

BRISTOL MYERS SQUIBB CO  
Form 10-K  
February 20, 2009  
[Table of Contents](#)

**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, 2008**

**Commission File Number 1-1136**

**BRISTOL-MYERS SQUIBB COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of

**22-0790350**  
(IRS Employer

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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 1,978,967,503 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, 2008) was approximately \$40,628,202,837. Bristol-Myers Squibb has no non-voting common equity. At February 6, 2009, there were 1,979,509,306 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 5, 2009 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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**Table of Contents**

**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 pharmaceutical and nutritional products.

**Acquisitions and Divestitures**

In January 2008, the Company completed the divestiture of Bristol-Myers Squibb Medical Imaging (Medical Imaging) to Avista Capital Partners L.P. (Avista) for a gross purchase price of approximately \$525 million, excluding post-closing adjustments. As a result of the transaction the Company recorded a pre-tax gain of \$25 million and an after-tax loss of \$43 million, which are included in discontinued operations in the consolidated statements of earnings.

In June 2008, the Company acquired Kosan Biosciences, Inc., a developer of novel oncology products, for a net purchase price of approximately \$191 million. In connection with the transaction, the Company recorded approximately \$32 million in acquisition-related in-process research and development charges.

In August 2008, the Company completed the divestiture of its ConvaTec business to Cidron Healthcare Limited, an affiliate of Nordic Capital Fund VII and Avista, for \$4.1 billion. As a result of the transaction, the Company recorded a pre-tax gain of \$3.4 billion, \$2.0 billion net of tax, subject to certain post-closing adjustments, which are included in discontinued operations in the consolidated statements of earnings.

In December 2008, the Company completed the sale of its mature brand business in Egypt to GlaxoSmithKline for \$209 million. As a result of the transaction, the Company recognized a pre-tax gain of \$144 million, \$88 million net of tax, in the fourth quarter of 2008.

**Business Segments**

The Company reports financial and operating information in two segments Pharmaceuticals and Nutritionals. The Nutritionals segment is operated through the Company's subsidiary Mead Johnson Nutrition Company (Mead Johnson). In August 2008, the Company completed the divestiture of its ConvaTec business to Cidron Healthcare Limited and Avista. The results of the ConvaTec business, previously presented as the former ConvaTec operating segment, are included in discontinued operations in all periods presented. In January 2008, the Company completed the divestiture of its Medical Imaging business to Avista, the results of which are included in discontinued operations in all periods presented.

For additional information about business segments, see Item 8. Financial Statements Note 22. 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 11 foreign countries.

The Pharmaceuticals segment is comprised of the global pharmaceutical and international consumer medicines businesses. The Pharmaceuticals segment accounted for 86% of the Company's net sales in each of 2008, 2007 and 2006.

U.S. pharmaceutical net sales accounted for 60%, 58% and 54% of total pharmaceutical net sales in 2008, 2007 and 2006, respectively, while pharmaceutical net sales in Europe, Middle East and Africa accounted for 24%, 25% and 28% of total pharmaceutical net sales in 2008, 2007 and 2006, respectively. Pharmaceutical net sales in Japan accounted for 3% of total pharmaceutical net sales in 2008 and 4% in each of 2007 and 2006.



## **Table of Contents**

### *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 involve more complex processes and are more costly than those of traditional pharmaceutical operations.

The chart below shows 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.

**Table of Contents**

The following schedule details sales of key products and estimated basic exclusivity loss in the U.S., EU and Japanese markets for the years ended December 31, 2008, 2007 and 2006:

Key Pharmaceutical Products Dollars in Millions	Net Sales by Products			Past or Currently Estimated Year of U.S. Basic Exclusivity Loss	Past or Currently Estimated Year of EU Basic Exclusivity Loss <sup>(a)</sup>	Past or Currently Estimated Year of Japanese Basic Exclusivity Loss
	2008	2007	2006			
<b>Cardiovascular</b>						
PLAVIX*	\$ 5,603	\$ 4,755	\$ 3,257	2011	2008-2013 <sup>(b)</sup>	++
AVAPRO*/AVALIDE*	1,290	1,204	1,097	2012	2007-2013	++
PRAVACHOL	203	443	1,197	2006	2002-2008	++
<b>Virology</b>						
REYATAZ	1,292	1,124	931	2017	2017 <sup>(c)</sup>	2017
SUSTIVA Franchise (total revenue)	1,149	956	791	2013 <sup>(d)</sup>	2013 <sup>(d)</sup>	++
BARACLUDE	541	275	83	2015	2011-2016	2016
<b>Oncology</b>						
ERBITUX*	749	692	652	2017 <sup>(e)</sup>	++	2009 <sup>(j)</sup>
TAXOL	385	422	563	2000	2003	2006
SPRYCEL	310	158	25	2020	2020 <sup>(f)</sup>	++
IXEMPRA	101	15		2018	2018	++
<b>Affective (Psychiatric) Disorders</b>						
ABILIFY*	2,153	1,660	1,282	2014 <sup>(g)</sup>	2014 <sup>(h)</sup>	++
<b>Immunoscience</b>						
ORENCIA	441	231	89	2019 <sup>(e)</sup>	2017 <sup>(i)</sup>	++

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 138.

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

(a) References to the EU throughout this Form 10-K include all 27 member states that were members of the European Union during the year ended December 31, 2008. 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) Data exclusivity in the EU expired in July 2008. In most of the major markets within Europe, the product has national patents, expiring in 2013, which specifically claim the bisulfate form of clopidogrel.

(c) Data exclusivity in the EU expires in 2014.

(d) Exclusivity period relates to SUSTIVA brand only.

(e) Biologic product approved under a BLA. In the U.S., there is currently no regulatory approval path for generic biologics.

(f) Pending application. EU patent application was not filed in Estonia, Latvia, Lithuania, Malta, Slovakia and Slovenia.

(g) The Company's rights to commercialize aripiprazole in the U.S. terminate in 2012.

(h) The Company's rights to commercialize aripiprazole in the EU terminate in 2014. Patent protection in Romania and Denmark expires in 2009.

(i) Data exclusivity in the EU expires in 2017.

(j) Data exclusivity in Japan expires 2016.



**Table of Contents**

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 the Circuit Court has upheld the District Court's decision sustaining the validity of the patent. Apotex has filed a petition with the Circuit Court to reconsider its decision *en banc*. 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 25. Legal Proceedings and Contingencies.

In the EU, regulatory data exclusivity protection expired in July 2008. In most of the major markets within Europe, PLAVIX\* benefits from national patents, expiring in 2013, which specifically claim the bisulfate form of clopidogrel. In the remainder of EU member countries, however, where there is no composition of matter patent covering clopidogrel bisulfate, competitors are seeking regulatory approval to enter those markets with generic clopidogrel bisulfate. In addition, at least one group of competitor companies has received marketing authorization for, and has started to market, an alternative salt form of clopidogrel in Germany. The competitor companies have announced that they plan to seek marketing authorization in other EU countries in addition to Germany.

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 Collaborations.

**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 global 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 basic composition of matter patent in the U.S. expires in 2012 (including pediatric extension) and in most countries in the EU in 2012-2013. Data exclusivity in the EU expired 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 Collaborations.

**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



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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.

**Table of Contents**

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.

The composition of matter patent has expired in all major markets.

The Company obtains its bulk requirements for pravastatin from Sankyo and finishes the product 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). In the U.S., the Company and Gilead share responsibility for commercializing ATRIPLA\*. 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 records revenues from net sales of ATRIPLA\* in most countries in Europe, and the Company records 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 Collaborations.

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

The composition of matter patent for efavirenz in the U.S. expires in 2013, but a method of use patent for the treatment of HIV infection expires in 2014 with a possible six month pediatric extension. Market exclusivity for SUSTIVA is expected to expire in 2013 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 a composition of matter patent that expires in the U.S. in 2015. The composition of matter patent expires in the EU between 2011 and 2016 and in Japan in 2016. There is uncertainty about China's exclusivity laws and, due to this uncertainty, it is possible that one or more companies in China could receive marketing authorization from China's health authority at any time.

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

**Table of Contents****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 predecessor company of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company (Lilly). 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\* received marketing approval in Japan in July 2008 for the use of ERBITUX\* in treating patients with advanced or recurrent 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 Collaborations.

There is no patent that specifically claims the composition of matter of cetuximab, the active molecule in 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 was challenged by three researchers from Yeda Research and Development Company Ltd. (Yeda). 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 did not change the royalty the Company pays to ImClone on ERBITUX\* sales.

Yeda 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 granted Amgen Inc. (Amgen) a license under the use patent. Amgen received FDA approval to market an EGFR-product that competes with ERBITUX\*.

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**

TAXOL (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 market exclusivity for TAXOL has expired in all major markets.

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

**Table of Contents**

**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.

Market exclusivity for SPRYCEL is expected to expire in 2020 in the U.S. 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 regulatory exclusivity 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 the 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). In the U.S., New Chemical Entity regulatory exclusivity 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 the manufacturing 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, bipolar mania disorder and major depressive 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 Collaborations.

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.



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## **Table of Contents**

Otsuka has received formal notices from each of Teva Pharmaceuticals USA (Teva), Barr Pharmaceuticals, Inc. (Barr), Sandoz Inc. (Sandoz), Synthon Laboratories, Inc. (Synthon), 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 state 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 purport 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 Synthon 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 supplementary 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. A patent term extension has been granted for one of the composition of matter patents, extending the term of the patent to 2019. In the majority of the EU countries, the Company has a patent covering abatacept that expires in 2012. In a majority of these EU countries, the Company has applied for supplementary protection certificates, which would extend the term of the patent if granted. Data exclusivity in the EU expires in 2017.

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

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, 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. 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. 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.

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



## Table of Contents

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 180 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 (with the exception of the commercialization agreement with Otsuka, as discussed below) and may vary on a country-by-country basis.

The Company's most significant current alliances and arrangements for both currently marketed products and investigational compounds are noted below.

### 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 Territories 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 Territories 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 statements of earnings. The Company's share of net income from these partnership entities before taxes was \$632 million in 2008, \$526 million in 2007 and \$439 million in 2006.

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



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## **Table of Contents**

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, net of taxes, which was \$976 million in 2008, \$746 million in 2007 and \$428 million in 2006.

The Company recorded net sales in Territory B, the U.S./Puerto Rico AVAPRO\*/AVALIDE\* Territory, and Territory A comarketing countries of \$6.9 billion in 2008, \$6.0 billion in 2007 and \$4.4 billion in 2006.

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 their jurisdictions.

The agreements with Sanofi expire on the later of (i) with respect to PLAVIX\*, 2013 and, with respect to AVAPRO\*/AVALIDE\*, 2012 in the Americas and Australia and 2013 in Europe and Asia, and (ii) the expiration of all patents and other exclusivity rights in the applicable territory.

The alliance arrangements may be terminated by the Company or Sanofi, either in whole or in any affected country or Territory, depending on the circumstances, in the event of (i) voluntary or involuntary bankruptcy or insolvency, which in the case of involuntary bankruptcy continues for 60 days or an order or decree approving same continues unstayed and in effect for 30 days; (ii) a material breach of an obligation under a major alliance agreement that remains uncured for 30 days following notice of the breach except where commencement and diligent prosecution of cure has occurred within 30 days after notice; (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 Collaborations.

**Otsuka** The Company maintains 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; and copromote the product with Otsuka in the U.S., Puerto Rico, 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. Early termination of the strategic alliance is immediate upon notice in the case of (i) voluntary bankruptcy, (ii) where minimum payments are not made to Otsuka, or (iii) 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\*.

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The Company recorded net sales for ABILIFY\* of \$2.2 billion in 2008, \$1.7 billion in 2007 and \$1.3 billion in 2006. Total milestone payments made to Otsuka under the agreement through 2008 were \$217 million.

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## Table of Contents

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

**ImClone** The Company has a commercialization agreement with ImClone, a wholly owned subsidiary of Lilly, for the codevelopment and copromotion of ERBITUX\* in the U.S. as well as codevelopment and copromotion rights in Canada and Japan to the extent the product is commercialized in such countries. ERBITUX\* is indicated for use in the treatment of patients with metastatic colorectal cancer and for use in the treatment of squamous cell carcinoma of the head and neck. 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%. The agreement expires as to ERBITUX\* in North America in September 2018.

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\*.

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. 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.

In July 2007, the Company and ImClone amended the terms of their agreement for the codevelopment and copromotion of ERBITUX\* in North America and 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, and expiring in 2032, among BMS, BMKK, E.R. Squibb & Sons, LLC, ImClone, Merck KGaA and Merck Japan. ImClone has the ability to terminate the agreement after 2018 if it determines that it is commercially unreasonable for ImClone to continue. ERBITUX\* received marketing approval in Japan in July 2008 for the use of ERBITUX\* in treating patients with advanced or recurrent colorectal cancer.

The Company recorded net sales for ERBITUX\* of \$749 million, \$692 million and \$652 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Upon initial execution of the commercialization agreement, the Company acquired an ownership interest in ImClone, which approximated 17% at the time of the transaction noted below, and had been accounting for its investment under the equity method. The Company received approximately \$1.0 billion in cash from the sale of its shares of ImClone to Lilly.

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

**Gilead** The Company and Gilead have a joint venture to develop and commercialize ATRIPLA\* (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg), a once-daily single tablet three-drug regimen combining the Company's SUSTIVA (efavirenz) and Gilead's TRUVADA\* (emtricitabine and tenofovir disoproxil fumarate), in the U.S., Canada and Europe. 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 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. In a limited number of EU countries, the Company records revenue for ATRIPLA\* where the Company agreed to purchase the product from Gilead

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and distribute it to third-party customers. The Company recorded efavirenz revenues of \$582 million, \$335 million and \$76 million in 2008, 2007 and 2006, respectively, related to ATRIPLA\* sales.

## Table of Contents

Gilead consolidates the results of the joint venture in their operating results and the Company accounts for its participation in the U.S. 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 statements of earnings.

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 Collaborations.

### Investigational Compounds Under Development

**Medarex** The Company maintains a worldwide collaboration and share purchase agreement with Medarex, Inc. (Medarex) to codevelop and copromote ipilimumab, a fully human antibody currently in Phase III development for the treatment of metastatic melanoma. The FDA has granted Fast Track status to ipilimumab in combination with MDX 1379 (gp100), a vaccine that is being developed in combination with ipilimumab, for treatment of patients with late stage unresectable metastatic melanoma who have failed or are intolerant to first-line therapy.

Future milestone payments are expected to be made by the Company to Medarex based 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.

The Company maintains a \$16 million equity investment in Medarex, representing 2.4% of their outstanding shares.

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.

**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. In October 2008, the Company received from AstraZeneca a milestone payment of \$50 million for the June 2008 filing of the New Drug Application to the Food and Drug Administration (FDA) for ONGLYZA. The companies have proposed the name ONGLYZA which, if approved by the FDA and the European Medicines Evaluation Agency will serve as the trade name for saxagliptin in the countries where it has been approved.

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



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## Table of Contents

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 and losses equally on a global basis, excluding Japan, (in the case of Saxagliptin), and the Company will manufacture both products and, with certain limited exceptions, record net sales in most key markets.

In December 2008, the Company and AstraZeneca executed an amendment to the SGLT Agreement to include the development and commercialization of dapagliflozin in Japan, with AstraZeneca having operational and cost responsibility for all development and regulatory activities on behalf of the collaboration. The two companies will jointly market the product in Japan, sharing all commercialization expenses and activities and splitting profits and losses equally. Bristol-Myers Squibb will manufacture dapagliflozin and also record sales. Dapagliflozin is currently being studied in Phase II clinical trials in Japan.

Otsuka In January 2007, the Company granted Otsuka exclusive rights in Japan to develop and commercialize saxagliptin. The Company will receive milestone payments based on certain regulatory events, as well as sales-based payments following regulatory approval of saxagliptin in Japan, and retained rights to co-promote saxagliptin with Otsuka in Japan. Otsuka is responsible for all development costs in Japan.

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. 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. Pfizer will fund 60% of all development costs effective January 1, 2007 going forward, and the Company will fund 40%. The Company records expenses for apixaban development costs, net of its alliance partner's share, in research and development. 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 and losses equally on a global basis.

Exelixis In December 2008, the Company and Exelixis, Inc. (Exelixis) entered into a global codevelopment and cocommercialization arrangement for XL-184 (a MET/VEG/RET inhibitor), an oral anti-cancer compound, and a license for XL-281 with utility in RAS and RAF mutant tumors under development by Exelixis. Under the terms of the arrangement, the Company agreed to pay Exelixis \$195 million in 2008 upon execution of the agreement and an additional \$45 million in 2009. The Company expensed as research and development the \$240 million upon execution of the agreement in 2008. Exelixis will fund the first \$100 million of development for XL-184. If Exelixis elects to continue sharing development costs and elects to copromote in the U.S., Exelixis will fund 35% of future global development costs (excluding Japan) and share U.S. profits and losses equally; failing such elections, Exelixis receives milestones and royalties. The Company will fund 100% of development costs in Japan. In addition to double-digit royalties on ex-U.S. sales, the Company could pay up to \$610 million if all development and regulatory milestones are met and up to an additional \$300 million if all sales-based milestones are met.

In addition, the Company and Exelixis have a history of collaborations to identify, develop and promote oncology targets. During December 2006, the Company and Exelixis entered into an oncology collaboration and license agreement under which Exelixis is pursuing the development of three small molecule INDs for codevelopment and copromotion. Under the terms of this agreement, the Company paid Exelixis \$60 million of upfront fees in 2006. During 2008, the Company paid Exelixis \$40 million in IND acceptance milestones. If Exelixis elects to fund development costs and copromote in the U.S., both parties will equally share development costs and profits. If Exelixis opts out of the codevelopment and copromotion agreement, BMS will take over full development and U.S. commercial rights, and if successful will pay Exelixis development and regulatory milestones up to \$190 million and up to an additional \$90 million of sales based milestones, as well as double digit royalties.

Since July 2001, the Company has held an equity interest in Exelixis, which at December 31, 2008 was less than 1%.

Other Additionally, the Company has other licensing arrangements such as with Novartis for REYATAZ and with HZI for IXEMPRA, a novel microtubule-stabilizing agent for the treatment of breast cancer. 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 arrangements with 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.



**Table of Contents**

For further information on alliances relating to products under development and drug discovery, see Research and Development below.

*Nutritionals Segment*

Infant formulas and toddler/children's nutritionals, representing 97%, 96% and 96% of total nutritional net sales in 2008, 2007 and 2006, respectively, were as follows:

Dollars in Millions	Net Sales			% Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
Infant Formulas	\$ 1,932	\$ 1,786	\$ 1,637	8%	9%
ENFAMIL	1,157	1,082	1,007	7%	7%
Toddler/Children's Nutritionals	856	693	606	24%	14%

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. Nutritional net sales accounted for 14% of the Company's net sales in each of 2008, 2007 and 2006. U.S. nutritional net sales accounted for 38%, 44% and 46% of total nutritional net sales in 2008, 2007 and 2006, respectively, while international nutritional net sales accounted for 62%, 56% and 54% of total nutritional net sales in 2008, 2007 and 2006, 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. For further information on key Nutritionals product lines and their sales, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations.

**Productivity Transformation Initiative**

In December 2007 and July 2008, the Company announced productivity transformation initiatives (PTI) designed to fundamentally change the way it runs its business to meet the challenges of a changing business environment and to take advantage of the diverse opportunities in the marketplace as the Company is transformed into a next-generation biopharmaceutical company, and to create a total of \$2.5 billion in annual productivity cost savings and cost avoidance by 2012. In connection with PTI, the Company aims to achieve a culture of continuous improvement to enhance its efficiency, effectiveness and competitiveness and substantially improve its cost base.

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.

The charges associated with the previously announced PTI are estimated to be an aggregate range of \$1.3 billion to \$1.6 billion, which includes \$695 million of costs already incurred. The incurred costs are net of \$159 million of gains related to the sale of mature product lines and business. Also, included in these charges are net termination benefits of \$174 million and \$182 million for the years ended December 31, 2008 and 2007, respectively, and other exit costs of \$44 million and \$1 million for the years ended December 31, 2008 and 2007, respectively. The exact timing of the recognition of PTI charges cannot be predicted with certainty and will be affected by the existence of triggering events for expense recognition, among other factors.

**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

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and alternative sourcing strategies. For further discussion of sourcing, see [Manufacturing and Quality Assurance](#) below and discussions of particular products.

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## **Table of Contents**

### **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 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. 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 the end of 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\*, BARACLUDGE, AVALIDE\*, REYATAZ, PRAVACHOL, ABILIFY\*, ERBITUX\*, the SUSTIVA Franchise and, ORENCIA. To maintain a stable supply of these products, the Company takes a variety of actions including inventory management and maintenance of additional quantities of materials, when possible, designed to provide for 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 biologics 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.

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 regulatory requirements and the Company's standards. These tests may involve chemical and

## **Table of Contents**

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 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*

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 Biologic License

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Application (BLA) is filed. The type of application filed affects regulatory exclusivity rights.

## Table of Contents

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 25. 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.

### *European Union*



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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

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## **Table of Contents**

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 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 actions is a long process between governments, 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.

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 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



## **Table of Contents**

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 2008, gross sales to three pharmaceutical wholesalers in the U.S., McKesson, Cardinal Health, Inc. (Cardinal) and AmerisourceBergen Corporation (AmerisourceBergen), accounted for approximately 20%, 16% and 12%, respectively, of the Company's total gross sales. In 2007, gross sales to McKesson, Cardinal and AmerisourceBergen accounted for approximately 18%, 15% and 11%, respectively, of the Company's total gross sales. In 2006, gross sales to McKesson, Cardinal and AmerisourceBergen accounted for approximately 17%, 15% and 10%, respectively, of the Company's total gross sales. Gross 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 products, see [Nutritionals 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 25. 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 Nutritionals segment. 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.

## **Table of Contents**

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 of 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.

## **Research and Development**

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The Company invests heavily in research and development because it believes it is critical to its long-term competitiveness. The Company 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 our research and development activities.

**Table of Contents**

The Company spent \$3.6 billion in 2008, \$3.2 billion in 2007 and \$3.0 billion in 2006 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 2008, the Company employed approximately 7,800 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. 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 12 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 was discovered internally and is in 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 a patent covering apixaban as composition of matter that expires in 2022 (extended to 2023 via patent term adjustment) in the U.S.
Saxagliptin	Saxagliptin is an oral compound for the potential treatment of diabetes, which was discovered internally and is currently under regulatory review in the U.S. and Europe. In January 2007, the Company entered into an agreement with AstraZeneca for the codevelopment and cocommercialization of saxagliptin. The Company owns a patent covering saxagliptin as composition of matter that expires in 2021 in the U.S.
Dapagliflozin	Dapagliflozin is an oral compound for the potential treatment of diabetes, which was discovered internally and is currently in Phase III clinical trials. The Company has entered into an agreement with AstraZeneca for the codevelopment and cocommercialization of dapagliflozin worldwide. The Company owns a patent covering dapagliflozin as composition of matter that expires in 2020 in the U.S.





**Table of Contents**

Ipilimumab	Ipilimumab, a biologic product, 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 patent covering ipilimumab as composition of matter that expires in 2016 in the U.S. and has rights to method of use patents licensed by Medarex that expire in 2015 in the U.S. The Company also has rights to a Medarex patent covering ipilimumab as composition of matter that expires in 2020 (extended to 2022 via patent term adjustment) in the U.S.
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 owns a patent covering belatacept as composition of matter that expires in 2021 in the U.S.
XL-184	XL-184 is an oral anticancer compound, which was discovered by and licensed from Exelixis and is in Phase III clinical testing. XL-184 targets three enzymes: MET, which encourages tumor cell survival and movement, VEGF2, which helps tumors develop new blood vessels, and RET, which is also involved in cell growth and migration and is found in many thyroid cancers. This compound is currently in Phase III clinical trials for medullary thyroid cancer.
Tanespimycin	Tanespimycin is an Hsp90 inhibitor currently in Phase III trials for the treatment of multiple myeloma. There is no composition of matter patent that specifically covers Tanespimycin. Tanespimycin has been granted approval for filing as an orphan drug for the treatment of chronic myelogenous leukemia and will obtain 7 years of exclusivity upon approval.
Brivanib	Brivanib is an oral small molecule dual kinase inhibitor that blocks both the VEGF receptor and the FGF receptor which is currently in Phase III trials as an anti-cancer treatment. The Company owns a patent covering brivanib as composition of matter that expires in 2023 in the U.S.

In September 2008, the Company terminated its collaboration agreement with Solvay Pharmaceuticals B.V. that included the Phase II compound ibipinabant, a cannabinoid-1 receptor antagonist, which was in Phase II clinical trials.

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 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 pharmaceuticals products 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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## **Table of Contents**

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

The Federal government has extensive enforcement powers over the activities of pharmaceutical 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 25. 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

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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

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## **Table of Contents**

member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states. As set forth above, pricing and reimbursement of the product continues to be the subject of member state law.

Whether or not FDA approval or approval of the 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 \$205 million in 2008, \$169 million in 2007 and \$174 million in 2006. 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 \$529 million in 2008, \$551 million in 2007 and \$624 million in 2006.

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 \$796 million in 2008, \$848 million in 2007 and \$872 million in 2006.

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 \$43 million, \$45 million and \$50 million on capital

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environmental projects undertaken specifically to meet environmental requirements in 2008, 2007 and 2006, respectively, and expects to spend approximately \$39 million in 2009. Although the Company believes that it is in substantial compliance with applicable environmental, health and safety requirements and the permits required for its operations, the Company nevertheless could incur additional costs, including civil or criminal fines or penalties, clean-up costs, or third-party claims for property damage or personal injury, for violations or liabilities under these laws.

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## **Table of Contents**

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 14 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 25. Legal Proceedings and Contingencies.

## **Employees**

As of December 31, 2008, the Company employed approximately 35,000 people.

During 2008, the Company continued to implement its comprehensive cost reduction program that included work force reduction in some areas and the rationalization of some facilities. Also, during 2008, the Company sold its ConvaTec and Medical Imaging businesses, which employed approximately 4,000 people.

For further discussion about PTI and 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 both of the same business segments as the Company's U.S. operations—Pharmaceuticals and Nutritionals.

For a geographic breakdown of net sales, see the table captioned Geographic Areas in Item 8. Financial Statements Note 22. 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 products, limitations on foreign participation in local enterprises and other restrictive governmental actions. The Company's international businesses are also subject to government-imposed constraints, including laws on pricing or reimbursement for use of products.

Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or reduce the reported dollar value of the Company's net assets and results of operations. In 2008, the change in foreign exchange rates had a net favorable impact on the growth rate of revenues, however the trend changed during the latter half of the year. 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 21. Financial Instruments.

## **Bristol-Myers Squibb Website**

The Company's internet website address is [www.bms.com](http://www.bms.com). On its website, the Company makes available, free of charge, 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 SEC.



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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

**Table of Contents**

Board Committees and Committee charters, and transactions in Bristol-Myers Squibb securities by Directors and executive officers, is available on the Company's website 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 under the Investors Stockholder Services caption.

The Company incorporates by reference certain information from parts of its proxy statement for the 2009 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 2009 Annual Meeting of Stockholders and 2008 Annual Report will be available on the Company's website under the Investors SEC Filings caption on or after March 23, 2009.

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**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 intense competition from other pharmaceutical manufacturers, including from lower-priced generic products.***

*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. Our Pharmaceuticals Segment is confronted by a record level of industry patent expirations and increasingly aggressive generic competition. 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; and (iv) business combinations among the Company's competitors and major customers.*

***The Company depends on key products for most of its net sales, cash flows and earnings.***

*The Company derives a majority of our revenue from a few key products. In 2008, net sales of PLAVIX\* contributed \$5.6 billion, representing 27% of total net sales, and net sales of ABILIFY\* contributed approximately \$2.2 billion, representing approximately 10% of total net sales. Three other products (AVAPRO\*/AVALIDE\*, REYATAZ and the SUSTIVA Franchise) each contributed more than \$1.0 billion in net sales. A reduction in sales of these products could significantly negatively impact the Company's net sales, cash flows and earnings.*

***It is possible that the Company may lose market exclusivity of a product earlier than expected.***

*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 are often 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, such as generic clopidogrel bisulfate in certain EU markets. 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 related 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.*

***Data protection for PLAVIX\* has expired in the EU and PLAVIX\* faces competition in European markets.***

*Data protection for PLAVIX\* expired on July 15, 2008 in the European Union (EU). In most of the major markets within Europe, the product benefits from national patents, expiring in 2013, which specifically claim the bisulfate form of clopidogrel. In the remainder of EU member states, however, where there is no composition of matter patent covering clopidogrel bisulfate, competitors are seeking regulatory authority to enter those markets with generic clopidogrel bisulfate. In addition, at least one group of competitor companies has received marketing authorization for, and has started to market, an alternate salt form of clopidogrel in Germany. The Company is aware that alternate salt applications have been filed in the EU. At this time, the Company cannot estimate reliably the impact of any such competition on the Company's financial results.*

***U.S. and foreign laws and 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*



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**Table of Contents**

*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, reimbursement 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, (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.*

***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) supply chain continuity including the failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable 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.*

***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.*



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## **Table of Contents**

### ***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 aggregate range of \$1.3 billion to \$1.6 billion on a pre-tax basis until 2012, with \$695 million of those charges having been incurred in 2008 and 2007.*

*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 2009, 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, certain financial outsourcing arrangements and certain human resource functions. 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.*

### ***Recent adverse changes in U.S., global, or regional economic conditions could have a continuing adverse effect on the profitability of some or all of our businesses.***

*Recent turmoil in the financial markets has adversely affected economic activity in the United States and other regions of the world in which we do business. Although we believe that based on our current cash, cash equivalents and marketable securities balances and expected operating cash flows, the current lack of liquidity in the credit markets will not have a material impact on our liquidity, cash flow, or financial flexibility, continued deterioration of the credit and capital markets could cause additional impairments to our investment portfolio, which could negatively impact our financial condition and reported earnings. The continued decline in economic activity could adversely affect demand for our products, thus reducing our revenue and earnings as well as have an adverse impact on our customers, distributors, alliance partners, suppliers, service providers and counterparties to certain financial instruments such as marketable securities and derivatives. The severe decline in equity markets have resulted in a decline in our pension plan assets which will increase future funding requirements.*

### ***Changes in foreign currency exchange rates and interest rates could have a material adverse effect on our results of operations.***

*We have significant operations outside of the U.S. Revenues from operations outside of the U.S. accounted for 42% of the Company's revenues in 2008. As such, we are exposed to changes in fluctuation of foreign currency exchange rates. We also have significant borrowings which are exposed to changes in interest rates. At December 31, 2008, the Company had short-term borrowings and long-term debt of \$6.7 billion. The Company is also exposed to other economic factors over which the Company has no control.*

### ***The illegal distribution and sale by third parties of counterfeit versions of the Company's products could have a negative impact on our reputation.***

*Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. A patient who receives a counterfeit drug may be at risk for a number of dangerous health consequences. Our reputation could suffer harm as a result of counterfeit drugs sold under the name of one of our products.*

**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 275,000 square feet of floor space, approximately 215,000 square feet of which is sublet to others.

The Company manufactures products at 27 major worldwide locations with an aggregate floor space of approximately 5.6 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.

	Pharmaceuticals	Nutritionals	Total Company
United States	4	2	6
Europe, Middle East and Africa	8	1	9
Other Western Hemisphere	4	1	5
Pacific	4	3	7
<b>Total</b>	<b>20</b>	<b>7</b>	<b>27</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.

As part of the Company's PTI, it has reduced and expects to continue to reduce the number of its manufacturing facilities.

**Item 3. LEGAL PROCEEDINGS.**

Information pertaining to legal proceedings can be found in Item 8. Financial Statements Note 25. 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, 2008.



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

Listed below is information on executive officers of the Company as of February 20, 2009. Executive officers are elected by the Board of Directors for an initial term, which continues until the first Board meeting following the next annual meeting of stockholders and thereafter are elected for a one-year term or until their successors have been elected. All executive officers serve at the pleasure of the Board of Directors.

<b><u>Name and Current Position</u></b>	<b><u>Age</u></b>	<b><u>Employment History for the Past 5 Years</u></b>
James M. Cornelius  <i>Chairman of the Board and Chief Executive Officer</i>  <i>Member of the Management Council</i>	65	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 Chief Operating Officer, Worldwide Pharmaceuticals</i> <i>Member of the Management Council</i>	58	2002 to 2005 Senior Vice President and President International, Worldwide Medicines Group, a division of the Company.  2005 to 2007 Executive Vice President and President, Worldwide Pharmaceuticals, a division of the Company.  2007 to present Executive Vice President and Chief Operating Officer, Worldwide Pharmaceuticals, a division of the Company.
Joseph C. Caldarella  <i>Vice President and Corporate Controller, Corporate Staff</i>	53	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.
John E. Celentano  <i>Senior Vice President, Strategy and Productivity Transformation</i> <i>Member of the Management Council</i>	49	2002 to 2005 President, Latin America and Canada, Worldwide Medicines Group, a division of the Company.  2005 to 2008 President, Health Care Group, a division of the Company.  2008 to present Senior Vice President, Strategy and Productivity Transformation, Corporate Staff of the Company.
Brian Daniels, M.D.  <i>Senior Vice President, Global Development and Medical Affairs, Research and Development</i> <i>Member of the Management Council</i>	49	2004 to 2008 Senior Vice President, Global Clinical Development, Research and Development, a division of the Company.  2008 to present Senior Vice President, Global Development and Medical Affairs, Research and Development, a division of the Company.

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Carlo de Notaristefani	51	2004 to 2004 Senior Vice President, International Finishing Operations, Worldwide Medicines Group, a division of the Company.
<i>President, Technical Operations, Worldwide Pharmaceuticals</i>		
<i>Member of the Management Council</i>		2004 to present President, Technical Operations, Worldwide Pharmaceuticals, a division of the Company.
Anthony C. Hooper	54	2004 to present President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of the Company.
<i>President, U.S. Pharmaceuticals</i>		
<i>Member of the Management Council</i>		

**Table of Contents**

<p>Jean-Marc Huet</p> <p><i>Senior Vice President and Chief Financial Officer,</i></p> <p><i>Corporate Staff</i></p> <p><i>Member of the Management Council</i></p>	<p>39 2003 to 2007 Chief Financial Officer, Royal Numico N.V. 2008 to present Chief Financial Officer, Corporate Staff of the Company.</p>
<p>Sandra Leung</p> <p><i>Senior Vice President and General Counsel,</i></p> <p><i>Corporate Staff</i></p> <p><i>Member of the Management Council</i></p>	<p>48 2002 to 2006 Vice President and Corporate Secretary, Corporate Staff of the Company.</p> <p>2006 to 2007 Vice President, Corporate Secretary and Acting General Counsel, Corporate Staff of the Company.</p> <p>2007 to present Senior Vice President and General Counsel, Corporate Staff of the Company.</p>
<p>Anthony A. McBride</p> <p><i>Senior Vice President, Human Resources,</i></p> <p><i>Corporate Staff</i></p> <p><i>Member of the Management Council</i></p>	<p>45 2002 to 2005 Vice President, Human Resources, International &amp; Global Marketing, a division of the Company,</p> <p>2005 to 2008 Vice President, Human Resources, Pharmaceutical Commercial Operations, a division of the Company.</p> <p>2008 to present Senior Vice President, Human Resources, Corporate Staff of the Company.</p>
<p>Elliott Sigal, M.D., Ph.D.</p> <p><i>Executive Vice President, Chief Scientific Officer</i></p> <p><i>and President, Research and Development</i></p> <p><i>Member of the Management Council</i></p>	<p>57 2002 to 2004 Senior Vice President, Global Clinical and Pharmaceutical Development, Research Institute, a division of the Company.</p> <p>2004 to present Chief Scientific Officer and President, Research and Development, a division of the Company.</p>
<p>Robert T. Zito</p> <p><i>Senior Vice President, Corporate and Business</i></p> <p><i>Communications and Chief Communications Officer</i></p> <p><i>Member of the Management Council</i></p>	<p>55 1999 to 2004 Executive Vice President, Communications, New York Stock Exchange.</p> <p>2004 to present Senior Vice President, Corporate Affairs, Corporate Staff of the Company.</p>

**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). A quarterly summary of the high and low market prices is presented below:

Common:

	2008		2007	
	High	Low	High	Low
First Quarter	\$ 27.37	\$ 20.05	\$ 29.39	\$ 25.73
Second Quarter	23.60	19.43	32.25	27.00
Third Quarter	22.93	19.70	32.35	26.38
Fourth Quarter	23.82	16.00	30.35	26.52

Preferred:

	2008		2007	
	High	Low	High	Low
First Quarter	\$ 500.00	\$ 500.00	\$ 600.00	\$ 460.00
Second Quarter	*	*	500.00	500.00
Third Quarter	*	*	503.00	475.00
Fourth Quarter	*	*	475.37	450.00

\* During the second, third and fourth quarters of 2008, there were no trades of the Company's preferred stock. The preferred stock pays a quarterly dividend of \$0.50 per share.

**Holders of Common Stock**

The number of record holders of common stock at December 31, 2008 was 66,305.

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 2009 Proxy Statement to be filed on or about March 23, 2009 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 2008 and 2007 in the quarters indicated below:

	Common		Preferred	
	2008	2007	2008	2007
First Quarter	\$ 0.31	\$ 0.28	\$ 0.50	\$ 0.50
Second Quarter	0.31	0.28	0.50	0.50
Third Quarter	0.31	0.28	0.50	0.50
Fourth Quarter	0.31	0.28	0.50	0.50
	\$ 1.24	\$ 1.12	\$ 2.00	\$ 2.00

In December 2008, the Board of Directors of the Company declared a quarterly dividend of \$0.31 per share on the common stock of the Company which was paid on February 2, 2009 to shareholders of record as of January 2, 2009. The Board of Directors also declared a quarterly dividend of \$0.50 per share on the preferred stock of the Company, payable on March 2, 2009 to shareholders of record as of February 6, 2009.

**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, 2008:

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>
<b>Dollars in Millions, except per share data</b>				
January 1 to 31, 2008	13,431	\$ 26.14		\$ 2,220
February 1 to 29, 2008	16,142	\$ 24.13		\$ 2,220
March 1 to 31, 2008	530,289	\$ 22.07		\$ 2,220
Three months ended March 31, 2008	559,862			
April 1 to 30, 2008	13,019	\$ 22.28		\$ 2,220
May 1 to 31, 2008	34,544	\$ 22.16		\$ 2,220
June 1 to 30, 2008	11,098	\$ 22.59		\$ 2,220
Three months ended June 30, 2008	58,661			
July 1 to 31, 2008	9,889	\$ 20.80		\$ 2,220
August 1 to 31, 2008	5,932	\$ 21.11		\$ 2,220
September 1 to 30, 2008	60,781	\$ 21.24		\$ 2,220
Three months ended September 30, 2008	76,602			

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October 1 to 31, 2008	334,477	\$ 20.53	\$ 2,220
November 1 to 30, 2008	24,174	\$ 20.53	\$ 2,220
December 1 to 31, 2008	14,084	\$ 20.54	\$ 2,220
Three months ended December 31, 2008	372,735		
Twelve months ended December 31, 2008	1,067,860		

- (a) Reflects transaction during the 12 months ended December 31, 2008 for the surrender to the Company of 1,067,860 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 \$14.0 billion of the Company's common stock. During the 12 months ended December 31, 2008, no shares were repurchased pursuant to this program.

**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 2008 Proxy Statement.

**Comparison of Five Year Cumulative Total Return**

	December 31,					
	2003	2004	2005	2006	2007	2008
Bristol-Myers Squibb	\$ 100	\$ 93	\$ 87	\$ 104	\$ 109	\$ 101
S&P 500 Index	\$ 100	\$ 109	\$ 112	\$ 128	\$ 132	\$ 81
Peer Group	\$ 100	\$ 97	\$ 99	\$ 112	\$ 114	\$ 95

Assumes \$100 invested on December 31, 2003 in Bristol-Myers Squibb Common Stock, S&P 500 Index and Peer Group. 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	2008	2007	2006	2005	2004
<b>Income Statement Data:<sup>(1)</sup></b>					
Net Sales	\$ 20,597	\$ 18,193	\$ 16,208	\$ 17,613	\$ 17,837
Earning from Continuing Operations Before					
Income Taxes and Minority Interest	5,471	3,186	2,085	4,016	3,911
Net Earnings from Continuing Operations	3,155	1,741	1,214	2,652	2,017
Net Earnings from Continuing Operations per Common Share:					
Basic	\$ 1.60	\$ 0.88	\$ 0.62	\$ 1.36	\$ 1.04
Diluted	\$ 1.59	\$ 0.88	\$ 0.62	\$ 1.35	\$ 1.02
Average common shares outstanding:					
Basic	1,977	1,970	1,960	1,952	1,942
Diluted	2,001	1,980	1,963	1,983	1,976
Dividends paid on common and preferred stock	\$ 2,461	\$ 2,213	\$ 2,199	\$ 2,186	\$ 2,174
Dividends declared per common share	\$ 1.24	\$ 1.15	\$ 1.12	\$ 1.12	\$ 1.12
<b>Financial Position Data at December 31:</b>					
Total Assets	\$ 29,552	\$ 25,926	\$ 25,271	\$ 28,068	\$ 30,435
Cash and cash equivalents	7,976	1,801	2,018	3,050	3,680
Marketable securities	289	424	1,995	2,749	3,794
Long-term debt	6,585	4,381	7,248	8,364	8,463
Stockholders' Equity	12,241	10,562	9,991	11,208	10,202

<sup>(1)</sup> The Company recorded items that affected the comparability of results. For a discussion of these items for the years 2008, 2007 and 2006, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Expenses/Gains.



**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 (which may be referred to as Bristol-Myers Squibb, BMS or the Company) is a global biopharmaceutical and nutritional products company whose mission is to extend and enhance human life by providing the highest quality pharmaceutical and nutritional products. The Company is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceuticals and nutritional products. The Company has two reportable segments Pharmaceuticals and Nutritionals. The Pharmaceuticals segment consists of the global pharmaceutical/biotechnology and international consumer medicines business, which accounted for approximately 86% of the Company's 2008 net sales. The Nutritionals segment consists of Mead Johnson Nutrition Company (Mead Johnson), primarily an infant formula and children's nutritionals business, which accounted for approximately 14% of the Company's 2008 net sales.

**2008 Financial Highlights**

The following table is a summary of operating activity:

Dollars in Millions	Year Ended December 31,	
	2008	2007
Net Sales	\$ 20,597	\$ 18,193
Net Earnings from Continuing Operations	3,155	1,741
Net Earnings from Discontinued Operations	2,092	424
Net Earnings	5,247	2,165
Net Cash/(Debt)	1,526	(4,047)

*Net Sales*

The Company's net sales from continuing operations increased 13%. PLAVIX\* (clopidogrel bisulfate) and ABILIFY\* continue to drive worldwide sales growth with sales increases of 18% and 30%, respectively. Significant contributions to sales growth are also provided by other key products including ORENCIA, SPRYCEL and the HIV and Hepatitis portfolio.

*Net Earnings from Continued Operations*

The increases in net earnings from continuing operations is attributed to increased sales growth and favorability in gross margins, a portion of which is attributed to a favorable product mix as well as cost savings and avoidances resulting from the Company's productivity transformation initiative (PTI). The \$582 million after-tax gain related to the tendering of the Company's shares in ImClone also had a significant impact on net earnings from continuing operations amongst other specified items discussed in Expenses/Gains below.

*Net Earnings from Discontinued Operations*

In 2008, the Company completed the divestitures of its Medical Imaging business for a gross purchase price of \$525 million resulting in an after-tax loss of \$43 million as well as the ConvaTec business for gross purchase price of approximately \$4.1 billion resulting in an after-tax gain of \$2.0 billion. The results of the Medical Imaging and ConvaTec businesses and the related gains and losses are included in discontinued operations for all years presented.

*Net Cash/(Debt)*

Net cash/(debt) position as of December 31, 2008 improved due to proceeds of \$4.6 billion from the divestiture of the ConvaTec and Medical Imaging businesses and proceeds of \$1.0 billion from the sale of our ImClone shares. Cash generated from operating activities of \$3.7 billion was more than adequate to fund dividend payments of \$2.5 billion as well as capital expenditure payments of \$941 million.

**Business Environment**

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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

## **Table of Contents**

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 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 United States (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 that 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 authorizing 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 result in major changes in the current 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. At the same time, 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 as more than two years can elapse after drug approval before new medicines become available in some countries.

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 MCO formularies and the Company generally has 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 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. The Company has expanded PTI activities in order to achieve additional savings in order to further reduce costs, streamline operations and rationalize global manufacturing 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 25. Legal Proceedings and Contingencies.

## **Strategy**

The Company's multi-year strategy is transformation 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.



## **Table of Contents**

Managing costs is one part of the Company's overall strategy as it transitions to a next-generation biopharmaceutical company, focused on delivering its present commitments, maximizing near-term growth opportunities and improving its earnings base in 2012-2013. The Company announced PTI designed to create a total of \$2.5 billion in annual productivity savings and cost avoidance by 2012. The first wave, announced in December 2007, targets \$1.5 billion in savings and cost avoidance by 2010. The second wave, announced in July 2008, targets an additional \$1.0 billion in savings and cost avoidance by 2012.

The Company will continue to focus on the development of our biopharmaceutical business and will maintain its growth by investing in research and development of new product pipeline. The Company will continue to invest in key growth products, including specialty and biologic medicines, and cardiovascular and metabolic drugs. The Company is seeking to reallocate resources to continue its string of pearls strategy and enable strategic transactions, such as the acquisition of Kosan Biosciences, Inc. (Kosan) and strategic alliances, such as the global codevelopment and cocommercialization agreement with Exelixis, Inc. (Exelixis) and a global collaboration agreement with ZymoGenetics, both entered in 2008. The Company will continue pursuing partnerships and expanding other collaborative arrangements with biopharmaceutical companies and will continue entering into strategic alliances with third parties in order to obtain rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are owned by such third parties.

The Company will continue to maximize the value of our non-core businesses. In 2008, the Company completed the divestiture of its ConvaTec and Medical Imaging businesses. The Company has also sold its mature brands business located in Egypt.

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

#### **SPRYCEL**

In January 2009, the Company announced the approval of SPRYCEL in Japan.

#### **IXEMPRA**

In December 2008, the Company announced new data from studies of IXEMPRA (ixabepilone) plus capecitabine compared to capecitabine alone, including a pre-specified sub set analysis demonstrating a significant increase in progression free survival in patients with triple negative breast cancer.

In November 2008, the Committee for Medicinal Products for Human Use (CHMP) in Europe issued a negative opinion on the marketing authorization application for IXEMPRA in the treatment of patients with metastatic breast cancer. The Company requested a re-examination of the case, which is currently under consideration by CHMP.

#### **Exelixis**

In December 2008, the Company announced a global collaboration with Exelixis covering two novel molecules for cancer with their associated development programs: Exelixis XL184, a small molecule inhibitor of MET, VEGFR2 and RET, which is currently in Phase III development for medullary thyroid cancer; and, Exelixis XL281, a small molecule inhibitor of RAF kinase, which is currently in Phase I development for the treatment of patients with advanced solid tumor malignancies. Under the agreement, the Company receives development and commercialization rights to both programs.

#### **Dapagliflozin**

In December 2008, the Company and AstraZeneca announced expansion of their worldwide collaboration to include the development and commercialization of dapagliflozin in Japan. Dapagliflozin, one of two investigational drugs under joint development by the companies, is currently being studied in Phase III clinical trials in several countries, including the U.S., to assess its efficacy and safety as a once-daily treatment for type 2 diabetes.

ERBITUX\*

In January 2009, the Company and its marketing partner ImClone Systems, Inc. (ImClone), a wholly-owned subsidiary of Eli Lilly and Company (Lilly), announced, that the companies will withdraw, and eventually resubmit, an application with the FDA to broaden the use of ERBITUX\* to include first-line treatment of patients with advanced non-small cell lung cancer in combination with platinum-based chemotherapy (cisplatin/vinorelbine).

In October 2008, the FDA has accepted for filing and priority review, the supplemental Biologics License Application (sBLA) to broaden the indication for ERBITUX\* to include use in combination with platinum-based chemotherapy for the first-line treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck.

In October 2008, publication of study results showing that metastatic colorectal cancer (mCRC) patients with wild-type or normal K-ras tumors who were treated with ERBITUX\* plus best supportive care (BSC) had a statistically significant increase in overall survival and progression-free survival compared to those treated with BSC alone. Specifically, patients whose tumors had the normal (mutant negative) K-ras gene achieved a near two-fold improvement in overall survival and progression-free survival over patients treated with BSC alone. In patients with mutated K-ras tumors, there was no significant difference in overall or progression-free survival between those treated with ERBITUX\* plus BSC and those treated with BSC alone. The Company and the FDA are in discussions regarding possible label changes related to this study.

## Table of Contents

In September 2008, the announcement of five year data showing significant improvements in overall survival for patients with locally or regionally advanced head and neck cancer and the EXTREME study was published in the New England Journal of Medicine showing that ERBITUX\* improved survival in first-line recurrent and/or metastatic head and neck cancer.

In July 2008, ERBITUX\* received marketing approval in Japan for treatment of patients with advanced or recurrent colorectal cancer.

In May 2008, at the annual meeting of the American Society of Clinical Oncology (ASCO), a landmark Phase III study (FLEX) showed that the addition of ERBITUX\* to platinum-based chemotherapy significantly increased overall survival in the first-line treatment of patients with advanced non-small cell lung cancer, when compared to platinum-based chemotherapy alone.

### ABILIFY\*

A supplemental New Drug Application for ABILIFY\* was approved by the FDA in February 2008 for the acute treatment of manic and mixed episodes associated with certain pediatric patients (age 10-17) with Bipolar I Disorder.

FDA approval was received in May 2008 for new ABILIFY\* indications for pediatric bipolar (ages 10-17) maintenance therapy, pediatric schizophrenia (ages 10-17) maintenance therapy, and as add-on treatment to lithium or valproate for acute treatment of bipolar disorder in both pediatric (age 10-17) and adult patients.

The European Commission authorized marketing of ABILIFY\* in March 2008 in the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to ABILIFY\* treatment.

### ORENCIA

In October 2008, the Company announced results from a 10-month study, which showed that ORENCIA, compared to placebo (PBO), significantly improved multiple aspects of health-related quality of life: physical and psychosocial well being, pain and sleep quality in juvenile idiopathic arthritis (JIA) patients between the ages 6 and 17 years. These results were part of a study looking at the safety and efficacy of ORENCIA in children with JIA who had failed on previous treatments such as methotrexate (MTX) or biologics.

In October 2008, the Company announced results from a Phase IIIb study in adult patients with early moderate-to-severe erosive rheumatoid arthritis (RA) who had never received previous MTX treatment. This study showed that ORENCIA in combination with MTX had significantly more patients achieve a Disease Activity Score 28 using C-reactive protein-defined remission, compared with MTX plus PBO. The safety profile of ORENCIA in combination with MTX was similar to that of MTX plus PBO. Also, in the same quarter, the Company filed an sBLA with the FDA for the use of ORENCIA for patients with early RA.

In June 2008, new Phase II data presented at the European League Against Rheumatism demonstrated that ORENCIA may delay the development of RA in people with undifferentiated inflammatory arthritis.

In April 2008, ORENCIA was approved by the FDA for treatment of juvenile RA. Additionally, the U.S. label for ORENCIA was revised with an indication that means ORENCIA is now an appropriate option for patients with moderate-to-severe RA, regardless of prior treatment received.

### REYATAZ

In October 2008, the Company announced 96-week data from the CASTLE study, in which 74% of the 440 patients in the REYATAZ/r arm achieved an undetectable viral load, defined as human immunodeficiency virus (HIV)-1 RNA less than 50 copies/mL, compared with 68% of the 443 patients in the lopinavir/r arm. The difference between treatment arms may have been related to the 16% discontinuation rate in the REYATAZ/r arm and the 21% discontinuation rate in the lopinavir/r arm.

In October 2008, the FDA approved the use of REYATAZ (atazanavir sulfate) 300 milligram once-daily boosted with ritonavir 100 milligram as part of combination therapy in previously untreated (treatment-naïve) HIV-1 infected patients. This use of once-daily REYATAZ/ritonavir in HIV-1 infected treatment-naïve adult patients is based upon 48-week results from the CASTLE study, which demonstrated similar antiviral efficacy of REYATAZ/ritonavir to twice-daily lopinavir/ritonavir, each as part of HIV combination therapy in treatment-naïve HIV-1 infected adult patients. Data from the CASTLE study was published in the August 23 issue of *The Lancet*.

In June 2008, European approval was received for an expanded indication for REYATAZ 300 mg once-daily boosted with ritonavir 100 mg as part of combination therapy in treatment-naïve HIV-1 infected patients.

In February 2008, the first data comparing boosted REYATAZ (REYATAZ plus ritonavir) and lopinavir/ritonavir was presented at the Congress on Retroviruses and Opportunistic Infections.



**Table of Contents**

BARACLUDE

The Company announced in November 2008 data from two separate cohort evaluations, in which long-term treatment with BARACLUDE was associated with improved liver histology, including improvement in fibrosis, in chronic hepatitis B patients. The histology data were presented at the 59th Annual Meeting of the American Association for the Study of Liver Diseases.

New data at the March 2008 Asian Pacific Association for the Study of the Liver meeting, demonstrated a continued low incidence of resistance to BARACLUDE in nucleoside-naïve patients through five years of treatment, which is important for many chronic hepatitis B patients requiring long-term treatment.

Apixaban

In September 2008, the Company and its development partner Pfizer announced a Phase II study (APPRAISE-1) of apixaban – a novel anticoagulant – provided encouraging trends suggesting that anticoagulation with apixaban on top of current standards of care and continued beyond the initial hospitalization may reduce the risk of a second heart attack, stroke or death.

The primary endpoint was not met in a Phase III study of apixaban for prevention of venous thromboembolism (VTE) in patients undergoing total knee replacement. The results of the trial do not necessitate any changes in protocols of any other ongoing apixaban studies. The companies are considering further studies in preventing VTE in knee surgery and will not submit the U.S. regulatory filing for VTE prevention in the second half of 2009, as previously communicated. Programs directed toward prevention of VTE, including European Medicines Evaluation Agency registration studies, treatment of VTE, Acute Coronary Systems and in the prevention of stroke in atrial fibrillation continue as planned.

Ipilimumab

Favorable updated survival data was announced in September 2008 from three Phase II studies of ipilimumab.

Saxagliptin

Favorable results were announced in September 2008 of Phase III studies of ONGLYZA (saxagliptin).

Regulatory submissions for ONGLYZA were made in both the U.S. and in Europe on June 30 and July 1, respectively.

At the annual scientific sessions of the American Diabetes Association, a Phase III study demonstrated that saxagliptin produced significant reductions in key measures of glucose control in treatment-naïve people with type 2 diabetes compared to placebo.

Elotuzumab

The Company entered into an agreement with PDL BioPharma, Inc. in August 2008, for the global development and commercialization of elotuzumab, an anti-CS1 antibody currently in Phase I development for multiple myeloma.

KAI-9803

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In May 2008, the Company entered into an agreement with KAI to develop and commercialize KAI's novel acute heart attack medicine, KAI-9803.

Kosan

In June 2008, Bristol-Myers Squibb completed the acquisition of Kosan, a cancer therapeutics company with a library of novel compounds, including Hsp90 inhibitors for cancer and microtubule stabilizers, which may have additional potential in neurodegenerative diseases.

ZymoGenetics

In January 2009, the Company and ZymoGenetics announced a global collaboration for PEG-Interferon lambda, a novel type 3 interferon currently in Phase Ib development for the treatment of Hepatitis C, and its related development program.

PLAVIX\*

The European Committee for Medicinal Products for Human Use in March 2008 issued a positive opinion recommending approval of the 300 milligram loading dose tablet of PLAVIX\*. This positive opinion was ratified by the European Commission.

**Table of Contents****RESULTS OF OPERATIONS**

The following discussions of the Company's results of continuing operations exclude the results related to the Medical Imaging business prior to its divestiture in January 2008, and the ConvaTec business prior to its divestiture in August 2008. Both Medical Imaging and ConvaTec were previously presented as a component of the former Other Health Care operating segment, which was renamed the ConvaTec operating segment subsequent to the Medical Imaging divestiture. These businesses have been segregated from continuing operations and included in discontinued operations for all periods presented.

The Company's results of operations were as follows:

Dollars in Millions	2008	2007	2006	% Change	
				2008 vs. 2007	2007 vs. 2006
Net Sales	\$ 20,597	\$ 18,193	\$ 16,208	13%	12%
Earnings from Continuing Operations Before Income Taxes and Minority Interest	\$ 5,471	\$ 3,186	\$ 2,085	72%	53%
<i>% of net sales</i>	26.6%	17.5%	12.9%		
Provision for Income Taxes	\$ 1,320	\$ 682	\$ 431	94%	58%
<i>Effective tax rate</i>	24.1%	21.4%	20.7%		
Net Earnings from Continuing Operations	\$ 3,155	\$ 1,741	\$ 1,214	81%	43%
<i>% of net sales</i>	15.3%	9.6%	7.5%		

The composition of the changes in net sales was as follows:

Dollars in Millions	Net Sales			2008 vs. 2007 Analysis of % Change				2007 vs. 2006 Analysis of % Change			
	2008	2007	2006	Total Change	Volume	Price	Foreign Exchange	Total Change	Volume	Price	Foreign Exchange
U.S.	\$ 12,042	\$ 10,422	\$ 8,785	16%	9%	7%		19%	15%	4%	
Non-U.S.	8,555	7,771	7,423	10%	4%	1%	5%	5%	(1)%		6%
Total	\$ 20,597	\$ 18,193	\$ 16,208	13%	7%	4%	2%	12%	7%	2%	3%

The 2008 and 2007 increase in U.S. net sales is primarily driven by growth in key U.S. pharmaceutical products which are described below in further detail. Increases in international net sales in 2008 and 2007 were aided by a weakened U.S. dollar relative to certain foreign currencies, especially the euro and U.K. pound.

In general, the Company's business is not seasonal. For information on U.S. pharmaceutical prescriber demand, reference is made to the table within Pharmaceuticals 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 pharmaceuticals products and new products sold by the U.S. pharmaceuticals business. The U.S. and non-U.S. net sales are based upon the location of the customer.

**Table of Contents**

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

Dollars in Millions	Net Sales			% Change		% of Total Net Sales		
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006	2008	2007	2006
Pharmaceuticals	\$ 17,715	\$ 15,622	\$ 13,861	13%	13%	86%	86%	86%
Nutritionals	2,882	2,571	2,347	12%	10%	14%	14%	14%
<b>Total</b>	<b>\$ 20,597</b>	<b>\$ 18,193</b>	<b>\$ 16,208</b>	<b>13%</b>	<b>12%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The Company recognizes revenue net of various sales adjustments to arrive at net sales as reported on the consolidated statements 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	Year Ended December 31,		
	2008	2007	2006
<b>Gross Sales</b>	<b>\$ 23,344</b>	<b>\$ 20,814</b>	<b>\$ 18,909</b>
<b>Gross-to-Net Sales Adjustments</b>			
Prime Vendor Charge-Backs	(529)	(551)	(624)
Women, Infants and Children (WIC) Rebates	(796)	(848)	(872)
Managed Health Care Rebates and Other Contract Discounts	(376)	(333)	(274)
Medicaid Rebates	(205)	(169)	(174)
Cash Discounts	(282)	(239)	(214)
Sales Returns	(228)	(155)	(224)
Other Adjustments	(331)	(326)	(319)
<b>Total Gross-to-Net Sales Adjustments</b>	<b>(2,747)</b>	<b>(2,621)</b>	<b>(2,701)</b>
<b>Net Sales</b>	<b>\$ 20,597</b>	<b>\$ 18,193</b>	<b>\$ 16,208</b>

The gross-to-net adjustments are primarily a function of gross sales and activity is typically correlated with current sales trends as is the case with managed health care rebates and other contract discounts, Medicaid rebates, cash discounts, and other adjustments in 2008, 2007 and 2006. Managed health care rebates and other contract discounts and Medicaid rebates are also affected by changes to sales mix and contractual and legislative discount rates. The 2007 increases in managed health care rebates and other contract discounts were also impacted by the reduction of reserves in 2006 related to the TRICARE Retail Pharmacy Refund Program.

Prime vendor charge-backs decreased throughout 2008 and 2007 as a result lower sales of TAXOL attributed to the loss of exclusivity. The Women, Infant and Children (WIC) rebates decrease is related to the net impact of several WIC contract transactions.

The 2008 increase in sales returns is primarily attributed to increased provisions for PRAVACHOL, driven by higher retail sales returns than previously assumed, and the loss of exclusivity of ZERIT. The 2007 variance in sales returns when compared to the prior year is attributed to higher provisions in 2006 for cardiovascular non-exclusive brands and from the discontinued commercialization of TEQUIN (gatifloxacin).

**Table of Contents**

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

Dollars in Millions	Prime Vendor	Women,	Managed	Medicaid	Cash	Sales	Other	Total
	Charge-Backs (WIC)	Children	Health	Rebates	Discounts	Returns	Adjustments	
	Rebates	and	Care	Discounts				
		Rebates	Rebates and					
			Other					
Balance at January 1, 2007	\$ 63	230	\$ 111	\$ 137	\$ 18	\$ 221	\$ 124	\$ 904
Provision related to sales made in current period	551	845	340	176	238	137	328	2,615
Provision related to sales made in prior periods		3	(7)	(7)	1	18	(2)	6
Returns and payments	(551)	(880)	(306)	(181)	(234)	(201)	(334)	(2,687)
Impact of foreign currency translation			6			4	10	20
Discontinued operations	7		(10)		1	(1)	2	(1)
Balance at December 31, 2007	\$ 70	\$ 198	\$ 134	\$ 125	\$ 24	\$ 178	\$ 128	\$ 857
Provision related to sales made in current period	529	799	383	213	281	136	338	2,679
Provision related to sales made in prior periods		(3)	(7)	(8)	1	92	(7)	68
Returns and payments	(531)	(799)	(357)	(197)	(274)	(189)	(333)	(2,680)
Impact of foreign currency translation			2		(1)	(5)	(3)	(7)
Discontinued operations	(23)		(1)			(3)	(8)	(35)
Balance at December 31, 2008	\$ 45	\$ 195	\$ 154	\$ 133	\$ 31	\$ 209	\$ 115	\$ 882

In 2008 and 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 \$92 million in 2008 and \$18 million in 2007, primarily resulting from higher than expected returns of certain non-exclusive products.

No other significant revisions were made to the estimates for gross-to-net sales adjustments in 2008 and 2007.

**Pharmaceuticals**

The composition of the changes in pharmaceutical net sales was as follows:

Dollars in Millions	Net Sales			2008 vs. 2007 Analysis of % Change				2007 vs. 2006 Analysis of % Change			
	2008	2007	2006	Total Change	Volume	Price	Foreign Exchange	Total Change	Volume	Price	Foreign Exchange
U.S.	\$ 10,611	\$ 8,992	\$ 7,417	18%	11%	7%		21%	16%	5%	
Non-U.S.	7,104	6,630	6,444	7%	3%	(1)%	5%	3%	(2)%	(1)%	6%
Total	\$ 17,715	\$ 15,622	\$ 13,861	13%	8%	3%	2%	13%	8%	2%	3%

In 2008, most of the key U.S. pharmaceutical products contributed to the growth in sales. PLAVIX\* and ABILIFY\*, represented approximately 46% and 16%, of total U.S. pharmaceuticals net sales and represented approximately 53% and 23% of the total growth in pharmaceuticals sales when compared to prior year. In 2007, PLAVIX\* and ABILIFY\* represented approximately 45% and 15%, of total U.S. pharmaceuticals net sales and contributed approximately 89% and 16%, of total growth in U.S. pharmaceuticals net sales. This growth more than offsets decreases in

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U.S. net sales attributed to generic competition for PRAVACHOL.

Both 2008 and 2007 international pharmaceuticals sales were aided by a weakened U.S. dollar against many foreign currencies when compared to the previous period. The Company's reported international net sales do not include copromotion sales reported by its alliance partner, Sanofi-Aventis (Sanofi) for PLAVIX\* and AVAPRO\*/AVALIDE\*, which continued to show growth in 2008.

Net sales of key pharmaceutical products represent 80%, 76% and 72% of total pharmaceutical net sales in 2008, 2007 and 2006, respectively. The following table details U.S. and international pharmaceuticals net sales by key products, the percentage change from prior year as well as the foreign exchange impact when compared to the prior year. Commentary detailing the reasons for significant variances by key product is provided below.

**Table of Contents**

Dollars in Millions	Net Sales			% Change		% Change Attributable to Foreign Exchange	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006	2008 vs. 2007	2007 vs. 2006
<b>Cardiovascular</b>							
<b>PLAVIX*</b>							
U.S.	\$ 4,920	\$ 4,060	\$ 2,655	21%	53%		
Non-U.S.	683	695	602	(2)%	15%	3%	8%
Total	5,603	4,755	3,257	18%	46%	1%	1%
<b>AVAPRO*/AVALIDE*</b>							
U.S.	735	692	647	6%	7%		
Non-U.S.	555	512	450	8%	14%	4%	8%
Total	1,290	1,204	1,097	7%	10%	2%	3%
<b>PRAVACHOL</b>							
U.S.	(10) <sup>(a)</sup>	139	553	(107)%	(75)%		
Non-U.S.	213	304	644	(30)%	(53)%	4%	3%
Total	203	443	1,197	(54)%	(63)%	2%	2%
<b>Virology</b>							
<b>REYATAZ</b>							
U.S.	667	587	514	14%	14%		
Non-U.S.	625	537	417	16%	29%	5%	8%
Total	1,292	1,124	931	15%	21%	2%	4%
<b>SUSTIVA Franchise (total revenue)</b>							
U.S.	724	604	495	20%	22%		
Non-U.S.	425	352	296	21%	19%	4%	10%
Total	1,149	956	791	20%	21%	2%	4%
<b>BARACLUDE</b>							
U.S.	140	88	50	59%	76%		
Non-U.S.	401	187	33	114%	**	9%	N/A
Total	541	275	83	97%	**	6%	N/A
<b>Oncology</b>							
<b>ERBITUX*</b>							
U.S.	739	683	646	8%	6%		
Non-U.S.	10	9	6	11%	50%		2%
Total	749	692	652	8%	6%		
<b>TAXOL</b>							
U.S.	6	14	12	(57)%	17%		
Non-U.S.	379	408	551	(7)%	(26)%	8%	1%
Total	385	422	563	(9)%	(25)%	8%	1%
<b>SPRYCEL</b>							
U.S.	92	58	22	59%	164%		
Non-U.S.	218	100	3	118%	**	8%	N/A
Total	310	158	25	96%	**	5%	N/A
<b>IXEMPRA</b>							
U.S.	98	15		**		N/A	
Non-U.S.	3						
Total	101	15		**		N/A	
<b>Affective (Psychiatric) Disorders</b>							
<b>ABILIFY*</b>							
U.S.	1,676	1,305	1,052	28%	24%		
Non-U.S.	477	355	230	34%	54%	7%	12%
Total	2,153	1,660	1,282	30%	29%	1%	2%
<b>Immunoscience</b>							
<b>ORENCIA</b>							
U.S.	363	216	88	68%	145%		
Non-U.S.	78	15	1	**	**	N/A	N/A
Total	441	231	89	91%	160%	1%	1%

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(a) Negative PRAVACHOL U.S. sales in 2008 reflect higher retail sales returns than previously assumed.

\*\* Change is in excess of 200%.

PLAVIX\* - a platelet aggregation inhibitor that is part of the Company's alliance with Sanofi

U.S. sales increases in 2008 and 2007 were primarily attributed to increased prescription demand and higher average selling prices. Demand was negatively affected beginning in the third quarter of 2006 through the second quarter of 2007 by the launch of a generic clopidogrel bisulfate. The generic in the distribution channel was substantially depleted by June 30, 2007. In 2008 and 2007, estimated total U.S. prescription demand for clopidogrel bisulfate (branded and generic) increased approximately 4% and 8%, respectively, whereas estimated U.S. prescription demand for branded PLAVIX\* increased 19% and 34% respectively.



**Table of Contents**

International net sales in 2008 were negatively impacted by the August 2008 launch of a clopidogrel alternative salt (clopidogrel beyslate) launched in Germany.

See Item 8. Financial Statements Note 25. Legal Proceedings and Contingencies PLAVIX\* Litigation, for further discussion on PLAVIX\* exclusivity litigation in both the U.S. and EU.

AVAPRO\* /AVALIDE\* (known in the EU as APROVEL\*/KARVEA\*) - an angiotensin II receptor blocker for the treatment of hypertension and diabetic nephropathy that is also part of the Sanofi alliance

Worldwide sales increases in 2008 and 2007 were primarily attributed to higher average selling prices which more than offset declines in overall demand. Total U.S. prescription demand for AVAPRO\*/AVALIDE\* decreased approximately 7% in 2008 and approximately 4% in 2007.

PRAVACHOL - an HMG Co-A reductase inhibitor for the treatment of hypercholesterolemia and reducing the risk of heart attack

Worldwide sales decreases in 2008 and 2007 were attributed to continued generic competition in the U.S. and key European markets. Market exclusivity ended in the U.S in April 2006 and in 2004 for most EU countries.

U.S. sales in 2008 were negatively impacted by higher retail sales returns than previously assumed.

REYATAZ - a protease inhibitor for the treatment of HIV

U.S. sales increases in 2008 and 2007 were primarily due to a higher prescription demand of 14% and 13%, respectively.

The international sales increase in 2008 was primarily due to higher demand across most markets with Europe being the key driver due to the June 2008 approval for front-line treatment. Growth in 2007 international revenue was attributed to increased demand in Europe and Latin America.

SUSTIVA Franchise - a non-nucleoside reverse transcriptase inhibitor for the treatment of HIV, which includes SUSTIVA, an antiretroviral drug, and bulk efavirenz, which is also included in the combination therapy, ATRIPLA\* (efavirenz 600mg/ emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), a product sold through a joint venture with Gilead Sciences, Inc.

Worldwide sales increases in 2008 and 2007 were primarily due to higher demand attributed to the successful launch of ATRIPLA\* in the U.S. in July 2006; in the EU in December 2007; and in Canada in October 2007. U.S. prescription demand for the Sustiva franchise increased approximately 14% in 2008 and 20% in 2007. To a lesser extent, higher average selling prices contributed to the increase in net revenues.

BARACLUDGE - an oral antiviral agent for the treatment of chronic hepatitis B

Worldwide sales increases in 2008 and 2007 were primarily due to the continued growth across all markets, particularly international markets, due to the successful launch in various countries including China in February 2006, the UK and Germany in July 2006, France and Japan in September 2006 and the U.S. in April 2005.

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There continues to be increased awareness and acceptance of its long-term efficacy, safety and resistance data as evidenced by the American Association for the Study of Liver Disease treatment guidelines that recommended BARACLUDGE as a first line treatment option.

ERBITUX\* - a monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor, which is expressed on the surface of certain cancer cells in multiple tumor types as well as normal cells and is currently indicated for use against colorectal cancer and head and neck cancer. ERBITUX\* is part of the Company's strategic alliance with ImClone

Sold by the Company almost exclusively in the U.S., the sales increases in 2008 and 2007 were primarily due to increased demand for a recent indication for usage in the treatment of head and neck cancer.

Sales in 2007 were also positively impacted by a transition to a broader distribution model resulting in higher sales associated with initial shipments of inventory to distributors.

TAXOL - an anti-cancer agent, currently sold almost exclusively in non-U.S. markets

Sales decreases in 2008 and 2007 were due primarily to generic competition in Japan.

## **Table of Contents**

**SPRYCEL** - an oral inhibitor of multiple tyrosine kinases, for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy, including GLEEVEC\* (imatinib mesylate)

Worldwide sales increases in 2008 and 2007 were primarily due to higher demand associated with the successful launch in the U.S. in July 2006 and in most European markets beginning in the fourth quarter of 2006, higher U.S. selling prices and continued launches in Russia and Turkey in 2008.

**IXEMPRA** - a microtubule inhibitor for the treatment of patients with metastatic or locally advanced breast cancer

The sales increase in 2008 reflects the launch of the product in the U.S. in October 2007.

**ABILIFY\*** - an antipsychotic agent for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder and is part of the Company's strategic alliance with Otsuka Pharmaceutical Co., Ltd. (Otsuka)

U.S. sales increases in 2008 and 2007 were primarily attributed to increased demand and higher average selling prices. Prescription demand increased approximately 23% in 2008 and approximately 12% in 2007. Contributing to the prescription growth are new indications in 2008 and 2007 for certain patients with bipolar disorder and major depressive disorder.

International sales increases in 2008 and 2007 were also primarily attributed to increased prescription demand. 2008 sales growth was aided by a new bipolar indication in the second quarter of 2008 in the EU.

**ORENCIA** - a fusion protein indicated for adult patients with moderate to severe RA who have had an inadequate response to one or more currently available treatments, such as MTX or anti-tumor necrosis factor therapy

U.S. sales increases in 2008 and 2007 were primarily due to the continued growth since the launch of this biologic product in the U.S. in February 2006.

International sales increase in 2008 reflects the European launch in May 2007.

The estimated U.S. prescription change data provided throughout this Form 10-K includes information only from the retail and mail order channels and does not reflect information from other channels, such as hospitals, institutions and long-term care, among others. The estimated prescription data is based on the Next-Generation Prescription Service (NGPS) version 2.0 of the National Prescription Audit provided by IMS Health (IMS), a supplier of market research for the pharmaceutical industry, as described below. The data provided by IMS is a product of IMS own recordkeeping process and is an estimate based on IMS sampling procedures. The data is subject to the inherent limitations of estimates based on sampling and may include a margin of error.

The Company has calculated the estimated total U.S. prescription change based on NGPS data on a weighted-average basis to reflect the fact that mail order prescriptions include a greater volume of product supplied compared to retail prescriptions. Mail order prescriptions typically reflect a 90-day prescription whereas retail prescriptions typically reflect a 30-day prescription. The calculation is derived by multiplying NGPS mail order prescription data by a factor that approximates three and adding to this the NGPS retail prescriptions. The Company believes that this calculation of the estimated total U.S. prescription change based on the weighted-average approach with respect to the retail and mail order channels provides a superior estimate of total prescription demand. The Company uses this methodology for its internal demand forecasts.

The Company continuously seeks to improve the quality of its estimates of prescription change amounts and ultimate patient/consumer demand through review of its methodologies and processes for calculation of these estimates and review and analysis of its own and third parties data used in such calculations. The Company expects that it will continue to review and refine its methodologies and processes for calculation of

these estimates and will continue to review and analyze its own and third parties' data used in such calculations.

**Table of Contents****Estimated End-User Demand**

The following tables set forth for each of the Company's key pharmaceutical products sold by the U.S. Pharmaceuticals business, for the years ended December 31, 2008, 2007 and 2006: (i) total U.S. net sales for the period; (ii) change in reported U.S. net sales for the period; (iii) estimated total U.S. prescription change for the retail and mail order channels calculated by the Company based on NGPS data on a weighted-average basis and (iv) months of inventory on hand in the wholesale distribution channel.

Dollars in Millions	Year Ended December 31,									At December 31,		
	Total U.S. Net Sales			% Change in U.S. Net Sales <sup>(a)</sup>			% Change in U.S. Total Prescriptions <sup>(b)</sup>			Months on Hand		
	2008	2007	2006	2008	2007	2006	2008	2007	2006	2008	2007	2006
PLAVIX*	\$ 4,920	\$ 4,060	\$ 2,655	21%	53%	(18)%	19%	34%	(21)%	0.4	0.5	0.6
AVAPRO*/AVALIDE*	735	692	647	6%	7%	13%	(7)%	(4)%	2%	0.5	0.5	0.5
PRAVACHOL <sup>(h)</sup>	(10)	139	553	(107)%	(75)%	(57)%	(75)%	(82)%	(59)%	0.8	0.7	0.6
REYATAZ	667	587	514	14%	14%	27%	14%	13%	14%	0.5	0.6	0.7
SUSTIVA Franchise <sup>(c)</sup>	724	604	495	20%	22%	23%	14%	20%	9%	0.6	0.6	0.7
BARACLUDE	140	88	50	59%	76%	**	55%	77%	**	0.7	0.6	0.7
ERBITUX <sup>(d)</sup>	739	683	646	8%	6%	57%	N/A	N/A	N/A	0.5	0.5	0.4
SPRYCEL <sup>(e)</sup>	92	58	22	59%	164%		36%	**		0.8	0.9	1.4
IXEMPRA <sup>(d, f)</sup>	98	15		**			N/A	N/A	N/A	0.7	0.9	
ABILIFY*	1,676	1,305	1,052	28%	24%	40%	23%	12%	21%	0.5	0.5	0.5
ORENCIA <sup>(d, g)</sup>	363	216	88	68%	145%		N/A	N/A	N/A	0.5	0.5	0.4

(a) Reflects percentage change in net sales in dollar terms.

(b) Derived by multiplying NGPS mail order prescription data by a factor that approximates three and adding to this the NGPS retail prescriptions.

(c) Beginning in the third quarter of 2006, the SUSTIVA Franchise (total revenue) includes sales of SUSTIVA, as well as revenue of bulk efavirenz included in the combination therapy, ATRIPLA\*. The change in U.S. total prescriptions growth for the SUSTIVA Franchise includes both branded SUSTIVA and ATRIPLA\* prescription units.

(d) ERBITUX\*, ORENCIA and IXEMPRA are parenterally administered products and do not have prescription-level data as physicians do not write prescriptions for these products.

(e) SPRYCEL was launched in the U.S. in July 2006.

(f) IXEMPRA was launched in the U.S. in October 2007.

(g) ORENCIA was launched in the U.S. in February 2006.

(h) Negative net sales attributed to higher retail returns than previously assumed.

\*\* Change is in excess of 200%.

Pursuant to the U.S. Securities and Exchange Commission (SEC) Consent Order described below under "SEC Consent Order", the Company monitors the level of inventory on hand in the U.S. wholesaler distribution channel and outside of the U.S. in the direct customer distribution channel. The Company is obligated to disclose products with levels of inventory in excess of one month on hand or expected demand, subject to a de minimis exception. The following products had estimated levels of inventory in the distribution channel in excess of one month on hand (1) in the case of the Company's U.S. Pharmaceuticals products, December 31, 2008 and (2) in the case of the Company's international Pharmaceuticals and Nutritionals products, September 30, 2008.

At September 30, 2008, BUFFERIN, a salicylate drug, had approximately 1.1 months of inventory on hand at direct customers compared to approximately 0.9 months of inventory on hand at December 31, 2007. The increased level of inventory on hand was due primarily to increased inventory levels in China caused by distributors' preparations for national holidays.

At September 30, 2008, DAFALGAN, an analgesic product sold principally in Europe, had approximately 1.1 months of inventory on hand as compared to 1.2 months of inventory on hand at December 31, 2007. The previously stated level of inventory on hand as of September 30, 2008 was due primarily to private pharmacists purchasing DAFALGAN approximately once every eight weeks and the seasonality of the product.

At September 30, 2008, VIDEX/VIDEX EC, an antiviral product, had approximately 1.3 months of inventory on hand at direct customers compared to 1.3 months of inventory on hand at December 31, 2007. The previously stated level of inventory on hand was due primarily to government purchasing patterns in Brazil. The Company is contractually obligated to provide VIDEX/VIDEX EC to the Brazilian government upon placement of an order for product by the government. Under the terms of the contract, the Company has no control over the inventory

levels relating to such orders.

**Table of Contents**

In the U.S., for all products sold exclusively through wholesalers or through distributors, the Company determines its months on hand estimates using information with respect to inventory levels of product on hand and the amount of out-movement of products provided by the Company's three largest wholesalers, which accounted for approximately 90% of total gross sales of U.S. Pharmaceuticals products in 2008, and provided by the Company's distributors. Factors that may influence the Company's estimates include generic competition, seasonality of products, wholesaler purchases in light of increases in wholesaler list prices, new product launches, new warehouse openings by wholesalers and new customer stockings by wholesalers. In addition, such estimates are calculated using third-party data, which represent their own record-keeping processes and may also reflect estimates.

For pharmaceutical products in the U.S. that are not sold exclusively through wholesalers or distributors and for the Company's Pharmaceuticals business outside of the U.S. and Nutritionals business units around the world, the Company has significantly more direct customers. Limited information on direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information, where available, varies widely. In cases where direct customer product level inventory, ultimate patient/consumer demand or out-movement data does not exist or is otherwise not available, the Company has developed a variety of other methodologies to calculate estimates of such data, including using such factors as historical sales made to direct customers and third-party market research data related to prescription trends and end-user demand. Accordingly, the Company relies on a variety of methods to estimate direct customer product level inventory and to calculate months on hand for these business units. Factors that may affect the Company's estimates include generic competition, seasonality of products, direct customer purchases in light of price increases, new product or product presentation launches, new warehouse openings by direct customers, new customer stockings by direct customers and expected direct customer purchases for governmental bidding situations.

**Nutritionals**

The composition of the change in nutritional net sales was as follows:

Dollars in Millions	Net Sales			2008 vs. 2007 Analysis of % Change			2007 vs. 2006 Analysis of % Change				
	2008	2007	2006	Total Change	Volume	Price	Foreign Exchange	Total Change	Volume	Price	Foreign Exchange
U.S.	\$ 1,108	\$ 1,128	\$ 1,091	(2)%	(6)%	4%		3%	1%	2%	
Non-U.S.	1,774	1,443	1,256	23%	8%	12%	3%	15%	4%	5%	6%
Total	\$ 2,882	\$ 2,571	\$ 2,347	12%	2%	8%	2%	10%	3%	4%	3%

Infant formulas and toddler/children's nutritionals, representing 97%, 96% and 96% of total nutritional net sales in 2008, 2007 and 2006, respectively, were as follows:

Dollars in Millions	Net Sales			% Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
Infant Formulas	\$ 1,932	\$ 1,786	\$ 1,637	8%	9%
ENFAMIL	1,157	1,082	1,007	7%	7%
Toddler/Children's Nutritionals	856	693	606	24%	14%

In 2008, the decrease in U.S. nutritional net sales was primarily due to decreased sales of infant formulas. The increase in international nutritionals net sales was primarily due to growth in both infant formulas and children's nutritionals.

In 2007, the increase in U.S. nutritional net sales was primarily due to increased sales of infant formulas. International nutritional net sales increased primarily due to growth in both infant formulas and children's nutritionals.

**Table of Contents****Geographic Areas**

In general, the Company's products are available in most countries in the world. The largest markets are in the U.S., France, Spain, Canada, China, Japan, Italy, Mexico and Germany. The Company's sales by geographic areas based on the location of the entity selling the product were as follows:

Dollars in Millions	Net Sales			% Change		% of Total Net Sales		
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006	2008	2007	2006
United States	\$ 12,042	\$ 10,422	\$ 8,785	16%	19%	58%	57%	54%
Europe, Middle East and Africa	4,514	4,036	3,979	12%	1%	22%	22%	25%
Other Western Hemisphere	1,622	1,628	1,517		7%	8%	9%	9%
Pacific	2,419	2,107	1,927	15%	9%	12%	12%	12%
<b>Total</b>	<b>\$ 20,597</b>	<b>\$ 18,193</b>	<b>\$ 16,208</b>	<b>13%</b>	<b>12%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

See items previously discussed in Item 1. Pharmaceuticals for items impacting the increase in U.S. net sales for 2008 and 2007.

Europe, Middle East and Africa sales increases in 2008 are primarily due to sales growth in major European markets for ABILIFY\*, SPRYCEL, and the HIV and hepatitis portfolio in addition to a favorable foreign exchange impact of 6%. Sales in 2007 were essentially flat as sales growth in major European markets for SPRYCEL, ABILIFY\* and the HIV and hepatitis portfolio, and a favorable foreign exchange impact of 8%, was offset by generic competition for PRAVACHOL and TAXOL.

Other Western Hemisphere countries sales in 2008 were essentially flat with a minimum foreign exchange impact. Sales increases in 2007 are primarily due to increased sales of PLAVIX\* in Canada and Mexico, key nutritional products and AVAPRO\*/AVALIDE\* in Canada, and a favorable foreign exchange impact of 4%. These increases were partially offset by the discontinued commercialization of TEQUIN.

Pacific region sales increases in 2008 and 2007 are primarily due to sales growth of BARACLUDGE in China, Japan, and Korea and key nutritional products throughout the region in addition to favorable foreign exchange impacts of 6% and 5%, respectively. In addition, sales in 2007 were negatively impacted by increased generic competition for TAXOL and PRAVACHOL.

No single country outside the U.S. contributed more than 10% of the Company's total revenues in 2008, 2007 or 2006. Net sales in France, Canada, Spain and Japan exceeded \$500 million in both 2008 and 2007. Net sales in China and Italy exceeded \$500 million in 2008, while Mexico had more than \$500 million in sales in 2007.



**Table of Contents****Expenses/Gains**

Dollars in Millions	2008	2007	2006	% Change		% of Net Sales		
				2008 vs. 2007	2007 vs. 2006	2008	2007	2006
Costs of products sold	\$ 6,396	\$ 5,868	\$ 5,420	9%	8%	31%	32%	33%
Marketing, selling and administrative	4,792	4,516	4,469	6%	1%	23%	25%	28%
Advertising and product promotion	1,550	1,415	1,304	10%	9%	8%	8%	8%
Research and development	3,585	3,227	2,951	11%	9%	17%	18%	18%
Acquired in-process research and development	32	230		(86)%	100%		1%	
Provision for restructuring, net	218	183	59	19%	**	1%	1%	
Litigation expense, net	33	14	302	136%	(95)%			2%
Gain on sale of product lines and businesses	(159)	(273)	(200)	42%	(37)%	(1)%	(2)%	(1)%
Equity in net income of affiliates	(617)	(524)	(474)	(18)%	(11)%	(3)%	(3)%	(3)%
Gain on sale of ImClone shares	(895)			(100)%		(4)%		
Other expense, net	191	351	292	(46)%	20%	1%	2%	2%
<b>Total Expenses, net</b>	<b>\$ 15,126</b>	<b>\$ 15,007</b>	<b>\$ 14,123</b>	<b>1%</b>	<b>6%</b>	<b>73%</b>	<b>82%</b>	<b>87%</b>

\*\* Change is in excess of 200%.

*Costs of products sold*

The improvement in costs of products sold as a percentage of net sales in 2008 was primarily attributed to a more favorable worldwide pharmaceuticals product sales mix, higher U.S. pharmaceuticals average selling prices, and realized manufacturing savings from PTI. These factors were partially offset by product and material price increases. The 2008 costs include manufacturing rationalization charges of \$249 million related to the implementation of PTI in 2008, or 1.2% of net sales, compared to \$179 million of rationalization charges recorded in 2007, or 1.0% of net sales.

The improvement in costs of products sold as a percentage of sales in 2007 was primarily due to sales growth in higher margin products including PLAVIX\*.

*Marketing, selling and administrative*

The increase in 2008 was primarily related to \$104 million of increased process standardization costs incurred as part of PTI when compared to the prior period, \$41 million of costs incurred as part of the initial public offering for Mead Johnson, higher selling expenses in support of key products, and an unfavorable 2% foreign exchange impact.

The increase in 2007 was primarily due to an unfavorable impact of foreign exchange and higher marketing expenses, partially offset by lower sales force expenses.

The decrease in marketing, selling and administrative expenses as a percentage of net sales was the result of increased sales growth outpacing expenses which are being managed through PTI.

*Advertising and product promotion*

The increase in 2008 was primarily related to increased promotions for new indications of ABILIFY\* in the U.S., increased promotion for ORENCIA, increased expenses in the international Nutritionals business, and an unfavorable foreign exchange impact.

The increase in 2007 was primarily related to increased spending for direct-to-customer advertising for PLAVIX\*, ABILIFY\* and ORENCIA, expenses to support the launch of IXEMPRA, higher spending on newer products in Europe, and an unfavorable foreign exchange impact.

*Research and development*

The increase in 2008 was primarily related to increased licensing and upfront and milestone payments, increased spending for pipeline compounds, and an unfavorable foreign exchange impact. The 2008 increase was partially offset by sharing of codevelopment costs with alliance partners AstraZeneca and Pfizer.

**Table of Contents**

The increase in 2007 was primarily attributed to continued investment in late-stage compounds and developing a pipeline in disease areas that address significant unmet medical needs, as well as increased upfront and milestone payments in 2007 when compared to 2006 as detailed below. The 2007 increase was partially offset by sharing of codevelopment costs with alliance partners AstraZeneca and Pfizer.

Upfront and milestone payments made in 2008 and expensed to research and development totaled \$348 million and were paid primarily to Exelixis, PDL BioPharma, Inc., and KAI. The 2007 charges totaled \$162 million and were paid to Exelixis, Pfizer, Adnexus and Isis. The 2006 charges totaled \$70 million and were paid to Exelixis and Solvay Global.

Research and development expenses dedicated to pharmaceutical products were 19.6%, 20.0% and 20.3% of pharmaceutical net sales in 2008, 2007 and 2006, respectively.

*Acquired in-process research and development*

Acquired in-process research and development costs (IPRD) consisted of the estimated fair value of research and development acquired as part of an acquisition which, through December 31, 2008, were immediately expensed at the acquisition date.

The 2008 charge related to IPRD from the acquisition of Kosan whereas the 2007 charge related to IPRD obtained from the acquisition of Adnexus Therapeutics, Inc. (Adnexus).

*Provision for restructuring, net*

The increase in provision for restructuring, net was attributed to the timing of the implementation of PTI, which was announced in December 2007 and expanded in July 2008.

The increase in 2007 was attributed to the charges, primarily severance related, associated with the announcement of the PTI in December 2007. See Item 8. Financial Statements Note 3. Restructuring.

*Litigation expense, net*

Litigation expenses in 2006 related to reserves for the settlement in principle of certain pricing and sales investigations, partially offset by insurance recoveries from an unrelated matter and positive settlement of a litigation matter. For additional information on litigation matters, see Item 8. Financial Statements Note 25. Legal Proceedings and Contingencies.

*Gain on sale of product lines and businesses*

The gain in 2008 was primarily attributable to the sale of the mature brands businesses in Egypt.

The gain in 2007 was attributed to the sale of the BUFFERIN\* and EXCEDRIN\* brands in Japan, Asia (excluding China and Taiwan) and certain Oceanic countries, as well as certain assets related to U.S. dermatology products.

The gain in 2006 was attributed to the sale of inventory, patent and intellectual property rights related to DOVONEX\*.

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For additional information on these transactions, see Item 8. Financial Statements Note 4. Acquisitions and Divestitures.

### *Equity in net income of affiliates*

Equity in net income of affiliates was principally related to the Company's international joint venture with Sanofi. The increases in 2008 and 2007 are correlated with increases in international PLAVIX\* sales. For additional information on equity in net income of affiliates, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

### *Gain on sale of ImClone shares*

The gain on sale of ImClone shares was attributed to the Company's receipt of approximately \$1.0 billion in cash for the tendering of its investment in ImClone. See Item 8. Financial Statements Note 2. Alliances and Collaborations for further detail.

**Table of Contents***Other expense, net*

The components of other expense, net are as follows:

Dollars in Millions	Year Ended December 31,		
	2008	2007	2006
Interest expense	\$ 310	\$ 422	\$ 498
Interest income	(130)	(241)	(274)
ARS impairment charge	305	275	
(Gain)/loss on debt buyback and termination of interest rate swap agreements	(57)		220
Foreign exchange transaction (gains)/losses	(76)	15	
Other, net	(161)	(120)	(152)
<b>Other expense, net</b>	<b>\$ 191</b>	<b>\$ 351</b>	<b>\$ 292</b>

Interest expense decreases in 2008 and 2007 were primarily due to decreases in interest rates.

Interest income relates primarily to interest earned on cash, cash equivalents and investments in marketable securities. The decrease in interest income in 2008 was primarily due to the change in mix in the Company's short-term investment portfolio as well as a decrease in the rate of return on short-term investments, including U.S. Treasury Bills, when compared to the prior year.

ARS impairment charge was attributed to the Company's auction rate securities (ARS). In addition, a \$19 million loss on the sale of ARS in 2008 was recognized and is included in other, net. See Item 8. Financial Statements Note 11. Cash, Cash Equivalents and Marketable Securities for further detail.

The gain on debt buyback in 2008 is attributed to the repurchase of certain debt and the monetization of certain interest rate swaps due to the recent appreciation of value. See Item 8. Financial Statements Note 18. Short-Term Borrowing and Long-Term Debt for further information.

Foreign exchange transaction gains in 2008 were attributed to a strengthening U.S. dollar impact on non-qualifying foreign exchange hedges and on the re-measurement of non-functional currency denominated transactions when compared to the prior year.

Other, net includes income from third-party contract manufacturing, certain royalty income and expense, debt retirement costs, gains and losses on sale of property, plant and equipment, gains and losses on the sale of marketable securities, insurance recoveries, deferred income recognized, certain other litigation matters, ConvaTec and Medical Imaging net transitional service fees, amortization of certain upfront payments related to the Company's alliances, proceeds from swap terminations, and pension curtailments. See Item 8. Financial Statements Note 8. Other Expense, Net for further information.

**Table of Contents**

During the years ended December 31, 2008, 2007 and 2006, the Company recorded the following specified expense/(income) items that affected the comparability of results of the periods presented herein. For a discussion of these items, see Item 8. Financial Statements Note 2. Alliances and Collaborations; Note 3. Restructuring; Note 4. Acquisitions and Divestitures; Note 9. Income Taxes; Note 11. Cash, Cash Equivalents and Marketable Securities; Note 18. Short-Term Borrowings and Long-Term Debt; and Note 25. Legal Proceedings and Contingencies.

Dollars in Millions	Cost of products sold	Marketing, selling and administrative	Research and development	Acquired in-process research and development	Provision for restructuring net	Litigation expense, net	Gain on sale of product lines and businesses	Gain on sale of ImClone shares	Other expense, net	Total
<b>Year Ended December 31, 2008</b>										
<b>Productivity Transformation Initiative:</b>										
Downsizing and streamlining of worldwide operations	\$	\$	\$	\$	\$ 189	\$	\$	\$	\$	\$ 189
Accelerated depreciation, asset impairment and other shutdown costs	213				20				8	241
Pension settlements/curtailments	9								8	17
Process standardization implementation costs		109								109
Gain on sale and leaseback of properties									(9)	(9)
Termination of lease contracts					9				6	15
Gain on sale of product lines and businesses							(159)			(159)
	222	109			218		(159)		13	403
<b>Other:</b>										
Litigation settlement						33				33
Insurance recovery									(20)	(20)
Mead Johnson charges		41							3	44
Product liability									18	18
Upfront and milestone payments and acquired in-process research and development			348	32						380
Asset impairment	27		13							40
ARS impairment charges and loss on sale									324	324
Debt buyback and swap terminations									(57)	(57)
Gain on sale of ImClone shares								(895)		(895)
	\$ 249	\$ 150	\$ 361	\$ 32	\$ 218	\$ 33	\$ (159)	\$ (895)	\$ 281	270
Income taxes on items above										39
Decrease to Net Earnings from Continuing Operations										\$ 309

**Table of Contents****Dollars in Millions**

	Cost of products sold	Marketing, selling and administrative	Research and development	Acquired in-process research and development	Provision for restructuring, net	Litigation expense, net	Gain on sale of product lines and businesses	Other expense, net	Total
<b><u>Year Ended December 31, 2007</u></b>									
<b>Productivity Transformation Initiative:</b>									
Downsizing and streamlining of worldwide operations	\$	\$	\$	\$	\$ 139	\$	\$	\$ 6	\$ 145
Accelerated depreciation and asset impairment	102	8							110
Process standardization implementation costs		5						32	37
	102	13			139			38	292
<b>Other:</b>									
Litigation settlement						14			14
Insurance recovery								(11)	(11)
Product liability								15	15
Upfront and milestone payments and acquired in-process research and development			162	230					392
ARS impairment charges								275	275
Downsizing and streamlining of worldwide operations						44			44
Accelerated depreciation, asset impairment and contract termination	77							23	100
Gain on sale of properties and product lines and businesses							(273)	(9)	(282)
	\$ 179	\$ 13	\$ 162	\$ 230	\$ 183	\$ 14	\$ (273)	\$ 331	839
Income taxes on items above									(33)
Change in estimate for taxes on a prior year specified item									(39)
Decrease to Net Earnings from Continuing Operations									\$ 767

**Dollars in Millions**

	Cost of products sold	Marketing, selling and administrative	Research and development	Provision for restructuring, net	Litigation expense, net	Gain on sale of product lines and businesses	Other expense, net	Total
<b><u>Year Ended December 31, 2006</u></b>								
<b>Litigation Matters:</b>								
Pharmaceutical pricing and sales litigation	\$	\$	\$	\$	\$ 353	\$	\$	\$ 353
Product liability							11	11
Claim for damages							13	13
Commercial litigations					(14)			(14)
Insurance recovery					(37)			(37)
					302		24	326
<b>Other:</b>								
Debt retirement costs							220	220
Accelerated depreciation, asset impairment and contract termination	167	4	15					186
Upfront and milestone payments			70					70
Downsizing and streamlining of worldwide operations					59			59
Gain on sale of product lines and businesses						(200)		(200)
	\$ 167	\$ 4	\$ 85	\$ 59	\$ 302	\$ (200)	\$ 244	661

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Income taxes on items above	(149)
Change in estimate for taxes on prior year specified items	39
<b>Decrease to Net Earnings from Continuing Operations</b>	<b>\$ 551</b>

The specified items presented above were reflected in the segment results as follows:

<b>Dollars in Millions</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Pharmaceuticals	\$ 673	\$ 579	\$ 208
Nutritionals	17		16
<b>Total segments</b>	<b>690</b>	<b>579</b>	<b>224</b>
Corporate/Other	(420) <sup>(1)</sup>	260	437
<b>Total</b>	<b>\$ 270</b>	<b>\$ 839</b>	<b>\$ 661</b>

(1) Includes \$895 million gain on sale of ImClone shares.



**Table of Contents****Earnings From Continuing Operations Before Income Taxes and Minority Interest**

Dollars in Millions	Earnings From Continuing Operations Before Income Taxes and Minority Interest			% Change		% Segment Net Sales		
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006	2008	2007	2006
	Pharmaceuticals	\$ 4,988	\$ 3,471	\$ 2,569	44%	35%	28%	22%
Nutritionals	830	708	696	17%	2%	29%	28%	30%
Total segments	5,818	4,179	3,265	39%	28%	28%	23%	20%
Corporate/Other	(347)	(993)	(1,180)	65%	16%			
<b>Total</b>	<b>\$ 5,471</b>	<b>\$ 3,186</b>	<b>\$ 2,085</b>	<b>72%</b>	<b>53%</b>	<b>27%</b>	<b>18%</b>	<b>13%</b>

**Pharmaceuticals**

Earnings increased in 2008 primarily due to increased sales of PLAVIX\*, ABILIFY\*, the HIV and hepatitis portfolio and ORENCIA. The increase in segment income as a percentage of segment net sales in 2008 was primarily due to similar factors discussed in the analysis of consolidated expenses. A more favorable product sales mix, higher average selling prices and realized manufacturing savings from PTI contributed to a reduction of costs of products sold as a percentage of net sales. The results of PTI also contributed to a reduction of marketing, selling and administrative expense as a percentage of net sales.

Earnings increased in 2007 primarily due to increased PLAVIX\* sales and strong sales growth of other key products. The increase in segment income as a percentage of segment net sales in 2007 was similar to the reasons discussed above although to a lesser extent as PTI was beginning in 2007.

**Nutritionals**

Earnings increased in 2008 primarily due to increased international net sales. The increase in segment income as a percentage of segment net sales in 2008 was primarily due to the growth rate in net sales exceeding the growth rate for marketing, selling and administrative expenses and research and development as well as a 2007 bad debt charge for a distributor insolvency. These factors were partially offset by higher dairy prices, advertising and promotion expenses and additional legal, accounting and consulting expenses incurred in preparation of the initial public offering.

Earnings increased in 2007 primarily due to growth of key products. The decrease in segment income as a percentage of segment net sales in 2007 was primarily due to higher dairy prices, unfavorable product mix and a bad debt charge for a distributor insolvency.

**Corporate/Other**

Earnings from continuing operations before income taxes and minority interest reported in Corporate/Other consists of:

Dollars in Millions	2008	2007	2006
Corporate administrative expense	\$ (532)	\$ (556)	\$ (558)
Stock-based compensation expense	(181)	(133)	(112)
Provision for restructuring, net	(218)	(183)	(59)
Litigation expense, net	(33)	(14)	(302)
Interest expense	(310)	(422)	(498)
Interest income	130	241	274
ARS impairment charge	(305)	(275)	
Gain on sale of ImClone shares	895		

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Gain on sale of product lines and businesses	159	273	200
Gain/(loss) on debt buyback and termination of interest rate swap agreements	57		(220)
Other	(9)	76	95
Total Corporate/Other earnings from continuing operations before income taxes and minority interest	\$ (347)	\$ (993)	\$ (1,180)

**Table of Contents****Income Taxes**

The effective income tax rate on earnings from continuing operations before income taxes and minority interest was 24.1% in 2008, compared with 21.4% in 2007 and 20.7% in 2006.

The increase in the 2008 effective tax rate from 2007 was primarily due to higher pre-tax income in the U.S., including the gain on sale of ImClone, and earnings mix in high tax jurisdictions in 2008. Partially off-setting these impacts were lower non-deductible charges in 2008 for acquired in-process research and development expenses and lower ARS impairment charges with little or no tax benefit. The tax rate in 2008 was favorably impacted by a benefit of \$91 million of tax related to the final settlement of the 2002-2003 audit with the Internal Revenue Service.

The 2007 tax rate was unfavorably impacted by the impairment on the Company's investment in certain ARS with little tax benefit and the non-deductible write-off of acquired in-process research and development expenses related to the acquisition of Adnexus, partially offset by a tax benefit of \$105 million in the first quarter of 2007 due to the favorable resolution of certain tax matters with the Internal Revenue Service related to the deductibility of litigation settlement expenses and U.S. foreign tax credits claimed. The effective tax rate for 2006 was unfavorably impacted by the elimination of tax benefits under Section 936 of the Internal Revenue Code, the treatment of provisions for a portion of certain litigation reserves as non-deductible, partially offset by favorable U.S. tax legislation enacted in 2006 related to the tax treatment of certain intercompany transactions amongst the Company's foreign subsidiaries, and the implementation of tax planning strategies related to the utilization of certain charitable contributions.

The Company has recognized significant deferred tax assets at December 31, 2008 related to U.S. Federal foreign tax credit carryforwards of approximately \$451 million and U.S. Federal research and development tax credit carryforwards of approximately \$271 million. The U.S. Federal charitable contribution carryforwards were fully utilized during 2008 due to gains related to the ConvaTec and Medical Imaging divestitures, while the foreign tax credit and research and development tax credit carryforwards expire in varying amounts beginning in 2014. The foreign tax credit and research and development tax credit carryforwards have been reduced due to derecognition under FIN No. 48. The ConvaTec and Medical Imaging divestitures have resulted in a significant reduction to the foreign tax credit and research and development tax credit carryforwards in 2008. The realization of the foreign tax credit and research and development tax credit carryforwards is dependent on generating sufficient domestic-sourced 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.

**Minority Interest**

Minority interest is primarily related to the Company's partnership with Sanofi for the territory covering the Americas related to PLAVIX\* sales. Increases of minority interest correspond to the increased sales of PLAVIX\*.

Dollars in Millions	2008	2007	2006
Sanofi partnership	\$ 1,444	\$ 1,106	\$ 609
Others	24	26	19
Minority interest, pre-tax	1,468	1,132	628
Income taxes	472	369	188
Minority interest, net of taxes	\$ 996	\$ 763	\$ 440

**Financial Position, Liquidity and Capital Resources**

The Company continues to maintain a sufficient level of working capital, which was approximately \$8.1 billion at December 31, 2008 and \$1.7 billion at December 31, 2007. In 2008 and future periods, the Company expects cash generated by its U.S. operations, together with existing cash, cash equivalents, marketable securities and borrowings from the capital markets, to be sufficient to cover cash needs for working capital, capital expenditures (which the Company expects to include investments in facilities to increase and maintain the Company's capacity to provide biologics on a commercial scale), strategic alliances and acquisitions, milestone payments and dividends paid in the U.S. Cash and cash equivalents, marketable securities, the conversion of other working capital items and borrowings are expected to fund near-term operations outside the U.S.

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In December 2006, the Company obtained a \$2.0 billion five year revolving credit facility from a syndicate of lenders, which is extendable on the anniversary date with the consent of the lenders. This facility contains customary terms and conditions, including a financial covenant whereby the ratio of consolidated debt to consolidated capital cannot exceed 50% at the end of each quarter. The Company has been in compliance with this covenant since the inception of this new facility. There were no borrowings outstanding under the revolving credit facility at December 31, 2008.

On February 17, 2009, Mead Johnson entered into a three year syndicated revolving credit facility agreement. The credit facility is unsecured and provides for borrowings and letters of credit up to \$410 million.

**Table of Contents***Net Financial Assets*

Net financial asset position at December 31 was as follows:

<b>Dollars in Millions</b>	<b>2008</b>	<b>2007</b>
<b>Financial assets:</b>		
Cash and cash equivalents	\$ 7,976	\$ 1,801
Marketable securities-current	289	424
<b>Total financial assets</b>	<b>8,265</b>	<b>2,225</b>
<b>Debt:</b>		
Short-term borrowings, including current portion of long-term debt	154	1,891
Long-term debt	6,585	4,381
<b>Total debt</b>	<b>6,739</b>	<b>6,272</b>
<b>Net cash/(debt)</b>	<b>\$ 1,526</b>	<b>\$ (4,047)</b>

*Net Cash/(Debt)*

Net cash/(debt) position at December 31, 2008 improved due to proceeds of \$4.6 billion from the divestiture of the ConvaTec and Medical Imaging businesses and proceeds of \$1.0 billion from the sale of our ImClone shares. Cash generated from operating activities of \$3.7 billion was more than adequate to fund dividend payments of \$2.5 billion as well as capital expenditure payments of \$941 million.

*Investments*

The following table summarizes the Company's carrying value and related unrealized (loss)/gain position of its current and non-current marketable securities, which include U.S. dollar-denominated floating rate securities (FRS) and ARS, both of which are accounted for as available for sale debt securities. See Item 8. Financial Statements Note 11. Cash, Cash Equivalents and Marketable Securities, for further discussion on the Company FRS and ARS portfolio including the related cost basis and fair value for each investment.

<b>Dollars in Millions</b>	<b>December 31, 2008</b>		<b>December 31, 2007</b>	
	<b>Carrying Value</b>	<b>Unrealized (Loss)/Gain in Accumulated OCI</b>	<b>Carrying Value</b>	<b>Unrealized (Loss)/Gain in Accumulated OCI</b>
<b>Current:</b>				
Available for sale				
Floating rate securities	\$ 109	\$ (6)	\$ 337	\$ (25)
U.S. Treasury Bills	180	1		
Other			87	
<b>Total current</b>	<b>\$ 289</b>	<b>\$ (5)</b>	<b>\$ 424</b>	<b>\$ (25)</b>
<b>Non-current:</b>				
Available for sale				
Auction rate securities	\$ 94		\$ 419	\$ (117)
Floating rate securities	94	(45)		
<b>Total non-current</b>	<b>\$ 188</b>	<b>\$ (45)</b>	<b>\$ 419</b>	<b>\$ (117)</b>

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During 2008, the Company received \$108 million of principal at par primarily on a FRS that matured in March 2008 and temporarily reduced the carrying value of the remaining FRS by \$26 million to \$203 million as an unrealized loss in accumulated other comprehensive income (OCI). In addition, during 2008 the Company reclassified \$94 million of the remaining FRS with maturity dates beyond 2009 from current assets to non-current other assets due to liquidity concerns and the continued uncertainty in the capital markets.

During 2008, the Company received \$118 million primarily in connection with the sale of ARS with a carrying value of \$137 million, resulting in a loss of \$19 million. In addition, a \$305 million other-than-temporary impairment charge was recognized, including \$117 million that was previously determined to be temporary at December 31, 2007. The 2008 impairment charge was required after an analysis of other-than-temporary impairment factors, including the severity and duration of the decline in value, future prospects of the issuer and the Company's ability and intent to hold the securities to recovery. The ARS sold were securities generally backed by sub-prime mortgages, collateralized debt obligations and structured credit. The ARS remaining at December 31, 2008 represents interests in insurance securitizations and to a lesser extent, structured credit.

**Table of Contents**

If uncertainties in the credit and capital markets continue, these markets deteriorate further or the Company experiences any additional ratings downgrades on any investments in its portfolio (including FRS and ARS), the Company may incur additional impairments to its investment portfolio, which could negatively affect the Company's financial condition and reported earnings. The Company believes that, based on the Company's current level of cash, cash equivalents and marketable securities and expected operating cash flows, the current lack of liquidity in the credit and capital markets will not have a material impact on the Company's liquidity, cash flow, financial flexibility or its ability to fund its operations, including the dividend.

*Credit Ratings*

The Moody's Investors Service (Moody's) long-term and short-term credit ratings for the Company are currently A2 and Prime-1, respectively. Moody's revised the long-term credit rating outlook to negative from stable. Standard & Poor's (S&P) long-term and short-term credit ratings for the Company are currently A+ and A-1, respectively. S&P's long-term credit rating remains on stable outlook. Fitch Ratings (Fitch) long-term and short-term credit ratings for the Company are currently A+ and F1, respectively. Fitch's long-term credit rating remains on stable outlook.

*Working Capital*

The following is a discussion of working capital:

Dollars in Millions	December 31,	
	2008	2007
Working capital	\$ 8,053	\$ 1,704

The increase in working capital of \$6.3 billion from December 31, 2007 to December 31, 2008 was impacted by:

Proceeds from the sale of the ConvaTec business (\$4.1 billion);

Proceeds from the sale of our ImClone shares (\$1.0 billion); and

Proceeds from issuance of 6.125% Notes due 2038 (\$1.0 billion) and 5.45% Notes due 2018 (\$600 million).

*Cash Flows*

The following is a discussion of cash flow activities:

Dollars in Millions	Year Ended December 31,		
	2008	2007	2006
Cash flow provided by/(used in):			
Operating activities	\$ 3,707	\$ 3,153	\$ 2,083
Investing activities	5,079	(202)	206
Financing activities	(2,582)	(3,213)	(3,351)

*Operating Activities*

Cash flow from operating activities represents the cash receipts and cash disbursements related to all activities of the Company other than to investing activities and financing activities. Operating cash flow is derived by adjusting net earnings for:

Non-cash operating items such as depreciation and amortization; impairment charges; stock-based compensation charges;

Gains and losses attributed to investing and financing activities such as gains and losses on the sale of product lines and businesses;  
and

Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

The Company's operating cash flow has grown consistently throughout the three years ended December 31, 2008 as the increases in net income, attributed to reasons noted throughout this MD&A, continue to directly impact operating cash flows. This is evident as the net income adjusted for non-cash operating items as well as gains and losses attributed to investing and financing activities amounted to \$3.6 billion in 2008, \$3.2 billion in 2007 and \$2.5 billion in 2006. These amounts exclude the changes in operating assets and liabilities, discussed below.

The net impact of the changes in operating assets and liabilities, which are discussed in more detail below, include the impact of changes in receivables, inventories, deferred income, accounts payable, income taxes receivable/payable and other operating assets and liabilities. The Company continues to maximize its operating cash flows with its recently announced working capital initiative designed to continue to improve those working capital items that are most directly affected by changes in sales volume, such as accounts receivable, inventories and accounts payable.



**Table of Contents**

In 2008, changes in operating assets resulted in a net cash inflow of \$117 million which was impacted by:

Cash inflows from income tax payable/receivable (\$371 million) which includes the impact of the receipt of a \$432 million tax refund, including interest, related to a prior year foreign tax credit carryback claim;

Cash inflows from accounts payables (\$253 million) which are primarily attributed to the timing of vendor and alliance payments;

Cash inflows from inventory (\$130 million) which is primarily attributed to the utilization of inventories which were built up in the prior year for new product launches and strategic builds for existing products launches including for new indications of ABILIFY\*;

Cash inflows from deferred income (\$61 million) which are primarily due to receipt of upfront and milestone payments from alliance partners;

Cash outflows from other operating assets and liabilities (\$333 million) which are primarily due to net litigation related payments made in the current period (\$190 million) attributed to the settlement of certain pricing and sales litigation accrued in prior periods; pension funding in excess of current year expense (\$120 million); and increase in non-current inventory (\$112 million); and

Cash outflows from accounts receivables (\$365 million) which are attributed to increased sales.

In 2007, changes in operating assets resulted in a net cash outflow of \$7 million which was impacted by:

Cash outflows from accounts receivable (\$519 million) which are primarily attributed to increased sales;

Cash outflows from U.S and foreign income taxes payable (\$199 million) which are primarily attributed to tax payments which included settlement payments associated with various tax issues for the 2002-2003 IRS audit;

Cash inflows from deferred income (\$454 million) which are primarily due to receipt of upfront and milestone payments from alliance partners including Pfizer and AstraZeneca;

Cash inflows from other operating assets and liabilities (\$170 million) which are primarily due to increases in accrued royalties attributed to increased PLAVIX\* sales; and increases in accrued salaries and bonuses due to the timing of payments; partially offset by cash outflows primarily related to litigation related payments (\$318 million) for the settlement of pricing and sales litigation accrued in prior periods; and

Cash inflows from accounts payables (\$141 million) which include the impact of increased purchases of raw materials for planned inventory buildup.

In 2006, changes in operating assets resulted in a net cash outflow of \$464 million which was impacted by:

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Cash outflows from other operating assets and liabilities (\$573 million) which are primarily due to the pay down of accrued rebates and returns primarily resulting from exclusivity loss of PRAVACHOL, volume erosion on highly rebated PARAPLATIN and TAXOL and lower PLAVIX\* volumes; and reduced royalties from lower PLAVIX\* sales; Additions in the litigation settlement accrual related to the pricing and sales litigation settlements are primarily offset by net litigation related payments related to other matters accrued in prior years (\$272 million);

Cash outflows from accounts payable (\$349 million) which are primarily due to lower purchases of PRAVACHOL raw materials, due to the loss of PRAVACHOL exclusivity and a significant reduction of payables in early 2006 resulting from lower payment of invoices in December 2005; and

Cash inflows from accounts receivables (\$444 million) are primarily due to lower PLAVIX\* sales and the loss of exclusivity of PRAVACHOL.

**Table of Contents**

*Investing Activities*

Net cash provided by investing activities was \$5.1 billion in 2008 and included:

Proceeds from the divestiture of ConvaTec (\$4.1 billion); Medical Imaging (\$483 million); and mature brands business in Egypt (\$209 million);

Proceeds from the tendering of the Company's shares in ImClone (\$1.0 billion);

Proceeds from the sale and leaseback of the Paris, France facility (\$227 million);

Capital expenditures (\$941 million) which included expenditures associated with the construction of the Company's biologic facility in Devens, Massachusetts; and

Acquisition of Kosan (\$191 million).

Net cash used in investing activities was \$202 million in 2007 and included:

Capital expenditures (\$843 million);

Acquisition of Adnexus (\$432 million);

Net proceeds from the sale of marketable securities (\$756 million); and

Proceeds from the sales of the BUFFERIN\* and EXCEDRIN\* brands in Japan, Asia (excluding China and Taiwan) and certain Oceanic countries and U.S. dermatology products (\$273 million).

Net cash provided by investing activities was \$206 million in 2006 and included:

Net proceeds from the sale of marketable securities (\$762 million);

Proceeds from the disposal of properties in connection with sale and lease back of administrative facilities in New Jersey (\$281 million);

Proceeds from the sale of various product assets primarily from the sale of several assets related to DOVONEX (\$226 million);

Capital expenditures (\$785 million); and

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Milestone payments primarily related to ImClone (\$280 million).

### Financing Activities

Net cash used in financing activities was \$2.6 billion in 2008 and included:

Dividend payments (\$2.5 billion);

Redemption of Floating Rate Convertible Senior Debentures due 2023 (\$1.2 billion);

Repayment of 4.00% Notes due August 2008 (\$400 million) and 1.10% Yen Notes due 2008 (\$117 million);

Repurchase of some of the Company's Notes (\$228 million);

Net proceeds from the issuance of 5.45% Notes due 2018 (\$600 million) and 6.125% Notes due 2038 (\$1.0 billion);

Net proceeds from the termination of interest rate swap agreements (\$211 million); and

Net proceeds from stock option exercises in 2008 (\$5 million) reflects the exercise of fewer stock options in 2008 due to the decrease in the average stock price when compared to the prior periods.

Net cash used in financing activities was \$3.2 billion in 2007 and included:

Dividend payments (\$2.2 billion);

Repayment of the floating rate bank facility (\$1.3 billion); and

Proceeds from the exercise of stock options (\$333 million).

Net cash used in financing activities was \$3.4 billion in 2006 and included:

Debt payments associated with the early retirement of 5.75% Notes due 2011 (\$2.5 billion) and floating rate bank facility (\$1.2 billion);

Dividend payments (\$2.2 billion); and

Proceeds from the issuance of 5.87% Notes due 2036 (\$1.3 billion), and Euro Notes (\$1.3 billion).

**Table of Contents**

Dividends declared per common share were \$1.24 for 2008, \$1.15 for 2007 and \$1.12 for 2006. In December 2008, the Company declared a quarterly dividend of \$0.31 per common share and indicated a dividend for the full year 2009 of \$1.24 per share. Dividend decisions are made on a quarterly basis by the Company's Board of Directors.

**Contractual Obligations**

Payments due by period for the Company's contractual obligations at December 31, 2008 were as follows:

Dollars in Millions	Obligations Expiring by Period						
	Total	2009	2010	2011	2012	2013	Later Years
Short-term borrowings	\$ 154	\$ 154	\$	\$	\$	\$	\$
Long-term debt <sup>(1)</sup>	5,737		45			647	5,045
Interest on long-term debt <sup>(2)</sup>	6,360	246	251	271	278	272	5,042
Operating leases	674	136	110	93	79	73	183
Purchase obligations	2,907	621	409	401	406	411	659
Stand-by letters of credit/performance guarantees	168	96	33	11	15	3	10
Uncertain tax positions <sup>(3)</sup>	120	120					
Other long-term liabilities <sup>(4)</sup>	381		120	57	34	25	145
<b>Total<sup>(5)</sup></b>	<b>\$ 16,501</b>	<b>\$ 1,373</b>	<b>\$ 968</b>	<b>\$ 833</b>	<b>\$ 812</b>	<b>\$ 1,431</b>	<b>\$ 11,084</b>

(1) The current portion of long-term debt obligations is included in short-term borrowings on the Company's consolidated balance sheet at December 31, 2008 and all balances approximate the outstanding nominal long-term debt values.

(2) Includes estimated future interest payments on our short-term and long-term debt. Also includes accrued interest payable recorded on our consolidated balance sheets, which consists primarily of the accrual of interest on short-term and long-term debt as well as the accrual of periodic cash settlements of derivatives, netted by counterparty.

(3) Due to the uncertainty related to the timing of the reversal of uncertain tax positions, only the short-term uncertain tax benefits have been provided in the table above.

(4) Does not include minority interest of \$33 million.

(5) The table above excludes future contributions by the Company to its pension, postretirement and postemployment benefit plans. Required contributions are contingent upon numerous factors including minimum regulatory funding requirements and the funded status of each plan. Due to the uncertainty of such future obligations, they are excluded from the table. Contributions for both U.S. and international plans are expected to be up to \$690 million in 2009. See Item 8. Financial Statements Note 24 Pension, Postretirement and Postemployment Benefits for further detail.

In addition to the above, the Company has committed to make approximately \$3.0 billion potential future research and development milestone payments to third parties as part of in-licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental and regulatory milestones, for which the specific timing cannot be predicted. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on the Company's consolidated balance sheets.

For a discussion of contractual obligations, see Item 8. Financial Statements Note 18. Short-Term Borrowings and Long-Term Debt, Note 21. Financial Instruments, Note 23. Leases, and Note 24. Pension, Postretirement and Postemployment Liabilities.

**SEC Consent Order**

As previously disclosed, on August 4, 2004, the Company entered into a final settlement with the SEC, concluding an investigation concerning certain wholesaler inventory and accounting matters. The settlement was reached through a Consent, a copy of which was attached as Exhibit 10 to the Company's quarterly report on Form 10-Q for the period ended September 30, 2004.

Under the terms of the Consent, the Company agreed, subject to certain defined exceptions, to limit sales of all products sold to its direct customers (including wholesalers, distributors, hospitals, retail outlets, pharmacies and government purchasers) based on expected demand or on amounts that do not exceed approximately one month of inventory on hand, without making a timely public disclosure of any change in practice. The Company also agreed in the Consent to certain measures that it has implemented including: (a) establishing a formal review and certification process of its annual and quarterly reports filed with the SEC; (b) establishing a business risk and disclosure group; (c) retaining an

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outside consultant to comprehensively study and help re-engineer the Company's accounting and financial reporting processes; (d) publicly disclosing any sales incentives offered to direct customers for the purpose of inducing them to purchase products in excess of expected demand; and (e) ensuring that the Company's budget process gives appropriate weight to inputs that come from the bottom to the top, and not just from the top to the bottom, and adequately documenting that process.

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## **Table of Contents**

The Company has established a company-wide policy to limit its sales to direct customers for the purpose of complying with the Consent. This policy includes the adoption of various procedures to monitor and limit sales to direct customers in accordance with the terms of the Consent. These procedures include a governance process to escalate to appropriate management levels potential questions or concerns regarding compliance with the policy and timely resolution of such questions or concerns. In addition, compliance with the policy is monitored on a regular basis.

The Company maintains Inventory Management Agreements (IMAs) with most of its U.S. pharmaceutical wholesalers, which account for nearly 100% of total gross sales of U.S. Pharmaceutical products. Under the current terms of the IMAs, the Company's three largest wholesaler customers provide the Company with weekly information with respect to months on hand product-level inventories and the amount of out-movement of products. These three wholesalers currently account for approximately 90% of total gross sales of U.S. Pharmaceuticals products in 2008, 2007 and 2006. The inventory information received from these wholesalers, together with the Company's internal information, is used to estimate months on hand product level inventories at these wholesalers. The Company estimates months on hand product inventory levels for its U.S. Pharmaceutical business's wholesaler customers other than the three largest wholesalers by extrapolating from the months on hand calculated for the three largest wholesalers. In contrast, for the Company's Pharmaceutical business outside of the U.S. and Nutritionals business units around the world, the Company has significantly more direct customers, limited information on direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information, where available, varies widely. Accordingly, the Company relies on a variety of methods to estimate months on hand product level inventories for these business units.

The Company believes the above-described procedures provide a reasonable basis to ensure compliance with the Consent.

### **Recently Issued Accounting Standards**

In 2008, the following new accounting pronouncements, critical to the Company's financial statements, discussed in Item 8. Financial Statements Note 1. Accounting Policies - Recently Issued Accounting Standards, have been considered and evaluated for required application and their impact:

*EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*

*SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities*

*SFAS No. 157, Fair Value Measurements*

*SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities*

*EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*

*SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*

*SFAS No. 141(R), Business Combinations*

### **Critical Accounting Policies**

The Company prepares its financial statements in conformity with accounting principles generally accepted in the U.S. The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the

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

The Company believes that the following discussion represents its critical accounting policies. Management has discussed the Company's critical accounting policies with the Audit Committee of the Board of Directors.

### ***Revenue Recognition***

The Company recognizes revenue in accordance with Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*. The Company's accounting policy for revenue recognition has a substantial impact on its reported results and relies on certain estimates that require difficult, subjective and complex judgments on the part of management. The Company recognizes revenue (net of the gross-to-net sales adjustments discussed below, all of which involve significant estimates and judgments) when title and substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment.



**Table of Contents**

In the case of new products for which the product introduction is not an extension of an existing line of product, where the Company determines that there are not products in a similar therapeutic category, or where the Company determines the new product has dissimilar characteristics with existing products, such that the Company cannot reliably estimate expected returns of the new product, the Company defers recognition of revenue until the right of return no longer exists or until the Company has developed sufficient historical experience to estimate sales returns.

For discussions on revenue recognition, see Item 8. Financial Statements Note 1. Accounting Policies Revenue Recognition and Sales Rebate and Return Accruals.

***Gross-to-Net Sales Adjustments***

The Company has the following significant categories of gross-to-net sales adjustments: prime vendor charge-backs, WIC rebates, managed health care rebates and other contract discounts, Medicaid rebates, cash discounts, sales returns, and other adjustments, all of which involve significant estimates and judgments and require the Company to use information from external sources. The Company accounts for these gross-to-net sales adjustments in accordance with EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, and SFAS No. 48, *Revenue Recognition When Right of Return Exists*, as applicable. See Net Sales section above for a reconciliation of the Company's gross sales to net sales by each significant category of gross-to-net sales adjustment.

***Prime vendor charge-backs***

The Company's U.S. businesses participate 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, and other parties whereby pricing on products is extended below wholesaler list price to participating entities. These entities purchase products through wholesalers at the lower prime vendor price and the wholesalers charge the difference between their acquisition cost and the lower prime vendor price back to the Company. The Company accounts for prime vendor charge-backs by reducing accounts receivable in an amount equal to the Company's estimate of charge-back claims attributable to a sale. The Company determines its estimate of the prime vendor charge-backs primarily based on historical experience regarding prime vendor charge-backs and current contract prices under the prime vendor programs. The Company considers prime vendor payments, levels of inventory in the distribution channel, and the Company's claim processing time lag and adjusts the reduction to accounts receivable periodically throughout each quarter to reflect actual experience.

***WIC rebates***

The Company's U.S. Nutritionals business participates on a competitive bidding basis in nutrition programs sponsored by states, tribal governments, the Commonwealth of Puerto Rico and the U.S. territories for WIC. Under these programs, the Company reimburses these entities for the difference between wholesaler list price and the contract price on eligible products. The Company accounts for WIC rebates by establishing an accrual in an amount equal to the Company's estimate of WIC rebate claims attributable to a sale. The Company determines its estimate of the WIC rebate accrual primarily based on historical experience regarding WIC rebates and current contract prices under the WIC programs. The Company considers levels of inventory in the distribution channel, new WIC contracts, terminated WIC contracts, changes in existing WIC contracts, and WIC participation and adjusts the accrual periodically throughout each quarter to reflect actual experience.

***Managed health care rebates and other contract discounts***

The Company offers rebates and discounts to managed health care organizations in the U.S. which manage prescription drug programs and Medicare Advantage prescription drug plans covering the Medicare Part D drug benefit in addition to their commercial plans, as well as globally to other contract counterparties such as hospitals and group purchasing organizations. In addition, the Company pays rebates under U.S. Department of Defense TRICARE Retail Pharmacy Refund Program. The Company accounts for managed health care rebates and other contract discounts by establishing an accrual in an amount equal to the Company's estimate of managed health care rebates and other contract discounts attributable to a sale. The Company determines its estimate of the managed health care rebates and other contract discounts accrual primarily based on historical experience regarding these rebates and discounts and current contract prices. The Company considers the sales performance of products subject to managed health care rebates and other contract discounts and levels of inventory in the distribution channel and adjusts the accrual periodically throughout each quarter to reflect actual experience.

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## **Table of Contents**

### **Medicaid rebates**

The Company's U.S. businesses participate 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. Discounts and rebates provided through these latter programs are included in the Company's Medicaid rebate accrual and are considered Medicaid rebates for the purposes of this discussion. The Company accounts for Medicaid rebates by establishing an accrual in an amount equal to the Company's estimate of Medicaid rebate claims attributable to a sale. The Company determines its estimate of the Medicaid rebates accrual primarily based on historical experience regarding Medicaid rebates, as well as any expansion on a prospective basis of its participation in the non-mandatory aspects of the qualifying Federal and state government programs, legal interpretations of applicable laws related to Medicaid and qualifying Federal and state government programs, and any new information regarding changes in the Medicaid programs' regulations and guidelines that would impact the amount of the rebates. The Company considers outstanding Medicaid claims, Medicaid payments, and levels of inventory in the distribution channel and adjusts the accrual periodically throughout each quarter to reflect actual experience.

### **Cash discounts**

In the U.S. and certain other countries, the Company offers cash discounts, approximating 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the full amount of the discounts. The Company considers payment performance and adjusts the accrual to reflect actual experience.

### **Sales returns**

The Company accounts for sales returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, by establishing an accrual in an amount equal to the Company's estimate of sales recorded for which the related products are expected to be returned. The provision for sales returns was \$228 million in 2008, \$155 million in 2007 and \$224 million in 2006, which approximates 1% of gross sales for each of the three years.

For returns of established products, the Company determines its estimate of the sales return accrual primarily based on historical experience regarding sales returns, but also considers other factors that could impact sales returns. These factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. The Company considers all of these factors and adjusts the accrual periodically throughout each quarter to reflect actual experience.

In the event of a product recall or product discontinuance, the Company considers the reasons for and impact of such actions and adjusts the sales return accrual as appropriate, taking into account historical experience, estimated levels of inventory in the distribution channel and, for product discontinuances, estimates of continuing demand.

Sales returns accruals from new products are estimated and primarily based on the historical sales returns experience of similar products, such as those within the same line of product or those within the same or similar therapeutic category. In limited circumstances, where the new product is not an extension of an existing line of product or where the Company has no historical experience with products in a similar therapeutic category, such that the Company cannot reliably estimate expected returns of the new product, the Company defers recognition of revenue until the right of return no longer exists or until the Company has developed sufficient historical experience to estimate sales returns. The Company also considers the shelf life of new products and determines whether it believes an adjustment to the sales return accrual is appropriate. The shelf life in connection with new products tends to be shorter than the shelf life for more established products because the Company may still be developing an optimal manufacturing process for the new product that would lengthen its shelf life. In addition, higher launch quantities may have been manufactured in advance of the launch date to ensure sufficient supply exists to satisfy market demand. In those cases, the Company assesses the reduced shelf life, together with estimated levels of inventory in the distribution channel and projected demand, and determines whether it believes an adjustment to the sales return accrual is appropriate.

### **Other adjustments**

In addition to the gross-to-net sales adjustments described above, the Company makes other gross-to-net sales adjustments. For example, the Company offers sales discounts, most significantly in its non-U.S. businesses, and also offers consumer coupons and rebates, most significantly in its U.S. Nutritionals and Pharmaceuticals businesses. In addition, in a number of countries outside the U.S., including certain major European countries, the Company provides rebates to government entities. The Company generally accounts for these other gross-to-net adjustments by establishing an accrual in an amount equal to the Company's estimate of the adjustments attributable to a sale. The Company generally determines its estimates of the accruals for these other gross-to-net sales adjustments primarily based on historical experience, performance on

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commitments to government entities and other relevant factors, including estimated levels of inventory in the distribution channel, and adjusts the accruals periodically throughout each quarter to reflect actual experience.

## **Table of Contents**

### Use of information from external sources

The Company uses information from external sources to estimate its gross-to-net sales adjustments. The Company's estimates of inventory at the wholesalers are based on the projected prescription demand-based sales for its products and historical inventory experience, as well as the Company's analysis of third-party information, including written and oral information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and the Company's internal information. The inventory information received from wholesalers is a product of their recordkeeping process and excludes inventory held by intermediaries to whom they sell, such as retailers and hospitals. The Company receives information from IMS, a supplier of market research to the pharmaceutical industry, which it uses to project the prescription demand-based sales for many of its U.S. Pharmaceutical products. In 2007, IMS refined and improved its NGPS projection methodology and fully rolled out NGPS Version 2.0 of the National Prescription Audit to all subscribers, which resulted in newly revised volume estimates for historic time periods. Therefore, since the first quarter of 2007, the Company has used the new IMS standard NGPS Version 2.0 projection methodology and has applied NGPS Version 2.0 data for reporting prescription growth and market shares to all periods presented in the Annual Report on Form 10-K. The Company has also continued the practice of combining retail and mail prescription volume on a retail-equivalent basis. The Company uses this methodology for its internal demand forecasts. The Company also uses information from external sources to identify prescription trends, patient demand and average selling prices. The Company's estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information was itself in the form of estimates, and reflect other limitations including lags between the date as of which third-party information is generated and the date on which the Company receives third-party information.

### **Retirement Benefits**

The Company's pension plans and postretirement benefit plans are accounted for using actuarial valuations. Management is required to make significant subjective judgments about a number of actuarial assumptions, including discount rates, salary growth, long-term return on plan assets, retirement, turnover, health care cost trend rates, and mortality rates. Depending on the assumptions and estimates used, the pension and postretirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. In addition, the assumptions can materially affect projected benefit obligations and future cash funding.

The Company adopted 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)*, in the year ended December 31, 2006 and the adoption of this accounting pronouncement resulted in a \$1.1 billion reduction of accumulated other comprehensive income in stockholders' equity, a \$767 million reduction in total assets and a \$297 million increase in total liabilities. The adoption of SFAS No. 158 did not impact the Company's results of operations or cash flows.

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

In determining the discount rate, the Company uses the yield on high quality corporate bonds that coincides with the cash flows of its plans estimated payouts. The Citigroup Above Median yield curve is used in determining the discount rate for the U.S. plans. The assumed rate of compensation increase used by the Company for determining future pension obligations reflects an estimate of the change in actual future compensation levels due to general price levels, productivity, seniority and other factors.

The U.S. plans' pension expense for 2008 was determined using a 6.75% assumed discount rate and a 3.56% assumed rate of compensation increase. The present value of benefit obligations at December 31, 2008 for the U.S. plans was determined using a 6.5% assumed discount rate and a 3.56% assumed rate of compensation increase. If the assumed discount rate used in determining the U.S. plans' pension expense for 2008 had been reduced by 0.25%, such expense would have increased by approximately \$17 million. If the assumed rate of compensation increase used in determining the U.S. plans' pension expense for 2008 had been reduced by 0.25%, such expense would have decreased by approximately \$9 million. If the assumed discount rate used in determining the projected benefit obligation at December 31, 2008 had been reduced by 0.25%, the projected benefit obligation would have increased by \$126 million.

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## **Table of Contents**

In determining the expected long-term rate of return on plan assets, the Company estimates returns for individual asset classes with input from external advisors. The Company also considers long-term historical returns including actual performance compared to benchmarks for similar investments.

The U.S. plans' pension expense for 2008 was determined using an 8.75% expected long-term rate of return on plan assets. If the expected long-term rate of return on plan assets used in determining the U.S. plans' pension expense for 2008 had been reduced by 1%, such expense would have increased by \$43 million.

For a more detailed discussion on retirement benefits, see Item 8. Financial Statements Note 24. Pension, Postretirement and Postemployment Liabilities.

### ***Acquisitions***

The Company's consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition. Acquired businesses are accounted for using the purchase method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to acquired IPRD are expensed at the date of acquisition.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations.

There are several methods that can be used to determine the fair value of assets acquired and liabilities assumed. For intangible assets, including IPRD, we typically use the income method. This method starts with our forecast of all of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income method or other methods include: the amount and timing of projected future cash flows; the amount and timing of projected costs to develop the IPRD into commercially viable products; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives. For example, the useful life of the right associated with a pharmaceutical product's exclusive patent will be finite and will result in amortization expense being recognized in the results of operations over a determinable period.

For a more detailed discussion on acquired in-process research and development, see Item 8. Financial Statements Note 1. Accounting Policies Acquired In-Process Research and Development.

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

The Company periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its estimated net realizable value.

Goodwill is tested at least annually for impairment using a two-step process. The first step is to identify a potential impairment, and the second step measures the amount of the impairment loss, if any. Goodwill is deemed to be impaired if the carrying amount of a reporting unit's goodwill exceeds its estimated fair value. All other long-lived assets are tested for impairment using a one-step process, which consists of a comparison of the fair value to the carrying value of the asset. Such assets are deemed to be impaired if their net book value exceeds their estimated fair value.

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



## **Table of Contents**

Impairment charges of long-lived assets were \$63 million in 2008, \$104 million in 2007 and \$120 million in 2006. For discussions on impairment of long-lived assets, see Item 8. Financial Statements Note 1. Accounting Policies Impairment of Long-Lived Assets and Goodwill and Other Intangible Assets.

### ***Equity Investments***

The Company reviews its equity investments for impairment based on its determination of whether the decline in market value of the investment below the Company's carrying value is other than temporary. In making this determination, the Company considers APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock and related interpretations*, which set forth factors to be evaluated in determining whether a loss in value should be recognized, including the Company's ability to hold its investment, the market price and market price fluctuations of the investment's publicly traded shares and inability of the investee to sustain an earnings capacity, which would justify the carrying amount of the investment. The Company's previous investment in ImClone was subject to this accounting. For a discussion of the Company's investment in ImClone, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

For discussions on equity investments, see Item 8. Financial Statements Note 1. Accounting Policies Investments and Note 2. Alliances and Collaborations.

### ***Marketable Securities***

The Company's marketable securities at December 31, 2008 consisted of U.S. Treasury Bills, FRS and ARS.

Due to the lack of availability of observable market quotes on the Company's investment portfolio of FRS and ARS, the Company utilizes valuation models including those that are based on expected cash flow streams and collateral values, including assessments of counterparty credit quality, default risk underlying the security, discount rates and overall capital market liquidity. The valuation is subject to uncertainties that are difficult to predict. Factors that may impact the Company's valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

A considerable amount of judgment and estimation is applied in the valuation of FRS and ARS. In addition, the Company also applies judgment in determining whether the marketable securities are other-than-temporarily impaired. The Company typically considers the severity and duration of the decline, future prospects of the issuer and the Company's ability and intent to hold the security to recovery.

Other-than-temporary impairment charges related to ARS were \$305 million and \$275 million in 2008 and 2007, respectively. The carrying value of ARS was \$94 million at December 31, 2008.

The credit and capital markets have continued to deteriorate in 2009. 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 impairment charges.

For discussions on marketable securities, FRS and ARS, see Item 8. Financial Statements Note 10. Fair Value Measurement and Note 11. Cash, Cash Equivalents and Marketable Securities.

### ***Restructuring***

To streamline operations and rationalize manufacturing facilities, the Company has periodically recorded restructuring charges. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. Actual results could vary from these estimates. Adjustments to reflect changes in estimates for restructuring actions taken in prior periods resulted in an increase of \$1 million in 2008, and a reduction of \$6 million in 2007 and \$14 million in 2006.

For discussions on restructuring, see Item 8. Financial Statements Note 1. Accounting Policies Restructuring and Note 3. Restructuring.

### ***Contingencies***

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In the normal course of business, the Company is subject to contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability. In accordance with SFAS No. 5, *Accounting for Contingencies*, the Company records



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## **Table of Contents**

accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. These estimates are subject to uncertainties that are difficult to predict and, as such, actual results could vary from these estimates.

For discussions on contingencies, see Item 8. Financial Statements Note 1. Accounting Policies Contingencies, Note 9. Income Taxes and Note 25. Legal Proceedings and Contingencies.

### ***Income Taxes***

The provision for income taxes has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax bases of the Company's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. The Company had net deferred tax assets of \$2.8 billion and \$3.5 billion at December 31, 2008 and 2007, respectively, net of valuation allowances of \$1.8 billion and \$2.0 billion.

The Company recognized significant deferred tax assets at December 31, 2008 related to U.S. Federal foreign tax credit carryforwards of \$451 million and U.S. Federal research and development tax credit carryforwards of \$271 million. The realization of these tax credit carryforwards is dependent on generating sufficient domestic-sourced 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 Company establishes liabilities for possible assessments by tax authorities resulting from known tax exposures including, but not limited to, transfer pricing matters, tax credits and deductibility of certain expenses. Such liabilities represent a reasonable provision for taxes ultimately expected to be paid and may need to be adjusted over time as more information becomes known.

For discussions on income taxes, see Item 8. Financial Statements Note 1. Accounting Policies Income Taxes and Note 9. Income Taxes.

### **Special Note Regarding Forward-Looking Statements**

This annual report and other written and oral statements the Company makes from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as should, expect, anticipate, estimate, target, may, project, guidance believe and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, the Company's goals, plans and projections regarding its financial position, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance or results of current and anticipated products and the outcome of contingencies such as legal proceedings, and financial results, which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years. The Company has included important factors in the cautionary statements included in this annual report, particularly under Item 1A. Risk Factors, that the Company believes could cause actual results to differ materially from any forward-looking statement.

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

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**Table of Contents**
**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

The Company is exposed to market risk due to changes in currency exchange rates, interest rates and to a lesser extent natural gas pricing. To reduce that risk, the Company enters into certain derivative financial instruments, when available on a cost-effective basis, to hedge its underlying economic exposure. The Company's primary net foreign currency translation exposures are the euro, Japanese yen, Canadian dollar, Chinese renminbi, and Mexican peso. To manage these exposures, the Company utilizes foreign currency contracts, which are subject to cash flow hedge accounting treatment. These instruments are managed on a consolidated basis to efficiently net exposures and thus take advantage of any natural offsets.

The Company also uses derivative instruments as part of its interest rate risk management strategy. The derivative instruments used are comprised principally of fixed-to-floating rate interest swaps, which are subject to fair-value hedge accounting treatment. In addition, all of the Company's financial instruments, including derivatives, are subject to counterparty credit risk which the Company considers as part of the overall fair value measurement. Derivative financial instruments are not used for speculative purposes.

**Foreign Exchange Risk**

A significant portion of the Company's revenues and earnings is exposed to changes in foreign currency rates. In addition, the Company is exposed to foreign exchange transaction risk that arises from non-functional currency denominated assets and liabilities. In order to manage this risk, the Company uses foreign exchange forward contracts to offset its exposure to certain assets and liabilities and earnings denominated in certain foreign currencies. These foreign exchange forward contracts are not designated as hedges and, therefore, changes in the fair value of these derivatives are recognized in earnings in other expense, net, as they occur. In addition, the Company utilizes foreign currency contracts to manage foreign exchange risk that primarily arises from certain intercompany transactions and designates these derivative instruments as foreign currency cash flow hedges when appropriate.

The notional amounts of the Company's foreign exchange derivative contracts were \$1.2 billion and \$1.7 billion at December 31, 2008 and 2007, respectively. For these derivatives, in which the majority qualify as hedges of future anticipated cash flows, the effective portion of changes in fair value is temporarily deferred in accumulated OCI and then recognized in earnings when the hedged item affects earnings. The Company estimates that a 10% appreciation or depreciation in the underlying currencies being hedged from their levels against the U.S. dollar at December 31, 2008, with all other variables held constant, would decrease by \$119 million or increase by \$109 million, respectively, the fair value of foreign exchange forward contracts held at December 31, 2008.

The Company is also exposed to translation risk on its non-U.S. dollar-denominated net assets. In order to manage this risk the Company uses non-U.S. dollar borrowings, primarily the \$500 Million Notes due 2016 and the \$500 Million Notes due 2021, to hedge the foreign currency exposures of the Company's net investment in certain foreign affiliates. These non-U.S. dollar borrowings are designated as hedges of net investments. The effective portion of foreign exchange gains or losses on these hedges is recorded as part of the foreign currency translation component of accumulated OCI.

For additional information, see Item 8. Financial Statements Note 21. Financial Instruments.

**Interest Rate Risk**

The Company uses interest rate swaps as part of its interest rate risk management strategy. The interest rate swaps used are principally fixed-to-floating rate swaps, which are designated as fair-value hedges. SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, requires interest rate swaps that qualify for fair-value hedge accounting, as well as the underlying debt, to be reported at fair value. As such, the swaps and the underlying debt have been revalued resulting in a \$647 million increase to non-current other assets and long-term debt at December 31, 2008. Swaps are generally held to maturity and intended to create an appropriate balance of fixed and floating rate debt for the Company. The Company estimates that an increase or decrease of 100 basis points in short-term or long-term interest rates would decrease or increase the fair value of the Company's interest rate swaps by \$455 million, excluding the effects of counterparty credit risk.

For additional information, see Item 8. Financial Statements Note 10. Fair Value Measurements, Note 11. Cash, Cash Equivalents and Marketable Securities, Note 18. Short-Term Borrowings and Long-Term Debt and Note 21. Financial Instruments.

**Table of Contents****BRISTOL-MYERS SQUIBB COMPANY****CONSOLIDATED STATEMENTS OF EARNINGS****Dollars and Shares in Millions, Except Per Share Data****Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

	Year Ended December 31,		
	2008	2007	2006
<b>EARNINGS</b>			
Net Sales	\$ 20,597	\$ 18,193	\$ 16,208
Costs of products sold	6,396	5,868	5,420
Marketing, selling and administrative	4,792	4,516	4,469
Advertising and product promotion	1,550	1,415	1,304
Research and development	3,585	3,227	2,951
Acquired in-process research and development	32	230	
Provision for restructuring, net	218	183	59
Litigation expense, net	33	14	302
Gain on sale of product lines and businesses	(159)	(273)	(200)
Equity in net income of affiliates	(617)	(524)	(474)
Gain on sale of ImClone shares	(895)		
Other expense, net	191	351	292
Total Expenses, net	15,126	15,007	14,123
Earnings from Continuing Operations Before Income Taxes and Minority Interest	5,471	3,186	2,085
Provision for income taxes	1,320	682	431
Minority interest, net of taxes	996	763	440
Net Earnings from Continuing Operations	3,155	1,741	1,214
<b>Discontinued Operations:</b>			
Earnings, net of taxes	113	424	371
Gain on Disposal, net of taxes	1,979		
	2,092	424	371
Net Earnings	\$ 5,247	\$ 2,165	\$ 1,585
<b>Earnings per Common Share</b>			
<b>Basic:</b>			
Net Earnings from Continuing Operations	\$ 1.60	\$ 0.88	\$ 0.62
<b>Discontinued Operations:</b>			
Earnings, net of taxes	0.05	0.22	0.19
Gain on Disposal, net of taxes	1.00		
Net Earnings per Common Share	\$ 2.65	\$ 1.10	\$ 0.81
<b>Diluted:</b>			

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Net Earnings from Continuing Operations	\$ 1.59	\$ 0.88	\$ 0.62
Discontinued Operations:			
Earnings, net of taxes	0.05	0.21	0.19
Gain on Disposal, net of taxes	0.99		
Net Earnings per Common Share	\$ 2.63	\$ 1.09	\$ 0.81
Average Common Shares Outstanding:			
Basic	1,977	1,970	1,960
Diluted	2,001	1,980	1,963
Dividends declared per common share	\$ 1.24	\$ 1.15	\$ 1.12

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

**Table of Contents**

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

Dollars in Millions

	Year Ended December 31,		
	2008	2007	2006
<b>COMPREHENSIVE INCOME</b>			
Net Earnings	\$ 5,247	\$ 2,165	\$ 1,585
Other Comprehensive Income/(Loss):			
Foreign currency translation	(123)	240	159
Foreign currency translation reclassified to net earnings due to business divestitures	(12)		
Foreign currency translation on hedge of a net investment	36	(141)	(30)
Derivatives qualifying as cash flow hedges, net of tax of \$3 in 2008, \$24 in 2007 and \$32 in 2006	9	(56)	(73)
Derivatives qualifying as cash flow hedges reclassified to net earnings, net of tax of \$23 in 2008, \$15 in 2007 and \$22 in 2006	42	42	34
Minimum pension liability adjustment, net of tax of \$44 in 2006			82
Pension and postretirement benefits, net of tax of \$697 in 2008 and \$52 in 2007	(1,387)	130	
Pension and postretirement benefits reclassified to net earnings, net of tax of \$50 in 2008 and \$50 in 2007	102	108	
Available for sale securities, net of tax of \$0 in 2008, \$19 in 2007 and \$6 in 2006	(37)	(139)	12
Available for sale securities reclassified to net earnings, net of tax of \$6 in 2008	112		
Total Other Comprehensive (Loss)/Income	(1,258)	184	184
Comprehensive Income	\$ 3,989	\$ 2,349	\$ 1,769
<b>RETAINED EARNINGS</b>			
Retained Earnings at January 1	\$ 19,762	\$ 19,845	\$ 20,464
Cumulative effect of adoption of FIN No. 48		27	
Net earnings	5,247	2,165	1,585
Cash dividends declared	(2,460)	(2,275)	(2,204)
Retained Earnings at December 31	\$ 22,549	\$ 19,762	\$ 19,845

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

**Table of Contents****BRISTOL-MYERS SQUIBB COMPANY****CONSOLIDATED BALANCE SHEETS****Dollars in Millions, Except Share and Per Share Data**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 7,976	\$ 1,801
Marketable securities	289	424
Receivables, net of allowances of \$128 and \$180	3,710	3,994
Inventories, net	1,765	2,162
Deferred income taxes, net of valuation allowances	703	851
Prepaid expenses	320	310
Assets held for sale		560
Total Current Assets	14,763	10,102
Property, plant and equipment, net	5,405	5,650
Goodwill	4,827	4,998
Other intangible assets, net	1,151	1,330
Deferred income taxes, net of valuation allowances	2,137	2,716
Other assets	1,269	1,130