

BRISTOL MYERS SQUIBB CO  
Form 10-K  
February 18, 2011  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

**For the fiscal year ended December 31, 2010**

**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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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.

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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 1,703,707,049 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, 2010) was approximately \$42,490,453,802. Bristol-Myers Squibb has no non-voting common equity. At February 1, 2011, there were 1,702,427,438 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 3, 2011 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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**PART I**

**Item 1. BUSINESS.**  
**General**

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS, the Company, we, our or us) 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. We are engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of biopharmaceutical products on a global basis.

Over the last few years, we executed our strategy to transform into a next generation biopharmaceutical company. This transformation encompassed all areas of our business and operations. As part of this strategy, we have divested our non-pharmaceutical businesses, implemented our acquisition and licensing strategy known as the “string-of-pearls”, and executed our productivity transformation initiative (PTI). With respect to divestitures, we sold our Medical Imaging business in January 2008, sold our ConvaTec business in August 2008, and divested the Mead Johnson Nutrition Company (Mead Johnson) in December 2009. During the same period, we completed numerous acquisition and licensing transactions, such as, Kosan Biosciences, Inc. in June 2008, Medarex, Inc. (Medarex) in September 2009 and ZymoGenetics, Inc. (ZymoGenetics) in October 2010.

We executed our PTI, which was first announced in December 2007, through which we realized \$2.5 billion in annual cost savings and cost avoidance based on previous strategic plans for future years. To achieve this, we reduced general and administrative operations by simplifying, standardizing and outsourcing certain processes and services, rationalized our mature brands portfolio, consolidated our global manufacturing network while eliminating complexity and enhancing profitability, simplified our geographic footprint and implemented a more efficient go-to-market model. We met our goal of \$2.5 billion of cost savings and cost avoidance on an annualized run-rate basis. Because the \$2.5 billion of annual cost savings and avoidance is based on previous strategic plans for future years and because our progress is measured on an annualized run-rate basis, the amount of cost savings and avoidance does not correlate directly with our results of operations. Approximately 60% of the \$2.5 billion in annual cost savings and cost avoidance relates to marketing, selling and administrative expenses, 20-25% relates to costs of products sold, and 15-20% relates to research and development expenses. In addition to the PTI, we continue to review our cost structure with the intent to create a modernized, efficient and robust balance between building competitive advantages, securing innovative products and planning for the future.

We report financial and operating information in one segment BioPharmaceuticals. For additional information about business segments, see Item 8. Financial Statements Note 3. Business Segment Information.

We compete with other worldwide research-based drug companies, smaller research companies and generic drug manufacturers. Our products are sold worldwide, primarily to wholesalers, retail pharmacies, hospitals, government entities and the medical profession. We manufacture products in the United States (U.S.), Puerto Rico and in 6 foreign countries.

U.S. net sales accounted for 65%, 63% and 60% of total net sales in 2010, 2009 and 2008, respectively, while net sales in Europe accounted for 18%, 19% and 21% of total net sales in 2010, 2009 and 2008. Net sales in Japan accounted for 3% of total net sales in 2010, 2009 and 2008. Net sales in Canada accounted for 3% of total net sales in 2010, 2009 and 2008.

**Products**

Our pharmaceutical products include chemically-synthesized drugs, or small molecules, and an increasing portion of products produced from biological processes (typically involving recombinant DNA technology), called biologics. Small molecule drugs are typically administered orally, e.g., in the form of a pill or tablet, although other drug delivery mechanisms are used as well. Biologics are typically administered to patients through injections or by infusion. Most of our revenues come from products in the following therapeutic classes: cardiovascular; virology, including human immunodeficiency virus (HIV) infection; oncology; neuroscience; immunoscience; and metabolics.

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. Our business is focused on innovative biopharmaceutical products, and we rely on patent rights and other forms of regulatory protection to maintain the market exclusivity of our products. In the U.S., the European Union (EU) 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 substantial and rapid declines in the sales of the original innovative product. For further discussion of patent rights and regulatory forms of

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exclusivity, see Intellectual Property and Product Exclusivity below. For further discussion of the impact of generic competition on our business, see *Generic Competition* below.

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The chart below shows our key products together with the year in which the earliest basic exclusivity loss (patent rights or data exclusivity) occurred or is currently estimated to occur in the U.S., the EU, Japan and Canada. We also sell our 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, Japan and Canada. 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, if there is only one 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.

We estimate the market exclusivity period for each of our products on a case-by-case basis for the purposes of business planning only. The length of market exclusivity for any of our 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. 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.

The following schedule presents net sales of our key products and estimated basic exclusivity loss in the U.S., EU, Japanese and Canadian markets:

Dollars in Millions	Net Sales by Products			Past or Currently Estimated Year of Basic Exclusivity Loss			
	2010	2009	2008	U.S.	EU (a)	Japan	Canada
<b>Key Products</b>							
PLAVIX*	\$ 6,666	\$ 6,146	\$ 5,603	2012	2008 <sup>(b)</sup>	++	2012
AVAPRO*/AVALIDE*	1,176	1,283	1,290	2012	2007-2013	++	2011
ABILIFY*	2,565	2,592	2,153	2015 <sup>(h)</sup>	2014 <sup>(i)</sup>	++	2017 <sup>(m)</sup>
REYATAZ	1,479	1,401	1,292	2017	2017-2019 <sup>(c)</sup>	2019	2017
SUSTIVA Franchise (total revenue)	1,368	1,277	1,149	2013 <sup>(d)</sup>	2013 <sup>(d)</sup>	++	2013
BARACLUDE	931	734	541	2015	2011-2016	2016	2011
ERBITUX*	662	683	749	2016 <sup>(e)</sup>	++	2009 <sup>(l)</sup>	2016
SPRYCEL	576	421	310	2020	2020 <sup>(f)</sup>	2021	2020
IXEMPRA	117	109	101	2018	++ <sup>(g)</sup>	++	++
ORENCIA	733	602	441	2019 <sup>(i)</sup>	2017 <sup>(k)</sup>	2018 <sup>(n)</sup>	2012 <sup>(o)</sup>
ONGLYZA/KOMBIGLYZE	158	24		2021	2021	++	2021

Note: The currently estimated earliest year of basic exclusivity loss includes any statutory extensions of exclusivity that have been earned, but not those that have not yet been granted. In some instances, we may be able to obtain an additional six months exclusivity for a product based on the pediatric extension, for example. In certain other 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 our products, but product exclusivity cannot be predicted or assured. Under the new U.S. healthcare law enacted in 2010, qualifying biologic products will receive 12 years of data exclusivity before a biosimilar can enter the market, as described in more detail in Intellectual Property and Product Exclusivity below.

\* Indicates brand names of products which are trademarks not owned by Bristol-Myers Squibb or its subsidiaries. Specific trademark ownership information can be found on page 139.

++ We do not currently market the product in the country or region 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, 2010. 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. However, generic and alternate salt forms of clopidogrel bisulfate are marketed and compete with PLAVIX\* throughout the EU.

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

(d) Exclusivity period relates to the SUSTIVA brand and does not include exclusivity related to any combination therapy.

(e) Biologic product approved under a BLA. Data exclusivity in the U.S. expires in 2016. There is no patent that specifically claims the composition of matter of cetuximab, the active ingredient in ERBITUX\*. Our rights to commercialize cetuximab terminate in 2018.

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

(g)

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Although ixabepilone is not approved to be marketed in the EU, it is approved and marketed in Switzerland and the composition of matter patent is expected to expire in 2018.

- (h) Our rights to commercialize aripiprazole in the U.S. terminate in April 2015.
- (i) Our rights to commercialize aripiprazole in the EU terminate in 2014. Patent protection in Romania and Denmark expired in 2009.
- (j) Biologic product approved under a BLA. Data exclusivity in the U.S. expires in 2017.
- (k) Data exclusivity in the EU expires in 2017. We have a patent covering abatacept in the majority of EU countries that expires in 2012.
- (l) Data exclusivity in Japan expires in 2016.
- (m) Exclusivity period is based on regulatory data protection.
- (n) Exclusivity period is based on regulatory data protection.
- (o) Data exclusivity in Canada expires in 2014.

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Below is a summary of the indication, intellectual property position, product partner, if any, and third-party manufacturing arrangements, if any, for each of the above products in the U.S. and, where applicable, the EU, Japan and Canada.

PLAVIX*	<p>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.</p> <p>In 2009 and 2010, the U.S. PLAVIX* labeling was updated with new warnings on the use of drugs that are strong or moderate CYP 2C19 inhibitors such as PRILOSEC* (omeprazole) that could interfere with PLAVIX* by reducing its effectiveness. The labeling was also updated to include warnings about the variability of response attributed to CYP 2C19 genetic polymorphisms. In 2010, the label was further revised to include a boxed warning concerning the diminished effectiveness of PLAVIX* in patients with the genetic variation leading to the reduced formation of the active metabolite.</p> <p>Clopidogrel bisulfate was codeveloped and is jointly marketed with sanofi-aventis (sanofi). For more information about our alliance with sanofi, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 2. Alliances and Collaborations.</p> <p>The composition of matter patent in the U.S. expires in November 2011 and the FDA has granted us an additional six-month period of exclusivity to market PLAVIX*. Exclusivity for PLAVIX* in the U.S. is expected to expire in May 2012. PLAVIX* is the subject of patent litigation in the U.S. with Apotex and other generic companies and the courts have upheld the validity of the composition of matter patent, entering a judgment in our favor and imposing damages on Apotex for infringing our patent. Apotex is appealing the amount of damages. For more information about these litigation matters, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.</p> <p>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. However, generic and alternative salt forms of clopidogrel bisulfate are marketed and compete throughout the EU.</p> <p>We obtain our bulk requirements for clopidogrel bisulfate from sanofi and a third-party. Both the Company and sanofi finish the product in our own respective facilities.</p>
AVAPRO*/AVALIDE*	<p>AVAPRO*/AVALIDE* (irbesartan/irbesartan-hydrochlorothiazide) is an angiotensin II receptor antagonist indicated for the treatment of hypertension and diabetic nephropathy.</p> <p>Irbesartan was codeveloped and is jointly marketed with sanofi. For more information about our alliance with sanofi, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 2. Alliances and Collaborations.</p> <p>The basic composition of matter patent in the U.S. expires in March 2012 (including a pediatric extension) and in most countries in the EU in 2012 to 2013. Data exclusivity in the EU expired in August 2007 for AVAPRO* and in October 2008 for AVALIDE*.</p> <p>Irbesartan is manufactured by both the Company and sanofi. We manufacture our bulk requirements for irbesartan and finish AVAPRO*/AVALIDE* in our facilities. For AVALIDE*, we purchase bulk requirements for hydrochlorothiazide from a third-party. See Item 1A. Risk Factors <i>We may experience difficulties and delays in the manufacturing, distribution and sale of our products</i> for information on the recent recall and supply shortage.</p>
ABILIFY*	<p>ABILIFY* (aripiprazole) is an atypical antipsychotic agent for adult patients with schizophrenia, bipolar mania disorder and major depressive disorder. ABILIFY* also has pediatric uses in schizophrenia and bipolar disorder, among others.</p> <p>We have a global commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka), except in Japan, China, Taiwan, North Korea, South Korea, the Philippines, Thailand, Indonesia, Pakistan and Egypt. For more information about our arrangement with Otsuka, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 2. Alliances and Collaborations.</p> <p>The basic U.S. composition of matter patent for ABILIFY* expires in April 2015 (including the granted patent term extension and six month pediatric extension). The basic composition of matter patent protecting aripiprazole is the</p>



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subject of patent litigation in the U.S. Otsuka has sole rights to enforce this patent. For more information about this litigation matter, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.

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A composition of matter patent is in force in Germany, the United Kingdom (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.

We obtain our bulk requirements for aripiprazole from Otsuka. Both the Company and Otsuka finish the product in our own respective facilities.

**REYATAZ**

REYATAZ (atazanavir sulfate) is a protease inhibitor for the treatment of HIV. REYATAZ was launched in the U.S. in July 2003.

We developed atazanavir under a worldwide license from Novartis Pharmaceutical Corporation (Novartis) for which a royalty is paid based on a percentage of net sales. We are entitled to promote REYATAZ for use in combination with NORVIR\* (ritonavir) under a non-exclusive license agreement with Abbott Laboratories, as amended, for which a royalty is paid based on a percentage of net sales.

Market exclusivity for REYATAZ is expected to expire in 2017 in the U.S. and the major EU member countries and in 2019 in Japan. Data exclusivity in the EU expires in 2014. Two U.S. patents are the subject of patent litigation in the U.S. For more information about this litigation matter, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.

We manufacture our bulk requirements for atazanavir and finish the product in our facilities.

**SUSTIVA Franchise**

SUSTIVA (efavirenz) is a non-nucleoside reverse transcriptase inhibitor 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 which is included in the combination therapy ATRIPLA\* (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg), a once-daily single tablet three-drug regimen combining our SUSTIVA and Gilead Sciences, Inc.'s (Gilead) TRUVADA\* (emtricitabine and tenofovir disoproxil fumarate). ATRIPLA\* 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 help simplify HIV therapy for patients and providers. For more information about our arrangement with Gilead, see

Strategic Alliances and Collaborations 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; we do not, but another company does, market efavirenz in Japan. Certain ATRIPLA\* patents are the subject of patent litigation in the U.S. At this time, our patents covering efavirenz composition of matter and method of use have not been challenged. For more information about this litigation matter, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.

We obtain our bulk requirements for efavirenz from third parties and produce finished goods in our facilities. We provide bulk efavirenz to Gilead, who is responsible for producing the finished ATRIPLA\* product.

**BARACLUDE**

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 is marketed in over 50 countries outside of the U.S., including China, Japan and the EU.

We have a composition of matter patent that expires in the U.S. in 2015. This patent is the subject of patent litigation in the U.S. For more information about this litigation matter, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.

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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 which has resulted in generic competition in the China market.

We manufacture our bulk requirements for entecavir and finish the product in our facilities.

**Table of Contents****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 for the treatment of patients with EGFR-expressing metastatic colorectal cancer (mCRC) who have failed an irinotecan-based regimen and as monotherapy for patients who are intolerant of irinotecan. The FDA has also 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.

In October 2008, the FDA accepted for filing a supplemental Biologics License Application (sBLA) for first-line squamous cell carcinoma of the head and neck and granted it a priority review status. The FDA has since requested interim data from an additional study to complete the review of this application. We continue to work with the FDA and expect to provide the requested information in 2011. See [Research and Development](#) below for additional information.

ERBITUX\* is marketed in North America by us under an agreement with ImClone Systems Incorporated (ImClone), the predecessor company of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company (Lilly). We share copromotion rights to ERBITUX\* with Merck KGaA in Japan under a codevelopment and cocommercialization agreement signed in October 2007 with ImClone, Merck KGaA and Merck Japan. ERBITUX\* received marketing approval in Japan in July 2008 for use in treating patients with advanced or recurrent colorectal cancer. For a description of our alliance with ImClone, see [Strategic Alliances and Collaborations](#) below and [Item 8. Financial Statements Note 2. Alliances and Collaborations](#).

Data exclusivity in the U.S. expires in 2016. 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 2018 (including the granted patent term extension). 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.

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. We are unable 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\*.

We obtain our finished goods requirements for cetuximab for use in North America from Lilly. Lilly manufactures bulk requirements for cetuximab in its own facilities and finishing is performed by a third-party for Lilly. For a description of our supply agreement with Lilly, see [Manufacturing and Quality Assurance](#) below.

**SPRYCEL**

SPRYCEL (dasatinib) is a multi-targeted tyrosine kinase inhibitor approved for treatment of adults with all phases of chronic myeloid leukemia with resistance or intolerance to prior therapy, including GLEEVEC\* (imatinib mesylate), and for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. In 2010, the FDA approved SPRYCEL for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

SPRYCEL was internally discovered and is part of our strategic alliance with Otsuka. For more information about our alliance with Otsuka, see [Strategic Alliances and Collaborations](#) below and [Item 8. Financial Statements Note 2. Alliances and Collaborations](#).

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A patent term extension has been granted in the U.S. extending the term on the basic composition of matter patent covering dasatinib until June 2020. Dasatinib is the subject of patent litigation in the U.S. For more information about this litigation matter, see Item 8. Financial Statements Note 26. Legal Proceedings and Contingencies.

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In several EU countries, the patent is pending and upon grant, would expire in April 2020 (excluding term extensions). 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.

We manufacture our bulk requirements for dasatinib and finish the product in our facilities.

**IXEMPRA**

IXEMPRA (ixabepilone) is a microtubule inhibitor belonging to a class of antineoplastic agents, the epothilones and their analogs. In 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. We withdrew the marketing authorization application in the EU in March 2009.

IXEMPRA was internally developed and is part of our alliance with Otsuka. For more information about our alliance with Otsuka, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 2. Alliances and Collaborations.

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. In the U.S., New Chemical Entity regulatory exclusivity protection expires in 2012.

Ixabepilone is subject to a license agreement with Helmholtz Zentrum fur Infektionsforschung GmbH (HZI), relating to epothilone technologies for which we pay a royalty based on a percentage of net sales.

We manufacture our bulk requirements for ixabepilone in our facilities including the manufacturing of the active ingredient. The drug product, which comprises a pharmaceutical kit, is finished by Baxter Oncology GmbH.

**ORENCIA**

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.

We have a series of patents covering abatacept and its method of use. In the U.S., a patent term extension has been granted for one of the composition of matter patents, extending the term of the U.S. patent to 2019. In the majority of the EU countries, we have a patent covering abatacept that expires in 2012. In a majority of these EU countries, we have applied for supplementary protection certificates, which would extend the term of the patent if granted. Data exclusivity in the EU expires in 2017.

We obtain bulk abatacept from a third-party and finish the product in our facilities.

**O N G L Y Z A /  
KOMBIGLYZE**

ONGLYZA (saxagliptin), a dipeptidyl peptidase-4 inhibitor, is an oral compound indicated for the treatment of type 2 diabetes as an adjunct to diet and exercise.

KOMBIGLYZE (saxagliptin and metformin) is a combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

Both ONGLYZA and KOMBIGLYZE were codeveloped by the Company and AstraZeneca PLC (AstraZeneca). We have a worldwide (except Japan) codevelopment and cocommercialization agreement with AstraZeneca for

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saxagliptin. For more information about our arrangement with AstraZeneca and with Otsuka for Japan, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 2. Alliances and Collaborations.

We own a patent covering saxagliptin as composition of matter that expires in 2021 in the U.S.

We manufacture our bulk requirements for saxagliptin in our facilities including the manufacturing of the active ingredient. We obtain the bulk metformin HCl for KOMBIGLYZE from a third party. Both the Company and a third-party finish the product in each of their own facilities.

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### **Emerging Markets**

We have refined our focus on emerging markets which represent significant opportunities for growth. Such markets are characterized by strong economic development, a rising gross domestic product, a growing middle class and increasing wealth amongst the middle class as well as a demand for quality healthcare. Emerging markets may provide most of the growth opportunity in the pharmaceuticals industry by the middle of the next decade. Our strategy to capitalize on this growth opportunity is an innovation-focused approach. With this approach, we will develop and commercialize select, innovative products in key high-growth markets, tailoring the approach to each market individually. We have identified five emerging markets on which to focus – Brazil, Russia, India, China and Turkey. The emerging public health interests of these countries best align with our strategy as well as our current portfolio and pipeline. These countries have also been identified as having improving intellectual property protection. In order to capitalize on the growth opportunities in the emerging markets, we must balance related risks as well as develop innovative pricing and access strategies to make products accessible to patients and provide a reasonable return on investment. The risks in these markets include intellectual property protection, currency volatility, reimbursement issues, government stability and scale issues. We monitor and mitigate against these risks to the extent possible.

### **Research and Development**

We invest heavily in research and development (R&D) because we believe it is critical to our long-term competitiveness. We have major R&D facilities in Princeton, Hopewell and New Brunswick, New Jersey, and Wallingford, Connecticut. Pharmaceutical research and development is also carried out at various other facilities throughout the world, including in Belgium, the UK, India and other sites in the U.S. We supplement our internal drug discovery and development programs with alliances and collaborative agreements. These agreements bring new products into the pipeline and help us remain on the cutting edge of technology in the search for novel medicines. In drug development, we engage 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. Management continues to emphasize leadership, innovation, productivity and quality as strategies for success in our research and development activities.

We concentrate our biopharmaceutical research and development efforts in the following disease areas with significant unmet medical need: affective (psychiatric) disorders, Alzheimer's/dementia, cardiovascular (primarily atherosclerosis/thrombosis), diabetes, hepatitis, HIV/AIDS, obesity, oncology, rheumatoid arthritis and related diseases and solid organ transplant. We also continue to analyze and may selectively pursue promising leads in other areas. In addition to discovering and developing new molecular entities, we look for ways to expand the value of existing products through new indications and formulations that can provide additional benefits to patients.

In order for a new drug to reach the market, industry practice and government regulations in the U.S., the EU and most foreign countries provide for the determination of a drug's effectiveness and safety through preclinical tests and controlled clinical evaluation. The clinical development of a potential new drug includes Phase I, Phase II and Phase III clinical trials that have been designed specifically to support a new drug application for a particular indication, assuming the trials are successful. The R&D process typically takes twelve years or longer, with over three years often spent in Phase III, or late-stage, development. We consider our R&D programs in Phase III, or late-stage development, to be our significant R&D programs. These programs include both investigational compounds in Phase III development for initial indications and marketed products that are in Phase III development for additional indications or formulations.

Drug development is time consuming, expensive and risky. 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. Drug candidates can fail at any stage of the process, and even late-stage product candidates sometimes fail to receive regulatory approval. According to the KMR Group, based on industry success rates from 2005-2009, over 90% of the compounds that enter Phase I development fail to achieve regulatory approval. The failure rate for compounds that enter Phase II development is approximately 85% and for compounds that enter Phase III development, it is approximately 45%.

Total research and development expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, as well as clinical trials and medical support of marketed products, proportionate allocations of enterprise-wide costs, and other appropriate costs. We spent \$3.6 billion in both 2010 and 2009 and \$3.5 billion in 2008 on research and development activities. Research and development spending includes payments under third-party collaborations and contracts. At the end of 2010, we employed approximately 8,000 people in R&D activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees and higher-skilled technical personnel.

We manage our R&D programs on a portfolio basis, investing resources in each stage of research and development from early discovery through late-stage development. We continually evaluate our portfolio of R&D assets to ensure that there is an appropriate balance of early-stage and late-stage programs to support the future growth of the Company. Spending on our late-stage development





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programs represents approximately 30-40% of our annual R&D expenses. No individual investigational compound or marketed product represented 10% or more of our R&D expenses in any of the last three years.

Listed below are several late-stage investigational compounds that we have in Phase III clinical trials for at least one potential indication. Whether or not any of these or our other investigational compounds ultimately becomes one of our marketed products depends on the results of 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 we will seek regulatory approval of any of these compounds or that, if such approval is sought, it will be obtained. There is also no assurance that a compound that is approved will be commercially successful. At this stage of development, we 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 includes patent term extensions that have been granted but does not include potential patent term extensions.

ELIQUIS*	ELIQUIS* (apixaban) is an oral Factor Xa inhibitor, targeted at the prevention and treatment of venous thromboembolic (VTE) disorders and stroke prevention in atrial fibrillation. It is currently in the registrational process in the EU for use in VTE prevention and we expect to submit regulatory filings in the U.S. and the EU for an indication in atrial fibrillation in either the third or fourth quarter of 2011. Apixaban was discovered internally and is part of our alliance with Pfizer, Inc. (Pfizer). We own a patent covering apixaban as composition of matter that expires in 2023 in the U.S.
NULOJIX	NULOJIX (belatacept), a biological product, is a fusion protein with novel immunosuppressive activity targeted at prevention of solid organ transplant rejection. It is currently in the registrational process in both the U.S. and the EU for the prophylaxis of organ rejection in kidney transplant patients. We own a patent covering belatacept as composition of matter that expires in 2022 in the U.S.
Brivanib	Brivanib is an oral small molecule dual kinase inhibitor that blocks both the VEGF receptor and the FGF receptor. It is currently in Phase III trials as an anti-cancer treatment with potential use in hepatocellular carcinoma and colorectal cancer. We own a patent covering brivanib as composition of matter that expires in 2023 in the U.S.
Dapagliflozin	Dapagliflozin is an oral SGLT2 inhibitor for the potential treatment of diabetes. It is currently in the registrational process in both the EU and the U.S. It was discovered internally and is part of our alliance with AstraZeneca. We own a patent covering dapagliflozin as composition of matter that currently expires in October 2020 in the U.S.
YERVOY	YERVOY (ipilimumab), a biologic product, is a monoclonal antibody currently in the registrational process for the treatment of metastatic melanoma in the U.S. and the EU. It is also being studied for lung cancer as well as adjuvant melanoma and hormone-refractory prostate cancer. It is in a novel class of agents intended to potentiate elements of the immunologic response. The compound was discovered by Medarex which is now our subsidiary. We own a patent covering ipilimumab as composition of matter that currently expires in 2022 in the U.S.
Necitumumab (IMC-11F8)	Necitumumab is a fully human monoclonal antibody being investigated as an anticancer treatment, which was discovered by ImClone and is part of the alliance between the Company and Lilly. It has been studied outside the U.S. in lung cancer and colorectal cancer and is in Phase III trials in non small cell lung cancer. Lilly owns a patent covering IMC-11F8 as composition of matter that expires in 2025 in the U.S.

During 2010, we terminated our global codevelopment and cocommercialization arrangement for XL-184 (a MET/VEG/RET inhibitor), an oral anti-cancer compound in Phase III clinical trials, with all rights returning to Exelixis, Inc. (Exelixis).

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The following table lists potential additional indications of key marketed products that are in Phase III development:

ERBITUX*	Potential additional indications in first-line non-small cell lung cancer, first-line head and neck cancer, first-line colorectal cancer and gastric cancer.
ORENCIA	Potential subcutaneous formulation and potential additional indication in lupus nephritis.
PLAVIX*	Potential additional indication in vascular event prevention in atrial fibrillation.
SPRYCEL	Potential additional indication in prostate cancer.
IXEMPRA	Potential additional indication in endometrial cancer.
REYATAZ	Potential pediatric indication.
SUSTIVA	Potential pediatric indication.
BARACLUDE	Potential pediatric extension.
ONGLYZA	Potential pediatric extension.

The table below presents key developments that we currently expect to occur during 2011 with respect to our significant pipeline programs. The outcome and timing of these expected developments are dependent upon a number of factors including, among other things, the availability of data, the outcome of certain clinical trials, acceptance of presentations at certain medical meetings and/or actions by health authorities. We do not undertake any obligation to publicly update this information, whether as a result of new information, future events, or otherwise.

ELIQUIS\* Potential EU approval and U.S. submission for VTE prevention.

ARISTOTLE trial results studying apixaban versus warfarin expected mid-2011.

Dapagliflozin Potential U.S. and EU submission for stroke prevention in atrial fibrillation.  
Data from remaining Phase III studies.

NULOJIX Potential U.S. approval for treatment of type 2 diabetes.  
Potential U.S. and EU approvals for prevention of organ rejection in kidney transplant patients.

ORENCIA Three-year Phase III data: potential presentation at the American Transplant Congress in May 2011.  
Potential U.S. approval and EU submission for subcutaneous formulation.

YERVOY Phase II/III lupus nephritis data available.  
Data available from -024 study, combination with dacarbazine (DTIC) in first-line metastatic melanoma.

Potential U.S. and EU approval for second line metastatic melanoma.

Planned Phase III start in lung cancer.

Brivanib

First Phase III study expected to complete in advanced unresectable hepatocellular carcinoma.

ERBITUX\*

Potential U.S. resubmission for first-line non-small cell lung cancer and first-line head and neck cancer.

Potential U.S. submission for first-line colorectal cancer.

#### **Strategic Alliances and Collaborations**

We enter into strategic alliances and collaborations with third parties, some of which give us rights to develop, manufacture, market and/or sell pharmaceutical products that are owned by third parties and some of which give third parties the rights to develop, manufacture, market and/or sell pharmaceutical products that are owned by us. These alliances and collaborations can take many forms, including licensing arrangements, codevelopment and comarketing agreements, copromotion arrangements and joint ventures. Such alliances and arrangements reduce the risk of incurring all research and development expenses for compounds that do not lead to revenue-generating products; however, profitability on alliance products are generally lower, sometimes substantially so, than profitability on our own products that are not partnered because profits from alliance products are shared with our alliance partners. While there can be no assurance that new alliances will be formed, we actively pursue such arrangements and view alliances as an important complement to our own discovery and development activities.

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Each of our strategic alliances and arrangements with third parties who own the rights to manufacture, market and/or sell pharmaceutical products contain customary early termination provisions typically found in agreements of this kind and are generally based on the other party's material breach or bankruptcy (voluntary or involuntary) and product safety concerns. The amount of notice required for early termination generally ranges from immediately upon notice to 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). A number of alliance agreements also permit the collaborator or us to terminate without cause, typically exercisable with substantial advance written notice and often exercisable only after a specified period of time has elapsed after the collaboration agreement is signed. Our 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, we do not retain any rights to a product brought to an alliance by another party or to the other party's intellectual property after an alliance terminates. The loss of rights to one or more products that are marketed and sold by us pursuant to a strategic alliance arrangement could be material to our results of operations and cash flows, and, in the case of PLAVIX\* or ABILIFY\*, could be material to our financial condition and liquidity. As is customary in the pharmaceutical industry, the terms of our strategic alliances and arrangements generally are co-extensive with the exclusivity period and may vary on a country-by-country basis.

Our most significant current alliances and arrangements for both currently marketed products and investigational compounds are described below.

**Current Marketed Products In-Licensed**

**sanofi** We have agreements with sanofi for the codevelopment and cocommercialization of AVAPRO\*/AVALIDE\* and PLAVIX\*. AVAPRO\*/AVALIDE\* is copromoted in certain countries outside the U.S. under the tradename APROVEL\*/COAPROVEL\* and comarketed in certain countries outside the U.S. by us under the tradename KARVEA\*/KARVEZIDE\*. PLAVIX\* is copromoted in certain countries outside the U.S. under the tradename PLAVIX\* and comarketed in certain countries outside the U.S. by us under the tradename ISCOVER\*.

The worldwide alliance operates under the framework of two geographic territories, one covering certain European and Asian countries, referred to as Territory A, and one covering the U.S., Puerto Rico, Canada, Australia and certain Latin American countries, referred to as Territory B. Territory B is managed by two separate sets of agreements: one for PLAVIX\* in the U.S. and Puerto Rico and both products in Australia, Mexico, Brazil, Colombia and Argentina and a separate set of agreements for AVAPRO\*/AVALIDE\* in the U.S. and Puerto Rico only. Within each territory, a territory partnership exists to supply finished product to each country within the territory and to manage or contract for certain central expenses such as marketing, research and development and royalties. Countries within Territories A and B are structured so that our local affiliate and sanofi's local affiliate either comarket separate brands (i.e., each affiliate operates independently and competes with the other by selling the same product under different trademarks), or copromote a single brand (i.e., the same product under the same trademark).

Within Territory A, the comarketing countries include Germany, Spain, Italy (irbesartan only), Greece and China (clopidogrel bisulfate only). We sell ISCOVER\* and KARVEA\*/KARVEZIDE\* and sanofi sells PLAVIX\* and APROVEL\*/COAPROVEL\* in these countries, except China, where we retain the right to, but do 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, Taiwan, South Korea and Hong Kong, and APROVEL\*/COAPROVEL\* in certain French export countries. In 2010 and prior, the Company and sanofi also copromoted PLAVIX\* in Singapore. Sanofi acts as the operating partner for Territory A and owns a 50.1% financial controlling interest in this territory. Our ownership interest in this territory is 49.9%. We account for the investment in partnership entities in Territory A under the equity method and recognize our share of the results in equity in net income of affiliates. Our share of net income from these partnership entities before taxes was \$325 million in 2010, \$558 million in 2009 and \$632 million in 2008.

Within Territory B, the Company and sanofi copromote PLAVIX\* and AVAPRO\*/AVALIDE\* in the U.S., Canada and Puerto Rico. The other Territory B countries, Australia, Mexico, Brazil, Colombia (clopidogrel bisulfate only) and Argentina are comarketing countries. We act as the operating partner for Territory B and own a 50.1% majority controlling interest in this territory. As such, we consolidate all partnership results in Territory B and recognize sanofi's share of the results as net earnings attributable to noncontrolling interest, net of taxes, which was \$1,394 million in 2010, \$1,159 million in 2009 and \$976 million in 2008.

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We recognized net sales in Territory B and Territory A comarketing countries of \$7.8 billion in 2010, \$7.4 billion in 2009 and \$6.9 billion in 2008.

The territory partnerships are governed by a series of committees with enumerated functions, powers and responsibilities. Each territory has two 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 relating to the products in the applicable territory.

The alliance arrangements may be terminated by sanofi or us, 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; (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, we 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 we are not the defaulting party.

For further discussion of our strategic alliance with sanofi, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

Otsuka We maintain a worldwide commercialization agreement with Otsuka, to codevelop and copromote ABILIFY\* (the ABILIFY\* Agreement), except in Japan, China, Taiwan, North Korea, South Korea, the Philippines, Thailand, Indonesia, Pakistan and Egypt. We also have a collaboration agreement with Otsuka relating to certain oncology products (the Oncology Agreement), which is more fully described under *Current Marketed Products Internally Discovered* below.

Under the terms of the ABILIFY\* Agreement, as amended, we purchase the product from Otsuka and perform finish manufacturing for sale by us or Otsuka to third-party customers. The ABILIFY\* Agreement expires in April 2015 in the U.S. and in June 2014 in all EU countries. In each other country where we have the exclusive right to sell ABILIFY\*, the agreement expires on the later of April 20, 2015 or loss of exclusivity in any such country.

In the U.S., Germany, France and Spain, the product is invoiced to third-party customers by us on behalf of Otsuka and we recognize alliance revenue for our contractual share of third-party net sales. In the U.S., our contractual share was 65% of net sales in 2008 and 2009 and was 58% in 2010, under the terms of our agreement with Otsuka to extend the U.S. portion of the ABILIFY\* Agreement described more fully below. We recognized all expenses related to the product in 2008 and 2009. In 2010 Otsuka was responsible for 30% of commercialization expenses related to the product in the U.S. In Germany, France and Spain, our contractual share is 65% of net sales and we recognize all expenses related to the product. In the UK, Italy and Canada, where we are presently the exclusive distributor for the product, we recognize 100% of the net sales and related cost of products sold and expenses. Beginning on January 1, 2011, we will invoice third-party customers in the UK on behalf of Otsuka and the Company will receive 65% of net sales with no expense reimbursement and we will continue to recognize 100% of the net sales and related cost of products sold and expenses in Italy and Canada. We also have an exclusive right to sell ABILIFY\* in other countries in Europe, the Americas and a number of countries in Asia. In these countries we recognize 100% of the net sales and related cost of products sold.

In April 2009, the Company and Otsuka extended the U.S. portion of the ABILIFY\* Agreement until the expected loss of product exclusivity in April 2015. Under the terms of the extension, we paid Otsuka \$400 million. Beginning on January 1, 2011, the share of U.S. net sales that we recognize for ABILIFY\* changed from 58% in 2010 to 53.5% and it will be further reduced to 51.5 % as of January 1, 2012. Otsuka will remain responsible for 30% of the U.S. expenses related to the commercialization of ABILIFY\* in the U.S. during this time.



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Beginning January 1, 2013, and through the expected loss of U.S. exclusivity in April 2015, we will receive the following percentages of U.S. annual net sales:

	Share as a % of U.S. Net Sales
\$0 to \$2.7 billion	50%
\$2.7 billion to \$3.2 billion	20%
\$3.2 billion to \$3.7 billion	7%
\$3.7 billion to \$4.0 billion	2%
\$4.0 billion to \$4.2 billion	1%
In excess of \$4.2 billion	20%

During this period, Otsuka will be responsible for 50% of all U.S. expenses related to the commercialization of ABILIFY\* in the U.S.

The U.S. portion of the ABILIFY\* Agreement and the Oncology Agreement described below include a change-of-control provision if we are acquired. If the acquiring company does not have a competing product to ABILIFY\*, then the new company will assume the ABILIFY\* Agreement (as amended) and the Oncology Agreement as it currently exists. If the acquiring company has a product that competes with ABILIFY\*, Otsuka can elect to request the acquiring company to choose whether to divest ABILIFY\* or the competing product. In the scenario where ABILIFY\* is divested, Otsuka would be obligated to acquire our rights under the ABILIFY\* Agreement (as amended) at a price according to a predetermined schedule. The agreements also provide that in the event of a generic competitor to ABILIFY\* after January 1, 2010, we have the option of terminating the ABILIFY\* April 2009 amendment (with the agreement as previously amended remaining in force). If we were to exercise such option then either (i) we would receive a payment from Otsuka according to a pre-determined schedule and the Oncology Agreement would terminate at the same time or (ii) the Oncology Agreement would continue for a truncated period according to a pre-determined schedule.

Early termination of the ABILIFY\* Agreement 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 has not been dismissed). In addition, termination is available to Otsuka upon 30 days notice in the event that we were to challenge Otsuka's patent rights or, on a market-by-market basis, in the event that we were to market a product in direct competition with ABILIFY\*. Upon termination or expiration of the ABILIFY\* Agreement, we do not retain any rights to ABILIFY\*.

We recognized net sales for ABILIFY\* of \$2.6 billion in both 2010 and 2009 and \$2.2 billion in 2008. In addition to the \$400 million extension payment in 2009, total upfront licensing and milestone payments made to Otsuka under the ABILIFY\* Agreement through 2010 were \$217 million.

For a discussion of our Oncology Agreement with Otsuka, see *Current Marketed Products Internally Discovered* below. For further discussion of our strategic alliance with Otsuka, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Lilly** We have an EGFR commercialization agreement with Lilly through Lilly's subsidiary ImClone for the codevelopment and copromotion of ERBITUX\* and necitumumab (IMC-11F8) in the U.S. as well as codevelopment and copromotion rights to both products in Canada and Japan. For more information on the agreement with respect to necitumumab, see *Investigational Compounds Under Development In-Licensed* below. Under the EGFR agreement, with respect to ERBITUX\* sales in North America, Lilly receives a distribution fee based on a flat rate of 39% of net sales in North America, plus reimbursement of certain royalties paid by Lilly, and the Company and Lilly share one half of the profits and losses evenly in Japan with Merck KgaA receiving the other half of the profits and losses in Japan. The parties share royalties payable to third parties pursuant to a formula set forth in the commercialization agreement. We purchase all of our North American commercial requirements for bulk ERBITUX\* from Lilly. 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 us 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, we do not retain any rights to ERBITUX\*.



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We share codevelopment and copromotion rights to ERBITUX\* with Merck KGaA in Japan under an agreement signed in October 2007, and expiring in 2032, with Lilly, Merck KGaA and Merck Japan. Lilly has the ability to terminate the agreement after 2018 if it determines that it is commercially unreasonable for it 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.

We recognized net sales for ERBITUX\* of \$662 million in 2010, \$683 million in 2009 and \$749 million in 2008.

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For further discussion of our strategic alliance with Lilly, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Gilead** We have a joint venture with Gilead to develop and commercialize ATRIPLA\* in the U.S., Canada and Europe. 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 recognizes 100% of ATRIPLA\* revenues in the U.S., Canada and most countries in Europe. Our revenue for the efavirenz component is determined by applying a percentage to ATRIPLA\* revenue to approximate revenue for the SUSTIVA brand. We recognized efavirenz revenues of \$1,053 million in 2010, \$869 million in 2009 and \$582 million in 2008 related to ATRIPLA\* net sales.

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 a party's component product(s) appear on the market in the U.S., the other party will have the right to terminate the joint venture and thereby acquire all of the rights to the combination product, both in the U.S. and Canada; however, for three years the terminated party will continue to receive a percentage of the net sales based on the contribution of bulk component(s) to ATRIPLA\*, and otherwise retains all rights to its own product(s).

For further discussion of our strategic alliance with Gilead, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Current Marketed Products Internally Discovered**

**AstraZeneca** In January 2007, we entered into a worldwide (except for Japan) codevelopment and cocommercialization agreement with AstraZeneca for ONGLYZA (the Saxagliptin Agreement). KOMBIGLYZE was codeveloped with AstraZeneca under the Saxagliptin Agreement. The exclusive rights to develop and sell ONGLYZA in Japan were licensed to Otsuka in December 2006, which is described below under *Investigational Compounds Under Development Internally Discovered*. The Company and AstraZeneca are also parties to a worldwide codevelopment and cocommercialization agreement for dapagliflozin, which is described below under *Investigational Compounds Under Development Internally Discovered*.

We manufacture ONGLYZA and KOMBIGLYZE and, with certain limited exceptions, recognize net sales in most key markets. We received \$300 million in upfront licensing and milestone payments from AstraZeneca for meeting certain development and regulatory milestones on ONGLYZA and KOMBIGLYZE and could receive up to an additional \$50 million if the remaining development and regulatory milestone under the Saxagliptin Agreement is met and up to an additional \$300 million if all sales-based milestones are met. The majority of costs under the initial development plans through 2008 were paid by AstraZeneca and additional development costs are generally shared equally. We expense ONGLYZA and KOMBIGLYZE development costs, net of AstraZeneca's share, in research and development. The two companies jointly develop the clinical and marketing strategy and share commercialization expenses and profits and losses equally on a global basis, excluding Japan.

For further discussion of our strategic alliance with AstraZeneca, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Otsuka** Simultaneously with the extension of the ABILIFY\* Agreement, in April 2009, the Company and Otsuka entered into an Oncology Agreement for SPRYCEL and IXEMPRA, which includes the U.S., Japan and the EU markets (the Oncology Territory). Beginning in 2010 through 2020, the collaboration fees that we will pay to Otsuka annually are the following percentages of the aggregate net sales of SPRYCEL and IXEMPRA in the Oncology Territory:

	% of Net Sales	
	2010 - 2012	2013 - 2020
\$0 to \$400 million	30%	65%
\$400 million to \$600 million	5%	12%
\$600 million to \$800 million	3%	3%
\$800 million to \$1.0 billion	2%	2%
In excess of \$1.0 billion	1%	1%

During these periods, Otsuka will contribute (i) 20% of the first \$175 million of certain commercial operational expenses relating to the oncology products in the Oncology Territory, and (ii) 1% of such commercial operational expenses relating to the products in the Oncology Territory in excess of \$175 million. Starting in 2011, Otsuka will have the right to copromote SPRYCEL in the U.S. and Japan and in 2012, in

the top five EU markets.

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The Oncology Agreement expires with respect to SPRYCEL and IXEMPRA in 2020 and includes the same change-of-control provision if we were acquired as the ABILIFY\* Agreement described above.

For a discussion of our ABILIFY\* Agreement with Otsuka, see *Current Marketed Products In-Licensed* above. For further discussion of our strategic alliance with Otsuka, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Investigational Compounds Under Development In-Licensed**

**Exelixis** In October 2010, we entered into two collaboration agreements with Exelixis, one for license to Exelixis small-molecule TGR5 agonist program including backups (the TGR5 Agreement) and the second to collaborate, discover, optimize and characterize small-molecule ROR antagonists (the ROR Agreement). We paid Exelixis an initial payment of \$40 million and could pay additional development and approval milestones of up to \$250 million on the TGR5 Agreement and \$255 million on the ROR Agreement. Exelixis is also eligible to receive sales performance milestones, and royalties on net sales of products from each of the TGR5 and ROR programs. We received an exclusive worldwide license to develop and commercialize small molecule TGR5 agonists and ROR antagonists. Under the TGR5 agreement, we have sole responsibility for research, development, manufacturing and commercialization. Under the ROR agreement, we are collaborating with Exelixis on ROR antagonist programs up to a pre-clinical transition point and then we have sole responsibility for the further research, development, manufacture, and commercialization of any resulting products.

In December 2008, the Company and Exelixis entered into a global codevelopment and cocommercialization arrangement for XL-184 and a license for XL-281 with utility in RAS and RAF mutant tumors under development by Exelixis. Under the terms of the arrangement, we paid Exelixis \$195 million upon execution of the agreement and an additional \$45 million in 2009. In June, 2010, the Company terminated its development collaboration with Exelixis for XL-184 with all rights returning to Exelixis resulting in a \$17 million termination fee which was expensed in research and development. The Company could pay Exelixis development and regulatory milestones up to \$315 million and up to an additional \$150 million of sales-based milestones related to XL-281.

In addition, the Company and Exelixis have a history of collaborations to identify, develop and promote oncology targets. In January 2007, 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, we paid Exelixis \$100 million of upfront licensing and milestone payments to date. Pursuant to an amendment to this agreement that was executed in October 2010, Exelixis has opted-out of further codevelopment of XL-139, and the Company made a payment to Exelixis in the amount of \$20 million. As a result, the Company has received an exclusive worldwide license to develop and commercialize XL-139 and will have sole responsibility for the further development, manufacture, and commercialization of the compound. If successful, we will pay Exelixis development and regulatory milestones up to \$170 million and up to an additional \$90 million of sales-based milestones, as well as royalties. Royalty percentage rates are tiered based on net sales.

We hold an equity interest in Exelixis, which at December 31, 2010 represented less than 1% of their outstanding shares.

**Lilly** In January 2010, the Company and Lilly restructured the EGFR commercialization agreement to provide for the codevelopment and cocommercialization of necitumumab (IMC-11F8), a fully human antibody currently in Phase III development for non-small cell lung cancer. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Product and Pipeline Developments for an update on one Phase III trial. As restructured, both companies will share in the cost of developing and will share in the profits and losses upon commercializing necitumumab in the U.S., Canada and Japan. Lilly maintains exclusive rights to necitumumab in all other markets. We will fund 55% of development costs for studies that will be used only in the U.S. and will fund 27.5% for global studies. We will pay \$250 million to Lilly as a milestone payment if first approval is granted in the U.S. In the U.S. and Canada, we will recognize all sales and will receive 55% of the profits (and bear 55% of the losses) for necitumumab. Lilly will provide 50% of the selling effort and the parties will, in general, equally participate in other commercialization efforts. In Japan, the Company and Lilly will share commercial costs and profits evenly. The agreement as it relates to necitumumab continues beyond patent expiration until both parties agree to terminate. Lilly will manufacture the bulk requirements and we will assume responsibility for fill/finish of necitumumab beginning in 2011.

**Alder** In November 2009, the Company and Alder Biopharmaceuticals, Inc. (Alder) entered into a global agreement for the development and commercialization of ALD518, a novel biologic that has completed Phase IIa development for the treatment of rheumatoid arthritis. Under the terms of the collaboration agreement, Alder granted us worldwide exclusive rights to develop and commercialize ALD518 for all potential indications except cancer, for which Alder retains rights and has granted us an option to codevelop ALD518 for cancer and to have exclusive rights to commercialize ALD518 for cancer outside the United States. We paid Alder an \$85 million upfront licensing payment in 2009, all of which was expensed as research and development. In addition, we could pay up to \$764 million of development-based and regulatory-based milestone payments, potential sales-based milestones which, under certain circumstances, may exceed \$200 million, and royalties on net sales. Royalty percentage rates are tiered based on net sales. If we choose the option to pursue cancer indications then we could pay up to an additional

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\$185 million of development-based and regulatory-based milestone payments, the aforementioned sales-based milestones and royalties on net sales. Royalty percentage rates are tiered based on net sales.

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**Investigational Compounds Under Development Internally Discovered**

**AstraZeneca** As mentioned above, we have a worldwide codevelopment and cocommercialization agreement with AstraZeneca for dapagliflozin (the SGLT2 Agreement). Dapagliflozin is being studied for the potential treatment of diabetes and was discovered by us.

Under the SGLT2 Agreement, we have received \$50 million of upfront licensing payments from AstraZeneca and could receive up to \$350 million more if all development and regulatory milestones are met for dapagliflozin and up to an additional \$390 million if all sales-based milestones are met. The majority of costs under the initial plans through 2009 were paid by AstraZeneca and any additional development costs will generally be shared equally except for Japan, where AstraZeneca bears substantially all of the development costs prior to approval of the first indication. We expense dapagliflozin development costs, net of our alliance partner's share, in research and development. Under the SGLT2 Agreement, like with the Saxagliptin Agreement, the two companies will jointly develop the clinical and marketing strategy and share commercialization expenses and profits and losses for dapagliflozin equally on a global basis, and we will manufacture dapagliflozin and, with certain limited exceptions, recognize net sales in most key markets. With respect to Japan, AstraZeneca has operational and cost responsibility for all development and regulatory activities on behalf of the collaboration, though the two companies will jointly market the product in Japan, sharing all commercialization expenses and activities and splitting profits and losses equally like in the rest of the world. We will also manufacture dapagliflozin and recognize net sales in Japan, like in the rest of the world. Dapagliflozin is currently being studied in Phase II clinical trials in Japan.

For further discussion of our strategic alliance with AstraZeneca, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Pfizer** The Company and Pfizer are parties to a worldwide codevelopment and cocommercialization agreement for ELIQUIS\*, an anticoagulant discovered by us and being studied for the prevention and treatment of a broad range of venous and arterial thrombotic conditions. Pfizer funds 60% of all development costs since January 2007 and we fund 40%. We have received \$474 million in upfront licensing and milestone payments from Pfizer to date, including a \$10 million milestone in 2010 for the filing of the marketing authorization application in the EU, and could receive up to an additional \$620 million from Pfizer if all development and regulatory milestones are met. The companies jointly develop the clinical and marketing strategy of ELIQUIS\*, and will share commercialization expenses and profits and losses equally on a global basis.

For further discussion of our strategic alliance with Pfizer, see Item 8. Financial Statements Note 2. Alliances and Collaborations.

**Otsuka** In January 2007, we granted Otsuka exclusive rights in Japan to develop and commercialize ONGLYZA. We are entitled to receive milestone payments based on certain regulatory events, as well as sales-based payments following regulatory approval of ONGLYZA in Japan. We retained rights to copromote ONGLYZA with Otsuka in Japan. Otsuka is responsible for all development costs in Japan.

**Royalty and Other Licensing Arrangements**

In addition to the strategic alliances described above, we have other in-licensing and out-licensing arrangements. With respect to in-licenses, we have agreements with Novartis for REYATAZ and with HZI for IXEMPRA, among others. Based on our current expectations with respect to the expiration of market exclusivity in our significant markets, the licensing arrangements with Novartis for REYATAZ are expected to expire in 2017 in the U.S. and the EU and 2019 in 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, Japan and Canada, see Products above.

As a result of our acquisitions of Medarex in August 2009 and ZymoGenetics in October 2010, we own certain compounds out-licensed to third parties for development and commercialization. We expect to receive milestone payments as these compounds move through the regulatory process and royalties based on product sales, if and when the products are commercialized.

**Intellectual Property and Product Exclusivity**

We own or license a number of patents in the U.S. and foreign countries primarily covering our products. We have also developed many brand names and trademarks for our products. We consider the overall protection of our patents, trademarks, licenses and other intellectual property rights to be of material value and act to protect these rights from infringement.

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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. 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, in the U.S., the EU, Japan, Canada and certain other markets, regulatory intellectual property rights are offered as incentives for research on medicines for rare diseases, or orphan drugs, and on medicines useful in treating pediatric patients. These incentives can extend the market exclusivity period on a product beyond the patent term.

The U.S., EU, Japan and Canada also 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, or data protection. In certain markets where patent protection and other forms of market exclusivity may have expired, data protection can be of particular importance. 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.

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

### *United States*

In the U.S., most of our key products are protected by patents with varying terms depending on the type of patent and the filing date. A significant portion of a product's patent life, however, is lost during the time it takes an innovative company to develop and obtain regulatory approval of a new drug. As compensation at least in part for the lost patent term, the innovator may, depending on a number of factors, extend the expiration date of one patent up to a maximum term of five years, provided that the extension cannot cause the patent to be in effect for more than 14 years from the date of drug approval.

A company seeking to market an innovative pharmaceutical in the U.S. must submit a complete set of safety and efficacy data to the FDA. If the innovative pharmaceutical is a chemical, the company files a New Drug Application (NDA). If the medicine is a biological product, a Biologics License Application (BLA) is filed. The type of application filed affects regulatory exclusivity rights.

### Chemical products

A competitor seeking to launch a generic substitute of a chemical innovative drug in the U.S. must file an abbreviated NDA (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.

An 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. From time to time, aNDAs, including Paragraph IV certifications, are filed with respect to certain of our products. We evaluate these aNDAs on a case-by-case basis and, where warranted, file suit against the generic manufacturer to protect our patent rights.

In addition to benefiting from patent protection, certain innovative pharmaceutical products can receive periods of regulatory exclusivity. A NDA that is designated as an orphan drug 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. 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.





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Medicines approved under a NDA can also receive several types of regulatory data protection. An innovative chemical pharmaceutical is entitled to five years of regulatory data protection in the U.S., during which competitors cannot file with the FDA for approval of generic substitutes. If an innovator's patent is challenged, as described above, a generic manufacturer may file its aNDA after the fourth year of the five-year data protection period. A pharmaceutical drug product that contains an active ingredient that has been previously approved in an NDA, but is approved in a new formulation, but not for the drug itself, or for a new indication on the basis of new clinical trials, receives three years of data protection for that formulation or indication.

### Biologic products

Under the new U.S. healthcare legislation enacted in 2010, there is now an abbreviated path for regulatory approval of biosimilar versions of biological products. The new path for approval of biosimilar products under the U.S. healthcare legislation significantly affects the regulatory data exclusivity for biological products. The new legislation provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. The legislation created an approval pathway for biosimilar versions of biological products, which did not previously exist. Innovative biological products no longer receive the essentially unlimited regulatory data exclusivity that existed prior to creation of a regulatory path for biosimilar versions. Under the new law, after an innovator has marketed its biological product for four years, a biosimilar manufacturer may file an application for approval of a biosimilar version of the innovator product. However, although an application for approval of a biosimilar may be filed four years after approval of the innovator product, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. The new law also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA.

In the U.S., the increased likelihood of generic and biosimilar 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. Second, statutory and regulatory provisions in the U.S. limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity.

### European Union

Patents on pharmaceutical products are generally enforceable in the EU and, as in the U.S., 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.

The primary route we use to obtain marketing authorization of pharmaceutical products in the EU is through the centralized procedure. This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the European Commission (EC) and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a mutual recognition procedure, in which an application is made to a single member state, and if the member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states.

After obtaining marketing authorization approval, a company must obtain pricing and reimbursement for the pharmaceutical product, which is typically subject to member state law. In certain EU countries, this process can take place simultaneously while the product is marketed but in other EU countries, this process must be completed before the company can market the new product. The pricing and reimbursement procedure can take months and sometimes years to complete.

Throughout the EU, all products for which marketing authorizations have been filed after October/November 2005 are subject to an 8+2+1 regime. Eight years after the innovator has received its first community authorization for a medicinal product, a generic company may file a marketing authorization application for that product with the health authorities. If the marketing authorization application is approved, 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 extension to 11 years 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. For products that were filed prior to October/November 2005, 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).



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In contrast to the U.S., patents in the EU are not listed with regulatory authorities. Generic versions of pharmaceutical products 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.

In general, EU law treats chemically-synthesized drugs and biologically-derived drugs the same with respect to intellectual property and data protection. In addition to the relevant legislation and annexes related to biologic medicinal products, the EMA has issued guidelines that outline the additional information to be provided for biosimilar products, also known as generic biologics, in order 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.

### *Canada*

In Canada as of 2006, 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. Currently, unlike the U.S., Canada has no patent term restoration to compensate for the patent term lost during the regulatory review process.

In Canada, biologics are generally treated the same as chemically-synthesized products with respect to patent rights and regulatory exclusivity. Health Canada has issued draft guidance that outlines the additional information to be provided for Subsequent Entry Biologics, also known as biosimilar products or generic biologics, in order to review an application for marketing approval.

### *Rest of World*

In countries outside of the U.S., the EU, Japan and Canada, 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. 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 our innovative drugs in developing countries, we take into account not only formal legal rights but political and other factors as well.

## **Marketing, Distribution and Customers**

We promote the appropriate use of our products directly to healthcare professionals and providers such as doctors, nurse practitioners, physician assistants, pharmacists, technologists, hospitals, Pharmacy Benefit Managers (PBMs) and Managed Care Organizations (MCOs). We also provide information about the appropriate use of our products to consumers in the U.S. through direct-to-consumer print, radio and television advertising. In addition, we sponsor general advertising to educate the public about our innovative medical research. For a discussion of the regulation of promotion and marketing of pharmaceuticals, see [Government Regulation and Price Constraints](#) below.

Through our sales and marketing organizations, we explain the approved uses and risks and benefits of our products to medical professionals. We work to gain access to health authorities, PBM and MCO formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by providing information about the clinical profile of our products. Marketing of prescription pharmaceuticals is limited to the approved uses of the particular product, but we continue to develop scientific data and other information about our products and provide such information in response to unsolicited inquiries from doctors, other medical professionals and managed care organizations.



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Our operations include several 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 key primary care physicians.

Our products are sold principally to wholesalers, and to a lesser extent, directly to distributors, retailers, hospitals, clinics, government agencies and pharmacies. Gross sales to the three largest pharmaceutical wholesalers in the U.S. as a percentage of our total gross sales were as follows:

	2010	2009	2008
McKesson Corporation	24%	25%	24%
Cardinal Health, Inc.	21%	20%	19%
AmerisourceBergen Corporation	16%	15%	14%

Our U.S. business has Inventory Management Agreements (IMAs) with substantially all of our direct wholesaler and distributor customers that allow us to monitor U.S. wholesaler inventory levels and requires those wholesalers to maintain inventory levels that are no more than one month of their demand. The IMAs have two-year terms, through December 31, 2012, subject to certain termination provisions.

In a number of smaller markets outside of the U.S. and the EU, we have moved to a distributor-based model of promotion and distribution. We have entered into contracts with one or more distributors in those markets who purchase our products from us and then promote and sell them within those countries. Sales in these distributor-based markets represented less than 1% of the Company's net sales in 2010.

**Competition**

The markets in which we compete are generally broad based and highly competitive. We compete 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, customer service and research and development of new products and processes. Sales of our products can be impacted by new studies that indicate a competitor's product is safer or more effective for treating a disease or particular form of disease than one of our products. Our sales also can be impacted by additional labeling requirements relating to safety or convenience that may be imposed on products by the FDA or by similar regulatory agencies in different countries. If competitors introduce new products and processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both.

*Generic Competition*

One of the biggest competitive challenges that we face is from generic pharmaceutical manufacturers. In the U.S. and the EU, the regulatory approval process exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. As a result, generic pharmaceutical manufacturers 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. Upon the expiration or loss of market exclusivity on a product, we can lose the major portion of sales of that product in a very short period of time.

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, though we have observed rapid declines in a number of EU countries as well. 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 key 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.

In certain countries outside the U.S., patent protection is weak or nonexistent and we must compete with generic versions shortly after we launch our innovative products. In addition, generic pharmaceutical companies may introduce a generic product before exclusivity has expired, and before the resolution of any related patent litigation. For more information about market exclusivity, see [Intellectual Property and Product Exclusivity](#) above.



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We believe our long-term competitive position depends upon our success in discovering and developing innovative, cost-effective products that serve unmet medical needs, together with our ability to manufacture products efficiently and to market them effectively in a highly competitive environment.

### **Managed Care Organizations**

The growth of MCOs in the U.S. is also a major factor in the healthcare marketplace. Over half of the U.S. population now participates in some version of managed care. MCOs can include medical insurance companies, medical plan administrators, health-maintenance organizations, Medicare Part D prescription drug plans, alliances of hospitals and physicians and other physician organizations. Those organizations have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance to us.

To successfully compete for business with MCOs, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care. Most new products that we introduce compete with other products already on the market or products that are later developed by competitors. As noted above, generic drugs are exempt from costly and time-consuming clinical trials to demonstrate their safety and efficacy and, as such, often have lower costs than brand-name drugs. MCOs that focus primarily on the immediate cost of drugs often favor generics for this reason. Many governments also encourage the use of generics as alternatives to brand-name drugs in their healthcare 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 essentially equivalent to a brand-name drug. The substitution must be made unless the prescribing physician expressly forbids it.

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. We have been generally, although not universally, successful in having our major products included on MCO formularies.

### **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 our 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, our operations are subject to complex Federal, state, local, and foreign environmental and occupational safety laws and regulations. We anticipate 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 and expense as well as significant capital investments.

Of particular importance is the FDA in the U.S. It has jurisdiction over virtually all of our activities and imposes requirements covering the testing, safety, effectiveness, manufacturing, labeling, marketing, advertising and post-marketing surveillance of our products. In many cases, FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the U.S.

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, recordkeeping and quality control to ensure that products meet applicable specifications and other requirements to ensure product safety and efficacy. The FDA periodically inspects our drug manufacturing facilities to ensure compliance with applicable cGMP requirements. Failure to comply with the statutory and regulatory requirements subjects us 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 product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy occur following approval.

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

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condition and results of operations and cash flows. For discussion of the warning letter we received relating to our manufacturing site in Manati, Puerto Rico, see Item 1A. Risk Factors *We may experience difficulties and delays in the manufacturing, distribution and sale of our products* and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations 2010 Highlights.



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Marketing authorization for our 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 product diversions. For discussion of recent settlement of certain investigations of drug pricing and sales and marketing activities, see Item 8. Financial Statements Note 26. 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 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 healthcare laws that are used to protect the integrity of government healthcare 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 healthcare program. The OIG has issued a series of Guidances to segments of the healthcare 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. We subscribe to the PhRMA Code, and have implemented a compliance program to address the requirements set forth in the OIG Guidance and our compliance with the healthcare laws. Failure to comply with these healthcare laws could subject us to administrative and legal proceedings, including actions by Federal and state 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 our business, financial condition and results of operations and cash flows.

We are 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. We are also licensed by the U.S. Drug Enforcement Agency to procure and produce controlled substances. We are, therefore, subject to possible administrative and legal proceedings and actions by these organizations. Such actions may result in the imposition of civil and criminal sanctions, which may include fines, penalties and injunctive or administrative remedies.

Our activities outside the U.S. are also subject to regulatory requirements governing the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of our products. These regulatory requirements vary from country to country. Whether or not FDA approval or approval of the EMA 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 a product will be approved in another country.

In many markets outside the U.S., we operate 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. In most EU countries, for example, the government regulates pricing of a new product at launch often through direct price controls, international price comparisons, controlling profits and/or reference pricing. In other markets, such as the UK and Germany, the government does not set pricing restrictions at launch, but pricing freedom is subsequently limited, such as by the operation of a profit and price control plan in the UK and by the operation of a reference price system in Germany. Companies also face significant delays in market access for new products, mainly in France, Spain, Italy and Belgium, 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 the EU due to the different national pricing and reimbursement laws leads to significant parallel trade flows.



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Both in the U.S. and internationally, the healthcare industry is subject to various government-imposed regulations authorizing prices or price controls that have and will continue to have an impact on our net sales. In March 2010, the U.S. government enacted healthcare reform legislation, signing into law the Patient Protection and Affordable Care Act (HR 3590) and a reconciliation bill containing a package of changes to the healthcare bill. The new legislation makes extensive changes to the current system of healthcare insurance and benefits intended to broaden coverage and reduce costs. These bills significantly change how Americans receive healthcare coverage and how they pay for it. They also have a significant impact on companies, in particular those companies in the pharmaceutical industry and other healthcare related industries, including BMS. We have experienced and will continue to experience additional financial costs and certain other changes to our business as the new healthcare law is implemented. For example, minimum rebates on our Medicaid drug sales have increased from 15.1 percent to 23.1 percent and Medicaid rebates have also been extended to drugs used in risk-based Medicaid managed care plans. In addition, we extend discounts to certain critical access hospitals, cancer hospitals and other covered entities as required by the expansion of the 340B Drug Pricing Program under the Public Health Service Act.

In 2011, we will also provide a 50 percent discount on our brand-name drugs to patients who fall within the Medicare Part D coverage gap, also referred to as the "Donut Hole" and we will pay an annual non-tax-deductible fee to the federal government based on an allocation of our market share of branded prior year sales to certain government programs including Medicare, Medicaid, Department of Veterans Affairs, Department of Defense and TRICARE. This fee will be classified for financial reporting purposes as an operating expense. Estimates for these new discounts and the new pharmaceutical company fee under the 2010 U.S. healthcare reform law, including related regulations for Medicare coverage gap, managed Medicaid and expansion of the Public Health Service 340B program require additional assumptions due to lack of historical claims experience.

In many markets outside the U.S., we operate 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 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.

Federal and state governments also have pursued direct methods to reduce the cost of drugs for which they pay. We participate in state government 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. We also participate in government programs that specify discounts to certain 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 programs in which we participate provide discounts for outpatient medicines purchased by certain specified entities under Section 340B of the Public Health Service Act.

For further discussion of these rebates and programs, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations "Net Sales" and "Critical Accounting Policies."

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

In general, we purchase our raw materials and supplies required for the production of our products in the open market. For some products, we purchase our raw materials and supplies from one source (the only source available to us) or a single source (the only approved source among many available to us), thereby requiring us to obtain such raw materials and supplies from that particular source. We attempt, if possible, to mitigate our raw material supply risks, through inventory management and alternative sourcing strategies. For further discussion of sourcing, see "Manufacturing and Quality Assurance" below and discussions of particular products.

### **Manufacturing and Quality Assurance**

To meet all expected product demand, we operate and manage our manufacturing network, including our third-party contract manufacturers, and the inventory related thereto, in a manner that permits us to improve efficiency while maintaining flexibility 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 as well as regulatory approvals, we maintain and operate our flexible manufacturing network, consisting of internal and external resources that minimize unnecessary product transfers and inefficient uses of manufacturing capacity. For further discussion of the regulatory impact on our manufacturing, see "Government Regulation and Price Constraints" above.



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Pharmaceutical manufacturing facilities require significant ongoing capital investment for both maintenance and compliance with increasing regulatory requirements. In addition, as our product line changes over the next several years, we expect to modify our 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. In February 2007, we purchased an 89-acre site to locate our large scale multi-product bulk biologics manufacturing facility in Devens, Massachusetts. Construction of the Devens, Massachusetts facility began in early 2007 and was substantially completed in 2009. We expect to submit the site for regulatory approval in late 2011 or 2012.

We rely on third parties to manufacture or supply us with active ingredients necessary for us to manufacture certain products, including PLAVIX\*, BARACLUDGE, AVALIDE\*, REYATAZ, ABILIFY\*, ERBITUX\*, the SUSTIVA Franchise, ORENCIA, ONGLYZA and KOMBIGLYZE. To maintain a stable supply of these products, we take 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 to be held by the third-party supplier, us or both, so that our manufacturing operations are not interrupted. As an additional protection, in some cases, we take steps to maintain an approved back-up source where available. For example, we will rely on the combined capacity of our Devens, Massachusetts, Syracuse, New York, and Manati, Puerto Rico facilities, and the capacity available at our third-party contract manufacturers to manufacture ORENCIA and the commercial quantities of our other investigational biologics compounds in late-stage development should those compounds receive regulatory approval.

If we or any third-party manufacturer that we rely on for existing or future products is unable to maintain a stable supply of products, operate at sufficient capacity to meet our order requirements, comply with government regulations for manufacturing pharmaceuticals or meet the heightened processing requirements for biologics, our business performance and prospects could be negatively impacted. Additionally, if we or any of our third-party suppliers were to experience extended plant shutdowns or substantial unplanned increases in demand or suspension of manufacturing for regulatory reasons, we 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 our products, or in certain other circumstances, we have entered into agreements under which we have agreed to supply such products to third parties. In addition to liabilities that could arise from our failure to supply such products under the agreements, these arrangements could require us 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 our own products.

Our success depends in great measure upon customer confidence in the quality of our 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 our operations, including research and development, purchasing, facilities planning, manufacturing, and distribution. We maintain 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. We perform tests at various stages of production processes and on the final product to ensure that the product meets regulatory requirements and our standards. These tests may involve chemical and physical chemical analyses, microbiological testing, or a combination of these along with other analyses. Quality control is provided by business unit/site quality assurance groups that monitor existing manufacturing procedures and systems used by us, our subsidiaries and third-party suppliers.

## **Environmental Regulation**

Our 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 our operations, and these permits are subject to modification, renewal or revocation by the issuing authorities.

Our environment, health and safety group monitors our operations around the world, providing us with an overview of regulatory requirements and overseeing the implementation of our standards for compliance. We also incur operating and capital costs for such matters on an ongoing basis. We expended approximately \$15 million in 2010, \$34 million in 2009 and \$41 million in 2008 on capital projects undertaken specifically to meet environmental requirements. Although we believe that we are in substantial compliance with applicable environmental, health and safety requirements and the permits required for our operations, we 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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Many of our current and former facilities have been in operation for many years, and over time, we and other operators of those facilities have generated, used, stored or disposed of substances or wastes that are considered hazardous under Federal, state and/or 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 we 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, we are involved in investigation and remediation at 13 current or former facilities. We have also been identified as a potentially responsible party (PRP) under applicable laws for environmental conditions at approximately 25 former waste disposal or reprocessing facilities operated by third parties at which investigation and/or remediation activities are ongoing.

We 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 we bear remediation responsibility pursuant to contractual 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 26. Legal Proceedings and Contingencies.

## **Employees**

As of December 31, 2010, we employed approximately 27,000 people.

During 2010, we continued to implement our comprehensive cost reduction program that included work force reductions and the rationalization of facilities.

For further discussion about PTI and restructuring activities, see Item 8. Financial Statements Note 4. Restructuring.

## **Foreign Operations**

We have significant operations outside the U.S. They are conducted both through our subsidiaries and through distributors.

For a geographic breakdown of net sales, see the table captioned Geographic Areas in Item 8. Financial Statements Note 3. Business Segment Information and for further discussion of our net 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. Our 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 decrease the reported dollar value of our net assets and results of operations. In 2010, the change in foreign exchange rates had a net favorable impact on the growth rate of revenues. While we cannot predict with certainty future changes in foreign exchange rates or the effect they will have on it, we attempt 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 24. Financial Instruments.

## **Bristol-Myers Squibb Website**

Our internet website address is [www.bms.com](http://www.bms.com). On our website, we make available, free of charge, our annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnishes such material to, the U.S. Securities and Exchange Commission (SEC).

Information relating to corporate governance at Bristol-Myers Squibb, including our 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 our Executive Committee, Board of Directors, including Board Committees and Committee charters, and transactions in Bristol-Myers Squibb securities by directors and executive officers, is available on our 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

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on our website. Information relating to stockholder services, including our Dividend Reinvestment Plan and direct deposit of dividends, is available on our website under the [Investors Stockholder Services](#) caption.

We incorporate by reference certain information from parts of our proxy statement for the 2011 Annual Meeting of Stockholders. The SEC allows us to disclose important information by referring to it in that manner. Please refer to such information. Our proxy statement for the 2011 Annual Meeting of Stockholders and 2010 Annual Report will be available on our website under the [Investors SEC Filings](#) caption on or about March 21, 2011.



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

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

***We face intense competition from other pharmaceutical manufacturers, including both innovative medicines and lower-priced generic products.***

*Competition from manufacturers of competing products, including lower-priced generic versions of our products is a major challenge, both within the U.S. and internationally. We are facing 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 our current products; (ii) technological advances and patents attained by competitors; (iii) results of clinical studies related to our products or a competitor's products; (iv) earlier-than-expected competition from generic companies; and (v) business combinations among our competitors and major customers. We also could experience limited or no market access due to real or perceived differences in value propositions of our products compared with competing products.*

***We depend on key products for most of our net sales, cash flows and earnings.***

*We derive a majority of our revenue and earnings from a few key products. In 2010, net sales of PLAVIX\* contributed approximately \$6.7 billion, representing approximately 34% of total net sales. Net sales of ABILIFY\* contributed approximately \$2.6 billion, representing approximately 13% of total net sales. Three other products (AVAPRO\*/AVALIDE\*, REYATAZ and the SUSTIVA Franchise) each contributed more than \$1.1 billion in net sales. A reduction in sales of one or more of these or other key products could significantly negatively impact our net sales, cash flows and earnings. In January 2011, we and our partner sanofi voluntarily recalled certain lots of AVALIDE\* from the U.S., Puerto Rican, Canadian, Mexican and Argentinean markets. Supply of AVALIDE\* to these markets may be affected indefinitely. Total AVALIDE\* sales in these countries were \$355 million in 2010. We are working with our partner sanofi to identify all possible solutions to this issue, including process adjustments and alternate supply sources. If we are unable to resupply to these markets in a timely manner, this may have a negative impact on our net sales, cash flows and earnings.*

***Market exclusivity for PLAVIX\* and AVAPRO\*/AVALIDE\* in the U.S. is expected to expire in May 2012 and March 2012, respectively.***

*PLAVIX\* is our top-selling product, with worldwide net sales of approximately \$6.7 billion and U.S. net sales of approximately \$6.2 billion in 2010. We expect that when PLAVIX\* loses exclusivity in May 2012, there may be a rapid, precipitous and material decline in PLAVIX\* net sales and a reduction in net income and operating cash flow. AVAPRO\*/AVALIDE\* loses patent protection in March 2012 after which we may experience a precipitous decline in AVAPRO\*/AVALIDE\* net sales. If we are unable to support and grow our currently marketed products, advance our late-stage pipeline and manage our costs effectively, the loss of exclusivity for PLAVIX\* and AVAPRO\*/AVALIDE\* could have a significant or material negative impact on our results of operations, cash flows and financial condition.*

***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 EU and PLAVIX\* faces competition from generic and alternate salt forms of clopidogrel bisulfate throughout the EU. Over the last two years, PLAVIX\* has experienced substantial market share erosion and price discounts. In 2010, PLAVIX\* sales in the EU decreased and, as such, our international net sales from PLAVIX\* and our equity in net income of affiliates decreased by 13% and 43%, respectively, compared to 2009 and are expected to continue to decline in 2011.*

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

*In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it 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 usually 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 our products is based upon patent rights and/or certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in that country. The failure to obtain patent and other intellectual property rights, or limitations on the use or loss of such rights, could be material to us. In some countries, including in certain EU member states, basic patent protection for our products may not exist because certain countries did not historically offer the right to obtain certain types of patents and/or we (or our 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.*

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*Manufacturers of generic products are also increasingly seeking to challenge patents before they expire. Key patents covering five of our key products (ABILIFY\*, ATRIPLA\*, BARACLUDE, REYATAZ, and SPRYCEL) are currently the subject of patent litigation. In some cases, generic manufacturers may choose to launch a generic product at risk 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 our 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.*

***We face increased pricing pressure and other restrictions in the U.S. and abroad from managed care organizations, institutional purchasers, and government agencies and programs that could negatively affect our net 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 organizations and institutional and governmental purchasers, (ii) judicial decisions and governmental laws and regulations related to Medicare, Medicaid and U.S. healthcare reform, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Patient Protection and Affordable Care Act, (iii) the potential impact of importation restrictions, legislative and/or regulatory changes, pharmaceutical reimbursement, Medicare Part D Formularies and product pricing in general, (iv) delays in gaining reimbursement and/or reductions in reimbursement amounts in countries with government mandated, cost-containment programs (e.g., major European markets, Japan and Canada), (v) other developments in technology and/or industry practices that could directly or indirectly impact the reimbursement policies and practices of third-party payers, and (vi) limited or no market access due to real or perceived differences in value propositions of our products compared to competing products.*

***Our business and results of operations have been affected, and will continue to be affected, by recent U.S. healthcare reform legislation in the U.S.***

*As described under Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Executive Summary Business Environment, the Patient Protection and Affordable Care Act (HR 3590) and a reconciliation bill containing a package of changes to the healthcare bill were signed into law during March 2010. These bills included provisions that increased the Medicaid rebate, expanded the Medicaid program, provided additional prescription drug discounts to certain patients under Medicare Part D and assesses a new, non-tax-deductible annual fee to pharmaceutical companies, among other things. We have experienced and will continue to experience significant financial costs and certain other changes to our business as the new healthcare law is implemented. In 2010, higher rebates to Medicaid and Medicaid managed care plans reduced our net sales by \$283 million and pre-tax income by \$222 million. On an incremental year-over-year basis, we expect U.S. healthcare reform to have a negative impact on earnings per share in 2011 of approximately \$0.15. This estimate includes an expected reduction of net sales of approximately \$250 million due to new discounts associated with the Medicare Part D Donut Hole coverage gap and an increase in marketing, sales and administrative expenses of approximately \$250 million due to the new annual non-tax-deductible pharmaceutical company fee. The laws also created a regulatory mechanism that allows for approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is the basis for a full BLA.*

***U.S. and foreign laws and regulations may negatively affect our net sales and profit margins.***

*We could become subject to new government laws and regulations, such as (i) additional healthcare reform initiatives in the U.S. at the Federal and state level and in other countries, including additional mandatory discounts; (ii) changes in the U.S. FDA and foreign regulatory approval processes that may cause delays in approving, or preventing the approval of, new products; (iii) tax changes such as the phasing out of tax benefits heretofore available in the U.S. and in certain foreign countries or other changes in tax law such as the recent amendment to the Puerto Rico Internal Revenue Code of 1994 imposing an excise tax on certain transactions, which could potentially have a negative impact on our results of operations; (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 to one or more of our products. Any legal or regulatory changes could negatively affect our business, and/or our operating results and the financial condition of our Company.*

***Changes to the product labeling for any of our marketed products or results from certain studies released after a product is approved could potentially have a negative impact on sales of that product.***

*The labeling for any pharmaceutical product can be changed by the regulatory authorities at any time, including after the product has been on the market for years. These changes are often the result of additional data from post-marketing studies, head-to-head trials, spontaneous reporting of adverse events from patients or healthcare professionals, studies that identify biomarkers (objective characteristics that can indicate a particular response to a product or therapy), or other studies that produce important additional information about a product. The new information added to a product's labeling can affect the safety (risk) and/or the efficacy (benefit) profile of the product. Sometimes the additional information from these studies identifies a portion of the patient population that may be non-responsive to the medicine. Changes to a*

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*labeling based on such studies may limit the patient population, such as the recent changes to the labeling for PLAVIX\* and ERBITUX\*. The studies providing such additional information may be sponsored by us, but they can also be sponsored by our competitors, insurance companies, government institutions, managed care organizations, influential scientists or investigators, or other interested parties. While additional safety and efficacy information from these studies assist us and healthcare providers in identifying the best patient population for each of our products, it can also have a negative impact on sales for any such product to the extent that the patient population or product labeling becomes more limited. Additionally, certain study results, especially from head-to-head trials, could affect a product's formulary listing, which could also have an adverse effect on sales.*

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**Table of Contents*****We may experience difficulties and delays in the manufacturing, distribution and sale of our products.***

*We may experience difficulties and delays inherent in the manufacturing, distribution and sale of our products, such as (i) seizure or recalls of products or forced closings of manufacturing plants; (ii) supply chain continuity including as a result of a natural or man made disaster at one of our facilities or at a critical supplier or vendor as well as our failure or the failure of any of our vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (iii) manufacturing, quality assurance/quality control, supply problems or governmental approval delays due to our consolidation and rationalization of manufacturing facilities and the sale or closure of certain sites; (iv) the failure of a sole source or single source supplier to provide us with necessary raw materials, supplies or finished goods for an extended period of time that could impact continuous supply; (v) the failure of a third-party manufacturer to supply us with finished product on a timely bases; (vi) construction or regulatory approval delays related to new facilities or the expansion of existing facilities, including those intended to support future demand for our biologics products; and (vii) other manufacturing or distribution problems including limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, such as biologics, physical limitations or other business interruptions that could impact continuous supply.*

*In 2010, we received a warning letter from the FDA regarding our manufacturing facility in Manati, Puerto Rico. The warning letter focused on certain GMP processes and practices, which the FDA identified during an inspection, that were to be improved or remediated. We have provided a response to the warning letter and have informed the FDA that the Manati facility is inspection-ready. If we are unable to timely and adequately improve or remediate the GMP issues identified to the FDA's satisfaction, we could be subject to additional inspectional observations by the FDA requiring remediation. If any of these observations are serious, we could face additional negative consequences including a temporary delay in production at the facility for further corrective action or delay in approval of filings.*

*In January 2011, we and our partner sanofi voluntarily recalled certain lots of AVALIDE\* from the U.S., Puerto Rican, Canadian, Mexican and Argentinean markets. We are working with our partner sanofi to identify all possible solutions to this issue, including process adjustments and alternate supply sources. If we are unable to resupply to these markets in a timely manner, this may have a negative impact on our net sales, cash flows and earnings.*

*The resolution of the manufacturing and supply issues discussed in this Form 10-K, as well as the potential impact of those issues on our revenues and earnings, are subject to substantial risks and uncertainties. These risks and uncertainties include the timing, scope and duration for resolving the manufacturing and supply issues.*

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

*We 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 product extensions or additional indications for any number of reasons, including efficacy or safety concerns, the delay or denial of necessary regulatory approvals, delays or difficulties with producing products at a commercial scale level or excessive costs to manufacture products; (ii) failure to enter into or successfully implement optimal alliances where appropriate for the discovery and/or commercialization of products; (iii) failure to maintain a consistent scope and variety of promising late-stage products; or (iv) failure of one or more of our products to achieve or maintain commercial viability. In addition, in the U.S., we have observed a recent trend by the FDA to delay its approval decision on a new product beyond its announced action date, sometimes by as much as six months or longer. Regulatory approval delays are especially common when the product is expected to have Risk Evaluation and Mitigation Strategy to address significant risk/benefit issues. The inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product could potentially have a negative impact on our net sales and earnings and could result in a significant impairment of in-process research and development or other intangible assets. Finally, a natural or man made disaster or sabotage of research and development labs and a loss of key molecules and intermediaries could negatively impact the product development cycle.*

***There are legal matters in which adverse outcomes could negatively affect our business.***

*We are currently involved in or could in the future become 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 after any possible insurance recoveries where available. Such legal matters include (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 promotional matters; (vii) lawsuits and claims asserting violations of securities, antitrust, federal and state pricing, antibribery (such as the Foreign Corrupt Practice Act) and other laws;*

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*(viii) environmental, health and safety matters; and (ix) tax liabilities. There can be no assurance that there will not be an increase in scope in any or all of these matters or there will not be additional lawsuits, claims, proceedings or investigations in the future; nor is there any assurance that any or all of these matters will not have a material adverse impact on us.*

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### ***We rely on third parties to meet their contractual, regulatory, and other obligations.***

*We rely on suppliers, vendors and partners, including alliances with other pharmaceutical companies for the manufacturing, development and commercialization of products, and other third parties to meet their contractual, regulatory, and other obligations in relation to their arrangements with us. 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 us. In addition, if these parties violate or are alleged to have violated any laws or regulations during the performance of their obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.*

### ***We are increasingly dependent on our outsourcing arrangements.***

*We are increasing our dependence on third-party providers for certain outsourced services, including certain research and development capabilities, certain financial outsourcing arrangements, certain human resource functions, and information technology activities and systems. Many of these third-party providers are located in markets that are subject to political risk, corruption, infrastructure problems and natural disasters in addition to country specific privacy and data security risks given current legal and regulatory environments. The failure of these service providers to meet their obligations, adequately deploy business continuity plans in the event of a crisis and/or the development of significant disagreements, natural or man made disasters or other factors that materially disrupt our ongoing relationship with these providers could negatively affect operations.*

### ***Failure to execute our business strategy could adversely impact our growth and profitability.***

*Over the last few years, we have transformed from a diversified pharmaceutical and related healthcare products company into a biopharmaceutical company with a focus on innovative products in areas of high unmet medical need. With the expected loss of exclusivity in the U.S. for our largest product, PLAVIX\*, in May 2012, after which time we expect a rapid, precipitous, material decline in PLAVIX\* net sales and a reduction in net income and operating cash flow, we are focused on building a foundation for the future. We plan to achieve this foundation by continuing to support and grow our currently marketed products, advancing our late-stage pipeline, managing our costs, and maintaining and improving our financial strength with a strong balance sheet. There are risks associated with this strategy. We may not be able to consistently replenish our innovative pipeline, through internal research and development or transactions with third parties. The competition among major pharmaceutical companies for acquisition and product licensing opportunities has become more intense, eliminating some opportunities and making others more expensive. We may not be able to locate suitable acquisition targets or licensing partners at reasonable prices or successfully execute such transactions. Additionally, changes in our structure, operations, revenues, costs, or efficiency resulting from major transactions such as acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives, may result in greater than expected costs, may take longer than expected to complete or encounter other difficulties, including the need for regulatory approval where appropriate. The inability to expand our product portfolio with new products or maintain a competitive cost basis could materially and adversely affect our future results of operations. If we are unable to support and grow our currently marketed products, advance our late-stage pipeline and manage our costs effectively, we could experience a significant or material negative impact on our results of operations and financial condition. In addition, our failure to hire and retain personnel with the right expertise and experience in operations that are critical to our business functions could adversely impact the execution of our business strategy.*

### ***We are increasingly dependent on information technology and expanding social media vehicles present new risks.***

*We are increasingly dependent on information technology systems and any significant breakdown, invasion, destruction or interruption of these systems could negatively impact operations. In addition, there is a risk of business interruption or reputational damage from an infiltration of a data center or data leakage of confidential information both internally and at our third-party providers.*

*The inappropriate use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection of personal information. Negative posts or comments about us on any social networking web site could seriously damage our reputation. In addition, the disclosure of non-public company sensitive information through external media channels could lead to information loss as there might not be structured processes in place to secure and achieve this information. Identifying new points of entry as social media continues to expand presents new challenges.*

***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.***

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*High government debt burdens and continued high unemployment rates, rising prices, including those related to commodities and energy, and lower economic growth has adversely affected commercial activity in the U.S., Europe and other regions of the world in which we do business. Further government austerity measures or declines in economic activity in markets in which we do business could adversely affect demand and pricing for our products, thus reducing our revenues, earnings and cash flow, as well as have pass-through effects on us resulting from any significant financial instability from our customers, distributors, alliance partners, suppliers, critical vendors, service providers and counterparties to certain financial instruments, such as marketable securities and derivatives. Future pension plan funding requirements continue to be sensitive to global economic conditions and related impact on equity markets.*



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***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 35% of our revenues in 2010. As such, we are exposed to fluctuations in foreign currency exchange rates. We also have significant borrowings which are exposed to changes in interest rates. We are also exposed to other economic factors over which we have no control.*

***The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business.***

*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 and business could suffer harm as a result of counterfeit drugs sold under the name of one of our products. In addition, thefts of inventory at warehouses, plants or while in-transit which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation and our business.*

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

None.

**Item 2. PROPERTIES.**

Our world headquarters are located at 345 Park Avenue, New York, NY, where we lease approximately 81,000 square feet of floor space. We own or lease approximately 200 properties in 44 countries.

We manufacture products at 12 worldwide locations, all of which are owned by us. Our manufacturing locations and aggregate square feet of floor space by geographic area were as follows at December 31, 2010:

	<b>Number of Locations</b>	<b>Square Feet</b>
United States	4	2,202,000
Europe	5	1,531,000
Latin America, Middle East and Africa	1	200,000
Japan, Asia Pacific and Canada	1	128,000
Emerging Markets	1	186,000
Total	12	4,247,000

Portions of these manufacturing locations and the other properties owned or leased by us in the U.S. and elsewhere are used for research and development, administration, storage and distribution. For further information about our properties, see Item 1. Business Manufacturing and Quality Assurance.

**Item 3. LEGAL PROCEEDINGS.**

Information pertaining to legal proceedings can be found in Item 8. Financial Statements Note 26. 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, 2010.

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

Listed below is information on our executive officers as of February 18, 2011. Executive officers are elected by the Board of Directors for an initial term, which continues until the first Board meeting following the next Annual Meeting of Stockholders, and thereafter, are elected for a one-year term or until their successors have been elected. All executive officers serve at the pleasure of the Board of Directors.

<b>Name and Current Position</b>	<b>Age</b>	<b>Employment History for the Past 5 Years</b>
Lamberto Andreotti  <i>Chief Executive Officer and Director</i>  <i>Member of the Senior Management Team</i>	60	2005 to 2007 Executive Vice President and President, Worldwide Pharmaceuticals, a division of the Company. 2007 to 2008 Executive Vice President and Chief Operating Officer, Worldwide Pharmaceuticals, a division of the Company.  2008 to 2009 Executive Vice President and Chief Operating Officer.  2009 to 2010 President and Chief Operating Officer and Director of the Company.  2010 to present Chief Executive Officer and Director of the Company.
Charles Bancroft  <i>Chief Financial Officer</i>  <i>Member of the Senior Management Team</i>	51	2005 to 2009 Vice President, Finance, Worldwide Pharmaceuticals, a division of the Company.  2010 to present Chief Financial Officer of the Company.
Joseph C. Caldarella  <i>Senior Vice President and Corporate Controller</i>	55	2005 to 2010 Vice President and Corporate Controller. 2010 to present Senior Vice President and Corporate Controller.
Beatrice Cazala  <i>Senior Vice President, Commercial Operations, and President, Global Commercialization, Europe and Emerging Markets</i>  <i>Member of the Senior Management Team</i>	54	2004 to 2008 President, EMEA, Worldwide Medicines International.  2008 to 2009 President, EMEA and Asia Pacific, Worldwide Medicines International.  2009 to 2010 President, Global Commercialization, and President, Europe.  2010 to present Senior Vice President, Commercial Operations, and President, Global Commercialization, Europe and Emerging Markets.
John E. Celentano  <i>Senior Vice President, Human Resources, Public Affairs and Philanthropy</i>  <i>Member of the Senior Management Team</i>	51	2005 to 2008 President, Health Care Group, a division of the Company.  2008 to 2009 Senior Vice President, Strategy and Productivity Transformation.  2009 to 2010 President, Emerging Markets and Asia Pacific.

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Francis Cuss, MB BChir, FRCP

*Senior Vice President, Research*

*Member of the Senior Management Team*

Brian Daniels, M.D.

*Senior Vice President, Global Development and*

*Medical Affairs*

*Member of the Senior Management Team*

2010 to present Senior Vice President, Human Resources, Public Affairs and Philanthropy.

56 2006 to 2010 Senior Vice President, Discovery and Exploratory Clinical Development.

2010 to present Senior Vice President, Research, Research and Development.

51 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.

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<p>Carlo de Notaristefani</p> <p><i>President, Technical Operations and Global Support Functions</i></p> <p><i>Member of the Senior Management Team</i></p>	<p>53</p>	<p>2004 to 2009 President, Technical Operations, Worldwide Pharmaceuticals, a division of the Company.</p> <p>2009 to present President, Technical Operations and Global Support Functions.</p>
<p>Anthony C. Hooper</p> <p><i>Senior Vice President, Commercial Operations, and President, U.S., Japan and Intercontinental.</i></p> <p><i>Member of the Senior Management Team</i></p>	<p>56</p>	<p>2004 to 2009 President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of the Company.</p> <p>2009 to 2010 President, Americas.</p> <p>2010 to present Senior Vice President, Commercial Operations, and President, U.S., Japan and Intercontinental.</p>
<p>Sandra Leung</p> <p><i>General Counsel and Corporate Secretary</i></p> <p><i>Member of the Senior Management Team</i></p>	<p>50</p>	<p>2006 to 2007 Vice President, Corporate Secretary and Acting General Counsel.</p> <p>2007 to present General Counsel and Corporate Secretary.</p>
<p>Jeremy Levin, D.Phil., MB BChir</p> <p><i>Senior Vice President, Strategy, Alliances and Transactions</i></p> <p><i>Member of the Senior Management Team</i></p>	<p>57</p>	<p>2006 to 2007 Global Head Business Development and Strategic Alliances, Member of the Executive Committee, Novartis Institutes of Biomedical Research.</p> <p>2007 to 2008 Senior Vice President, External Science, Technology and Licensing.</p> <p>2008 to 2010 Senior Vice President, Strategic Transactions.</p> <p>2010 to present Senior Vice President, Strategy, Alliances and Transactions.</p>
<p>Elliott Sigal, M.D., Ph.D.</p> <p><i>Executive Vice President, Chief Scientific Officer and President, Research and Development</i></p> <p><i>Member of the Senior Management Team</i></p>	<p>59</p>	<p>2006 to present Executive Vice President, Chief Scientific Officer and President, Research and Development.</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) (Symbol: BMY). A quarterly summary of the high and low market prices is presented below:

	2010		2009	
	High	Low	High	Low
<b>Common:</b>				
First Quarter	\$ 27.00	\$ 23.89	\$ 23.88	\$ 17.51
Second Quarter	26.95	22.44	21.97	19.15
Third Quarter	27.93	24.65	22.95	19.37
Fourth Quarter	27.51	25.24	25.96	21.77
<b>Preferred:</b>				
First Quarter	\$ 501.00	\$ 432.01	\$ 525.00	\$ 474.00
Second Quarter	525.04	400.00	400.00	400.00
Third Quarter	*	*	371.61	371.61
Fourth Quarter	570.00	570.00	440.00	426.07

\* During the third quarter of 2010, there were no observable trades of the Company's preferred stock.

**Holders of Common Stock**

The number of record holders of common stock at December 31, 2010 was 59,670.

The number of record holders is based upon the actual number of holders registered on our books 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.

**Dividends**

Our Board of Directors declared the following dividends per share, which were paid in 2010 and 2009 in the quarters indicated below:

	Common		Preferred	
	2010	2009	2010	2009
First Quarter	\$ 0.32	\$ 0.31	\$ 0.50	\$ 0.50
Second Quarter	0.32	0.31	0.50	0.50
Third Quarter	0.32	0.31	0.50	0.50
Fourth Quarter	0.32	0.31	0.50	0.50
	\$ 1.28	\$ 1.24	\$ 2.00	\$ 2.00

In December 2010, our Board of Directors declared a quarterly dividend of \$0.33 per share on our common stock which was paid on February 1, 2011 to shareholders of record as of January 7, 2011. The Board of Directors also declared a quarterly dividend of \$0.50 per share on our preferred stock, payable on March 1, 2011 to shareholders of record as of February 4, 2011.



**Table of Contents****Issuer Purchases of Equity Securities**

The following table summarizes the surrenders and repurchases of our equity securities during the 12 month period ended December 31, 2010:

<b>Period</b>	<b>Total Number of Shares Purchased<sup>(a)</sup></b>	<b>Average Price Paid per Share<sup>(a)</sup></b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs<sup>(b)</sup></b>	<b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs<sup>(b)</sup></b>
<b>Dollars in Millions, Except Per Share Data</b>				
January 1 to 31, 2010	4,280	\$ 25.07		\$ 2,220
February 1 to 28, 2010	4,589	\$ 24.19		\$ 2,220
March 1 to 31, 2010	1,492,277	\$ 24.60		\$ 2,220
Three months ended March 31, 2010	1,501,146			
April 1 to 30, 2010	9,065	\$ 26.67		\$ 2,220
May 1 to 31, 2010	4,742,159	\$ 23.48	4,731,211	\$ 2,889
June 1 to 30, 2010	2,556,972	\$ 24.28	2,548,826	\$ 2,827
Three months ended June 30, 2010	7,308,196		7,280,037	
July 1 to 31, 2010	2,787,760	\$ 25.03	2,777,198	\$ 2,758
August 1 to 31, 2010	1,958,670	\$ 26.12	1,950,682	\$ 2,707
September 1 to 30, 2010	2,543,114	\$ 27.16	2,508,500	\$ 2,638
Three months ended September 30, 2010	7,289,544		7,236,380	
October 1 to 31, 2010	2,994,353			