

BRISTOL MYERS SQUIBB CO  
Form 10-K  
February 15, 2013

**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, 2012**

**Commission File Number 1-1136**

**BRISTOL-MYERS SQUIBB COMPANY**

(Exact name of registrant as specified in its charter)

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

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

**22-0790350**  
(IRS Employer  
Identification No.)

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(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.

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 "large accelerated filer", "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 1,676,515,493 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, 2012) was approximately \$60,270,731,973. Bristol-Myers Squibb has no non-voting common equity. At February 1, 2013, there were 1,637,354,662 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 1, 2013 are incorporated by reference into Part III of this Annual Report on Form 10-K.

## 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). Our divestitures included Medical Imaging in January 2008, ConvaTec in August 2008, and Mead Johnson in December 2009. Our acquisition and licensing transactions included Kosan Biosciences, Inc. in June 2008, Medarex, Inc. (Medarex) in September 2009, ZymoGenetics, Inc. (ZymoGenetics) in October 2010, Amira Pharmaceuticals, Inc. (Amira) in September 2011, Inhibitex, Inc. (Inhibitex) in February 2012, and Amylin Pharmaceuticals, Inc. (Amylin) in August 2012 as well as several license and other collaboration arrangements. We continue to review our cost structure with the intent to maintain a modernized, efficient, and robust balance between building competitive advantages, securing innovative products and planning for the future.

We operate in one segment BioPharmaceuticals. For additional information about business segments, see Item 8. Financial Statements Note 2. 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.

The percentage of total net sales by significant region were as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
United States	59%	66%	66%
Europe	21%	18%	19%
Japan	4%	3%	3%
China	3%	2%	2%
Canada	2%	3%	3%
Net Sales	17,621	21,244	19,484

#### 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 various 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 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 following chart 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, China 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 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, Chinese and Canadian markets:

Dollars in Millions	Net Sales by Products			Past or Currently Estimated Year of Basic Exclusivity Loss				
	2012	2011	2010	U.S.	EU (a)	Japan	China	Canada
<b>Key Products</b>								
<i>Plavix*</i>	\$ 2,547	\$ 7,087	\$ 6,666	2012	2008 <sup>(b)</sup>	++	++	2011
<i>Avapro*/Avalide*</i>	503	952	1,176	2012	2007-2013	++	--	2011
<i>Eliquis</i>	2		N/A	2023	2022	2022	++	2022
<i>Abilify*</i>	2,827	2,758	2,565	2015 <sup>(c)</sup>	2014 <sup>(d)</sup>	++	++	2017 <sup>(e)</sup>
<i>Reyataz</i>	1,521	1,569	1,479	2017	2017-2019 <sup>(f)</sup>	2019	2017	2017
<i>Sustiva Franchise</i>	1,527	1,485	1,368	2015 <sup>(g)</sup>	2013 <sup>(h)</sup>	++	++	2013
<i>Baraclude</i>	1,388	1,196	931	2013 <sup>(i)</sup>	2011-2016	2016	--	2011
<i>Erbitux*</i>	702	691	662	2016 <sup>(j)</sup>	++	2016 <sup>(k)</sup>	++	2016 <sup>(k)</sup>
<i>Sprycel</i>	1,019	803	576	2020	2020	2021	2020	2020
<i>Yervoy</i>	706	360	N/A	2023 <sup>(k)</sup>	2021 <sup>(k)</sup>	++	++	2020
<i>Orencia</i>	1,176	917	733	2019	2017 <sup>(k)</sup>	2018 <sup>(k)</sup>	++	2014 <sup>(l)</sup>
<i>Nulojix</i>	11	3	N/A	2023	2021	++	++	++
<i>Onglyza/Kombiglyze</i>	709	473	158	2021	2021	++	2016	2021
<i>Byetta*</i>	149	N/A	N/A	2016 <sup>(m)</sup>	2016 <sup>(e)</sup>	2018 <sup>(e)</sup>	++	2019 <sup>(e)</sup>
<i>Bydureon*</i>	78	N/A	N/A	2025 <sup>(n)</sup>	2021 <sup>(e)</sup>	2020 <sup>(e)</sup>	++	++
<i>Forxiga</i>		N/A	N/A	++	2023	++	++	++

Note: The currently estimated earliest year of basic exclusivity loss includes any statutory extensions of exclusivity that have been granted. In some instances, we may be able to obtain an additional six months exclusivity for a product based on the pediatric extension. 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 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 or wholly owned by BMS. Specific trademark ownership information is included on page 119.

++ We do not currently market the product in the country or region indicated.

-- There is uncertainty about China's exclusivity laws which has resulted in generic competition in the China market.

(a) References to the EU throughout this Form 10-K include all 27 member states of the European Union during the year ended December 31, 2012. 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. 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) Our rights to commercialize *Abilify\** (aripiprazole) in the U.S. terminate in 2015.

(d) Our rights to commercialize *Abilify\** in the EU terminate in 2014.

(e) Exclusivity period is based on regulatory data protection.

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

(g) Exclusivity period relates to the *Sustiva* brand and does not include exclusivity related to any combination therapy. 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. Pediatric exclusivity has been granted, which provides an additional six month period of exclusivity added to the term of the patents listed in the Orange Book.

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- (h) Exclusivity period relates to the *Sustiva* brand and does not include exclusivity related to any combination therapy. Market exclusivity for *Sustiva* is expected to expire in 2013 in countries in the EU. Data exclusivity for *Sustiva* expired in the EU in 2009.
- (i) In February 2013, the U.S. District Court for the District of Delaware invalidated the composition of matter patent covering *Baraclude*, which was scheduled to expire in 2015. We may face generic competition with this product beginning in 2013.
- (j) Biologic product approved under a Biologics License Application (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.
- (k) Exclusivity period is based on regulatory data protection.
- (l) Data exclusivity in Canada expires in 2014.
- (m) Exclusivity period is based on method of use patent. The composition of matter patent has expired.
- (n) Exclusivity period is based on formulation patents.

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\**

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

Clopidogrel bisulfate was codeveloped and is jointly marketed with Sanofi. In October 2012, BMS and Sanofi announced a restructuring of their alliance following the loss of exclusivity of *Plavix\** and *Avapro\*/Avalide\** in many major markets. For more information about our alliance with Sanofi and the restructuring of it, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 3. Alliances and Collaborations.

The composition of matter patent in the U.S. expired on May 17, 2012.

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.

We obtain our bulk requirements for clopidogrel bisulfate from Sanofi. Prior to January 1, 2013, both the Company and Sanofi finished the product in our own respective facilities. Effective January 1, 2013, the Company will no longer finish clopidogrel bisulfate in our facilities.

*Avapro\*/Avalide\**

*Avapro\*/Avalide\** (irbesartan/irbesartan-hydrochlorothiazide) is an angiotensin II receptor antagonist indicated for the treatment of hypertension and diabetic nephropathy.

Irbesartan was codeveloped and jointly marketed with Sanofi until the end of 2012. In October 2012, BMS and Sanofi announced a restructuring of their alliance following the loss of exclusivity of *Plavix\** and *Avapro\*/Avalide\** in many major markets. For more information about our alliance with Sanofi and the restructuring of it, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 3. Alliances and Collaborations.

The composition of matter patent in the U.S. expired on March 30, 2012 and expires in most countries in the EU in 2012 through 2013. Data exclusivity in the EU expired in August 2007 for *Avapro\** and in October 2008 for *Avalide\**. The composition of matter patent expired in Canada in March 2011.

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. With the alliance restructuring, BMS's manufacturing obligations will phase out with Sanofi assuming all the Company's manufacturing and supply obligations of irbesartan products at the end of 2015.

*Eliquis*

*Eliquis* (apixaban) is an oral Factor Xa inhibitor targeted at stroke prevention in atrial fibrillation and the prevention and treatment of venous thromboembolic (VTE) disorders. It is currently approved in the EU, Canada and Japan for the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors and for use in VTE prevention in adult patients who have undergone elective hip or knee surgery. In December 2012, the U.S. Food and Drug Administration (FDA) approved *Eliquis* to reduce the risk of stroke and systemic embolism in patients with NVAF.

Apixaban was discovered internally and is part of our alliance with Pfizer, Inc. (Pfizer). For more information about our alliance with Pfizer, see Item 8. Financial Statements Note 3. Alliances and Collaborations.

The composition of matter patent covering apixaban in the U.S. expires in February 2023(excluding potential patent term extensions) and in the EU it expires in 2022. We have applied for supplementary protection certificates. Some of these supplementary protection certificates have been granted and expire in 2026. Data exclusivity in the EU expires in 2021. The composition of matter patent expires in Canada in 2022.

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Apixaban is manufactured by both the Company and a third-party. The product is then finished in our facilities.

*Abilify\**

*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.



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 3. Alliances and Collaborations.

The basic U.S. composition of matter patent covering aripiprazole and the term of the current *Abilify*\* agreement expire in April 2015 (including the granted patent term extension and six month pediatric extension).

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 and the rights to commercialize in the EU expire in 2014. Data exclusivity in Canada expires in 2017.

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 human immunodeficiency virus (HIV).

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. We have a licensing agreement with Gilead Sciences, Inc. (Gilead) to develop and commercialize a fixed-dose combination containing *Reyataz* and one of Gilead's compounds in development.

Market exclusivity for *Reyataz* is expected to expire in 2017 in the U.S., Canada and China and 2019 in the major EU member countries and Japan. Data exclusivity in the EU expires in 2014.

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's *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 3. Alliances and Collaborations.

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

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 an additional six month period of pediatric exclusivity added to the term of these patents.

Market exclusivity for *Sustiva* is expected to expire in 2013 in countries in the EU and Canada. Data exclusivity for *Sustiva* expired in the EU in 2009. 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, the U.S. patents covering efavirenz composition of matter and method of use have not been challenged. The EU patent for efavirenz is the subject of litigation in the Netherlands, Germany and the UK. For more information about these litigation matters, see Item 8. Financial Statements Note 21. Legal Proceedings and Contingencies.

We obtain our bulk requirements for efavirenz from third parties and produce finished goods in our facilities. We supply our third parties 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 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.



In February 2013, the U.S. District Court for the District of Delaware invalidated the composition of matter patent covering *Baraclude*, which was scheduled to expire in 2015. We may face generic competition with this product beginning in 2013. For more information about this patent litigation matter, see Item 8. Financial Statements Note 21. Legal Proceedings and Contingencies.

The composition of matter patent expires in the EU between 2011 and 2016 and in Japan in 2016. The composition of matter patent expired in Canada in 2011. There is uncertainty about China's exclusivity laws which has resulted in generic competition in the China market.

Entecavir is manufactured by both the company and a third-party. The product is then finished in our facilities.

*Erbix\**

*Erbix\** (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. *Erbix\**, 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 also approved *Erbix\** for use in the treatment of squamous cell carcinoma of the head and neck. Specifically, *Erbix\** 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. The FDA also approved *Erbix\** for first-line recurrent locoregional or metastatic head and neck cancer in combination with platinum-based chemotherapy with 5-Fluorouracil.

*Erbix\** 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 *Erbix\** with Merck KGaA in Japan under a codevelopment and cocommercialization agreement signed in October 2007 with ImClone, Merck KGaA and Merck Serono Japan. *Erbix\** 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 3. 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 *Erbix\**. *Erbix\** has been approved by the FDA and other health authorities for monotherapy, for which there is no use patent. The use of *Erbix\** 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. Data exclusivity in Japan and Canada expire in 2016.

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 *Erbix\** 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 *Erbix\**.

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 filling and finishing is performed by a third-party for which BMS has oversight responsibility. 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

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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 3. Alliances and Collaborations.

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 21. Legal Proceedings and Contingencies. In the U.S., orphan drug exclusivity expires in 2013, which protects the product from generic applications for the currently approved orphan indications only.

In the majority of the EU countries, we have a composition of matter patent covering dasatinib that expires in April 2020 (excluding potential term extensions). The composition of matter patent expires in 2021 in Japan and in 2020 in Canada and China.

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

*Yervoy*

*Yervoy* (ipilimumab), a biological product, is a monoclonal antibody for the treatment of patients with unresectable (inoperable) or metastatic melanoma. Ipilimumab was approved in the U.S. in March 2011 and in the EU in July 2011. It is currently also being studied for other indications including lung cancer as well as adjuvant melanoma and hormone-refractory prostate cancer. For more information, about research and development of *Yervoy*, see Research and Development below.

*Yervoy* was discovered by Medarex and codeveloped by the Company and 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. and 2020 in the EU (excluding potential patent term extensions) and 2020 in Canada. Data exclusivity expires in 2023 in the U.S. and 2021 in the EU.

We obtain bulk ipilimumab from a third-party manufacturer and finish the product at a third party facility.

*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 is available in both an intravenous formulation and beginning in 2011, a subcutaneous formulation in the U.S. *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. We have applied for supplementary protection certificates and also pediatric extension of the supplementary protection certificates for protection until 2017. Some of these protection certificates have been granted.

Data exclusivity expires in 2014 in Canada, 2017 in the U.S. and EU and 2018 in Japan.

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We obtain bulk abatacept from a third-party manufacturer and also manufacture bulk at own facility. We finish the product in our facilities for both formulations.

### *Nulojix*

*Nulojix* (belatacept), a biological product, is a fusion protein with novel immunosuppressive activity for the prevention of kidney transplant rejection. It was approved and launched in the U.S. in June 2011, and approved in the EU in June 2011 and launched in July 2011. Belatacept was internally discovered and developed.

We own a patent covering belatacept as composition of matter that expires in April 2023 in the U.S. and May 2021 in the EU.

Data exclusivity expires in the U.S. in June 2023 and in the EU in June 2021.

We manufacture our bulk requirements for belatacept and finish the products in our facilities.

### *Onglyza / 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 hydrochloride extended-release) is approved in the U.S. as 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. *Komboglyze* (saxagliptin and metformin immediate-release) is approved in the EU as a combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. In this document unless specifically noted, we refer to both *Kombiglyze* and *Komboglyze* as *Kombiglyze*.

*Onglyza* was internally discovered by the Company and *Kombiglyze* was codeveloped by the Company and AstraZeneca PLC (AstraZeneca). We have a worldwide (except Japan) codevelopment and cocommercialization agreement with AstraZeneca for 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 3. Alliances and Collaborations.

We own a patent covering saxagliptin as composition of matter that expires in March 2021 in the U.S., the EU and Canada. Market exclusivity in China expires in 2016.

We manufacture our bulk requirements for saxagliptin in our facilities. We obtain the bulk metformin for *Kombiglyze* from a third party. Both the Company and AstraZeneca finish *Onglyza* in their own facilities. The Company finishes *Kombiglyze* in its own facility.

*Byetta\**

*Byetta\**(exenatide) is a twice daily glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of type 2 diabetes. *Byetta\** was acquired from our Amylin acquisition in August 2012. *Byetta\** was internally discovered by Amylin, now a wholly-owned subsidiary of the Company. We have a worldwide development and commercialization agreement with AstraZeneca for *Byetta\**. We also have an agreement with Lilly regarding the termination of their collaboration for the global development and commercialization of *Byetta\** and *Bydureon\**. The Company and Lilly are in the process of transferring the rights to the Company and AstraZeneca. For more information about our arrangement with AstraZeneca, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 3. Alliances and Collaborations.

The composition of matter patent covering exenatide has expired. The method of use patent expires in 2016 in the U.S. Data exclusivity expires in 2016 in Europe, 2018 in Japan and 2019 in Canada.

We obtain the bulk requirements for exenatide from third parties. Manufacturing and finishing also takes place in third party facilities.

*Bydureon\**

*Bydureon\** (exenatide extended-release for injectable suspension) is a once-weekly GLP-1 receptor agonist for the treatment of type 2 diabetes. *Bydureon\** was acquired from our Amylin acquisition in August 2012. *Bydureon\** was internally discovered by Amylin, now a wholly-owned subsidiary of the Company. We have a worldwide development and commercialization agreement with AstraZeneca for *Bydureon\**. For more information about our arrangement with AstraZeneca, see Strategic Alliances and Collaborations below and Item 8. Financial Statements Note 3. Alliances and Collaborations.

The formulation patents expire in 2025 in the U.S. Data exclusivity expires in 2021 in Europe and 2020 in Japan.

The bulk requirements for exenatide are obtained from third parties and the microspheres manufacturing process required for the extended release formulation is performed by the Company. We finish the product in our facilities.

*Forxiga*

*Forxiga* (dapagliflozin) is an oral sodium-glucose cotransporter 2 (SGLT2) for the treatment of diabetes.

It was approved in the EU in November 2012 as an adjunct to diet and exercise in combination with other glucose-lowering medicinal products, including insulin, or as a monotherapy in metformin-intolerant patients and is currently in the registrational review process in the U.S. For further discussion, See Item 7. Management Discussion and Analysis of Financial Condition and Results of Operations Product and Pipeline Developments. *Forxiga* was internally discovered and we have a worldwide codevelopment and cocommercialization agreement with AstraZeneca for dapagliflozin.

We own a patent covering dapagliflozin as composition of matter that expires in October 2020 in the U.S. and May 2023 in the EU.

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



## 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, diabetes, hepatitis, HIV/Acquired Immunodeficiency Syndrome (AIDS), oncology, immunologic disorders and fibrotic disease. 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.

Phase I clinical trials involve a small number of healthy patients or patients suffering from the indicated disease to test for safety and proper dosing. Phase II clinical trials involve a larger patient population to investigate side effects, efficacy, and optimal dosage of the drug candidate. Phase III clinical trials are conducted to confirm Phase II results in a significantly larger patient population over a longer term and to provide reliable and conclusive data regarding the safety and efficacy of a drug candidate.

The R&D process typically takes thirteen years or longer, with nearly 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 2007-2011, approximately 95% 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 88% and for compounds that enter Phase III development, it is approximately 46%.

Total research and development expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, as well as post-commercialization and medical support of marketed products, proportionate allocations of enterprise-wide costs, and other appropriate costs. Research and development spending was \$3.9 billion in 2012, \$3.8 billion in 2011 and \$3.6 billion in 2010 and includes payments under third-party collaborations and contracts. At the end of 2012, 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 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 only patent term extensions that have been granted.

Asunaprevir	Asunaprevir is an oral small molecule NS3 protease inhibitor in Phase III development (which commenced in 2012) for the treatment of hepatitis C virus infection. We own a patent covering asunaprevir as a composition of matter that expires in 2027 in the U.S.
Daclatasvir	Daclatasvir is an oral small molecule NS5A replication complex inhibitor in Phase III development (which commenced in 2011) for the treatment of hepatitis C virus infection. We own a patent covering daclatasvir as a composition of matter that expires in 2027 in the U.S.
Peginterferon lambda	Peginterferon lambda is a novel type 3 interferon in Phase III development (which commenced in 2012) for hepatitis C virus infection. We own a patent covering peginterferon lambda as a composition of matter that expires in 2024 in the U.S.
Elotuzumab	Elotuzumab is a humanized monoclonal antibody being investigated as an anticancer treatment, which was discovered by PDL BioPharma and became part of the Facet Biotech Corporation (Facet) spin-off. Facet was subsequently acquired by Abbott Laboratories (Abbott) and became part of AbbVie Inc. (AbbVie) following a spin-off from Abbott. Elotuzumab is part of our alliance with AbbVie. It is in Phase III trials (which commenced in 2011) in multiple myeloma. AbbVie owns a patent covering elotuzumab as a composition of matter that expires in 2026 in the U.S.
Nivolumab	Nivolumab is a fully human monoclonal antibody that binds to the programmed death receptor-1 (PD-1) on T and NKT cells. It is being investigated as an anticancer treatment. It is in Phase III trials (which commenced in 2012) in non small cell lung cancer, renal cell cancer and melanoma. We own a patent covering nivolumab as a composition of matter that expires in 2027 in the U.S.
Metreleptin	Metreleptin was acquired as part of the Amylin acquisition and is being co-developed with AstraZeneca. Metreleptin is a protein in development for the treatment of lipodystrophy and is currently in the registrational process. We own a patent covering metreleptin as a composition of matter that expires in 2016 in the U.S. Data exclusivity in the U.S. will expire 12 years after regulatory approval.

During 2012, we provided notice of the termination of our global codevelopment and cocommercialization arrangement for necitumumab (IMC-11F8), 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, with all rights returning to Lilly. The termination is effective May 2014, though we and Lilly may terminate earlier.

During 2012, we terminated our development program for brivanib, which was in Phase III trials as an anti-cancer treatment with potential use in hepatocellular carcinoma and colorectal cancer.

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The following table lists potential additional indications and/or formulations of key marketed products that are in Phase III development or currently under regulatory review:

<b>Key marketed product</b>	<b>Potential indication and/or formulation</b>
<i>Eliquis</i>	Additional indication for VTE treatment
<i>Reyataz</i>	Pediatric extension
<i>Baraclude</i>	Pediatric extension
<i>Erbbitux*</i>	Additional indication in esophageal cancer
<i>Yervoy</i>	Additional indications in adjuvant melanoma, prostate cancer, non-small cell lung cancer and small cell lung cancer
	Additional indication in first-line metastatic melanoma in the EU
<i>Orencia</i>	Additional indication in lupus nephritis
	Additional formulation (subcutaneous) in Japan
<i>Onglyza</i>	Additional use in cardiovascular risk reduction and pediatric extension
<i>Bydureon*</i>	Dual chamber pen and weekly suspension
<i>Forxiga</i>	Fixed dose combination with metformin
The following key developments are currently expected to occur during 2013 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.	
<i>Eliquis</i>	Data available from Phase III study in VTE treatment
<i>Daclatasvir</i>	Data available from Phase III hepatitis C virus infection combination studies
<i>Asunaprevir</i>	Data available from Phase III hepatitis C virus infection combination studies
<i>Sprycel</i>	Data available from Phase III study in prostate cancer
	Four year data available in first line CML
<i>Yervoy</i>	Data available from Phase III study in prostate cancer
<i>Orencia</i>	Phase III start in psoriatic arthritis
<i>Nulojix</i>	Five year data available from Phase III studies in the prevention of kidney transplant rejection
<i>Onglyza</i>	Data available from cardiovascular risk reduction study
<i>Bydureon*</i>	Planned submission of dual chamber pen in the U.S. and Europe
<i>Forxiga</i>	Planned resubmission in the U.S. for the treatment of type 2 diabetes

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Data available from Phase III blood pressure studies

Two year data available from Phase III studies in diabetic patients with history of cardiovascular disease

*Metreleptin*

Planned U.S. submission for the treatment of lipodystrophy

## Strategic Alliances and Collaborations

We enter into strategic alliances and collaborations with third parties that transfer rights to develop, manufacture, market and/or sell pharmaceutical products that are owned by other parties. These alliances and collaborations include 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 because profits from alliance products are shared with our alliance partners. We actively pursue such arrangements and view alliances as an important complement to our own discovery and development activities.

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** In September 2012, BMS and Sanofi restructured the terms of the codevelopment and cocommercialization agreements discussed below. Effective as of January 1, 2013, subject in certain countries to the receipt of regulatory approvals, Sanofi will assume the worldwide operations of the alliance with the exception of *Plavix*\* for the U.S. and Puerto Rico. The alliance for *Plavix*\* in these two markets will continue unchanged through December 2019 under the same terms as in the original alliance arrangements. BMS will return to Sanofi its rights and receive quarterly royalties from January 1, 2013 until December 31, 2018 and a terminal payment from Sanofi of \$200 million at the end of 2018. All ongoing disputes between the companies have been resolved, including a one-time payment of \$80 million by BMS to Sanofi related to the *Avalide*\* supply disruption in the U.S. in 2011 (accrued for in 2011).

Pursuant to the Master Restructuring Agreement, the Company will, through various mechanisms depending on the territory, return to Sanofi its rights for clopidogrel and irbesartan in all markets with the exception of clopidogrel in the U.S. and Puerto Rico, where the Company will continue to act as the operating partner and own a 50.1% majority controlling interest. All currently existing local arrangements in Territory A and Territory B (with the exception of clopidogrel in the U.S. and Puerto Rico), will be terminated by mutual agreement. No products will continue to be sold through such local country entities in these territories. In addition, Sanofi will assume all marketing authorizations for the products, to the extent currently held by the Company or any of its affiliates. As a result, Sanofi will assume control of all activities relating to the distribution, commercialization and medical affairs of clopidogrel and irbesartan in these regions.

Pursuant to the Master Restructuring Agreement and related alliance agreements, Sanofi will assume the Company's manufacturing and supply obligations of irbesartan products at the end of 2015. The Company does not manufacture bulk clopidogrel and will no longer finish clopidogrel products in its facilities. The Company will retain rights to the intellectual property developed by the alliance necessary to fulfill its continuing obligations under the alliance arrangements.

Under the Master Restructuring Agreement and related alliance agreements, the alliance will remain in effect through December 2018 until Sanofi's payment of the terminal fee, with the exception of the U.S. and Puerto Rico, where the alliance will remain in effect through December 2019.

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We had 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*\* was 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*\*.

Prior to 2013, the worldwide alliance operated 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 was 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 existed 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 were structured so that our local affiliate and Sanofi's local affiliate either comarket separate brands (i.e., each affiliate operated independently and competed with the other by selling the same product under different trademarks), or copromoted 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 sold *Iscover*\* and *Karvea*\*/*Karvezide*\* and Sanofi sold *Plavix*\* and *Aprovel*\*/*Coaprovel*\* in these countries, except China, where we retained the right to, but did not currently comarket *Iscover*\*. The Company and Sanofi copromoted *Plavix*\* and *Aprovel*\*/*Coaprovel*\* in France, the UK, Belgium, Netherlands, Switzerland and Portugal. In addition, the Company and Sanofi copromoted *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 acted as the operating partner for Territory A and owned a 50.1% financial controlling interest in this territory. Our ownership interest in this territory was 49.9%. We accounted for the investment in partnership entities in Territory A under the equity method and recognized our share of the results in equity in net income of affiliates. Our share of net income from these partnership entities before taxes was \$201 million in 2012, \$298 million in 2011 and \$325 million in 2010.

Within Territory B, the Company and Sanofi copromoted *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 were comarketing countries. We act as the operating partner for Territory B and owned a 50.1% majority controlling interest in this territory. As such, we consolidated all partnership results in Territory B and recognized Sanofi's share of the results as net earnings attributable to noncontrolling interest, net of taxes, which was \$531 million in 2012, \$1,536 million in 2011 and \$1,394 million in 2010.

We recognized net sales in Territory B and Territory A comarketing countries of \$3.1 billion in 2012, \$8.0 billion in 2011 and \$7.8 billion in 2010.

The territory partnerships were governed by a series of committees with enumerated functions, powers and responsibilities. Each territory had 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 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 included 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 was 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 3. Alliances and Collaborations.

Otsuka We maintain a worldwide commercialization agreement with Otsuka to codevelop and copromote *Abilify*\* (the *Abilify*\* Agreement), excluding certain Asia Pacific countries. In April 2009, the Company and Otsuka agreed to extend the U.S. portion of the commercialization and manufacturing agreement until the expected loss of product exclusivity in April 2015. The contractual share of *Abilify*\* net sales recognized by the Company pursuant to the extension was 58% in 2010, 53.5% in 2011 and 51.5% in 2012.

In the UK, Germany, France and Spain, the Company receives 65% of third-party net sales. In these countries and the U.S., third-party customers are invoiced by the Company on behalf of Otsuka and alliance revenue is recognized when *Abilify*\* is shipped and all risks and rewards of ownership have transferred to third party customers. 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.





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. Under the terms of the extension agreement, we paid Otsuka \$400 million, which is amortized as a reduction of net sales through the extension period. The unamortized balance is included in other assets. Otsuka receives a royalty based on 1.5% of total U.S. net sales, which is included in cost of products sold. Otsuka is responsible for 30% of the U.S. expenses related to the commercialization of *Abilify*\* from 2010 through 2012. BMS also receives additional reimbursement from Otsuka for sales force costs incurred by BMS in excess of requirements specified in the agreement. Reimbursements are netted principally in marketing, selling and administrative and advertising and product promotion expenses.

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.

Beginning January 1, 2013, BMS will receive the following percentages of U.S. annual net sales. Net sales will be initially recognized at 35% and adjusted to reflect the actual level of net sales in 2013:

	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%

The U.S. commercialization agreement was amended in October 2012, requiring Otsuka to assume full responsibility for providing and funding all sales force efforts effective January 2013. In consideration BMS paid Otsuka \$27 million in January 2013, and will be responsible for funding certain operating expenses up to \$82 million in 2013, \$56 million in 2014 and \$8 million in 2015. In the EU, Otsuka will reimburse BMS for its sales force effort provided through March 31, 2013. Beginning April 1, 2013 Otsuka will assume responsibility for providing and funding sales force effort.

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*\*, 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 \$2.8 billion in 2012 and \$2.8 billion in 2011 and \$2.6 billion in 2010. In addition to the \$400 million extension payment in 2009, total upfront, milestone and other licensing payments made to Otsuka under the *Abilify*\* Agreement through 2012 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 3. 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., 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 even in Japan with Merck KgaA receiving the other half of the

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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 *Erbix*\* from Lilly. The agreement expires as to *Erbix*\* 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 *Erbix*®.

We share codevelopment and copromotion rights to *Erbix*® 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. *Erbix*® received marketing approval in Japan in July 2008 for the use of *Erbix*® in treating patients with advanced or recurrent colorectal cancer.

We recognized net sales for *Erbix*® of \$702 million in 2012, \$691 million in 2011 and \$662 million in 2010.

For further discussion of our strategic alliance with Lilly, see Item 8. Financial Statements Note 3. 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 \$1.3 billion in 2012, \$1.2 billion in 2011 and \$1.1 billion in 2010 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).

In 2011, we entered into a licensing agreement with Gilead to develop and commercialize a fixed-dose combination containing *Reyataz* and Gilead's cobicistat, a pharmacoenhancing or boosting agent currently in Phase III clinical trials that increases blood levels of certain HIV medicines to potentially allow for one pill once daily dosing. Cobicistat is currently in the registrational process with the FDA.

For further discussion of our strategic alliance with Gilead, see Item 8. Financial Statements Note 3. 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) and dapagliflozin (the SGLT2 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 and in June 2012 were assigned by Otsuka to Kyowa Hakko Kirin (KHK), 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, milestone and other licensing payments from AstraZeneca for meeting certain development and regulatory milestones on *Onglyza* and *Kombiglyze*, and could receive up to an additional \$300 million if all sales-based milestones are met. The majority of costs under the initial development plans 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.

Under the SGLT2 Agreement, we have received \$250 million of upfront, milestone and other licensing payments from AstraZeneca, including \$80 million received in January 2013, and could receive up to \$150 million more if all development and regulatory milestones for dapagliflozin are met and up to an additional \$390 million if all sales-based milestones for dapagliflozin 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

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key markets. With respect to Japan, AstraZeneca has operational and cost responsibility for all development and regulatory activities on behalf of the collaboration, related to certain trials. All other development costs are shared by the two companies. 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.

In August 2012, BMS and AstraZeneca Pharmaceuticals LP, a wholly-owned subsidiary of AstraZeneca, entered into a collaboration regarding the worldwide development and commercialization of Amylin's portfolio of products, including *Bydureon\**, *Byetta\**, *Symlyn\**. The arrangement is based on the framework of the existing diabetes alliance agreements for *Onglyza* and *Forxiga* discussed above, including the equal sharing of profits and losses arising from the collaboration. AstraZeneca has indicated its intent to establish equal governance rights over certain key strategic and financial decisions regarding the collaboration pending required anti-trust approvals in certain international markets.

BMS received preliminary proceeds of \$3.6 billion from AstraZeneca as consideration for entering into the collaboration during 2012, which was accounted for as deferred income and is amortized as a reduction to cost of products sold on a pro-rata basis over the estimated useful lives of the related long-lived assets assigned in the purchase price allocation (primarily intangible assets with a weighted-average estimated useful life of 12 years and property, plant and equipment with a weighted-average estimated useful life of 15 years). The net proceeds that BMS will receive from AstraZeneca as consideration for entering into the collaboration are subject to certain other adjustments including the right to receive an additional \$135 million when AstraZeneca exercises its option for equal governance rights.

BMS and AstraZeneca agreed to share in certain tax attributes related to the Amylin collaboration. The preliminary proceeds of \$3.6 billion that BMS received from AstraZeneca included \$207 million related to sharing of certain tax attributes.

For further discussion of our strategic alliance with AstraZeneca, see Item 8. Financial Statements Note 3. Alliances and Collaborations and Investigational Compounds Under Development Internally Discovered.

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* (ixabepilone), 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. Beginning in 2011, Otsuka copromotes *Sprycel* in the U.S. and Japan and has exercised the right to copromote in the top five EU markets beginning in January 2012.

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 3. Alliances and Collaborations.

Pfizer The Company and Pfizer are parties to a worldwide codevelopment and cocommercialization agreement for *Eliquis*, an anticoagulant discovered by us for the prevention and treatment of atrial fibrillation and venous thromboembolic (VTE) disorders. Pfizer funds 60% of all development costs since January 2007 and we fund 40%. We have received \$654 million in upfront, milestone and other licensing payments from Pfizer to date, including \$95 million received in February 2013 and could receive up to an additional \$230 million from Pfizer if all development and regulatory milestones are met. The companies jointly develop the clinical and marketing strategy of *Eliquis*, and 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 3. Alliances and Collaborations.

Investigational Compounds Under Development In-Licensed

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. In November 2012, BMS provided notice of termination of the collaboration agreement with Lilly for necitumumab. The termination is effective May 2014, though we and Lilly may terminate earlier.

AbbVie In August 2008, we were granted exclusive rights from Facet Biotech Corporation (now AbbVie) for the codevelopment and cocommercialization of elotuzumab, a humanized monoclonal antibody being investigated as treatment for multiple myeloma. Under the terms of the agreement, we fund 80% of the development costs for elotuzumab. Upon commercialization, Abbott will share 30% of all profits and losses in the U.S., and will be paid tiered royalties outside of the U.S. We will be solely responsible for commercialization of elotuzumab. In addition, Abbott may receive milestone payments from us based on certain regulatory events and sales thresholds, if achieved.

Investigational Compounds Under Development Internally Discovered

Otsuka In January 2007, we granted Otsuka exclusive rights in Japan to develop and commercialize *Onglyza*. Under that agreement, 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, and we retained rights to copromote *Onglyza* with Otsuka in Japan. Otsuka is responsible for all development costs in Japan. In June 2012, Otsuka assigned all rights to *Onglyza*, with the exception of specific transition services, to KHK. As part of its consent to this assignment, BMS waives its rights to co-promote *Onglyza* in Japan. BMS will supply finished saxagliptin to KHK.

AstraZeneca As part of the collaboration with AstraZeneca, BMS and AstraZeneca are codeveloping metreleptin for the treatment of lipodystrophy, which is currently in the registrational process in Japan. Metreleptin was acquired by BMS as part of the Amylin acquisition. Please see the AstraZeneca description under *Current Marketed Products Internally Discovered and* Item 8. Financial Statements Note 3. Alliances and Collaborations for more information regarding the collaboration.

Other Collaborations

In February 2013, BMS and Reckitt Benckiser Group plc (RBL) agreed to enter into a license and three year collaboration regarding several over-the-counter-products sold primarily in Mexico and Brazil. The transaction is expected to close during the first or second quarter of 2013, subject to customary closing conditions and regulatory approvals. In connection with the collaboration, RBL will be responsible for all sales, distribution, marketing and certain regulatory matters and BMS will be responsible for the exclusive supply of the products. Upon expiration of the collaboration, RBL will have the right to purchase the remaining assets of the business held by BMS at a price determined based on a multiple of sales (plus the cost of any remaining inventory held by BMS at that time). RBL would then assume all responsibility for the products, though RBL may extend the term of the supply agreement with BMS under certain circumstances. If the option is not exercised, all assets previously transferred to RBL during the collaboration period revert back to BMS. BMS is expected to receive proceeds of \$482 million at the start of the collaboration period which will be allocated to the license and other rights transferred to RBL and the written option.

In February 2013, BMS and The Medicines Company entered into a global license and two year collaboration for *Recothrom*, a recombinant thrombin for use as a topical hemostat to control non-arterial bleeding during surgical procedures (previously acquired by BMS in connection with its acquisition of ZymoGenetics in 2010). The Medicines Company is responsible for all sales, distribution, marketing and regulatory matters relating to *Recothrom*, and BMS is responsible for the exclusive supply of the product. BMS received an upfront payment of \$115 million. The collaboration expires February 2015 at which time The Medicines Company has the right to purchase the remaining assets of the business held by BMS at a price determined based on a multiple of sales (plus the carrying cost of the inventory). If the option is not exercised, all assets previously transferred to The Medicines Company, during the collaboration period revert back to BMS.

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* 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. 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.

We own certain compounds out-licensed to third parties for development and commercialization, including those obtained as a result of our acquisitions of ZymoGenetics in October 2010 and Medarex in August 2009. We are entitled 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.

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, China 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 some regions such as China, however, it is questionable whether such data protection laws are enforceable. 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.

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

The U.S. healthcare legislation enacted in 2010 created an approval pathway for biosimilar versions of innovative biological products that did not previously exist. Prior to that time, innovative biologics had essentially unlimited regulatory exclusivity. Under the new regulatory mechanism, the FDA can approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full BLA. After an innovator has marketed its product for four years, any 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 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 products 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).



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.

#### *China*

In China, medicines of new chemical entities are generally afforded six years of data exclusivity for approved indications and dosage. There is uncertainty about China's exclusivity laws which has resulted in generic competition in the China market. Generic copies can receive regulatory approval after data exclusivity and patent expirations. Currently, unlike the U.S., China has no patent term restoration to compensate for the patent term lost during the regulatory process.

In general, Chinese 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 the World*

In countries outside of the U.S., the EU, Japan, China 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, television, and digital advertising and promotion. In addition, we sponsor general advertising to educate the public about our innovative medical research and corporate mission. For a discussion of the regulation of promotion and marketing of pharmaceuticals, see [Government Regulation and Price](#)

Constraints below.

Through our field sales and medical organizations, we explain the risks and benefits of the approved uses of our products to medical professionals. We work to gain access for our products on formularies and reimbursement plans (lists of recommended or approved medicines and other products), including Medicare Part D plans by providing information about the clinical profiles of our products. Our marketing and sales 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.

Our operations include several marketing and sales organizations. Each product marketing organization is supported by a sales force, which may be responsible for selling one or more products. We also have marketing organizations that focus on certain classes of customers such as managed care entities or certain types of marketing tools, such as digital or consumer communications. Our sales forces focus on communicating information about new products or new uses, as well as established products, and promotion to physicians is increasingly targeted at physician specialists who treat the patients in need of our medicines.

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 global gross sales were as follows:

	2012	2011	2010
McKesson Corporation	23%	26%	24%
Cardinal Health, Inc.	19%	21%	21%
AmerisourceBergen Corporation	14%	16%	16%

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 for our three largest wholesalers expire on March 31, 2013, while the other IMAs expire on December 14, 2014, all subject to certain termination provisions. We have reached agreements in principal with our three largest wholesalers, subject to negotiation and execution of final agreements, which would extend the termination dates of those IMAs to December 14, 2014, subject to certain termination provisions.

In a number of defined markets outside of the U.S., we have established a full scale distributor model to make medically necessary drugs available to patients. We continue to own the marketing authorization and trademarks for these products, but have contracted the services of a full-service distributor to provide distribution and logistics; regulatory and pharmacovigilance; and sales, advertising and promotion for certain products. These contracts clearly define terms and conditions, along with the services we will provide (such as supply through a firm order period). We monitor in-market sales and forecasts to ensure that reasonable inventory levels for all products for sale are maintained to fully and continuously meet the demand for the products within the distributor's territory or responsibility. Sales in these distributor-based markets represented less than 1% of the Company's net sales in 2012.

## 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.

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 condition and results of operations and cash flows.

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.

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.

In the U.S. 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. 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. 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 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 were also required to 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.

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 other 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.

Our pharmaceutical manufacturing facilities are located in the U.S., Puerto Rico, France, Italy, Ireland, Japan, Mexico and China and 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 continue modification of 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. The FDA approved our large scale multi-product bulk biologics manufacturing facility in Devens, Massachusetts in May 2012.



We rely on third parties to manufacture or supply us with certain active ingredients necessary for us to manufacture various products, including *Plavix\**, *Baraclude*, *Avalide\**, *Reyataz*, *Abilify\**, *Erbix\**, the *Sustiva* Franchise, *Orencia*, *Yervoy*, *Onglyza*, *Kombiglyze* and *Forxiga*. 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 capacity of our Devens, Massachusetts facility and the capacity available at our third-party contract manufacturers to manufacture *Orencia*.

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 requirements, comply with government regulations for manufacturing pharmaceuticals or meet the complex 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 \$21 million in 2012, \$16 million in 2011 and \$15 million in 2010 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.

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 14 current or former facilities. We have also been identified as a potentially responsible party (PRP) under applicable laws for environmental conditions at approximately 23 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 21. Legal

Proceedings and Contingencies.

## Employees

As of December 31, 2012, we employed approximately 28,000 people.

## 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 2. 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 Net Sales.

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. The change in foreign exchange rates had a net unfavorable impact on the growth rate of revenues in 2012. While we cannot predict with certainty future changes in foreign exchange rates or the effect they will have on the growth rate of revenues, 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 9. 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 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 2013 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 2013 Annual Meeting of Stockholders and 2012 Annual Report will be available on our website under the Investors SEC Filings caption on or about March 21, 2013.

**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 biopharmaceutical manufacturers, including for both innovative medicines and lower-priced generic products.***

*Competition, including lower-priced generic versions of our products, is a major challenge both within the U.S. and internationally. We face patent expirations and increasingly aggressive generic competition. Such competition may include (i) new products developed by competitors that have lower prices, real or perceived superior efficacy (benefit) or safety (risk) profiles, or that are otherwise competitive with our products; (ii) technological advances and patents attained by our competitors; (iii) earlier-than-expected competition from generic companies; (iv) clinical study results from our products or a competitor's products; (v) business combinations among our competitors and major customers; and (vi) competing interests for external partnerships to develop and bring new products to markets. We could also experience limited or no market access from real or perceived differences in value propositions for our products compared with competitors.*

***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.*

*Market exclusivity for our products is based upon patent rights and/or certain regulatory forms of exclusivity. The scope of our patent rights 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 certain EU member states, basic patent protection for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment outside the U.S. can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions of the product can be approved and marketed. In addition, prior to the expiration of data exclusivity, a competitor could seek regulatory approval by submitting its own clinical trial data to obtain marketing approval.*

*Manufacturers of generic products are also increasingly seeking to challenge patents before they expire. Key patents covering three of our key products (Atripla\*, Baraclude 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. For example, we may face generic competition for Baraclude beginning in 2013 following a federal court's decision to invalidate the composition of matter patent in February 2013. There is 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.*

***Increased pricing pressure and other restrictions in the U.S. and abroad from managed care organizations, institutional purchasers, and government agencies and programs could negatively affect our net sales and profit margins.***

*Pharmaceutical products continue to be subject to increasing price pressures and other restrictions in the U.S., the EU and other regions around the world, including but not limited to: (i) rules and practices of managed care organizations and institutional and governmental purchasers; (ii) judicial decisions and governmental laws and regulations for Medicare, Medicaid and U.S. healthcare reform, including the 2010 Patient Protection and Affordable Care Act and any potential additional U.S. healthcare reform measures; (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; (v) government price erosion mechanisms across Europe, resulting in deflation for pharmaceutical product pricing; (vi) other developments in technology and/or industry practices that could directly or indirectly impact the reimbursement policies and practices of third-party payers; and (vii) limited or no market access due to real or perceived differences in value propositions for our products compared to competing products.*

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

*Developing and commercializing new products includes inherent risks and uncertainties, 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, including for efficacy or safety concerns, the delay or denial of necessary regulatory approvals,*



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*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 for the development and/or commercialization of new products; (iii) failure to maintain a consistent scope and variety of promising late-stage products; (iv) failure of one or more of our products to achieve or maintain commercial viability; and (v) changes in the regulatory approval processes that may cause delays or denials of new product approvals. We have observed a recent trend by the U.S. Food & Drug Administration to delay its approval decision on a new product beyond its announced action date by as much as six months or longer.*

*Regulatory approval delays are especially common when the product is expected to have a Risk Evaluation and Mitigation Strategy as required by the FDA 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, if the product was acquired, it could result in a significant impairment of in-process research and development or other intangible assets. Further, if certain acquired pipeline programs are cancelled or if we believe that their commercial prospects have been reduced, we may recognize material non-cash impairment charges for those programs. These non-cash impairment charge could be material such as the \$1.8 billion impairment for BMS-986094, which we recorded in 2012. Finally, a natural or man-made disaster or sabotage of research and development labs, our compound library and/or a loss of key molecules and intermediaries could negatively impact the product development cycle.*

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

*We are a biopharmaceutical company with a focus on innovative products for high unmet medical needs. To build a foundation for the future, our strategy is to grow our key marketed products, advance our late-stage pipeline and manage our costs. 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 is intense, and we may not be able to locate suitable acquisition targets or licensing partners at reasonable prices, or successfully execute such transactions. We also may not be able to realize the expected increased efficiencies and effectiveness from continuous improvement initiatives or other changes in our structure or operations, including from the recent reorganization of our commercial operations and the creation of our Enterprises Services organization. In addition, realizing synergies and other expected benefits from acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives, may take longer than expected to complete or may encounter other difficulties, including the need for regulatory approval where applicable. If we are unable to support and grow our currently marketed products, successfully execute the launches of newly approved products, advance our late-stage pipeline and manage our costs effectively, we could experience a significant or material negative impact to our operating results and financial condition. In addition, our failure to hire and retain personnel with the right expertise and experience in critical operations could adversely impact the execution of our business strategy.*

***The businesses we acquire may underperform, and we may not be able to successfully integrate them into our existing business.***

*We may continue to support our pipeline with our licensing and acquisitions strategy. In August 2012, we acquired Amylin Pharmaceuticals Inc. (Amylin), a biopharmaceuticals company dedicated to the discovery, development and commercialization of innovative medicines for patients with diabetes and other metabolic diseases. Amylin and our other acquired businesses, products and technologies may underperform relative to expectations, which may negatively impact our financial results including potential impairment charges for acquired intangible assets, including identifiable intangible assets attributed to the Amylin acquisition of \$6.5 billion at the acquisition date. Future sales, profits and cash flows of an acquired company's products, technologies and pipeline candidates, may not materialize due to lower product uptake, delayed or missed pipeline opportunities, the inability to capture expected synergies, increased competition, safety concerns, regulatory issues, supply chain problems, or other factors beyond our control. Substantial difficulties, costs and delays could result from integrating our acquisitions including for (i) research & development, manufacturing, distribution, sales, marketing, promotion and information technology activities; (ii) policies, procedures, processes, controls and compliance; (iii) company cultures; (iv) compensation structures and other human resource activities; and (v) tax considerations.*

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

*We have historically derived a majority of our revenue and earnings from a few key products. For example, Plavix\* represented over 33% of our revenues in 2011. While we are becoming less dependent on any single product, we still derive a significant amount of our revenues from a few key products. In 2012, Abilify\* net sales of \$2.8 billion represented 16% of revenues. Reyataz and the Sustiva franchise, with combined net sales of \$3.0 billion, each represented approximately 9% of revenues, Baraclude, Sprycel and Orencia net sales each exceeded \$1.0 billion. A reduction in net sales of one or more of these products could significantly negatively impact our net sales, cash flows and earnings.*

***Changes in U.S. or 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. or in other countries, including additional mandatory discounts; (ii) changes in corporate tax regulation, including as part of the proposed U.S. budget deficit reduction package, which could include limiting foreign tax credits, taxing certain tax havens, taxing certain excess income from transferring intellectual property, limiting or disallowing certain U.S. deductions for operating and interest expenses, changing rules for earnings repatriations and eliminating certain tax credits, as well as changing the tax rate or phasing out currently available tax benefits in the U.S. and in certain foreign countries or other changes in tax law; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, receivable repayment, access or marketing within or across jurisdictions; (iv) changes in intellectual property law; (v) changes in accounting standards; (vi) increasing data privacy regulations and enforcement; (vii) emerging and new requirements regarding payments to healthcare professionals, and (viii) 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, our operating results*

*and the financial condition of our company. Emerging legislation to reduce the budget deficit in the U.S. or in other countries, if enacted, will likely further reduce our operating results.*

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***Product labeling changes for our marketed products could potentially result in unexpected safety or efficacy concerns and have a negative impact on that product's sales.***

Regulatory authorities can change the labeling for any pharmaceutical product 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, reporting of adverse events, 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 label can affect the safety and/or the efficacy profile of the product, leading to product recalls, withdrawals, or declining revenue, as well as product liability claims. Sometimes the additional information from these studies identifies a portion of the patient population that may be non-responsive to a medicine and labeling changes based on such studies may limit the patient population, such as the changes to the labeling for Plavix\* and Erbitux\* a few years ago. 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, 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 adversely affect sales.

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

Our product supply and related patient access to products could be negatively impacted by, among other things: (i) seizure or recalls of products or forced closings of manufacturing plants; (ii) supply chain continuity including from natural or man-made disasters 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; (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; (v) the failure of a third-party manufacturer to supply us with finished product on time; (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; (vii) the failure to meet new and emerging regulations requiring products to be tracked throughout the distribution channels using unique identifiers; and (viii) other manufacturing or distribution issues including limits to manufacturing capacity due to regulatory requirements; changes in the types of products produced, such as biologics; physical limitations or other business interruptions.

***Adverse outcomes in legal matters could negatively affect our business.***

Current or future lawsuits, claims, proceedings and government investigations could preclude or delay commercialization of products or could potentially 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; (vi) product pricing and promotional matters; (vii) lawsuits and claims asserting, or investigations into, violations of securities, antitrust, Federal and state pricing, consumer protection, antibribery (such as the U.S. Foreign Corrupt Practice Act or UK Anti-Bribery Act) and other laws; (viii) environmental, health and safety matters; and (ix) tax liabilities.

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

We rely on suppliers, vendors, outsourcing partners, alliance partners and other third parties to research, develop, manufacture, commercialize, co-promote and sell our products; manage certain human resource, finance, information technology and other functional services; and meet their contractual, regulatory, and other obligations in relation to their arrangements with us. Some 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 any critical third party to meet its obligations; adequately deploy business continuity plans in the event of a crisis; and/or satisfactorily resolve significant disagreements with us or address other factors, could have a material adverse impact on the Company's operations and results. In addition, if these third parties violate or are alleged to have violated any laws or regulations, including the U.S. Foreign Corrupt Practice Act, U.K. Bribery Act and other similar laws and 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 information technology and our systems and infrastructure face certain risks, including from cyber security and data leakage.***

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*A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems, or infrastructure by employees, others with authorized access to our systems, or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for data leakage of confidential information. We could also experience a business interruption, information theft, or reputational damage from malware or other cyber attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the targets of events of this nature and expect them to continue. We have invested in industry appropriate protections and monitoring practices of our data and information technology to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third party providers databases or systems that could adversely affect our business.*

***The expansion of social media platforms presents new risks and challenges.***

*The inappropriate and/or unauthorized use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about us on any social networking web site could damage our reputation, brand image and goodwill. Further, 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 protect information. Identifying new points of entry as social media continues to expand presents new challenges.*

***Adverse changes in U.S., global, regional or local economic conditions could adversely affect our profitability.***

*The world's major economies hold historically-high debt levels while experiencing slow economic growth and high unemployment. The European sovereign debt crisis has strained government spending and created capital markets volatility. We have significant operations in Europe, including for manufacturing. Our exposure to customer credit risks in Europe, including from government-guaranteed hospital receivables, will likely increase as our ability to factor receivables becomes more limited. In addition, future pension plan funding requirements continue to be sensitive to global economic conditions and the related impact on equity markets. We are also exposed to other commercial risks and economic factors over which we have no control, which could pose significant challenges to our underlying profitability.*

***Changes in foreign currency exchange rates and interest rates could have a material adverse effect on our operating results and liquidity.***

*We have significant operations outside of the U.S. Net sales from operations outside of the U.S. accounted for approximately 41% of our net sales in 2012. As such, we are exposed to fluctuations in foreign currency exchange rates which can be difficult to mitigate. We are also exposed to changes in interest rates. Our ability to access the money markets and/or capital markets could be impeded if adverse liquidity market conditions occur.*

***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 our rigorous manufacturing and testing standards. 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 our brand name. 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.*

**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 218 properties in 48 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, 2012:

	Number of Locations	Square Feet
United States	5	2,767,000
Europe	4	1,531,000
Rest of the World	3	514,000
Total	12	4,812,000

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 21. Legal Proceedings and Contingencies and is incorporated by reference herein.

**Item 4. MINE SAFETY DISCLOSURES.**

Not applicable.



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

Listed below is information on our executive officers as of February 15, 2013. 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>	62	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>Executive Vice President and Chief Financial Officer</i> <i>Member of the Senior Management Team</i>	53	2005 to 2009 Vice President, Finance, Worldwide Pharmaceuticals, a division of the Company.  2010 to 2011 Chief Financial Officer of the Company.  2011 to present Executive Vice President and Chief Financial Officer of the Company.
Giovanni Caforio, M.D. <i>President, U.S. Pharmaceuticals</i> <i>Member of the Senior Management Team</i>	48	2007 to 2009 Senior Vice President, U.S. Oncology, Worldwide Pharmaceuticals, a division of the Company.  2009 to 2010 Senior Vice President, Oncology, Global Commercialization.  2011 to 2011 Senior Vice President, Oncology and Immunoscience, Global Commercialization.  2011 to present President, U.S. Pharmaceuticals.
Joseph C. Caldarella <i>Senior Vice President and Corporate Controller</i>	57	2005 to 2010 Vice President and Corporate Controller.  2010 to present Senior Vice President and Corporate Controller.
Beatrice Cazala <i>Executive Vice President, Commercial Operations</i> <i>Member of the Senior Management Team</i>	56	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 2011 Senior Vice President, Commercial Operations, and President, Global Commercialization, Europe and Emerging Markets.  2011 to present Executive Vice President, Commercial Operations.

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Francis Cuss, MB BChir, FRCP

58 2006 to 2010 Senior Vice President, Discovery and Exploratory Clinical Research.

*Senior Vice President, Research*

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

*Member of the Senior Management Team*

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Brian Daniels, M.D.	53	2004 to 2008	Senior Vice President, Global Clinical Development, Research and Development, a division of the Company.
<i>Senior Vice President, Global Development and Medical Affairs, Research and Development</i>		2008 to present	Senior Vice President, Global Development and Medical Affairs, Research and Development.
<i>Member of the Senior Management Team</i>			
John E. Elicker	53	2000 to 2002	Senior Director, Investor Relations.
<i>Senior Vice President, Public Affairs and Investor Relations</i>		2002 to 2010	Vice President, Investor Relations.
		2010 to 2012	Senior Vice President, Investor Relations.
<i>Member of the Senior Management Team</i>		2012 to present	Senior Vice President, Public Affairs and Investor Relations.
Frances Heller	46	2003 to 2008	Head, Strategic Alliances at Novartis Pharmaceuticals.
<i>Senior Vice President, Business Development</i>		2008 to 2011	Executive Vice President, Exelixis.
<i>Member of the Senior Management Team</i>		2011 to 2012	Instructor, Stanford University.
		2012 to present	Senior Vice President, Business Development.
Sandra Leung	52	2006 to 2007	Vice President, Corporate Secretary and Acting General Counsel.
<i>General Counsel and Corporate Secretary</i>		2007 to present	General Counsel and Corporate Secretary.
<i>Member of the Senior Management Team</i>			
Samuel J. Moed	50	2005 to 2010	Senior Vice President, Worldwide Strategy and Operations.
<i>Senior Vice President, Strategic Planning and Analysis</i>		2010 to 2012	Senior Vice President, Strategy.
<i>Member of the Senior Management Team</i>		2012 to present	Senior Vice President, Strategic Planning and Analysis.
Louis S. Schmukler	57	2007 to 2009	Senior Vice President, Pharmaceutical Operating Unit, Wyeth.
<i>President, Global Manufacturing and Supply</i>		2009 to 2011	Senior Vice President, Specialty/Biotechnology Operating Unit, Pfizer.
<i>Member of the Senior Management Team</i>		2011 to present	President, Global Manufacturing and Supply.
Elliott Sigal, M.D., Ph.D.	61	2006 to 2011	Executive Vice President, Chief Scientific Officer and President, Research and Development.
<i>Executive Vice President, Chief Scientific Officer and President, Research and Development and Director</i>		2011 to present	Executive Vice President, Chief Scientific Officer and President, Research and Development, and Director of the Company.
<i>Member of the Senior Management Team</i>			
Paul von Autenried	51	2007 to 2011	Vice President and Chief Information Officer.
<i>Senior Vice President, Enterprise Services and Chief Information Officer</i>		2011 to 2012	Senior Vice President and Chief Information Officer.
		2012 to present	Senior Vice President, Enterprise Services and Chief Information Officer.
<i>Member of the Senior Management Team</i>			



## 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:

	2012		2011	
	High	Low	High	Low
<b>Common:</b>				
First Quarter	\$ 35.01	\$ 31.85	\$ 27.29	\$ 24.97
Second Quarter	35.95	32.47	29.33	26.46
Third Quarter	36.15	31.57	31.49	26.38
Fourth Quarter	34.38	30.81	35.29	30.15
<b>Preferred:</b>				
First Quarter	\$ *	\$ *	\$ *	\$ *
Second Quarter	*	*	570.10	570.10
Third Quarter	*	*	*	*
Fourth Quarter	*	*	*	*

\* During 2012 and the first, third and fourth quarters of 2011, 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, 2012 was 53,969.

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 2012 and 2011 in the quarters indicated below:

	Common		Preferred	
	2012	2011	2012	2011
First Quarter	\$ 0.34	\$ 0.33	\$ 0.50	\$ 0.50
Second Quarter	0.34	0.33	0.50	0.50
Third Quarter	0.34	0.33	0.50	0.50
Fourth Quarter	0.34	0.33	0.50	0.50
	\$ 1.36	\$ 1.32	\$ 2.00	\$ 2.00

In December 2012, our Board of Directors declared a quarterly dividend of \$0.35 per share on our common stock which was paid on February 1, 2013 to shareholders of record as of January 6, 2013. The Board of Directors also declared a quarterly dividend of \$0.50 per share on our preferred stock, payable on March 1, 2013 to shareholders of record as of February 3, 2013.



**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, 2012:

Period	Total Number of Shares Purchased <sup>(a)</sup>	Average Price Paid per Share <sup>(a)</sup>	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(b)</sup>		Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(b)</sup>
Dollars in Millions, Except Per Share Data					
January 1 to 31, 2012	5,482,912	\$ 33.35	5,477,200		\$ 1,005
February 1 to 29, 2012	4,372,415	\$ 32.22	4,360,900		\$ 864
March 1 to 31, 2012	1,750,695	\$ 32.51			\$ 864
Three months ended March 31, 2012	11,606,022		9,838,100		
April 1 to 30, 2012	5,613,737	\$ 33.42	5,606,834		\$ 677
May 1 to 31, 2012	5,876,829	\$ 33.14	5,858,755		\$ 483
June 1 to 30, 2012	4,912,492	\$ 34.52	4,906,631		\$ 3,313
Three months ended June 30, 2012	16,403,058		16,372,220		
July 1 to 31, 2012	6,304,273	\$ 35.30	6,299,644		\$ 3,091
August 1 to 31, 2012	16,960,023	\$ 32.36	16,949,219		\$ 2,543
September 1 to 30, 2012	8,052,099	\$ 33.36	8,045,000		\$ 2,274
Three months ended September 30, 2012	31,316,395		31,293,863		
October 1 to 31, 2012	3,681,350	\$ 33.61	3,655,700		\$ 2,151
November 1 to 30, 2012	7,609,053	\$ 32.09	7,597,176		\$ 1,908
December 1 to 31, 2012	3,862,578	\$ 32.63	3,858,020		\$ 1,782
Three months ended December 31, 2012	15,152,981		15,110,896		
Twelve months ended December 31, 2012	74,478,456		72,615,079		

(a) The total number of shares purchased and the total number of shares purchased as part of publicly announced programs is different because shares of common stock are withheld by us from employee restricted stock awards in order to satisfy our applicable tax withholding obligations.

(b) In May 2010, the Board of Directors authorized the repurchase of up to \$3.0 billion of common stock. In June 2012, the Board of Directors increased its authorization for the repurchase of common stock by an additional \$3.0 billion. The repurchase program does not have an expiration date and may be suspended or discontinued at any time.

**Item 6. SELECTED FINANCIAL DATA.**  
**Five Year Financial Summary**

Amounts in Millions, except per share data	2012	2011	2010	2009	2008
<b>Income Statement Data:<sup>(a)</sup></b>					
Net Sales	\$ 17,621	\$ 21,244	\$ 19,484	\$ 18,808	\$ 17,715
<i>Continuing Operations:</i>					
Net Earnings	2,501	5,260	4,513	4,420	3,686
Net Earnings Attributable to:					
Noncontrolling Interest	541	1,551	1,411	1,181	989
BMS	1,960	3,709	3,102	3,239	2,697
Net Earnings per Common Share Attributable to BMS:					
Basic	\$ 1.17	\$ 2.18	\$ 1.80	\$ 1.63	\$ 1.36
Diluted	\$ 1.16	\$ 2.16	\$ 1.79	\$ 1.63	\$ 1.35
Average common shares outstanding:					
Basic	1,670	1,700	1,713	1,974	1,977
Diluted	1,688	1,717	1,727	1,978	1,999
Cash dividends paid on BMS common and preferred stock	\$ 2,286	\$ 2,254	\$ 2,202	\$ 2,466	\$ 2,461
Cash dividends declared per common share	\$ 1.37	\$ 1.33	\$ 1.29	\$ 1.25	\$ 1.24
<b>Financial Position Data at December 31:</b>					
Cash and cash equivalents	\$ 1,656	\$ 5,776	\$ 5,033	\$ 7,683	\$ 7,976
Marketable securities <sup>(b)</sup>	4,696	5,866	4,949	2,200	477
Total Assets	35,897	32,970	31,076	31,008	29,486
Long-term debt <sup>(c)</sup>	7,232	5,376	5,328	6,130	6,585
Equity	13,638	15,867	15,638	14,785	12,208

(a) For a discussion of items that affected the comparability of results for the years 2012, 2011 and 2010, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Non-GAAP Financial Measures.

(b) Marketable securities include current and non-current assets.

(c) Also includes the current portion of long-term debt.



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

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS, the Company, we, our or us) is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We license, manufacture, market, distribute and sell pharmaceutical products on a global basis.

The following key events and transactions occurred during 2012 as discussed in further detail in the Strategy, Product and Pipeline Developments and Results of Operations sections of Management's Discussion and Analysis:

Our net sales and earnings declined as a result of the loss of exclusivity of *Plavix*\* (clopidogrel bisulfate) and *Avapro*\*/*Avalide*\* (irbesartan/irbesartan-hydrochlorothiazide).

We received significant regulatory approvals pertaining to *Eliquis* (apixaban) for stroke prevention in patients with nonvalvular atrial fibrillation (NVAf), *Forxiga* (dapagliflozin) and the *Orencia* (abatacept) subcutaneous formulation.

We acquired Amylin Pharmaceuticals, Inc (Amylin) and expanded our diabetes alliance arrangement with AstraZeneca PLC (AstraZeneca) to include Amylin-related products.

We discontinued the development of BMS-986094 (formerly INX-189), a compound which we acquired as part of our acquisition of Inhibitex, Inc. (Inhibitex) to treat hepatitis C virus infection, in the interest of patient safety, which resulted in a \$1.8 billion pre-tax impairment charge.

**Highlights**

The following table is a summary of our financial highlights:

Dollars in Millions, except per share data	Year Ended December 31,		
	2012	2011	2010
Net Sales	\$ 17,621	\$ 21,244	\$ 19,484
Total Expenses	15,281	14,263	13,413
Earnings before Income Taxes	2,340	6,981	6,071
Provision for/(Benefit from) Income Taxes	(161)	1,721	1,558
<i>Effective tax/(benefit) rate</i>	<i>(6.9)%</i>	<i>24.7 %</i>	<i>25.7 %</i>
Net Earnings Attributable to BMS			
GAAP	1,960	3,709	3,102
Non-GAAP	3,364	3,921	3,735
Diluted Earnings Per Share			
GAAP	1.16	2.16	1.79
Non-GAAP	1.99	2.28	2.16
Cash, Cash Equivalents and Marketable Securities	6,352	11,642	9,982

Our non-GAAP financial measures, including non-GAAP earnings and related EPS information, are adjusted to exclude specified items which represent certain costs, expenses, gains and losses and other items impacting the comparability of financial results. For a detailed listing of all specified items and further information and reconciliations of non-GAAP financial measures see **Non-GAAP Financial Measures** below.

**Business Environment**

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The pharmaceutical/biotechnology industry is highly competitive and subject to numerous government regulations. Many competitive factors may significantly affect sales of our products, including product efficacy, safety, price, demand, competition and cost-effectiveness; marketing effectiveness; market access; product labeling; quality control and quality assurance of our manufacturing operations; and research and development of new products. To successfully compete in the healthcare industry, we must demonstrate that our products offer medical benefits and cost advantages. Our new product introductions often compete with other products already on the market in the same therapeutic category, in addition to potential competition of new products that competitors may introduce in the future. We manufacture branded products, which are priced higher than generic products. Generic competition is one of our leading challenges.

In the pharmaceutical/biotechnology industry, the majority of an innovative product's commercial value is usually realized during its market exclusivity period. Afterwards, it is no longer protected by a patent and is subject to new competing products in the form of generic brands. Upon exclusivity loss, we can experience a significant reduction of that product's sales in a short period of time. Competitors seeking approval of biological products under a full Biologics License Application (BLA) must file their own safety and efficacy data and address the challenges of biologics manufacturing, involving more complex processes and costs than those of other pharmaceutical operations. Under the U.S. healthcare legislation enacted in 2010, there is an abbreviated path for regulatory approval of generic versions of biological products. This path for approval of biosimilar products under the U.S. healthcare legislation significantly affects the regulatory data exclusivity for biological products. The legislation provides a regulatory mechanism allowing for regulatory approval of biologic drugs similar to (but not generic copies of) innovative drugs on the basis of less extensive data than required by a full BLA. It is not possible at this time to reasonably assess the impact of the U.S. biosimilar legislation on the Company.

Globally, the healthcare industry is subject to various government-imposed regulations authorizing prices or price controls that will continue to impact 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. We will continue to experience additional financial costs and certain other changes to our business as healthcare law provisions become effective.

The aggregate financial impact of U.S. healthcare reform over the next few years depends on a number of factors, including but not limited to pending implementation guidance, potential changes in sales volume eligible for the new rebates, discounts or fees, and the impact of cost sharing arrangements with certain alliance partners. Our future net sales beginning in 2014 could potentially be positively impacted from the expected increase in the number of people with healthcare coverage from the Patient Protection and Affordable Care Act.

In many markets outside the U.S., we operate in environments of government-mandated, cost-containment programs, or under other regulatory bodies or groups exerting downward pressure on pricing. For example, pricing freedom is limited in the UK by the operation of a profit control plan and in Germany by the operation of a reference price system. Many European countries have continuing fiscal challenges as healthcare payers, including government agencies, have reduced and are expected to continue to reduce the cost of healthcare through actions that directly or indirectly impose additional price restrictions. Companies also face significant delays in market access for new products as more than two years can elapse after drug approval before new medicines are available in some countries.

The growth of Managed Care Organizations (MCOs) in the U.S. significantly impacted competition in the healthcare industry. MCOs seek to reduce healthcare expenditures for participants through volume purchases and long-term contractual discounts with various pharmaceutical providers. Because of the market potential created by the large pool of participants, marketing prescription drugs to MCOs is an important part of our strategy. Companies compete for inclusion in MCO formularies and we generally are successful in having our key products included. We believe that developments in the managed care industry, including continued consolidation, continue to have a downward pressure on prices.

Pharmaceutical and biotechnology production processes are complex, highly regulated and vary widely by product. Shifting or adding manufacturing capacity is usually a lengthy process requiring significant capital expenditures and regulatory approvals. Biologics manufacturing involves more complex processes than those of traditional pharmaceutical operations. As biologics become a larger percentage of our product portfolio, we will continue to maintain supply arrangements with third-party manufacturers and incur substantial investments to increase our internal capacity to produce biologics on a commercial scale. The FDA approved our large scale multi-product bulk biologics manufacturing facility in Devens, Massachusetts in May 2012.

We maintain a competitive position in the market and strive to uphold this position, depending on our success in discovering, developing and delivering innovative, cost-effective products to help patients prevail over serious diseases.

We are the subject of a number of significant pending lawsuits, claims, proceedings and investigations. It is not possible at this time to reasonably assess the final outcomes of these investigations or litigations. For additional discussion of legal matters, see Item 8. Financial Statements Note 21. Legal Proceedings and Contingencies.

## **Strategy**

Over the past few years, we transformed our Company into a focused biopharmaceutical company. We continue to focus on sustaining our business and building a foundation for the future by growing our newer key marketed products, advancing our pipeline portfolio and managing our costs. We expect that our portfolio will become increasingly diversified across products and geographies over the next few years.

We experienced substantial exclusivity losses this year for *Plavix*\* and *Avapro*\*/*Avalide*\*, which together had more than \$8 billion of net sales in 2011. We had been preparing for this for a number of years. As expected, we experienced a rapid, precipitous, and material decline in *Plavix*\* and *Avapro*\*/*Avalide*\* net sales and a reduction in net income and operating cash flow. Such events are the norm in the industry when companies experience the loss of exclusivity of a significant product. We will also face additional exclusivity losses in the coming years. We also face significant challenges with an increasingly complex global and regulatory environment and global economic uncertainty, particularly in the European Union (EU). We believe our strategy to grow our newer marketed products and our robust research and development (R&D) pipeline, particularly within the therapeutic areas of immuno-oncology, cardiovascular/metabolic disease and virology, position us well for the future.

We continue to expand our biologics capabilities. We still rely significantly on small molecules as our strongest, most reliable starting point for discovering potential new medicines, but large molecules or biologics, derived from recombinant DNA technologies are becoming increasingly important. Currently, more than 40% of our pipeline compounds are biologics, as are four of our key marketed products, including *Yervoy* (ipilimumab).

We also continue to support our pipeline with our licensing and acquisitions strategy, referred to as our string of pearls. During the third quarter of 2012, we acquired Amylin, a biopharmaceutical company dedicated to the discovery, development and commercialization of innovative medicines for patients with diabetes and other metabolic diseases. Following the completion of our acquisition of Amylin, we entered into a collaboration with AstraZeneca Pharmaceuticals LP, a wholly-owned subsidiary of AstraZeneca, which builds upon our existing alliance, further expanding our collaboration strategy. We are currently integrating the Amylin business into our development, manufacturing and commercial operations. We are also seeking to build relationships with academic organizations that have innovative programs and capabilities that complement our own internal efforts.

### Product and Pipeline Developments

We manage our research and development (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 future growth. We consider our R&D programs that have entered into Phase III development to be significant, as these programs constitute our late-stage development pipeline. These Phase III development 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. Spending on these 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. While we do not expect all of our late-stage development programs to make it to market, our late-stage development programs are the R&D programs that could potentially have an impact on our revenue and earnings within the next few years. The following are the recent significant developments in our marketed products and our late-stage pipeline:

*Eliquis* – an oral Factor Xa inhibitor, targeted at stroke prevention in NVAF and the prevention and treatment of venous thromboembolic (VTE) disorders. *Eliquis* is part of our strategic alliance with Pfizer, Inc. (Pfizer)

In December 2012, the U.S. Food and Drug Administration (FDA) approved *Eliquis* to reduce the risk of stroke and systemic embolism in patients with NVAF. *Eliquis* also received regulatory approval for this indication in Japan and Canada in December 2012, in the EU in November 2012, and in South Korea in January 2013.

In December 2012, the Company announced the results of the Phase III AMPLIFY-EXT trial, which evaluated treatment with *Eliquis* compared to placebo over a one year period for the prevention of recurrent VTE in 2,486 patients who had already completed six to 12 months of anticoagulation treatment for VTE, including deep vein thrombosis or pulmonary embolism. In the trial, extended treatment with *Eliquis* 2.5 mg and 5 mg twice daily, demonstrated superiority versus placebo in the reduction of the composite endpoint of symptomatic, recurrent VTE and death from any cause. *Eliquis* also was superior to placebo for the predefined secondary efficacy outcome of recurrent VTE and VTE-related death. The rate of the primary safety outcome of major bleeding was comparable across treatment groups.

In October 2012, the Company announced in a publication in *The Lancet* that the reductions in stroke or systemic embolism, major bleeding and mortality demonstrated with *Eliquis* compared to warfarin in the ARISTOTLE trial were consistent across a wide range of stroke and bleeding risk scores in patients with NVAF.

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In March 2012, additional analyses from the ARISTOTLE and AVERROES clinical trials were presented at the American College of Cardiology's 61st Annual Scientific Session.

*Forxiga* an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor for the treatment of diabetes that is part of our alliance with AstraZeneca

In November 2012, the EC approved *Forxiga* for the treatment of type 2 diabetes in the EU.

In June 2012, at the 72<sup>nd</sup> American Diabetes Association Scientific Sessions, the Company and AstraZeneca announced results from a Phase III clinical study that showed *Forxiga* 10 mg demonstrated significant reductions in blood sugar levels (glycosylated hemoglobin levels, or HbA1c) compared with placebo at 24 weeks when either agent was added to existing sitagliptin therapy (with or without metformin) in adult patients with type 2 diabetes. The results were maintained over a 24-week extension and similar results were observed when the data were stratified by background therapy. The study also demonstrated significant reductions in total body weight and fasting plasma glucose levels in patients taking *Forxiga* added to sitagliptin (with or without metformin), with results maintained throughout the duration of the study.

In January 2012, the FDA issued a Complete Response Letter (CRL) regarding the NDA for dapagliflozin. The CRL requests additional clinical data to allow a better assessment of the benefit-risk profile for dapagliflozin. The companies will continue to work closely with the FDA to determine the appropriate next steps for the dapagliflozin application, and are in ongoing discussions with health authorities in other countries as part of the application procedures. The Company has met with the FDA and now has a path forward for potential approval for *Forxiga* in the U.S. The Company will provide additional data from ongoing studies to the FDA and expects to be able to resubmit the NDA for *Forxiga* in mid-2013. At this time, the Company expects that the FDA will have a six month period in which to review the resubmission and will hold an Advisory Committee meeting.

Hepatitis C Portfolio (Peginterferon lambda a novel and potential first-in-class type 3 interferon in development; Daclatasvir a NS5A replication complex inhibitor in development; Asunaprevir a NS3 protease inhibitor in development)

In November 2012, the Company announced the results of the global, D-LITE Phase IIb study, in which a 24-week regimen combining the investigational compound peginterferon lambda-1a with the investigational direct-acting antiviral (DAA) daclatasvir and ribavirin, achieved sustained virologic response 12 weeks post-treatment of treatment-naïve, genotype 1b chronic hepatitis C virus infection patients who achieved a protocol-defined response

In November 2012, the Company announced Phase II data demonstrating that the 12-week Triple DAA treatment regime of daclatasvir, asunaprevir, and BMS-791325 (an NS5B non-nucleoside polymerase inhibitor) achieved sustained virologic response 12 weeks post-treatment in 94% of treatment naïve, genotype 1 chronic hepatitis C virus infection patients.

In November 2012, the Company announced Phase II data demonstrating that the dual regimen of daclatasvir and asunaprevir, without interferon or ribavirin, achieved high rates of sustained virologic response 12 weeks post-treatment in patients with genotype 1b hepatitis C virus infections who were prior null responders to alfa interferon and ribavirin.

Elotuzumab an anti-CS1 antibody under investigation for the treatment of multiple myeloma

In December 2012, the Company announced the results of a small, randomized Phase II study in patients with previously treated myeloma. Two doses were tested, 10mg/kg and 20 mg/kg in combination with lenalidomide and low-dose dexamethasone. In the 10 mg/kg arm, median progression-free survival (PFS), or the time without disease progression or death, was not reached after 20.8 months of follow up (N=36) and the objective response rate (ORR) was 92%. Of patients who received elotuzumab at a dose of 20 mg/kg, median PFS was 18.6 months (N=37) and ORR was 76%.

Necitumumab a novel targeted cancer therapy for non-small cell lung cancer

In November 2012, we provided notice of the termination of our global codevelopment and cocommercialization arrangement for necitumumab (IMC-11F8), a fully human monoclonal antibody being investigated as an anticancer treatment, which was discovered by ImClone and was part of the alliance between the Company and Eli Lilly and Company (Lilly), with all rights returning to Lilly. The termination is effective May 2014, though we and Lilly may terminate earlier.

*Sustiva* (efavirenz) a non-nucleoside reverse transcriptase inhibitor for the treatment of HIV.

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In February 2013, the Company announced that the FDA has granted an additional six-month period of exclusivity to market *Sustiva*. Exclusivity for *Sustiva* in the U.S. is now scheduled to expire in March 2015.  
*Baraclude* (entecavir) an oral antiviral agent for the treatment of chronic hepatitis B

In February 2013, the U.S. District Court for the District of Delaware invalidated the composition of matter patent covering *Baraclude*, which was scheduled to expire in 2015.

In October 2012, a labeling update for *Baraclude* was approved by the FDA to include data on African Americans and liver transplant recipients with chronic hepatitis B infection.

*Erbix*\* (cetuximab) a monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor, which is expressed on the surface of certain cancer cells in multiple tumor types as well as normal cells and is currently indicated for use against colorectal cancer and head and neck cancer. *Erbix*\* is part of our alliance with Lilly.

In July 2012, the FDA granted full approval of *Erbix*\* in combination with the chemotherapy regimen folfiri (irinotecan, 5-fluorouracil, leucovorin) for the first-line treatment of patients with KRAS mutation-negative epidermal growth factor receptor-expressing metastatic colorectal cancer as determined by FDA-approved tests for the use.

In April 2012, the FDA issued a CRL regarding the supplemental Biologics License Application (sBLA) in first-line non-small cell lung cancer which stated that, based on the current data package, the first-line indication for *Erbix*\* in combination with vinorelbine and cisplatin is not approvable. Lilly and the Company do not plan to resubmit the filing.

*Yervoy* (ipilimumab) a monoclonal antibody for the treatment of patients with unresectable (inoperable) or metastatic melanoma

In November 2012, the National Institute of Health and Clinical Excellence (NICE) recommended *Yervoy*, which is approved in the EU for the treatment for previously, treated metastatic (advanced) melanoma, within the Final Appraisal Determination. This important recommendation will enable eligible patients in England and Wales to routinely access treatment with *Yervoy* through the National Health Services.

In September 2012, the Company announced at the European Society for Medical Oncology 2012 Congress long-term follow-up data of the 024 study which evaluated newly-diagnosed patients treated with *Yervoy* 10mg/kg in combination with dacarbazine versus dacarbazine alone and five-year follow-up data from the rollover 025 study which evaluated patients with *Yervoy* 0.3 mg/kg or 10 mg/kg. The survival rates observed in study 024 at years three and four were not only stable but higher in patients treated with *Yervoy* plus dacarbazine versus patients who received dacarbazine alone. The estimated survival rates in the 025 study remained unchanged or relatively stable at five years compared to four years in newly-diagnosed patients and previously-diagnosed patients.

*Orencia* a fusion protein indicated for rheumatoid arthritis (RA)

In October 2012, the EC granted marketing authorization for a subcutaneous formulation of *Orencia* in combination with methotrexate for the treatment of moderate to severe active RA in adults.

In June 2012, at the European League Against Rheumatism Annual European Congress of Rheumatology, the Company announced that AMPLE, a head-to-head trial of 646 patients comparing the subcutaneous formulation of *Orencia* vs. *Humira*\* (adalimumab), each on a background of methotrexate (MTX), in biologic naïve patients with moderate to severe RA met its primary endpoint (as measured by non-inferiority) demonstrating that *Orencia* plus MTX achieved comparable rates of efficacy for the American College of Rheumatology criteria of 20 percent (ACR 20) response at one year of 64.8% vs. 63.4% *Humira*\* plus MTX.

In May 2012, the Company announced that the FDA had approved the Company's biologics manufacturing facility in Devens, Massachusetts for commercial production of *Orencia*.

*Nulojix* (belatacept) a fusion protein with novel immunosuppressive activity for the prevention of kidney transplant rejection

In June 2012, at the 2012 American Transplant Congress, the Company announced new four-year results from the long-term extensions (LTE) of the BENEFIT and BENEFIT-EXT clinical trials of *Nulojix*, the first T-cell costimulation blocker indicated for the prophylaxis of organ rejection in adult Epstein-Barr Virus seropositive patients receiving a kidney transplant, in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Results showed that the safety profile of *Nulojix* through year four was consistent compared with results at year three with no new safety signals being identified, and that the renal function benefit versus cyclosporine was



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maintained through four years in patients enrolled in the LTE from both the BENEFIT and BENEFIT-EXT trials. *Onglyza/Kombiglyze* (saxagliptin/once daily combination of saxagliptin and metformin hydrochloride extended-release) a treatment for type 2 diabetes that is part of our strategic alliance with AstraZeneca

In July 2012, the Company and AstraZeneca announced at the 17<sup>th</sup> World Congress on Heart Disease the results of analyses showing that Onglyza 5mg demonstrated improvements across key measures of blood sugar control (glycosylated hemoglobin levels, or HbA1c; fasting plasma glucose, or FPG and post-prandial glucose, or PPG) compared to placebo in adult patients with type 2 diabetes at high risk for cardiovascular disease.

In addition, in August 2012, the Company discontinued development of BMS-986094. This decision was made in the interest of patient safety. See Item 8. Financial Statements Note 13. Goodwill and Other Intangible Assets for further information.

**RESULTS OF OPERATIONS***Net Sales*

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

Dollars in Millions	Year Ended December 31, Net Sales			2012 vs. 2011 Analysis of % Change				2011 vs. 2010 Analysis of % Change			
	2012	2011	2010	Total Change	Volume	Price	Foreign Exchange	Total Change	Volume	Price	Foreign Exchange
United States <sup>(a)</sup>	\$ 10,384	\$ 14,039	\$ 12,800	(26)%	(30)%	4%		10%	3%	7%	
Europe <sup>(b)</sup>	3,706	3,879	3,672	(4)%	6%	(3)%	(7)%	6%	5%	(4)%	5%
Rest of the World <sup>(c)</sup>	3,204	3,237	2,900	(1)%	2%	(1)%	(2)%	12%	8%	(2)%	6%
Other <sup>(d)</sup>	327	89	112	**	N/A	N/A		(21)%	N/A	N/A	
<b>Total</b>	<b>\$ 17,621</b>	<b>\$ 21,244</b>	<b>\$ 19,484</b>	<b>(17)%</b>	<b>(17)%</b>	<b>2%</b>	<b>(2)%</b>	<b>9%</b>	<b>4%</b>	<b>3%</b>	<b>2%</b>

(a) Includes Puerto Rico.

(b) Includes Russia and Turkey.

(c) Includes Japan, China, Canada, Australia and Brazil, among other countries.

(d) Includes royalty-related revenues and sales attributed to supply agreements.

\*\* Change in excess of 100%.

The change in U.S. net sales in 2012 attributed to volume reflects the recent exclusivity losses of *Plavix\** and *Avapro\*/Avalide\**, partially offset by increased demand for most key products and the addition of *Byetta\**, *Bydureon\**, and *Symlin\** following the completion of our acquisition of Amylin (\$262 million). The change in U.S. net sales in 2011 attributed to volume reflects the launch of *Yervoy* and increased demand for several key products partially offset by decreased prescription demand for *Avapro\*/Avalide\** and *Plavix\**. The change in U.S. net sales attributed to price in both periods was a result of higher average net selling prices for *Plavix\** and *Abilify\** partially offset by the reduction in our contractual share of *Abilify\** net sales from 58% to 53.5% in 2011 and a further reduction to 51.5% in 2012, and higher rebates and discounts resulting from U.S. healthcare reform legislation in 2011. See [Key Products](#) for further discussion of sales by key product.

Net sales in Europe decreased in 2012 primarily due to unfavorable foreign exchange and lower sales of certain mature brands from divestitures and generic competition as well as generic competition for *Plavix\** and *Avapro\*/Avalide\** partially offset by sales growth of most key products. Net sales in Europe increased in 2011 as favorable foreign exchange and sales growth of most key products more than offset the previously mentioned lower sales of certain mature brands and generic competition for *Plavix\** and *Avapro\*/Avalide\**. Net sales in both periods were negatively impacted by continuing fiscal challenges in many European countries as healthcare payers, including government agencies, have reduced and are expected to continue to reduce the cost of healthcare through actions that directly or indirectly impose additional price reductions. These measures include, but are not limited to, mandatory discounts, rebates, other price reductions and other restrictive measures.

Net sales in the Rest of the World decreased in 2012 as growth in certain key products in Japan, China, and South Korea was more than offset by generic competition for *Plavix\** and *Avapro\*/Avalide\**, the timing of government purchases in certain countries and lower sales of mature brands from generic competition and divestitures. Net sales in the Rest of the World increased in 2011 primarily due to growth in certain key products in Japan, China and South Korea and favorable foreign exchange, which were partially offset by generic competition for *Avapro\*/Avalide\** and lower sales of mature brands from generic competition and divestitures.

Other net sales increased in 2012 because of enhanced royalty-related revenues and higher sales attributed to active pharmaceutical ingredients supply agreements resulting from recent divestitures of manufacturing facilities and restructured alliance agreements. Other net sales are expected to continue to increase in 2013 as a result of higher royalties and alliance revenue attributed to the restructured Sanofi agreement and new mature/over-the-counter brands collaborative agreements.

No single country outside the U.S. contributed more than 10% of our total net sales in 2012, 2011 or 2010.

In general, our business is not seasonal. For information on U.S. pharmaceutical prescriber demand, reference is made to the table within

Estimated End-User Demand below, which sets forth a comparison of changes in net sales to the estimated total prescription growth (for both retail and mail order customers) for certain of our key products. U.S. and non-U.S. net sales are categorized based upon the location of the

customer.

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Revenue is reduced for and presented net of gross-to-net sales adjustments that are further described in Critical Accounting Policies below.

The reconciliation of gross sales to net sales by each significant category of gross-to-net sales adjustments was as follows:

Dollars in Millions	Year Ended December 31,			% Change	
	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
<b>Gross Sales</b>	\$ 19,816	\$ 24,007	\$ 21,681	(17)%	11%
<b>Gross-to-Net Sales Adjustments</b>					
Charge-Backs Related to Government Programs	(651)	(767)	(605)	(15)%	27%
Cash Discounts	(192)	(282)	(255)	(32)%	11%
Managed Healthcare Rebates and Other Contract Discounts	(284)	(752)	(499)	(62)%	51%
Medicaid Rebates	(386)	(536)	(453)	(28)%	18%
Sales Returns	(248)	(76)	(88)	226%	(14)%
Other Adjustments	(434)	(350)	(297)	24%	18%
<b>Total Gross-to-Net Sales Adjustments</b>	<b>(2,195)</b>	<b>(2,763)</b>	<b>(2,197)</b>	<b>(21)%</b>	<b>26%</b>
<b>Net Sales</b>	<b>\$ 17,621</b>	<b>\$ 21,244</b>	<b>\$ 19,484</b>	<b>(17)%</b>	<b>9%</b>

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

Dollars in Millions	Charge-Backs Related to		Healthcare Rebates and Other				Total
	Government Programs	Cash Discounts	Contract Discounts	Medicaid Rebates	Sales Returns	Other Adjustments	
Balance at January 1, 2011	\$ 48	\$ 29	\$ 216	\$ 327	\$ 187	\$ 127	\$ 934
Provision related to sales made in current period	767	282	752	541	120	357	2,819
Provision related to sales made in prior periods				(5)	(44)	(7)	(56)
Returns and payments	(764)	(283)	(550)	(452)	(101)	(296)	(2,446)
Impact of foreign currency translation			(1)		(1)		(2)
Balance at December 31, 2011	\$ 51	\$ 28	\$ 417	\$ 411	\$ 161	\$ 181	\$ 1,249
Provision related to sales made in current period	651	191	351	423	256	451	2,323
Provision related to sales made in prior periods		1	(67)	(37)	(8)	(17)	(128)
Returns and payments	(663)	(208)	(561)	(459)	(88)	(435)	(2,414)
Amylin acquisition	2	1	34	13	23	3	76
Impact of foreign currency translation			1		1		2
Balance at December 31, 2012	\$ 41	\$ 13	\$ 175	\$ 351	\$ 345	\$ 183	\$ 1,108

Gross-to-net sales adjustment rates are primarily a function of changes in sales mix and contractual and legislative discounts and rebates. Gross-to-net sales adjustments decreased in 2012 and increased in 2011 due to:

All gross-to-net adjustment categories other than sales returns and other adjustments decreased in 2012 as a result of lower *Plavix*\* sales following its loss of exclusivity.

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Managed healthcare rebates and other contract discounts also decreased in 2012 due to a \$67 million reduction in the estimated amount of Medicare Part D coverage gap discounts attributable to prior period rebates after receiving actual invoices and the nonrenewal of *Plavix*\* contract discounts in the Medicare Part D program as of January 1, 2012. These rebates and discounts increased in 2011 due to the 50% discount for patients within the Medicare Part D coverage gap.

Medicaid rebates also decreased in 2012 due to a \$37 million reduction in the estimated amount of managed Medicaid rebates attributable to prior periods after receiving actual invoices. In 2011, Medicaid rebates increased due to the full year impact of the expansion of rebates for drugs used in risk-based Medicaid managed care plans, higher average net selling prices for *Plavix*\* and higher Medicaid channel sales.

The provision for sales returns increased as a result of the loss of exclusivity in the U.S. of *Plavix*\* in May 2012 and *Avapro*\*/*Avalide*\* in March 2012. The U.S. sales return reserves for these products at December 31, 2012 were \$173 million and determined after considering several factors including estimated inventory levels in the distribution channels. In accordance with Company policy, these products are eligible to be returned between six months prior to and 12 months after product expiration. Additional adjustments to these reserves might be required in the future for revised estimates to various assumptions including actual returns which are generally not expected to occur until 2014. In 2011, sales returns included a \$29 million reduction of a \$44 million U.S. return reserve established in 2010 in connection with a recall of certain lots of *Avalide*\* due to lower returns than expected.

Other adjustments increased in 2012 as a result of co-pay and coupon programs.

Although not presented as a gross-to-net adjustment in the above tables, our contractual share of *Abilify*\* and *Atripa*\* gross-to-net sales adjustments were approximately \$1.5 billion in 2012, \$1.3 billion in 2011 and \$1.0 billion in 2010. These increases were primarily attributed to additional rebates and discounts required under U.S. healthcare reform.

Key Products

Net sales of key products represented 84% of total net sales in 2012, 86% in 2011 and 84% in 2010. The following table presents U.S. and international net sales by key product, the percentage change from the prior period and the foreign exchange impact when compared to the prior period. Commentary detailing the reasons for significant variances for key products is provided below:

Dollars in Millions	Year Ended December 31,			% Change 2012 vs. 2011	% Change Attributable to Foreign Exchange			
	2012	2011	2010		2012 vs. 2011	2012 vs. 2011	2012 vs. 2011	
<b>Key Products</b>								
<i>Plavix* (clopidogrel bisulfate)</i>	\$ 2,547	\$ 7,087	\$ 6,666	(64)%	6 %			
U.S.	2,424	6,709	6,236	(64)%	8 %			
Non-U.S.	123	378	430	(67)%	(12)%	(1)%	3 %	
<i>Avapro*/Avalide*</i>								
(irbesartan/irbesartan-hydrochlorothiazide)	503	952	1,176	(47)%	(19)%	(1)%	2 %	
U.S.	155	549	679	(72)%	(19)%			
Non-U.S.	348	403	497	(14)%	(19)%	(3)%	4 %	
<i>Eliquis* (apixaban)</i>	2	N/A	N/A	N/A	N/A			
U.S.		N/A	N/A	N/A	N/A			
Non-U.S.	2	N/A	N/A	N/A	N/A			
<i>Abilify* (aripiprazole)</i>	2,827	2,758	2,565	3 %	8 %	(1)%	2 %	
U.S.	2,102	2,052	1,971	2 %	4 %			
Non-U.S.	725	706	594	3 %	19 %	(7)%	6 %	
<i>Reyataz (atazanavir sulfate)</i>	1,521	1,569	1,479	(3)%	6 %	(3)%	2 %	
U.S.	783	771	766	2 %	1 %			
Non-U.S.	738	798	713	(8)%	12 %	(6)%	5 %	
<i>Sustiva (efavirenz) Franchise</i>	1,527	1,485	1,368	3 %	9 %	(2)%	2 %	
U.S.	1,016	950	891	7 %	7 %			
Non-U.S.	511	535	477	(4)%	12 %	(5)%	5 %	
<i>Baraclude (entecavir)</i>	1,388	1,196	931	16 %	28 %	(2)%	5 %	
U.S.	241	208	179	16 %	16 %			
Non-U.S.	1,147	988	752	16 %	31 %	(2)%	6 %	
<i>Erbix* (cetuximab)</i>	702	691	662	2 %	4 %			
U.S.	688	681	654	1 %	4 %			
Non-U.S.	14	10	8	40 %	25 %	(2)%	5 %	
<i>Sprycel (dasatinib)</i>	1,019	803	576	27 %	39 %	(4)%	3 %	
U.S.	404	299	190	35 %	57 %			
Non-U.S.	615	504	386	22 %	31 %	(6)%	6 %	
<i>Yervoy (ipilimumab)</i>	706	360	N/A	96 %	N/A			
U.S.	503	323	N/A	56 %	N/A			
Non-U.S.	203	37	N/A	**	N/A			
<i>Orencia (abatacept)</i>	1,176	917	733	28 %	25 %	(2)%	2 %	
U.S.	797	621	552	28 %	13 %			
Non-U.S.	379	296	181	28 %	64 %	(6)%	8 %	
<i>Nulojix (belatacept)</i>	11	3	N/A	**	N/A			
U.S.	9	3	N/A	**	N/A			
Non-U.S.	2		N/A	N/A	N/A			
<i>Onglyza/Kombiglyze</i>	709	473	158	50 %	**	(2)%	3 %	

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*(saxagliptin/saxagliptin and metformin)*

U.S.	516	346	121	49 %	**		
Non-U.S.	193	127	37	52 %	**	(9)%	**

\*\* Change in excess of 100%.

Dollars in Millions	Year Ended December 31,			% Change			% Change Attributable to Foreign Exchange	
	2012	2011	2010	2012 vs. 2011	2011 vs. 2010	2012 vs. 2011	2011 vs. 2010	2010 vs. 2010
<b>Key Products (continued)</b>								
<i>Byetta* (exenatide)</i>	\$ 149	\$ N/A	\$ N/A	N/A	N/A	N/A	N/A	N/A
U.S.	147	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Non-U.S.	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Bydureon*</i>								
(exenatide extended-release for injectable suspension)	78	N/A	N/A	N/A	N/A	N/A	N/A	N/A
U.S.	75	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Non-U.S.	3	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<b>Mature Products and All Other</b>	2,756	2,950	3,170	(7)%	(7)%	(3)%	4 %	
U.S.	524	527	561	(1)%	(6)%			
Non-U.S.	2,232	2,423	2,609	(8)%	(7)%	(3)%	5 %	

\*\* Change in excess of 100%.

*Plavix\** a platelet aggregation inhibitor that is part of our alliance with Sanofi

U.S. net sales decreased in 2012 and will continue to decrease in 2013 due to the loss of exclusivity in May 2012. U.S. net sales increased in 2011 primarily due to higher average net selling prices. Estimated total U.S. prescription demand decreased 60% in 2012 and 5% in 2011.

International net sales continue to be negatively impacted by generic clopidogrel products in the EU, Canada, and Australia.

*Avapro\*/Avalide\** (known in the EU as *Aprovel\*/Karvea\**) an angiotensin II receptor blocker for the treatment of hypertension and diabetic nephropathy that is also part of the Sanofi alliance

U.S. net sales decreased in 2012 due to the loss of exclusivity in March 2012 and decreased in 2011 due to market share losses subsequent to the *Avalide\** supply shortage in the first quarter of 2011 associated with previously reported recalls. The decrease in U.S. net sales in 2011 was partially offset by higher average net selling prices and estimated returns. Total estimated U.S. prescription demand decreased 71% in 2012 and 39% in 2011.

International net sales decreased in both periods due to lower demand including generic competition in certain EU markets and Canada.

*Eliquis* an oral Factor Xa inhibitor, targeted at stroke prevention in atrial fibrillation and the prevention and treatment of VTE disorders. *Eliquis* is part of our strategic alliance with Pfizer.

*Eliquis* was approved in the U.S. for prevention of stroke and systemic embolism in adult patients with NVAf in December 2012.

*Eliquis* was approved in the EU for VTE prevention in May 2011 and was launched in a limited number of EU countries beginning in May 2011. *Eliquis* was also approved in the EU for the prevention of stroke and systemic embolism in adult patients with NVAf in November 2012. *Eliquis* was approved in December 2012 by the Japanese Ministry of Health, Labor and Welfare for the prevention of ischemic stroke and systemic embolism in patients with NVAf.

*Abilify\** an antipsychotic agent for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder and is part of our strategic alliance with Otsuka



U.S. net sales increased in 2012 due to higher average net selling prices and a \$62 million reduction in BMS' s share in the estimated amount of customer rebates and discounts attributable to 2011 based on actual invoices received that were partially offset by fluctuations in retail buying patterns. U.S. net sales increased in 2011 due to higher overall demand and higher average net selling prices. U.S. net sales in both periods were negatively impacted by the reduction in our contractual share of net sales from 58.0% in 2010 to 53.5% in 2011 to 51.5% in 2012 and are expected to continue to be negatively impacted in 2013 as a result of a further reduction in BMS' s contractual share of *Abilify*\* net sales (estimated at approximately 35%). Estimated total U.S. prescription demand increased 1% in 2012 and 5% in 2011.

International net sales increased in both periods primarily due to higher demand. International net sales were impacted by unfavorable foreign exchange in 2012 and favorable foreign exchange in 2011.

*Reyataz* a protease inhibitor for the treatment of the human immunodeficiency virus (HIV)

U.S. net sales increased in 2012 due to higher average net selling prices. Estimated total prescription demand decreased 5% in 2012 and increased 2% in 2011.

International net sales decreased in 2012 due to unfavorable foreign exchange, the timing of government purchases in certain countries and lower demand resulting from competing products. International net sales increased in 2011 due to higher demand.

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

U.S. net sales increased in both periods primarily due to higher demand and higher average net selling prices. Estimated total U.S. prescription demand decreased 1% in 2012 and increased 7% in 2011.

International net sales decreased in 2012 due to unfavorable foreign exchange. International net sales in 2011 increased primarily due to higher demand.

*Baraclude* an oral antiviral agent for the treatment of chronic hepatitis B

Net sales in both periods increased primarily due to higher demand.

We may experience a rapid and significant decline in U.S. net sales beginning in 2013 due to possible generic competition following a federal court's decision in February 2013 invalidating the composition of matter patent.

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

Sold by us almost exclusively in the U.S., net sales remained relatively flat in 2012 and increased in 2011 primarily due to higher demand.

*Sprycel* an oral inhibitor of multiple tyrosine kinases indicated for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy, including *Gleevec*\* (imatinib mesylate) and first-line treatment of adults with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. *Sprycel* is part of our strategic alliance with Otsuka.

U.S. net sales in both periods increased primarily due to higher demand and higher average net selling prices. Estimated total U.S. prescription demand increased 29% in 2012 and 30% in 2011.

International net sales in both periods increased primarily due to higher demand. International net sales were impacted by unfavorable foreign exchange in 2012 and favorable foreign exchange in 2011.

Demand in 2011 was positively impacted by the approval of *Sprycel* for first-line treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase in the U.S. and the EU in the fourth quarter of 2010.

*Yervoy* a monoclonal antibody for the treatment of patients with unresectable (inoperable) or metastatic melanoma

*Yervoy* net sales increased from higher demand since its launch in the U.S. in the second quarter of 2011 and continued launches in a number of international countries since the second quarter of 2011.

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

U.S. net sales increased in both periods primarily due to higher demand, including the launch of the *Orencia* subcutaneous formulation (SC) in the fourth quarter of 2011, and higher average net selling prices.

International net sales increased in both periods primarily due to higher demand, including the launch of *Orencia SC* in certain European markets beginning in the second quarter of 2012. International net sales were impacted by unfavorable foreign exchange in 2012 and favorable foreign exchange in 2011.

*Nulojix* a fusion protein with novel immunosuppressive activity targeted at prevention of kidney transplant rejection

*Nulojix* was approved and launched in the U.S. and EU during 2011.

*Onglyza/Kombiglyze* (known in the EU as *Onglyza/Komboglyze*) a once-daily oral tablet for the treatment of type 2 diabetes that is part of our strategic alliance with AstraZeneca

U.S. net sales of *Onglyza/Kombiglyze* increased in both periods primarily due to higher overall demand and higher average net selling prices in 2012. *Kombiglyze* was launched in the U.S. in the fourth quarter of 2010.

International net sales increased in both periods primarily due to higher demand, which was partially offset by unfavorable foreign exchange in 2012.

*Byetta*\* a twice daily glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of type 2 diabetes

*Byetta*\* net sales are included in our results following the completion of our acquisition of Amylin in the third quarter of 2012.  
*Bydureon*\* a once-weekly GLP-1 receptor agonist for the treatment of type 2 diabetes

*Bydureon*\* was launched by Amylin in the U.S. in the first quarter of 2012 and in the EU in the second quarter of 2012. Net sales are included in our results following the completion of our acquisition of Amylin in the third quarter of 2012.  
Mature Products and All Other includes all other products, including those which have lost exclusivity in major markets, over-the-counter brands and royalty-related revenue

U.S. net sales continued to decrease in 2012 from generic erosion of certain products which was partially offset by sales of *Symlyn*\* following the completion of our Amylin acquisition in the third quarter of 2012.

International net sales decreased in both periods due to the continued generic erosion of certain brands and unfavorable foreign exchange in 2012.

The estimated U.S. prescription change data provided throughout this report includes information only from the retail and mail order channels and does not reflect product demand within other channels such as hospitals, home health care, clinics, federal facilities including Veterans Administration hospitals, and long-term care, among others. The data is provided by Wolters Kluwer Health (WK), except for *Sprycel*, and is based on the Source Prescription Audit. *Sprycel* demand is based upon information from the Next-Generation Prescription Service version 2.0 of the National Prescription Audit provided by the IMS Health (IMS). The data is a product of each respective service providers own recordkeeping and projection processes and therefore subject to the inherent limitations of estimates based on sampling and may include a margin of error.

We continuously seek to improve the quality of our estimates of prescription change amounts and ultimate patient/consumer demand by reviewing the calculation methodologies employed and analyzing internal and third-party data. We expect to continue to review and refine our methodologies and processes for calculation of these estimates and will monitor the quality of our own and third parties data used in such calculations.

We calculated the estimated total U.S. prescription change on a weighted-average basis to reflect the fact that mail order prescriptions include a greater volume of product supplied, compared to retail prescriptions. Mail order prescriptions typically reflect a 90-day prescription whereas retail prescriptions typically reflect a 30-day prescription. The calculation is derived by multiplying mail order prescription data by a factor that approximates three and adding to this the retail prescriptions. We believe that a calculation of estimated total U.S. prescription change based on this weighted-average approach provides a superior estimate of total prescription demand in retail and mail order channels. We use this methodology for our internal demand reporting.

Estimated End-User Demand

The following tables set forth for each of our key products sold in the U.S. for the years ended December 31, 2012, 2011 and 2010: (i) change in reported U.S. net sales for each year; (ii) estimated total U.S. prescription change for the retail and mail order channels calculated by us based on third-party data on a weighted-average basis, and (iii) months of inventory on hand in the wholesale distribution channel.

Dollars in Millions	Year Ended December 31,				At December 31,		
	Change in U.S. Net Sales		% Change in U.S. Total Prescriptions		Months on Hand		
	2012	2011	2012	2011	2012	2011	2010
<i>Plavix</i> *	(64)%	8%	(60)%	(5)%	1.3	0.5	0.5
<i>Avapro</i> */ <i>Avalide</i> *	(72)%	(19)%	(71)%	(39)%	1.9	0.6	0.4
<i>Abilify</i> *	2%	4%	1%	5%	0.4	0.5	0.4
<i>Reyataz</i>	2%	1%	(5)%	2%	0.5	0.5	0.5
<i>Sustiva Franchise</i> <sup>(a)</sup>	7%	7%	(1)%	7%	0.6	0.6	0.4
<i>Baraclude</i>	16%	16%	11%	9%	0.5	0.6	0.6
<i>Erbix</i> <sup>(b)</sup>	1%	4%	N/A	N/A	0.6	0.6	0.5
<i>Sprycel</i>	35%	57%	29%	30%	0.7	0.7	0.6
<i>Yervoy</i> <sup>(b)(d)</sup>	56%	N/A	N/A	N/A	0.6	0.6	N/A
<i>Orencia</i> <sup>(c)</sup>	28%	13%	N/A	N/A	0.5	0.5	0.6
<i>Nulojix</i> <sup>(b)(d)</sup>	**	N/A	N/A	N/A	0.9	3.5	N/A
<i>Onglyza/Kombiglyze</i>	49%	**	47%	**	0.5	0.5	0.8
<i>Byetta</i> <sup>(e)</sup>	N/A	N/A	N/A	N/A	0.8	N/A	N/A
<i>Bydureon</i> <sup>(e)</sup>	N/A	N/A	N/A	N/A	0.8	N/A	N/A

(a) The *Sustiva Franchise* includes sales of *Sustiva*, as well as revenue of bulk efavirenz included in the combination therapy *Atripla*\*. The months on hand relates only to *Sustiva*.

(b) *Erbix*\*, *Yervoy* and *Nulojix* are parenterally administered products and do not have prescription-level data as physicians do not write prescriptions for these products.

(c) *Orencia* intravenous formulation is a parenterally administered product and does not have prescription-level data as physicians do not write prescriptions for this product. The *Orencia* subcutaneous formulation (*Orencia SC*) is not parenterally administered and was launched in the U.S. in the fourth quarter of 2011. *Orencia SC* sales were \$201 million in 2012 and \$15 million in 2011.

(d) *Yervoy* and *Nulojix* were launched in the U.S. in the second quarter of 2011.

(e) *Byetta*\* and *Bydureon*\* net sales are included in our results following the completion of our acquisition of Amylin in the third quarter of 2012.

\*\* Change in excess of 100%.

Pursuant to the U.S. Securities and Exchange Commission (SEC) Consent Order described below under "SEC Consent Order", we monitor the level of inventory on hand in the U.S. wholesaler distribution channel and outside of the U.S. in the direct customer distribution channel. We are obligated to disclose products with levels of inventory in excess of one month on hand or expected demand, subject to a de minimis exception. Estimated levels of inventory in the distribution channel in excess of one month on hand for these products were not material as of the dates indicated above. Below are U.S. products that had estimated levels of inventory in the distribution channel in excess of one month on hand at December 31, 2012, and international products that had estimated levels of inventory in the distribution channel in excess of one month on hand at September 30, 2012.

*Plavix*\* had 1.3 months of inventory on hand in the U.S. compared to 0.5 months of inventory on hand at December 31, 2011 due to the loss of exclusivity in May 2012. We expect a gradual decrease in inventory on hand of *Plavix*\* to occur over the next few years as product in the wholesale distribution channel continues to be worked down or returned. Levels of inventory on hand in the wholesale and retail distribution channels were considered in assessing the sales return reserves established as of December 31, 2012.

*Avapro*\*/*Avalide*\* had 1.9 months of inventory on hand in the U.S. compared to 0.6 of inventory on hand at December 31, 2011 due to the loss of exclusivity in March 2012 and a one-time increase of \$3 million of inventory in the wholesale and retail distribution channels corresponding with the transition of *Avapro*\*/*Avalide*\* manufacturing to Sanofi pursuant to the restructured agreement. Levels of inventory on hand in the wholesale and retail distribution channels were considered in assessing the sales return reserves established as of December 31, 2012.

*Dafalgan*, an analgesic product sold principally in Europe, had 1.1 months of inventory on hand at direct customers compared to 1.0 months of inventory on hand at December 31, 2011. The level of inventory on hand was primarily due to ordering patterns of pharmacists in France.



*Fervex*, a cold and flu product, had 2.9 months of inventory on hand internationally at direct customers compared to 5.3 months of inventory on hand at December 31, 2011. The level of inventory on hand decreased following the peak of flu season, with the remaining inventory on hand primarily attributable to ordering patterns of pharmacists in France.

*Luftal*, an antacid product, had 1.5 months of inventory on hand internationally at direct customers compared to 1.9 months of inventory on hand at December 31, 2011. The level of inventory on hand was primarily due to government purchasing patterns in Brazil.

In the U.S., for all products sold exclusively through wholesalers or through distributors, we generally determined our months on hand estimates using inventory levels of product on hand and the amount of out-movement provided by our three largest wholesalers, which account for approximately 90% of total gross sales of U.S. products, and provided by our distributors. Factors that may influence our estimates include generic competition, seasonality of products, wholesaler purchases in light of increases in wholesaler list prices, new product launches, new warehouse openings by wholesalers and new customer stockings by wholesalers. In addition, these estimates are calculated using third-party data, which may be impacted by their recordkeeping processes.

For our businesses outside of the U.S., we have significantly more direct customers. Limited information on direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information, where available, varies widely. In cases where direct customer product level inventory, ultimate patient/consumer demand or out-movement data does not exist or is otherwise not available, we have developed a variety of other methodologies to estimate such data, including using such factors as historical sales made to direct customers and third-party market research data related to prescription trends and end-user demand. Accordingly, we rely on a variety of methods to estimate direct customer product level inventory and to calculate months on hand. Factors that may affect our estimates include generic competition, seasonality of products, direct customer purchases in light of price increases, new product launches, new warehouse openings by direct customers, new customer stockings by direct customers and expected direct customer purchases for governmental bidding situations. As such, all of the information required to estimate months on hand in the direct customer distribution channel for non-U.S. business for the year ended December 31, 2012 is not available prior to the filing of this annual report on Form 10-K. We will disclose any product with levels of inventory in excess of one month on hand or expected demand, subject to a de minimis exception, in the next quarterly report on Form 10-Q.

## Expenses

Dollar in Millions	2012	2011	2010	% Change	
				2012 vs. 2011	2011 vs. 2010
Cost of products sold	\$ 4,610	\$ 5,598	\$ 5,277	(18)%	6%
Marketing, selling and administrative	4,220	4,203	3,686	%	14%
Advertising and product promotion	797	957	977	(17)%	(2)%
Research and development	3,904	3,839	3,566	2%	8%
Impairment charge for BMS-986094 intangible asset	1,830			N/A	N/A
Other (income)/expense	(80)	(334)	(93)	(76)%	**
<b>Total Expenses</b>	<b>\$ 15,281</b>	<b>\$ 14,263</b>	<b>\$ 13,413</b>	<b>7%</b>	<b>6%</b>

\*\* Change is in excess of 100%.

### Cost of products sold

Cost of products sold consists of material costs, internal labor and overhead from our owned manufacturing sites, third-party processing costs, other supply chain costs and the settlement of foreign currency forward contracts that are used to hedge forecasted intercompany inventory purchase transactions. Essentially all of these costs are managed by our global manufacturing and supply organization. Cost of products also includes royalties and profit sharing attributed to licensed products and alliances, amortization of acquired developed technology costs from business combinations and milestone payments that occur on or after regulatory approval.

Cost of products sold can vary between periods as a result of product mix (particularly resulting from royalties and profit sharing expenses in connection with our alliances), price, inflation and costs attributed to the rationalization of manufacturing sites resulting in accelerated depreciation, impairment charges and other stranded costs. In addition, changes in foreign currency may also provide volatility given a high percentage of total costs are denominated in foreign currencies. Cost of products sold as a percentage of net sales were 26.2% in 2012, 26.4% in 2011, and 27.1% in 2010.

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The decrease in cost of products sold in 2012 was primarily attributed to lower sales volume following the loss of exclusivity of *Plavix*\* and *Avapro*\*/*Avalide*\* which resulted in lower royalties in connection with our Sanofi alliance and favorable foreign exchange partially offset by impairment charges discussed below and higher amortization costs resulting from the Amylin acquisition (net of the amortization of the Amylin collaboration proceeds).

Impairment charges of \$147 million were recognized in 2012, of which \$120 million was related to a partial write-down to fair value of developed technology costs related to a non-key product (*Recothrom*) acquired in the acquisition of ZymoGenetics, Inc. (ZymoGenetics). The developed technology impairment charge resulted from continued competitive pricing pressures and a reduction



in the undiscounted projected cash flows to an amount less than the carrying value of the intangible asset. The impairment charge was calculated as the difference between the fair value of the asset based on the discounted value of the estimated future cash flows and the carrying value of the intangible asset. The remaining \$27 million impairment charge related to the abandonment of a manufacturing facility resulting from the outsourcing of a manufacturing process.

The increase in 2011 was primarily attributable to higher sales volume resulting in additional royalties, collaboration fees, and profit sharing expense, and unfavorable foreign exchange.

#### Marketing, selling and administrative

Marketing, selling and administrative expenses consist of salary and benefit costs, third-party professional and marketing fees, outsourcing fees, shipping and handling costs and other expenses that are not attributed to product manufacturing costs or research and development expenses. These expenses are managed through regional commercialization organizations or global corporate organizations such as finance, law, information technology and human resources.

Marketing, selling and administrative expenses increased slightly in 2012 primarily as a result of the Amylin acquisition (\$125 million, including \$67 million related to the accelerated vesting of stock options and restricted stock units), partially offset by a reduction in sales-related activities for *Plavix\** and *Avapro\*/Avalide\**. Marketing, selling and administrative expenses were also impacted by favorable foreign exchange.

The increase in 2011 was attributed to the annual pharmaceutical company fee, unfavorable foreign exchange and higher marketing costs to support new launches and key products and to a lesser extent, higher bad debt expense in the EU, charitable funding and information technology expenses.

The annual pharmaceutical company fee was \$246 million in 2012 and \$220 million in 2011. For further information regarding the annual pharmaceutical company fee, refer to Item 1. Business Government Regulation and Price Constraints.

#### Advertising and product promotion

Advertising and product promotion expenses consist of related media, sample and direct to consumer programs.

The decrease in 2012 was primarily attributed to lower spending on the promotion of *Plavix\**, *Avapro\*/Avalide\**, *Abilify\**, and certain mature brands in the U.S. to coincide with their product life cycle.

#### Research and development

Research and development expenses consist of salary and benefit costs, third-party grants and fees paid to clinical research organizations, supplies and facility costs. 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, facilities, information technology, and employee stock compensation costs, and other appropriate costs. These expenses also include third-party licensing fees that are typically paid upfront as well as when regulatory or other contractual milestones are met. Certain expenses are shared with alliance partners based upon contractual agreements.

Most expenses are managed by our global research and development organization of which, approximately \$1.9 billion of the total spend was attributed to development activities with the remainder attributed to preclinical and research activities. These expenses can vary between periods for a number of reasons, including the timing of upfront, milestone and other licensing payments.

Research and development expenses increased in 2012 primarily from \$60 million of expenses related to the Amylin acquisition (including \$27 million related to the accelerated vesting of Amylin stock options and restricted stock units), partially offset by favorable foreign exchange and the net impact of upfront, milestone, and other licensing payments and IPRD impairment charges. Refer to Specified Items

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included in Non-GAAP Financial Measures for amounts attributed to each period. IPRD impairment charges relate to projects previously acquired in the Medarex, Inc. (Medarex) acquisition and Inhibitex acquisition (including \$45 million in 2012 related to FV-100, a nucleoside inhibitor for the reduction of shingles-associated pain) resulting from unfavorable clinical trial results and decisions to cease further development.

The increase in 2011 was attributed to higher upfront, milestone and other licensing payments, unfavorable foreign exchange, and additional development costs resulting from the acquisition of ZymoGenetics. Upfront, milestone and other licensing payments were \$207 million in 2011, including an \$88 million payment associated with an amendment of an intellectual property license agreement for *Yervoy* prior to its FDA approval and payments for exclusive licenses to develop and commercialize certain programs and compounds.

Impairment charge for BMS-986094 intangible asset

A \$1.8 billion impairment charge was recognized when the development of BMS-986094 (formerly INX-189), a compound which we acquired as part of our acquisition of Inhibitex to treat hepatitis C virus infection, was discontinued in the interest of patient safety. See Item 1. Financial Statements Note 13. Goodwill and Other Intangible Assets for further information.

Other (income)/expense

Other (income)/expense include:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Interest expense	\$ 182	\$ 145	\$ 145
Investment income	(106)	(91)	(75)
Provision for restructuring	174	116	113
Litigation charges/(recoveries)	(45)	6	(2)
Equity in net income of affiliates	(183)	(281)	(313)
Impairment and loss on sale of manufacturing operations			236
Out-licensed intangible asset impairment	38		
Gain on sale of product lines, businesses and assets	(53)	(37)	(39)
Other income received from alliance partners, net	(312)	(140)	(137)
Pension curtailments and settlements	158	10	28
Other	67	(62)	(49)
Other (income)/expense	\$ (80)	\$ (334)	\$ (93)

Interest expense increased due to the termination of interest rate swap contracts in 2011 and higher borrowings in 2012.

Investment income included a \$10 million gain from the sale of auction rate securities in 2012.

Provision for restructuring was primarily attributable to employee termination benefits for continuous improvement initiatives. Additional employee termination costs of approximately \$300 million are expected to be incurred in 2013 as a result of workforce reductions in several European countries. The majority of the costs will not be recognized until the completion of discussions with local workers council, subject to local regulations. The expected employee reductions are primarily attributed to sales force personnel resulting from restructuring of the Sanofi and Otsuka agreements and streamlining of the operations due to challenging market conditions in Europe.

Litigation charges/(recoveries) in 2012 included \$172 million for our share of the Apotex damages award concerning *Plavix*\*, partially offset by increases in reserves for product liability, pricing, sales and promotional matters.

Equity in net income of affiliates is primarily related to our international partnership with Sanofi which decreased in 2012 as a result of the continued impact of generic competition on international *Plavix*\* net sales, conversion of certain territories to opt-out markets and the impact of unfavorable foreign exchange.

Impairment and loss on sale of manufacturing operations in 2010 was primarily attributed to the disposal of our manufacturing operations in Latina, Italy.

Out-licensed intangible asset impairment charges are related to assets acquired in the Medarex, Inc. (Medarex) and ZymoGenetics acquisitions and resulted from unfavorable clinical trial results and/or abandonment of the programs. Similar charges of \$15 million were included in research and development in 2011.

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Gain on sale of product lines, businesses and assets was primarily related to the sale of a building in Mexico in 2012 and the sale of mature brands in 2011 and 2010.

Other income from alliance partners includes income earned from the Sanofi partnership and amortization of certain upfront, milestone and other licensing payments related to other alliances. The decrease in U.S. *Plavix*\* net sales resulted in lower development royalties owed to Sanofi in 2012.

A pension settlement charge was recognized in 2012 for the primary U.S. pension plan as a result of annual lump sum payments exceeding interest and service costs during the fourth quarter. The charge included the acceleration of a portion of unrecognized actuarial losses. Similar charges might occur in the future. See Item 8. Financial Statements Note 18. Pension, Postretirement and Postemployment Liabilities for further detail.

The change in Other is primarily related to higher acquisition costs and losses on debt repurchases in 2012 and sales tax reimbursements, gains on debt repurchases, and higher upfront, milestone and licensing receipts in 2011.

**Non-GAAP Financial Measures**

Our non-GAAP financial measures, including non-GAAP earnings and related EPS information, are adjusted to exclude certain costs, expenses, gains and losses and other specified items that due to their significant and/or unusual nature are evaluated on an individual basis. Similar charges or gains for some of these items have been recognized in prior periods and it is reasonably possible that they could reoccur in future periods. Non-GAAP information is intended to portray the results of our baseline performance which include the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceutical products on a global basis and to enhance an investor's overall understanding of our past financial performance and prospects for the future. For example, non-GAAP earnings and EPS information is an indication of our baseline performance before items that are considered by us to not be reflective of our ongoing results. In addition, this information is among the primary indicators we use as a basis for evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. This information is not intended to be considered in isolation or as a substitute for net earnings or diluted EPS prepared in accordance with GAAP.

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Specified items were as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Accelerated depreciation, asset impairment and other shutdown costs	\$ 147	\$ 75	\$ 113
Amortization of acquired Amylin intangible assets	229		
Amortization of Amylin collaboration proceeds	(114)		
Amortization of Amylin inventory adjustment	23		
<b>Cost of products sold</b>	<b>285</b>	<b>75</b>	<b>113</b>
Stock compensation from accelerated vesting of Amylin awards	67		
Process standardization implementation costs	18	29	35
<b>Marketing, selling and administrative</b>	<b>85</b>	<b>29</b>	<b>35</b>
Stock compensation from accelerated vesting of Amylin awards	27		
Upfront, milestone and other licensing payments	47	207	132
IPRD impairment	142	28	10
<b>Research and development</b>	<b>216</b>	<b>235</b>	<b>142</b>
<b>Impairment charge for BMS-986094 intangible asset</b>	<b>1,830</b>		
Provision for restructuring	174	116	113
Impairment and loss on sale of manufacturing operations			236
Gain on sale of product lines, businesses and assets	(51)	(12)	
Pension curtailments and settlements	151	13	18
Acquisition related items	43		10
Litigation charges/(recoveries)	(45)	9	(2)
Upfront, milestone and other licensing receipts	(10)	(20)	
Out-licensed intangible asset impairment	38		
Loss on debt repurchases	27		
<b>Other (income)/expense</b>	<b>327</b>	<b>106</b>	<b>375</b>
<b>Decrease to pretax income</b>	<b>2,743</b>	<b>445</b>	<b>665</b>
Income tax on items above	(947)	(136)	(180)
Out-of period tax adjustment			(59)
Specified tax (benefit)/charge*	(392)	(97)	207
<b>Income taxes</b>	<b>(1,339)</b>	<b>(233)</b>	<b>(32)</b>
<b>Decrease to net earnings</b>	<b>\$ 1,404</b>	<b>\$ 212</b>	<b>\$ 633</b>

\* The 2012 specified tax benefit relates to a capital loss deduction. The 2011 specified tax benefit relates to releases of tax reserves that were specified in prior periods. The 2010 specified tax charge relates to a tax charge from additional U.S. taxable income from earnings of foreign subsidiaries previously considered to be indefinitely reinvested offshore.

The reconciliations from GAAP to Non-GAAP were as follows:

Dollars in Millions, except per share data	Year Ended December 31,		
	2012	2011	2010
Net Earnings Attributable to BMS GAAP	\$ 1,960	\$ 3,709	\$ 3,102
Earnings attributable to unvested restricted shares	(1)	(8)	(12)

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Net Earnings Attributable to BMS used for Diluted EPS Calculation	GAAP	\$ 1,959	\$ 3,701	\$ 3,090
Net Earnings Attributable to BMS	GAAP	\$ 1,960	\$ 3,709	\$ 3,102
Less Specified Items		1,404	212	633
Net Earnings Attributable to BMS	Non-GAAP	3,364	3,921	3,735
Earnings attributable to unvested restricted shares		(1)	(8)	(12)
Net Earnings Attributable to BMS used for Diluted EPS Calculation	Non-GAAP	\$ 3,363	\$ 3,913	\$ 3,723
Average Common Shares Outstanding	Diluted	1,688	1,717	1,727
Diluted EPS Attributable to BMS	GAAP	\$ 1.16	\$ 2.16	\$ 1.79
Diluted EPS Attributable to Specified Items		0.83	0.12	0.37
Diluted EPS Attributable to BMS	Non-GAAP	\$ 1.99	\$ 2.28	\$ 2.16



**Income Taxes**

The \$161 million income tax benefit in 2012 was attributable to a \$392 million capital loss deduction resulting from the tax insolvency of Inhibitex. The impact of this deduction reduced the effective tax rate by 16.7 percentage points. In addition to this impact, the effective tax rate in 2012 was substantially lower than 24.7% in 2011 and 25.7% in 2010 resulting primarily from favorable earnings mix between high and low tax jurisdictions. The change in earnings mix was primarily attributed to lower *Plavix*\* sales and a \$1,830 million impairment charge for BMS-986094 intangible asset in the U.S and to a lesser extent, an internal transfer of intellectual property. The transfer of selected intellectual property rights outside the U.S. (for existing and new products) is part of our strategy to place key assets closer to where manufacturing, distribution, and other operational decisions are made. The favorable earnings mix between high and low tax jurisdictions is expected to continue at least through 2013 (excluding the impact of the impairment charge).

Historically, the effective income tax rate is lower than the U.S. statutory rate of 35% due to our decision to indefinitely reinvest the earnings for certain of our manufacturing operations in Ireland and Puerto Rico. We have favorable tax rates in Ireland and Puerto Rico under grants not scheduled to expire prior to 2023.

The American Taxpayer Relief Act of 2012 (the Act) was signed into law on January 2, 2013. The provisions of the Act included the retroactive reinstatement of the R&D tax credit and look through exception for 2012 and 2013. As a result, the 2012 R&D tax credit and look through exception benefit will be recognized in the first quarter of 2013. For a more detailed discussion of income taxes and changes in the effective tax rates, refer to Item 8. Financial Statements Note 7. Income Taxes.

**Noncontrolling Interest**

Noncontrolling interest is primarily related to our *Plavix*\* and *Avapro*\*/*Avalide*\* partnerships with Sanofi for the territory covering the Americas. See Item 8. Financial Statements Note 3. Alliances and Collaborations. The decrease in noncontrolling interest in 2012 resulted from the exclusivity loss in the U.S. of *Avapro*\*/*Avalide*\* in March 2012 and *Plavix*\* in May 2012. The increase in noncontrolling interest in 2011 corresponds to increased net sales of *Plavix*\* in the U.S. A summary of noncontrolling interest is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Sanofi partnerships	\$ 844	\$ 2,323	\$ 2,074
Other	14	20	20
Noncontrolling interest-pre-tax	858	2,343	2,094
Income taxes	(317)	(792)	(683)
Net earnings attributable to noncontrolling interest-net of taxes	\$ 541	\$ 1,551	\$ 1,411

**Financial Position, Liquidity and Capital Resources**

Our net cash/(debt) position was as follows:

Dollars in Millions	2012	2011
Cash and cash equivalents	\$ 1,656	\$ 5,776
Marketable securities - current	1,173	2,957
Marketable securities - non-current	3,523	2,909
Total cash, cash equivalents and marketable securities	6,352	11,642
Short-term borrowings and current portion of long-term debt	(826)	(115)
Long-term debt	(6,568)	(5,376)
Net cash/(debt) position	\$ (1,042)	\$ 6,151

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Working capital

\$ 1,242      \$ 7,538

The current net debt position and reduction in working capital during 2012 resulted primarily from net cash used in connection with the acquisitions of Amylin and Inhibitex. Cash, cash equivalents and marketable securities held in the U.S. were approximately \$1.3 billion at December 31, 2012. Most of the remaining \$5.1 billion is held primarily in low-tax jurisdictions and is attributable to earnings that are expected to be indefinitely reinvested offshore. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and additional U.S. income taxes. We started issuing commercial paper to meet near-term domestic liquidity requirements in preparation for the Amylin acquisition during the third quarter of 2012. The average amount of commercial paper outstanding was \$224 million at a weighted-average interest rate of 0.16% during 2012. The maximum month-end amount of commercial paper outstanding was \$700 million with no outstanding borrowings at December 31, 2012. We will likely continue to issue commercial paper to meet domestic liquidity requirements as needed.

Our investment portfolio includes non-current marketable securities which are subject to changes in fair value as a result of interest rate fluctuations and other market factors, which may impact our results of operations. Our investment policy places limits on these investments and the amount and time to maturity of investments with any institution. The policy also requires that investments are only entered into with corporate and financial institutions that meet high credit quality standards. See Item 8. Financial Statements Note 9. Financial Instruments.

We currently have two separate \$1.5 billion five-year revolving credit facilities from a syndicate of lenders, including a new facility entered into in July 2012. The facilities provide for customary terms and conditions with no financial covenants and are extendable on any anniversary date with the consent of the lenders. No borrowings were outstanding under either revolving credit facility at December 31, 2012 or 2011.

In connection with the 2012 Amylin acquisition, BMS issued \$2.0 billion of senior unsecured notes in a registered public offering consisting of \$750 million in aggregate principal amount of 0.875% Notes due 2017, \$750 million in aggregate principal amount of 2.000% Notes due 2022 and \$500 million in aggregate principal amount of 3.250% Notes due 2042.

BMS completed its acquisition of Amylin for an aggregate purchase price of \$5.3 billion in 2012. BMS also assumed Amylin's net debt and a contractual payment obligation to Lilly, together totaling \$2.0 billion (substantially all of which was repaid during 2012). The acquisition was financed through the use of existing cash balances, the issuance of commercial paper and long-term debt borrowings described above.

Additional regulations in the U.S. could be passed in the future which could further reduce our results of operations, operating cash flow, liquidity and financial flexibility. We also continue to monitor the potential impact of the economic conditions in certain European countries and the related impact on prescription trends, pricing discounts, creditworthiness of our customers, and our ability to collect outstanding receivables from our direct customers. Currently, we believe these economic conditions in the EU will not have a material impact on our liquidity, cash flow or financial flexibility.

As a mechanism to limit our overall credit exposures, and an additional source of liquidity, we sell trade receivables to third parties, principally from wholesalers in Japan and certain government-backed entities in Italy, Portugal, and Spain. Sales of trade receivables in Italy, Portugal and Spain were \$322 million in 2012, \$484 million in 2011 and \$476 million in 2010. Sales of receivables in Japan were \$634 million in 2012, \$593 million in 2011 and \$456 million in 2010. Our sales agreements do not allow for recourse in the event of uncollectibility and we do not retain interest to the underlying assets once sold.

We continue to manage our operating cash flows with initiatives designed to improve working capital items that are most directly affected by changes in sales volume, such as receivables, inventories, and accounts payable. During 2012, the following changes in receivables, inventories and accounts payable resulted primarily from the rapid reduction of *Plavix*\* sales, the acquisition of Amylin and timing of expenditures in the ordinary course of business.

Dollars in Millions	December 31, 2012	% of Trailing Twelve Month Net Sales	December 31, 2011	% of Trailing Twelve Month Net Sales
Net trade receivables	\$ 1,708	9.7 %	\$ 2,250	10.6 %
Inventories	1,657	9.4 %	1,384	6.5 %
Accounts payable	(2,202)	(12.5)%	(2,603)	(12.2)%
Total	\$ 1,163	6.6 %	\$ 1,031	4.9 %

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