arrive at net sales as reported on the Consolidated Statement of Earnings. These adjustments are referred to as gross-to-net sales adjustments and are further described in Critical Accounting Policies below. The reconciliations of the Company's gross sales to net sales by each significant category of gross-to-net sales adjustments were as follows:

Dollars in Millions	For the Years Ended December 31,		
	2007	2006	2005
<b>Gross Sales</b>	\$ 22,175	\$ 20,120	\$ 22,389
<b>Gross-to-Net Sales Adjustments</b>			
Prime Vendor Charge-Backs	(662)	(703)	(1,090)
Women, Infants and Children (WIC) Rebates	(848)	(872)	(843)
Managed Health Care Rebates and Other Contract Discounts	(387)	(322)	(502)
Medicaid Rebates	(169)	(174)	(595)
Cash Discounts	(251)	(224)	(271)
Sales Returns	(160)	(230)	(164)
Other Adjustments	(350)	(339)	(319)
<b>Total Gross-to-Net Sales Adjustments</b>	(2,827)	(2,864)	(3,784)
<b>Net Sales</b>	\$ 19,348	\$ 17,256	\$ 18,605

The slight decrease in gross-to-net sales adjustments in 2007 compared to 2006 was affected by a number of factors. Sales returns decreased primarily due to higher accruals in 2006 for Cardiovascular non-exclusive brands and from the discontinued commercialization of TEQUIN (gatifloxacin). The decrease in prime vendor charge-backs was primarily due to lower sales of TAXOL<sup>®</sup> (paclitaxel) as a result of loss of exclusivity. This was partially offset by increases in managed health care rebates and other contract discounts, primarily as a result of higher PLAVIX\* sales and the reversal of reserves in 2006 related to the TRICARE Retail Pharmacy Refund Program, partially offset by lower sales of PRAVACHOL due to loss of exclusivity. Additionally, the increase in cash discounts was primarily due to higher PLAVIX\* sales volumes.

The decrease in gross-to-net sales adjustments in 2006 compared to 2005 was affected by a number of factors, including changes in customer mix and a portfolio shift, in each case towards products that required lower rebates, as well as changes in contract status. The decrease in prime vendor charge-backs was primarily the result of lower PLAVIX\* net sales, volume erosion on highly-rebated PARAPLATIN (carboplatin) and TAXOL<sup>®</sup> (paclitaxel) due to generic competition, as well as the impact from the discontinued commercialization of TEQUIN. Managed health care rebates and other contract discounts decreased primarily as a result of the reversal of reserves related to the TRICARE Retail Pharmacy Refund Program, as well as the exclusivity loss of PRAVACHOL, which also reduced Medicaid rebates. In addition, lower PLAVIX\* net sales and the shift in patient enrollment from Medicaid to Medicare under Medicare Part D, resulted in a decrease in Medicaid rebates, partially offset by a corresponding increase in managed health care rebates. The decrease in cash discounts was primarily due to lower sales of PRAVACHOL

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due to loss of exclusivity and lower PLAVIX\* sales volumes. The increase in sales returns was primarily due to higher returns trends for non-exclusive brands as well as from the discontinued commercialization of TEQUIN.

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The activities and ending balances of each significant category of gross-to-net sales adjustments were as follows:

Dollars in Millions	Prime Vendor Charge-Backs	Women, Infants and Children Rebates	Managed Health Care Rebates and Other Contract Discounts	Medicaid Rebates	Cash Discounts	Sales Returns	Other Adjustments	Total
Balance at January 1, 2006	\$ 107	\$ 252	\$ 167	\$ 326	\$ 26	\$ 185	\$ 124	\$ 1,187
Provision related to sales made in current period	706	867	355	174	221	200	348	2,871
Provision related to sales made in prior periods	(3)	5	(33)		3	30	(9)	(7)
Returns and payments	(747)	(894)	(380)	(363)	(232)	(196)	(343)	(3,155)
Impact of foreign currency translation			1			2	4	7
Discontinued operations			1					1
Balance at December 31, 2006	63	230	111	137	18	221	124	904
Provision related to sales made in current period	662	845	394	176	250	142	352	2,821
Provision related to sales made in prior periods		3	(7)	(7)	1	18	(2)	6
Returns and payments	(655)	(880)	(360)	(181)	(245)	(207)	(356)	(2,884)
Impact of foreign currency translation			6			4	10	20
Discontinued operations			(10)					(10)
Balance at December 31, 2007	\$ 70	\$ 198	\$ 134	\$ 125	\$ 24	\$ 178	\$ 128	\$ 857

In 2007, the Company recorded gross-to-net sales adjustments related to sales made in prior periods. The significant items included charges for sales returns of \$18 million primarily related to higher than expected returns for certain non-exclusive products.

In 2006, the Company recorded gross-to-net sales adjustments related to sales made in prior periods. The significant items included charges for sales returns of \$30 million primarily related to higher than expected return trends for certain non-exclusive products, as well as from the discontinued commercialization of TEQUIN; and credits in other contract discounts of \$33 million, primarily due to the reversal of reserves related to the TRICARE Retail Pharmacy Refund Program.

No other significant revisions were made to the estimates for gross-to-net sales adjustments in 2007 and 2006.

**Pharmaceuticals**

The composition of the change in pharmaceutical sales were as follows:

	Total Change	Analysis of % Change		
		Volume	Price	Foreign Exchange
2007 vs. 2006	13%	8%	2%	