

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.)

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

(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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

- (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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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>Erbitux</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

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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 product is first approved by the FDA.

In the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. Second, statutory and regulatory provisions in the U.S. limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity.

#### European Union

Patents on pharmaceutical products are generally enforceable in the EU and, as in the U.S., may be extended to compensate for the patent term lost during the regulatory review process. Such extensions are granted on a country-by-country basis.

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

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

Throughout the EU, all products for which marketing authorizations have been filed after October/November 2005 are subject to an 8+2+1 regime. Eight years after the innovator has received its first community authorization for a medicinal product, a generic company may file a marketing authorization application for that product with the health authorities. If the marketing authorization application is approved, the generic company may not commercialize the product until after either 10 or 11 years have elapsed from the initial marketing authorization granted to the innovator. The possible extension to 11 years is available if the innovator, during the first eight years of the marketing authorization, obtains an additional indication that is of significant clinical benefit in comparison with existing treatments. For products that were filed prior to October/November 2005, there is a 10-year period of data protection under the centralized procedures and a period of either six or 10 years under the mutual recognition procedure (depending on the member state).



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,*



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

*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.*

---

***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.***

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

*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.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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*

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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**

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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	2011 vs. 2010	
<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 %	

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

*(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</i> / <i>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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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)

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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 %

#### Credit Ratings

Moody's Investors Service long-term and short-term credit ratings are currently A2 and Prime-1, respectively, and their long-term credit outlook remains stable. Standard & Poor's (S&P) long-term and short-term credit ratings are currently A+ and A-1+, respectively, and their long-term credit outlook remains stable. S&P upgraded our short-term credit rating from A-1 to A-1+ in May 2012. Fitch Ratings (Fitch) long-term and short-term credit ratings are currently A and F1, respectively, and their long-term credit outlook remains negative. Fitch lowered our long-term credit rating from A+ to A in July 2012. Our credit ratings are considered investment grade. Our long-term ratings designate that we have a low default risk but are somewhat susceptible to adverse effects of changes in circumstances and economic conditions. Our short-term ratings designate that we have the strongest capacity for timely repayment.

*Cash Flows*

The following is a discussion of cash flow activities:

Dollars in Millions	2012	2011	2010
Cash flow provided by/(used in):			
Operating activities	\$ 6,941	\$ 4,840	\$ 4,491
Investing activities	(6,727)	(1,437)	(3,812)
Financing activities	(4,333)	(2,657)	(3,343)

Operating Activities

Cash flow from operating activities represents the cash receipts and cash disbursements from all of our activities other than investing activities and financing activities. Operating cash flow is derived by adjusting net earnings for noncontrolling interest, non-cash operating items, gains and losses attributed to investing and financing activities and changes in operating assets and liabilities resulting from timing differences between the receipts and payments of cash and when the transactions are recognized in our results of operations. As a result, changes in cash from operating activities reflect the timing of cash collections from customers and alliance partners; payments to suppliers, alliance partners and employees; pension contributions and tax payments in the ordinary course of business.

The \$2.1 billion increase in operating cash flow in 2012 was primarily attributable to preliminary proceeds of \$3.6 billion received from AstraZeneca as consideration for entering into the Amylin collaboration partially offset by lower operating cash flows attributed to *Plavix*\* and *Avapro*\*/*Avalide*\* sales reductions following the exclusivity loss of these products.

Investing Activities

Cash was used to fund the acquisitions of Amylin (\$5.0 billion) and Inhibitex (\$2.5 billion) in 2012, Amira (\$360 million, including a \$50 million contingent payment) in 2011 and ZymoGenetics (\$829 million) in 2010.

Net sales and maturities of marketable securities of \$1.3 billion in 2012 were primarily attributed to the funding of the Amylin acquisition. Net purchases of marketable securities of \$859 million in 2011 and \$2.6 billion in 2010 were primarily attributed to the timing of investments in time deposits and corporate debt securities with maturities greater than 90 days.

Other investing activities included litigation recoveries of \$102 million in 2011.

Financing Activities

Dividend payments were \$2.3 billion in 2012, \$2.3 billion in 2011 and \$2.2 billion in 2010. Dividends declared per common share were \$1.37 in 2012, \$1.33 in 2011 and \$1.29 in 2010. In December 2012, we declared a quarterly dividend of \$0.35 per common share and expect to pay a dividend for the full year of 2013 of \$1.40 per share. Dividend decisions are made on a quarterly basis by our Board of Directors.

Proceeds received from the issuance of senior unsecured notes and repayments of debt assumed in the Amylin acquisition were \$2.0 billion each in 2012.

Management periodically evaluates potential opportunities to repurchase certain debt securities and terminate certain interest rate swap contracts prior to their maturity. Cash outflows related to the repurchase of debt were \$109 million in 2012, \$78 million in 2011 and \$855 million in 2010. Proceeds from the termination of interest rate swap contracts were \$2 million in 2012, \$296 million in 2011 and \$146 million in 2010.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The Board of Directors increased its authorization for the repurchase of common stock by \$3.0 billion in June 2012. The common stock repurchase capacity remaining was \$1.8 billion at December 31, 2012. Cash used to repurchase common stock was \$2.4 billion in 2012, \$1.2 billion in 2011 and \$576 million in 2010.

Proceeds from stock option exercises were \$463 million (including \$71 million of cash retained from excess tax benefits) in 2012, \$601 million (including \$47 million of cash retained from excess tax benefits) in 2011 and \$252 million in 2010. The amount of proceeds vary each period based upon fluctuations in the market value of our stock relative to the exercise price of the stock options and other factors.

**Contractual Obligations**

Payments due by period for our contractual obligations at December 31, 2012 were as follows:

Dollars in Millions	Total	2013	Obligations Expiring by Period				Later Years
			2014	2015	2016	2017	
Short-term borrowings	\$ 162	\$ 162	\$	\$	\$	\$	\$
Long-term debt	6,631	648	27		659	750	4,547
Interest on long-term debt <sup>(a)</sup>	4,814	217	237	237	240	215	3,668
Operating leases	756	167	152	130	123	76	108
Purchase obligations	2,089	874	506	336	198	128	47
Uncertain tax positions <sup>(b)</sup>	83	83					
Other long-term liabilities	475		101	58	41	44	231
Total <sup>(c)</sup>	\$ 15,010	\$ 2,151	\$ 1,023	\$ 761	\$ 1,261	\$ 1,213	\$ 8,601

- (a) Includes estimated future interest payments on our short-term and long-term debt securities. Also includes accrued interest payable recognized on our consolidated balance sheets, which consists primarily of accrued interest on short-term and long-term debt as well as accrued periodic cash settlements of derivatives.
- (b) Due to the uncertainty related to the timing of the reversal of uncertain tax positions, only the short-term uncertain tax benefits have been provided in the table above. See Item 8. Financial Statements Note 7. Income Taxes for further detail.
- (c) The table above excludes future contributions by us to our pensions, postretirement and postemployment benefit plans. Required contributions are contingent upon numerous factors including minimum regulatory funding requirements and the funded status of each plan. Due to the uncertainty of such future obligations, they are excluded from the table. Contributions for both U.S. and international plans are expected to be \$100 million in 2013. See Item 8. Financial Statements Note 18. Pension, Postretirement and Postemployment Liabilities for further detail.

In addition to the above, we are committed to \$6.0 billion (in the aggregate) of potential future research and development milestone payments to third parties as part of in-licensing and development programs. Early stage milestones, defined as milestones achieved through Phase III clinical trials, comprised \$1.1 billion of the total committed amount. Late stage milestones, defined as milestones achieved post Phase III clinical trials, comprised \$4.9 billion of the total committed amount. Payments under these agreements generally are due and payable only upon achievement of certain developmental and regulatory milestones, for which the specific timing cannot be predicted. In addition to certain royalty obligations that are calculated as a percentage of net sales, some of these agreements also provide for sales-based milestones aggregating \$2.1 billion that we would be obligated to pay to alliance partners upon achievement of certain sales levels. We also have certain manufacturing, development, and commercialization obligations in connection with alliance arrangements. It is not practicable to estimate the amount of these obligations. See Item 8. Financial Statements Note 3. Alliances and Collaborations for further information regarding our alliances.

For a discussion of contractual obligations, see Item 8. Financial Statements Note 18. Pension, Postretirement and Postemployment Liabilities, Note 9. Financial Instruments and Note 20. Leases.

**SEC Consent Order**

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

Under the terms of the Consent, we agreed, subject to certain defined exceptions, to limit sales of all products sold to our direct customers (including wholesalers, distributors, hospitals, retail outlets, pharmacies and government purchasers) based on expected demand or on amounts that do not exceed approximately one month of inventory on hand, without making a timely public disclosure of any change in practice. We also agreed in the Consent to certain measures that we have implemented including: (a) establishing a formal review and certification process of our annual and quarterly reports filed with the SEC; (b) establishing a business risk and disclosure group; (c) retaining an outside consultant to comprehensively study and help re-engineer our accounting and financial reporting processes; (d) publicly disclosing any sales incentives offered to direct customers for the purpose of inducing them to purchase products in excess of expected demand; and (e) ensuring that our budget process gives appropriate weight to inputs that come from the bottom to the top, and not just from the top to the bottom, and adequately documenting that process.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

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

We maintain inventory management agreements (IMAs) with our U.S. pharmaceutical wholesalers, which account for nearly 100% of our gross U.S. sales. Under the current terms of the IMAs, our wholesaler customers provide us with weekly information with respect to months on hand product-level inventories and the amount of out-movement of products. The three largest wholesalers currently account for approximately 90% of our gross U.S. sales. The inventory information received from our wholesalers, together with our internal information, is used to estimate months on hand product level inventories at these wholesalers. We estimate months on hand product inventory levels for our U.S. business s wholesalers other than the three largest wholesalers by extrapolating from the months on hand calculated for the three largest wholesalers. In contrast, our non-U.S. business has significantly more direct customers, limited information on direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information, where available, varies widely. Accordingly, we rely on a variety of methods to estimate months on hand product level inventories for these business units.

We believe the above-described procedures provide a reasonable basis to ensure compliance with the Consent.

#### **Recently Issued Accounting Standards**

None applicable.

#### **Critical Accounting Policies**

The preparation of financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses. Our critical accounting policies are those that significantly impact our financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of this uncertainty, actual results may vary from these estimates. These accounting policies were discussed with the Audit Committee of the Board of Directors.

#### ***Revenue Recognition***

Our accounting policy for revenue recognition has a substantial impact on reported results and relies on certain estimates. We recognize revenue when persuasive evidence of an arrangement exists, the sales price is fixed and determinable, collectability is reasonably assured and title and substantially all of the risks and rewards of ownership have transferred, which is generally at time of shipment. Revenue is also reduced for gross-to-net sales adjustments discussed below, all of which involve significant estimates and judgment after considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix (e.g. Medicare or Medicaid), current contract prices under applicable programs, unbilled claims and processing time lags and inventory levels in the distribution channel. Estimates are assessed each period and adjusted as required to revised information or actual experience. In addition, See **Net Sales** above for further discussion and analysis of each significant category of gross-to-net sales adjustments.

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

The following categories of gross-to-net sales adjustments involve significant estimates, judgments and information obtained from external sources. See **Net Sales** above for further discussion and analysis of each significant category of gross-to-net sales adjustments.

#### **Charge-backs related to government programs**

Our U.S. business participates in programs with government entities, the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs, and other parties, including covered entities under the 340B Drug Pricing Program, whereby pricing on products is extended below wholesaler list price to participating entities. These entities purchase products through wholesalers at the lower program price and the wholesalers then charge us the difference between their acquisition cost and the lower program price. Accounts receivable is reduced for the estimated amount of un-processed charge-back claims attributable to a sale (typically within a two to four week time lag).

#### **Cash discounts**

In the U.S. and certain other countries, cash discounts are offered as an incentive for prompt payment, generally approximating 2% of the sales price. Accounts receivable is reduced for the estimated amount of un-processed cash discounts (typically within a 1 month time lag).



Managed healthcare rebates and other contract discounts

Rebates and discounts are offered to managed healthcare organizations in the U.S. managing prescription drug programs and Medicare Advantage prescription drug plans covering the Medicare Part D drug benefit in addition to their commercial plans, as well as other contract counterparties such as hospitals and group purchasing organizations globally. Beginning in 2011, the rebates for the Medicare Part D program included a 50% discount on the Company's brand-name drugs to patients who fall within the Medicare Part D coverage gap. Rebates are also required under the U.S. Department of Defense TRICARE Retail Pharmacy Refund Program. The estimated amount for these unpaid or unbilled rebates and discounts are presented as a liability. A \$67 million reversal for the estimated amount of 2011 Medicare Part D coverage gap discounts occurred in 2012 after receipt of the actual invoices.

Medicaid rebates

Our U.S. businesses participate in state government Medicaid programs and other qualifying Federal and state government programs requiring discounts and rebates to participating state and local government entities. All discounts and rebates provided through these programs are included in our Medicaid rebate accrual. Retroactive to January 1, 2010, minimum rebates on Medicaid drug sales increased from 15.1% to 23.1%. Medicaid rebates have also been extended to drugs used in managed Medicaid plans beginning in March 2010. The estimated amount for these unpaid or unbilled rebates is presented as a liability. A \$37 million reversal for the estimated amount of 2010 and 2011 Managed Medicaid discounts occurred in 2012 after receipt of the actual invoices.

Sales returns

Products are typically eligible to be returned between six months prior to and twelve months after product expiration, in accordance with our policy. Estimated returns for established products are determined after considering historical experience and other factors including levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products, introductions of competitive new products and instances of expected precipitous declines in demand following the loss of exclusivity. The estimated amount for product returns is presented as a liability. Reserves of \$173 million were established for *Plavix*\* and *Avapro*\*/*Avalide*\* at December 31, 2012 after considering the relevant factors as well as estimated future retail and wholesale inventory work down that would occur after the loss of exclusivity.

Estimated returns for new products are determined after considering historical sales return experience of similar products, such as those within the same product line or similar therapeutic category. We defer recognition of revenue until the right of return expires or until sufficient historical experience to estimate sales returns is developed in limited circumstances. This typically occurs when the new product is not an extension of an existing line of product or when historical experience with products in a similar therapeutic category is lacking. Estimated levels of inventory in the distribution channel and projected demand are also considered in estimating sales returns for new products. Although not reflected as a gross to net adjustment, \$27 million of revenue related to *Yervoy* was deferred in 2011 as a result of limited returns experience.

Use of information from external sources

Information from external sources is used to estimate gross-to-net sales adjustments. Our estimate of inventory at the wholesalers are based on the projected prescription demand-based sales for our products and historical inventory experience, as well as our analysis of third-party information, including written and oral information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and our internal information. The inventory information received from wholesalers is a product of their recordkeeping process and excludes inventory held by intermediaries to whom they sell, such as retailers and hospitals.

We have also continued the practice of combining retail and mail prescription volume on a retail-equivalent basis. We use this methodology for internal demand forecasts. We also use information from external sources to identify prescription trends, patient demand and average selling prices. Our estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information was itself in the form of estimates, and reflect other limitations including lags between the date as of which third-party information is generated and the date on which we receive third-party information.

**Retirement Benefits**

Accounting for pension and postretirement benefit plans requires actuarial valuations based on significant assumptions for discount rates and expected long-term rates of return on plan assets. In consultation with our actuaries, these significant assumptions and others such as salary growth, retirement, turnover, healthcare trends and mortality rates are evaluated and selected based on expectations or actual experience during each remeasurement date. Pension expense could vary within a range of outcomes and have a material effect on reported earnings, projected benefit obligations and future cash funding. Actual results in any given year may differ from those estimated because of economic and other factors.



The yield on high quality corporate bonds that coincides with the cash flows of the plans' estimated payouts is used in determining the discount rate. The Citigroup Pension Discount curve is used for the U.S. plans. The U.S. plans' pension expense for 2012 was determined using a 4.25% weighted-average discount rate. The present value of benefit obligations at December 31, 2012 for the U.S. pension plans was determined using a 3.74% discount rate. If the discount rate used in determining the U.S. plans' pension expense for 2012 was reduced by an additional 1%, such expense would increase by approximately \$12 million. If the assumed discount rate used in determining the U.S. pension plans' projected benefit obligation at December 31, 2012 was reduced by an additional 1%, the projected benefit obligation would increase by approximately \$1.2 billion.

The expected long-term rate of return on plan assets is estimated considering expected returns for individual asset classes with input from external advisors. We also consider long-term historical returns including actual performance compared to benchmarks for similar investments. The U.S. plans' pension expense for 2012 was determined using an 8.75% expected long-term rate of return on plan assets. If the expected long-term rate of return on plan assets used in determining the U.S. plans' pension expense for 2012 was reduced by 1%, such expense would increase by \$47 million.

For a more detailed discussion on retirement benefits, see Item 8. Financial Statements' Note 18. Pension, Postretirement and Postemployment Liabilities.

### ***Business Combinations***

Goodwill and other intangible assets acquired in business combinations, licensing and other transactions were \$16.4 billion at December 31, 2012, representing 46% of total assets.

Assets acquired and liabilities assumed are recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. The fair value of intangible assets, including IPRD, is typically determined using the income method. This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success (for IPRD) and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams. All assets are valued from a market participant view which might be different than specific BMS views. The valuation process is very complex and requires significant input and judgment using internal and external sources. Although the valuations are required to be finalized within a one-year period, it must consider all and only those facts and evidence available at the acquisition date. The most complex and judgmental matters applicable to the valuation process are summarized below:

*Unit of account* Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.

*Estimated useful life* The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.

*Probability of Technical and Regulatory Success (PTRS) Rate* PTRS rates are determined based upon industry averages considering the respective programs development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.

*Projections* Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

well as significantly alter the costs to develop the respective asset into commercially viable products.

*Tax rates* The expected future income is tax effected using a market participant tax rate. Our recent valuations typically use a U.S. tax rate (and applicable state taxes) after considering the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also considered that any earnings repatriation would likely have U.S. tax consequences.

*Discount rate* Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

See Item 8. Financial Statements Note 4. Acquisitions for specific details and values assigned to assets acquired and liabilities assumed in our acquisitions of Amylin and Inhibitex in 2012, Amira in 2011 and ZymoGenetics in 2010. Significant estimates utilized at the time of the valuations to support the fair values of the lead compounds within the acquisitions include:

Dollars in Millions	Fair value	Discount rate utilized	Estimated useful life (in years)	Phase of Development as of acquisition date	PTRS Rate utilized	Year of first projected positive cash flow
<b>Commercialized products:</b>						
<i>Bydureon*</i>	\$ 5,260	11.1%	13	N/A	N/A	N/A
<i>Byetta*</i>	770	10.0%	7	N/A	N/A	N/A
<i>Symlin*</i>	310	10.0%	9	N/A	N/A	N/A
<i>Recothrom</i>	230	11.0%	10	N/A	N/A	N/A
<b>IPRD:</b>						
BMS-986094 (formerly INX-189)	1,830	12.0%	N/A	Phase II	38.0%	2017
Metreleptin	120	12.0%	N/A	Phase III	75.0%	2017
AM152	160	12.5%	N/A	Phase I	12.5%	2021
Peginterferon lambda	310	13.5%	N/A	Phase IIB	47.6%	2014

**Impairment**

Goodwill

Goodwill was \$7.6 billion at December 31, 2012. Goodwill is tested at least annually for impairment on an enterprise level by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors assessed in the current year included our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test performed in the prior year. Positive and negative influences of each relevant factor were assessed both individually and in the aggregate and as a result it was concluded that no additional quantitative testing was required.

For discussion on goodwill, acquired in-process research and development and other intangible assets, see Item 8. Financial Statements Note 1. Accounting Policies Goodwill, Acquired In-Process Research and Development and Other Intangible Assets.

Other Intangible Assets, including IPRD

Other intangible assets were \$8.8 billion at December 31, 2012, including licenses (\$626 million), developed technology rights (\$7.2 billion), capitalized software (\$261 million) and IPRD (\$668 million). Intangible assets are tested for impairment whenever current facts or circumstances warrant a review, although IPRD is required to be tested at least annually. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products or IPRD. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation.

Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPRD impairment charges are likely to occur in future periods. We recognized charges of \$2.1 billion in 2012 including a \$1.8 billion charge resulting from the discontinued development of BMS-986094 and for other projects previously acquired in the Medarex, Inc and Inhibitex acquisition resulting from unfavorable clinical trial results, additional development costs, extended development periods and decisions to cease further development. We also recognized charges of \$30 million in 2011 and \$10 million in 2010 related to three Medarex projects for which development has ceased. IPRD is closely monitored and assessed each period for impairment.

In addition to IPRD, commercial assets are also subject to impairment. For example, an impairment charge of \$120 million was recognized in 2012 related to a non-key product (*Recothrom*) acquired in the acquisition of ZymoGenetics after continuing competitive pricing pressures. The preliminary estimated fair value of developed technology rights resulting from the acquisition of Amylin was \$6.3 billion, including \$5.3 billion allocated to a recently-launched single asset, *Bydureon\**. These assets are monitored for changes in expectations from those used in the initial valuation, including revenue trends and operating synergies.



---

**Contingencies**

In the normal course of business, we are subject to contingencies, such as legal proceedings and claims arising out of our business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, contractual claims and tax matters. We recognize accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. These estimates are subject to uncertainties that are difficult to predict and, as such, actual results could vary from these estimates.

For discussions on contingencies, see Item 8. Financial Statements Note 1. Accounting Policies Contingencies, Note 7. Income Taxes and Note 21. Legal Proceedings and Contingencies.

**Income Taxes**

Valuation allowances are recognized to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment including long-range forecasts of future taxable income and evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. Our deferred tax assets were \$5.1 billion, net of valuation allowances of \$4.4 billion at December 31, 2012 and \$3.2 billion, net of valuation allowances of \$3.9 billion at December 31, 2011.

Deferred tax assets related to a U.S. Federal net operating loss carryforward of \$170 million and a U.S. Federal tax credit carryforward of \$31 million were recognized at December 31, 2012. The net operating loss carryforward expires in varying amounts beginning in 2022. The U.S. Federal tax credit carryforward expires in varying amounts beginning in 2017. The realization of these carryforwards is dependent on generating sufficient domestic-sourced taxable income prior to their expiration. Although realization is not assured, we believe it is more likely than not that these deferred tax assets will be realized.

In addition, a deferred tax asset related to a U.S. Federal and state capital loss of \$794 million was recognized at December 31, 2012 that can be carried back three years and carried forward five years. The realization of this carryforward is dependent upon generating sufficient capital gains prior to its expiration. A \$411 million valuation allowance was established for this item at December 31, 2012.

Taxes are not provided on undistributed earnings of foreign subsidiaries expected to be reinvested indefinitely offshore. During 2010, the Company completed an internal reorganization of certain legal entities which contributed to a \$207 million tax charge recognized in the fourth quarter of 2010. It is possible that U.S. tax authorities could assert additional material tax liabilities arising from the reorganization. If such assertion were to occur, the Company would vigorously challenge any such assertion and believes it would prevail; however there can be no assurance of such a result.

Prior to the Mead Johnson Nutrition Company (Mead Johnson) split-off in 2009, the following transactions occurred: (i) an internal spin-off of Mead Johnson shares while still owned by us; (ii) conversion of Mead Johnson Class B shares to Class A shares; and; (iii) conversion of Mead Johnson & Company to a limited liability company. These transactions as well as the split-off of Mead Johnson through the exchange offer should qualify as tax-exempt transactions under the Internal Revenue Code based upon a private letter ruling received from the Internal Revenue Service related to the conversion of Mead Johnson Class B shares to Class A shares, and outside legal opinions. Certain assumptions, representations and covenants by Mead Johnson were relied upon regarding the future conduct of its business and other matters which could affect the tax treatment of the exchange. For example, the current tax law generally creates a presumption that the exchange would be taxable to us, if Mead Johnson or its shareholders were to engage in transactions that result in a 50% or greater change in its stock ownership during a four year period beginning two years before the exchange offer, unless it is established that the exchange offer were not part of a plan or series of related transactions to effect such a change in ownership. If the internal spin-off or exchange offer were determined not to qualify as a tax exempt transaction, the transaction could be subject to tax as if the exchange was a taxable sale by us at market value.

In addition, a negative basis or excess loss account (ELA) existed in our investment in stock of Mead Johnson prior to these transactions. We received an opinion from outside legal counsel to the effect that it is more likely than not that we eliminated the ELA as part of these transactions and do not have taxable income with respect to the ELA. The tax law in this area is complex and it is possible that even if the internal spin-off and the exchange offer is tax exempt under the Internal Revenue Code, the IRS could assert that we have additional taxable income for the period with respect to the ELA. We could be exposed to additional taxes if this were to occur. Based upon our understanding of the Internal Revenue Code and opinion from outside legal counsel, a tax reserve of \$244 million was established reducing the gain on disposal of Mead Johnson included in discontinued operations in 2009.

We agreed to certain tax related indemnities with Mead Johnson as set forth in the tax sharing agreement. For example, Mead Johnson has agreed to indemnify us for potential tax effects resulting from the breach of certain representations discussed above as well as certain transactions related to the acquisition of Mead Johnson's stock or assets. We have agreed to indemnify Mead Johnson for certain taxes related to



its business prior to the completion of the IPO and created as part of the restructuring to facilitate the IPO.

We established liabilities for possible assessments by tax authorities resulting from known tax exposures including, but not limited to, transfer pricing matters, tax credits and deductibility of certain expenses. Such liabilities represent a reasonable provision for taxes ultimately expected to be paid and may need to be adjusted over time as more information becomes known.

For discussions on income taxes, see Item 8. Financial Statements Note 1. Accounting Policies Income Taxes and Note 7. Income Taxes.

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

This annual report on Form 10-K (including documents incorporated by reference) and other written and oral statements we make from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as should , expect , anticipate , estimate , target , may , project , guidance , intend , plan , believe and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our goals, plans and projections regarding our financial position, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance or results of current and anticipated products and the outcome of contingencies such as legal proceedings and financial results, which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under Item 1A. Risk Factors, that we believe could cause actual results to differ materially from any forward-looking statement.

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

---

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

We are exposed to market risk resulting from changes in currency exchange rates and interest rates. Certain derivative financial instruments are used when available on a cost-effective basis to hedge our underlying economic exposure. All of our financial instruments, including derivatives, are subject to counterparty credit risk considered as part of the overall fair value measurement. Derivative financial instruments are not used for trading purposes.

**Foreign Exchange Risk**

Significant amounts of our revenues, earnings and cash flow is exposed to changes in foreign currency rates. Our primary net foreign currency translation exposures are the euro, Japanese yen, Chinese renminbi, Canadian dollar and British pound. Foreign currency forward contracts are used to manage foreign exchange risk that primarily arises from certain intercompany purchase transactions and are designated as foreign currency cash flow hedges when appropriate. In addition, we are exposed to foreign exchange transaction risk that arises from non-functional currency denominated assets and liabilities and earnings denominated in non-U.S. dollar currencies. Foreign currency forward contracts are used to offset a portion of these exposures and are not designated as hedges. Changes in the fair value of these derivatives are recognized in earnings as incurred.

We estimate that a 10% appreciation in the underlying currencies being hedged from their levels against the U.S. dollar (with all other variables held constant) would decrease the fair value of foreign exchange forward contracts by \$162 million at December 31, 2012. If realized, this appreciation would negatively affect earnings over the remaining life of the contracts.

We are also exposed to translation risk on non-U.S. dollar-denominated net assets. Non-U.S. dollar borrowings are used to hedge the foreign currency exposures of our net investment in certain foreign affiliates and are designated as hedges of net investments. The effective portion of foreign exchange gains or losses on these hedges is recognized as part of the foreign currency translation component of accumulated OCI. If our net investment were to fall below the equivalent value of the non-U.S. debt borrowings, the change in the remeasurement basis of the debt would be subject to recognition in income as changes occur. For additional information, see Item 8. Financial Statements Note 9. Financial Instruments.

**Interest Rate Risk**

Fixed-to-floating interest rate swap contracts are used and designated as fair-value hedges as part of our interest rate risk management strategy. These contracts are intended to provide us with an appropriate balance of fixed and floating rate debt. We estimate that an increase of 100 basis points in short-term or long-term interest rates would decrease the fair value of our interest rate swap contracts by \$66 million, excluding the effects of our counterparty and our own credit risk. If realized, the fair value reduction would affect earnings over the remaining life of the contracts.

We estimate that an increase of 100 basis points in long-term interest rates would decrease the fair value of long-term debt by \$621 million. Our marketable securities are subject to changes in fair value as a result of interest rate fluctuations and other market factors. Our policy is to invest only in institutions that meet high credit quality standards. We estimate that an increase of 100 basis points in interest rates in general would decrease the fair value of our debt security portfolio by approximately \$95 million.

**Credit Risk**

Although not material, certain European government-backed entities with a higher risk of default were identified by monitoring economic factors including credit ratings, credit-default swap rates and debt-to-gross domestic product ratios in addition to entity specific factors. Historically, our exposure was limited by factoring receivables and deferring revenues until the collection of cash. However, during 2012, counterparties in our factoring arrangements suspended factoring of receivables from Spanish and Portuguese government-backed entities and limited factoring of receivables from certain Italian government-backed entities. Our credit exposures in Europe may increase in the future due to further reductions in our factoring arrangements and the ongoing sovereign debt crisis. Our credit exposure to government-backed trade receivables in Greece, Portugal, Italy and Spain were approximately \$252 million at December 31, 2012, of which approximately 75% is from government-backed entities.

We monitor our investments with counterparties with the objective of minimizing concentrations of credit risk. Our investment policy places limits on the amount and time to maturity of investments with any individual counterparty. The policy also requires that investments are made primarily with highly rated corporate, financial, U.S. government and government supported institutions.

The use of derivative instruments exposes us to credit risk. When the fair value of a derivative instrument contract is positive, we are exposed to credit risk if the counterparty fails to perform. When the fair value of a derivative instrument contract is negative, the counterparty is exposed to credit risk if we fail to perform our obligation. Under the terms of the agreements, posting of collateral is not required by any party whether derivatives are in an asset or liability position. We have a policy of diversifying derivatives with counterparties to mitigate the overall risk of

counterparty defaults. For additional information, see Item 8. Financial Statements Note 9. Financial Instruments.

## BRISTOL-MYERS SQUIBB COMPANY

## CONSOLIDATED STATEMENTS OF EARNINGS

Dollars and Shares in Millions, Except Per Share Data

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

EARNINGS	Year Ended December 31,		
	2012	2011	2010
Net Sales	\$ 17,621	\$ 21,244	\$ 19,484
Cost of products sold	4,610	5,598	5,277
Marketing, selling and administrative	4,220	4,203	3,686
Advertising and product promotion	797	957	977
Research and development	3,904	3,839	3,566
Impairment charge for BMS-986094 intangible asset	1,830		
Other (income)/expense	(80)	(334)	(93)
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
Net Earnings	2,501	5,260	4,513
Net Earnings Attributable to Noncontrolling Interest	541	1,551	1,411
Net Earnings Attributable to BMS	\$ 1,960	\$ 3,709	\$ 3,102
Earnings per Common Share			
Basic	\$ 1.17	\$ 2.18	\$ 1.80
Diluted	\$ 1.16	\$ 2.16	\$ 1.79
Cash dividends declared per common share	\$ 1.37	\$ 1.33	\$ 1.29

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

## BRISTOL-MYERS SQUIBB COMPANY

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Dollars in Millions

COMPREHENSIVE INCOME	Year Ended December 31,		
	2012	2011	2010
Net Earnings	\$ 2,501	\$ 5,260	\$ 4,513
Other Comprehensive Income/(Loss), net of taxes:			
Derivatives qualifying as cash flow hedges:			
Unrealized gains	9	24	15
Realized gains	(36)	32	(5)
Pension and postretirement benefits:			
Actuarial losses	(311)	(830)	(88)
Amortization	90	81	67
Settlements and curtailments	103	7	16
Available for sale securities:			
Unrealized gains	12	28	44
Realized gains	(9)		
Foreign currency translation	(7)	(27)	37
Foreign currency translation on net investment hedges	(8)	11	84
Total Other Comprehensive Income/(Loss), net of taxes	(157)	(674)	170
Comprehensive Income	2,344	4,586	4,683
Comprehensive Income Attributable to Noncontrolling Interest	535	1,558	1,411
Comprehensive Income Attributable to BMS	\$ 1,809	\$ 3,028	\$ 3,272

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

## BRISTOL-MYERS SQUIBB COMPANY

## CONSOLIDATED BALANCE SHEETS

Dollars in Millions, Except Share and Per Share Data

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 1,656	\$ 5,776
Marketable securities	1,173	2,957
Receivables	3,083	3,743
Inventories	1,657	1,384
Deferred income taxes	1,597	1,200
Prepaid expenses and other	355	258
<b>Total Current Assets</b>	<b>9,521</b>	<b>15,318</b>
Property, plant and equipment	5,333	4,521
Goodwill	7,635	5,586
Other intangible assets	8,778	3,124
Deferred income taxes	203	688
Marketable securities	3,523	2,909
Other assets	904	824
<b>Total Assets</b>	<b>\$ 35,897</b>	<b>\$ 32,970</b>
<b>LIABILITIES</b>		
Current Liabilities:		
Short-term borrowings and current portion of long-term debt	\$ 826	\$ 115
Accounts payable	2,202	2,603
Accrued expenses	2,573	2,791
Deferred income	825	337
Accrued rebates and returns	1,054	1,170
U.S. and foreign income taxes payable	193	167
Dividends payable	606	597
<b>Total Current Liabilities</b>	<b>8,279</b>	<b>7,780</b>
Pension, postretirement and postemployment liabilities	1,882	2,017
Deferred income	4,024	866
U.S. and foreign income taxes payable	648	573
Deferred income taxes	383	107
Other liabilities	475	384
Long-term debt	6,568	5,376
<b>Total Liabilities</b>	<b>22,259</b>	<b>17,103</b>

Commitments and contingencies (Note 21)

**EQUITY**

Bristol-Myers Squibb Company Shareholders' Equity:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Preferred stock, \$2 convertible series, par value \$1 per share: Authorized 10 million shares; issued and outstanding 5,117 in 2012 and 5,268 in 2011, liquidation value of \$50 per share		
Common stock, par value of \$0.10 per share: Authorized 4.5 billion shares; 2.2 billion issued in both 2012 and 2011	221	220
Capital in excess of par value of stock	2,694	3,114
Accumulated other comprehensive loss	(3,202)	(3,045)
Retained earnings	32,733	33,069
Less cost of treasury stock 570 million common shares in 2012 and 515 million in 2011	(18,823)	(17,402)
<b>Total Bristol-Myers Squibb Company Shareholders Equity</b>	<b>13,623</b>	<b>15,956</b>
Noncontrolling interest	15	(89)
<b>Total Equity</b>	<b>13,638</b>	<b>15,867</b>
<b>Total Liabilities and Equity</b>	<b>\$ 35,897</b>	<b>\$ 32,970</b>

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



**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

Dollars in Millions

	Year Ended December 31,		
	2012	2011	2010
<b>Cash Flows From Operating Activities:</b>			
Net earnings	\$ 2,501	\$ 5,260	\$ 4,513
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Net earnings attributable to noncontrolling interest	(541)	(1,551)	(1,411)
Depreciation and amortization, net	681	628	607
Deferred income taxes	(1,230)	415	422
Stock-based compensation	154	161	193
Impairment charges	2,180	28	228
Proceeds from Amylin diabetes collaboration	3,570		
Other	(35)	(147)	(32)
Changes in operating assets and liabilities:			
Receivables	648	(220)	(270)
Inventories	(103)	(193)	156
Accounts payable	(232)	593	315
Other deferred income	295	58	254
U.S. and foreign income taxes payable	(50)	(134)	(236)
Other	(897)	(58)	(248)
<b>Net Cash Provided by Operating Activities</b>	<b>6,941</b>	<b>4,840</b>	<b>4,491</b>
<b>Cash Flows From Investing Activities:</b>			
Proceeds from sale and maturities of marketable securities	4,890	5,960	3,197
Purchases of marketable securities	(3,607)	(6,819)	(5,823)
Additions to property, plant and equipment and capitalized software	(548)	(367)	(424)
Proceeds from sale of businesses and other investing activities	68	149	67
Purchase of businesses, net of cash acquired	(7,530)	(360)	(829)
<b>Net Cash Used in Investing Activities</b>	<b>(6,727)</b>	<b>(1,437)</b>	<b>(3,812)</b>
<b>Cash Flows From Financing Activities:</b>			
Short-term debt borrowings/(repayments)	49	(1)	(33)
Proceeds from issuance of long-term debt	1,950		6
Long-term debt repayments	(2,108)	(78)	(936)
Interest rate swap terminations	2	296	146
Issuances of common stock	463	601	252
Common stock repurchases	(2,403)	(1,221)	(576)
Dividends paid	(2,286)	(2,254)	(2,202)
<b>Net Cash Used in Financing Activities</b>	<b>(4,333)</b>	<b>(2,657)</b>	<b>(3,343)</b>
Effect of Exchange Rates on Cash and Cash Equivalents	(1)	(3)	14
Increase/(Decrease) in Cash and Cash Equivalents	(4,120)	743	(2,650)
Cash and Cash Equivalents at Beginning of Year	5,776	5,033	7,683
<b>Cash and Cash Equivalents at End of Year</b>	<b>\$ 1,656</b>	<b>\$ 5,776</b>	<b>\$ 5,033</b>

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



## **Note 1. ACCOUNTING POLICIES**

### **Basis of Consolidation**

The consolidated financial statements are prepared in conformity with United States (U.S.) generally accepted accounting principles (GAAP), including the accounts of Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS, or the Company) and all of its controlled majority-owned subsidiaries. All intercompany balances and transactions are eliminated. Material subsequent events are evaluated and disclosed through the report issuance date.

Codevelopment, cocommercialization and license arrangements are assessed to determine whether the terms provide economic or other control over the entity requiring consolidation of an entity. Entities controlled by means other than a majority voting interest are referred to as variable interest entities. There were no arrangements with material variable interest entities during any of the periods presented.

### **Use of Estimates**

The preparation of financial statements requires the use of management estimates and assumptions. The most significant assumptions are employed in estimates used in determining the fair value and potential impairment of intangible assets; sales rebate and return accruals; legal contingencies; income taxes; and pension and postretirement benefits. Actual results may differ from estimated results.

### **Reclassifications**

Certain prior period amounts were reclassified to conform to the current period presentation. The presentation of depreciation and amortization in the consolidated statements of cash flows includes the depreciation of property, plant and equipment, the amortization of intangible assets and deferred income. The provision for restructuring, equity in net income of affiliates, and litigation expense, net, previously presented separately on the consolidated statements of earnings are currently presented as components of other (income)/expense.

### **Revenue Recognition**

Revenue is recognized when persuasive evidence of an arrangement exists, the sales price is fixed and determinable, collectability is reasonably assured and title and substantially all risks and rewards of ownership is transferred, generally at time of shipment. However, certain sales of non-U.S. businesses are recognized on the date of receipt by the purchaser. See Note 3. Alliances and Collaborations for further discussion of revenue recognition related to alliances. Provisions are made at the time of revenue recognition for expected sales returns, discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances including the impact of applicable healthcare legislation. Such provisions are recognized as a reduction of revenue.

Revenue is deferred until the right of return no longer exists or sufficient historical experience to estimate sales returns is developed when a new product is not an extension of an existing line of product or there is no historical experience with products in a similar therapeutic category.

### **Income Taxes**

The provision for income taxes includes income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax basis of assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recognized to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement.

### **Cash and Cash Equivalents**

Cash and cash equivalents include U.S. Treasury securities, government agency securities, bank deposits, time deposits and money market funds. Cash equivalents consist of highly liquid investments with original maturities of three months or less at the time of purchase and are

recognized at cost, which approximates fair value.

### **Marketable Securities and Investments in Other Companies**

Marketable securities are classified as available-for-sale on the date of purchase and reported at fair value. Fair value is determined based on observable market quotes or valuation models using assessments of counterparty credit worthiness, credit default risk or underlying security and overall capital market liquidity.

Investments in 50% or less owned companies are accounted for using the equity method of accounting when the ability to exercise significant influence is maintained. The share of net income or losses of equity investments is included in equity in net income of affiliates in other (income)/expense. Equity investments are reviewed for impairment by assessing if the decline in market value of the investment below the carrying value is other than temporary, which considers the intent and ability to retain the investment, the length of time and extent that the market value has been less than cost, and the financial condition of the investee.

### **Inventory Valuation**

Inventories are stated at the lower of average cost or market.

### **Property, Plant and Equipment and Depreciation**

Expenditures for additions, renewals and improvements are capitalized at cost. Depreciation is computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of depreciable assets range from 20 to 50 years for buildings and 3 to 20 years for machinery, equipment, and fixtures.

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

Current facts or circumstances are periodically evaluated to determine if the carrying value of depreciable assets to be held and used may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows generated by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists at its lowest level of identifiable cash flows. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques using Level 3 fair value inputs, including a discounted value of estimated future cash flows. Long-lived assets held for sale are reported at the lower of its carrying value or its estimated net realizable value.

### **Capitalized Software**

Eligible costs to obtain internal use software for significant systems projects are capitalized and amortized over the estimated useful life of the software. Insignificant costs to obtain software for projects are expensed as incurred.

### **Business Combinations**

Businesses acquired are consolidated upon obtaining control of the acquiree. The fair value of assets acquired and liabilities assumed are recognized at the date of acquisition. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. Legal, audit, business valuation, and all other business acquisition costs are expensed when incurred.

### **Goodwill, Acquired In-Process Research and Development and Other Intangible Assets**

The fair value of intangible assets is typically determined using the income method which utilizes Level 3 fair value inputs. The market participant valuations assume a global view considering all potential jurisdictions and indications based on discounted after-tax cash flow projections, risk adjusted for estimated probability of technical and regulatory success (for IPRD).

Finite-lived intangible assets, including licenses, developed technology rights and IPRD projects that reach commercialization are amortized on a straight-line basis over their estimated useful life. Estimated useful lives are determined considering the period in which the assets are expected to contribute to future cash flows.

Goodwill is tested at least annually for impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts. Examples of qualitative factors assessed in 2012 include our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test performed in the

prior year. Each relevant factor is assessed both individually and in the aggregate.

IPRD is tested for impairment on an annual basis and more frequently if events occur or circumstances change that would indicate a potential reduction in the fair values of the assets below their carrying value. If the carrying value of IPRD is determined to exceed the fair value, an impairment loss is recognized for the difference.

Finite-lived intangible assets are tested for impairment when facts or circumstances suggest that the carrying value of the asset may not be recoverable. If the carrying value exceeds the projected undiscounted pre-tax cash flows of the intangible asset, an impairment loss equal to the excess of the carrying value over the estimated fair value (discounted after-tax cash flows) is recognized.

### **Restructuring**

Restructuring charges are recognized as a result of actions to streamline operations and rationalize manufacturing facilities. Judgment is used when estimating the impact of restructuring plans, including future termination benefits and other exit costs to be incurred when the actions take place. Actual results could vary from these estimates.

### **Contingencies**

Loss contingencies from legal proceedings and claims may occur from a wide range of matters, including, government investigations, shareholder lawsuits, product and environmental liability, contractual claims and tax matters. Accruals are recognized when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Gain contingencies are not recognized until realized. Legal fees are expensed as incurred.

### **Derivative Financial Instruments**

Derivatives are used principally in the management of interest rate and foreign currency exposures and are not held or used for trading purposes.

Derivatives are recognized at fair value with changes in fair value recognized in earnings unless specific hedge criteria are met. If the derivative is designated as a fair value hedge, changes in fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as a cash flow hedge, the effective portions of changes in the fair value of the derivative are reported in accumulated other comprehensive income (OCI) and subsequently recognized in earnings when the hedged item affects earnings. Cash flows are classified consistent with the underlying hedged item.

Derivatives are designated and assigned as hedges of forecasted transactions, specific assets or specific liabilities. When hedged assets or liabilities are sold or extinguished or the forecasted transactions being hedged are no longer probable to occur, a gain or loss is immediately recognized in earnings.

Non-derivative instruments, primarily euro denominated long-term debt, are also designated as hedges of net investments in foreign affiliates. The effective portion of the designated non-derivative instrument is recognized in the foreign currency translation section of OCI and the ineffective portion is recognized in earnings.

### **Shipping and Handling Costs**

Shipping and handling costs are included in marketing, selling and administrative expenses and were \$125 million in 2012, \$139 million in 2011 and \$135 million in 2010.

### **Advertising and Product Promotion Costs**

Advertising and product promotion costs are expensed as incurred.

### **Foreign Currency Translation**

Foreign subsidiary earnings are translated into U.S. dollars using average exchange rates. The net assets of foreign subsidiaries are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recognized in OCI.

### **Research and Development**

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Strategic alliances with third parties provide rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are owned by the other party. Certain research and development payments to alliance partners are contingent upon the achievement of certain pre-determined criteria. Milestone payments achieved prior to regulatory approval of the product are expensed as research and development. Milestone payments made in

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

connection with regulatory approvals are capitalized and amortized to cost of products sold over the remaining useful life of the asset. Capitalized milestone payments are tested for recoverability periodically or whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Research and development is recognized net of reimbursements in connection with collaboration agreements.



Upfront, pre-approval milestone and other licensing receipts obtained during development are deferred and amortized over the estimated life of the product in other income. If the Company has no future obligation for development, upfront milestone and other licensing receipts are recognized immediately in other income. The amortization period of upfront, licensing and milestone receipts is assessed and determined after considering terms of the arrangements.

## Note 2. BUSINESS SEGMENT INFORMATION

BMS operates in a single segment engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of innovative medicines that help patients prevail over serious diseases. A global research and development organization and supply chain organization are utilized and responsible for the development and delivery of products to the market. Regional commercial organizations are used to distribute and sell the product. The business is also supported by global corporate staff functions. Segment information is consistent with the financial information regularly reviewed by the chief operating decision maker, the chief executive officer, for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods.

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 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%

Selected geographic area information was as follows:

Dollars in Millions	Net Sales			Property, Plant and Equipment	
	2012	2011	2010	2012	2011
United States <sup>(a)</sup>	\$ 10,384	\$ 14,039	\$ 12,800	\$ 4,464	\$ 3,538
Europe <sup>(b)</sup>	3,706	3,879	3,672	740	886
Rest of the World <sup>(c)</sup>	3,204	3,237	2,900	129	97
Other <sup>(d)</sup>	327	89	112		
<b>Total</b>	<b>\$ 17,621</b>	<b>\$ 21,244</b>	<b>\$ 19,484</b>	<b>\$ 5,333</b>	<b>\$ 4,521</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.

Net sales of key products were as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Plavix* ( <i>clopidogrel bisulfate</i> )	\$ 2,547	\$ 7,087	\$ 6,666
Avapro*/Avalide* ( <i>irbesartan/irbesartan-hydrochlorothiazide</i> )	503	952	1,176
Eliquis ( <i>apixaban</i> )	2		
Abilify* ( <i>aripiprazole</i> )	2,827	2,758	2,565
Reyataz ( <i>atazanavir sulfate</i> )	1,521	1,569	1,479
Sustiva ( <i>efavirenz</i> ) Franchise	1,527	1,485	1,368
Baraclude ( <i>entecavir</i> )	1,388	1,196	931
Erbix* ( <i>cetuximab</i> )	702	691	662
Sprycel ( <i>dasatinib</i> )	1,019	803	576
Yervoy ( <i>ipilimumab</i> )	706	360	

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

<i>Orencia (abatacept)</i>	1,176	917	733
<i>Nulojix (belatacept)</i>	11	3	
<i>Onglyza/Kombiglyze (saxagliptin/saxagliptin and metformin)</i>	709	473	158
<i>Byetta* (exenatide)</i>	149	N/A	N/A
<i>Bydureon*(exenatide extended-release for injectable suspension)</i>	78	N/A	N/A
Mature Products and All Other	2,756	2,950	3,170
Net Sales	\$ 17,621	\$ 21,244	\$ 19,484

**Note 3. ALLIANCES AND COLLABORATIONS**

Alliances and collaborations are utilized with third parties for the development and commercialization of certain products. These collaborations can include arrangements for access to intellectual property, research, development, manufacturing and/or commercial capabilities. The arrangements are often entered into in order to share risks and rewards related to a specific program or product or as part of a specific divestiture strategy. Unless otherwise noted, operating results associated with the alliances and collaborations are generally treated as follows: product revenues from BMS sales are included in net sales; royalties, collaboration, profit sharing and distribution fees are included in cost of goods sold; post-approval milestone payments to partners are deferred and amortized over the useful life of the related products in cost of products sold; cost sharing reimbursements offset the applicable operating expense; payments to BMS attributed to upfront, pre-approval based milestone and other licensing payments are deferred and amortized over the estimated useful life of the related products in other income/expense or as a reduction to cost of products sold for the Amylin diabetes collaboration; income and expenses attributed to a collaboration's non-core activities, such as supply and manufacturing arrangements and compensation for opting-out of commercialization in certain countries, are included in other income/expense; partnerships and joint ventures are either consolidated or accounted for under the equity method of accounting and related cash receipts and distributions are treated as operating cash flow.

**Sanofi**

BMS has agreements with Sanofi for the codevelopment and cocommercialization of *Avapro\*/Avalide\**, an angiotensin II receptor antagonist indicated for the treatment of hypertension and diabetic nephropathy, and *Plavix\**, a platelet aggregation inhibitor. The worldwide alliance operates under the framework of two geographic territories; one in the Americas (principally the U.S., Canada, Puerto Rico and Latin American countries) and Australia and the other in Europe and Asia. Accordingly, territory partnerships were formed to manage central expenses, such as marketing, research and development and royalties, and to supply finished product to the individual countries. In general, at the country level, agreements either to copromote (whereby a partnership was formed between the parties to sell each brand) or to comarket (whereby the parties operate and sell their brands independently of each other) are in place.

BMS acts as the operating partner and owns a 50.1% majority controlling interest in the territory covering the Americas and Australia and consolidates all country partnership results for this territory with Sanofi's 49.9% share of the results reflected as a noncontrolling interest. BMS recognizes net sales in this territory and in comarketing countries outside this territory (e.g. Germany, Italy for irbesartan only, Spain and Greece). Royalties owed to Sanofi are included in cost of products sold (other than development royalties). Sanofi acts as the operating partner and owns a 50.1% majority controlling interest in the territory covering Europe and Asia. BMS has a 49.9% ownership interest in this territory which is included in equity in net income of affiliates. Distributions of profits relating to the partnerships are included in operating activities.

BMS and Sanofi have a separate partnership governing the copromotion of irbesartan in the U.S. Sanofi paid BMS \$350 million for their acquisition of an interest in the irbesartan license for the U.S. upon formation of the alliance.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
<b>Territory covering the Americas and Australia:</b>			
Net sales	\$ 2,766	\$ 7,761	\$ 7,464
Royalty expense	530	1,583	1,527
Noncontrolling interest pre-tax	844	2,323	2,074
Distributions to Sanofi	742	2,335	2,093
<b>Territory covering Europe and Asia:</b>			
Equity in net income of affiliates	201	298	325
Distributions to BMS	229	283	313
<b>Other:</b>			
Net sales in Europe comarketing countries and other	284	279	378
Amortization (income)/expense irbesartan license fee	(29)	(31)	(31)
Supply activities and development and opt-out royalty (income)/expense	(142)	23	(3)

Dollars in Millions	December 31,	
	2012	2011
Investment in affiliates territory covering Europe and Asia	\$ 9	\$ 37

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Deferred income - irbesartan license fee		29
Noncontrolling interest	(30)	(131)

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The following is summarized financial information for interests in the partnerships with Sanofi for the territory covering Europe and Asia, which are not consolidated but are accounted for using the equity method:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Net sales	\$ 1,077	\$ 1,469	\$ 1,879
Cost of products sold	624	811	1,047
<b>Gross profit</b>	<b>453</b>	<b>658</b>	<b>832</b>
Marketing, selling and administrative	47	75	129
Advertising and product promotion	8	15	29
Research and development	2	5	16
Other (income)/expense	2	1	(1)
<b>Net income</b>	<b>\$ 394</b>	<b>\$ 562</b>	<b>\$ 659</b>

Current assets	\$ 417	\$ 584	\$ 751
Current liabilities	417	584	751

Cost of products sold includes discovery royalties of \$133 million in 2012, \$184 million in 2011 and \$307 million in 2010, which are paid directly to Sanofi. All other expenses are shared based on the applicable ownership percentages. Current assets and current liabilities include approximately \$293 million in 2012, \$400 million in 2011 and \$567 million in 2010 related to receivables/payables attributed to cash distributions to BMS and Sanofi as well as intercompany balances between partnerships within the territory. The remaining current assets and current liabilities consist of third-party trade receivables, inventories and amounts due to BMS and Sanofi for the purchase of inventories, royalties and expense reimbursements.

In September 2012, BMS and Sanofi restructured the terms of the codevelopment and cocommercialization agreements discussed above. Effective as of January 1, 2013, subject to the receipt of regulatory approvals in certain countries, 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. In exchange for the rights being assumed by Sanofi, BMS will 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).

### Otsuka

BMS has a worldwide commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka), to codevelop and copromote *Abilify*\*, for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder, excluding certain Asian countries. The U.S. portion of the amended commercialization and manufacturing agreement expires upon the expected loss of product exclusivity in April 2015. The contractual share of *Abilify*\* net sales recognized by BMS was 58% in 2010 and 53.5% in 2011 and 51.5% in 2012.

In the UK, Germany, France and Spain, BMS receives 65% of third-party net sales. In these countries and the U.S., third-party customers are invoiced by BMS 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. BMS recognizes all of the net sales in certain countries where it is the exclusive distributor for the product or has an exclusive right to sell *Abilify*\*.

BMS purchases the product from Otsuka and performs finish manufacturing for sale to third-party customers by BMS or Otsuka. Under the terms of the amended agreement, BMS paid Otsuka \$400 million, which is amortized as a reduction of net sales through the expected loss of U.S. exclusivity in April 2015. The unamortized amount 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 costs incurred by BMS in excess of the resource requirements specified in the agreement.

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:

	<b>Share as a % of U.S. Net Sales</b>
\$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.

BMS and Otsuka also entered into an oncology collaboration for *Sprycel* and *Ixempra* (ixabepilone) for the U.S., Japan and European Union (EU) markets (the Oncology Territory). A collaboration fee, classified in cost of products sold, is paid to Otsuka based on the following percentages of annual 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 contributes (i) 20% of the first \$175 million of certain commercial operational expenses relating to the oncology products, and (ii) 1% of such commercial operational expenses relating to the products in the 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 U.S. extension and the oncology collaboration include a change-of-control provision in the case of an acquisition of BMS. 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 collaboration as it exists today. 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 the rights of BMS under the *Abilify*\* agreement (as amended). The agreements also provide that in the event of a generic competitor to *Abilify*\* after January 1, 2010, BMS has the option of terminating the *Abilify*\* April 2009 amendment (with the agreement as previously amended remaining in force). If BMS were to exercise such option then either (i) BMS would receive a payment from Otsuka according to a pre-determined schedule and the oncology collaboration would terminate at the same time or (ii) the oncology collaboration would continue for a truncated period according to a pre-determined schedule.

The EU agreement remained unchanged and will expire in June 2014. In other countries where BMS has the exclusive right to sell *Abilify*\*, the agreement expires on the later of April 2015 or expiration of the applicable patent or data exclusivity in such country.

In addition to the \$400 million extension payment, total milestones paid to Otsuka were \$217 million, of which \$157 million was expensed as IPRD in 1999. The remaining \$60 million was capitalized in other intangible assets and was amortized to cost of products sold over the remaining life of the original agreement in the U.S.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
<i>Abilify</i> * net sales, including amortization of extension payment	\$ 2,827	\$ 2,758	\$ 2,565
Oncology Products collaboration fee expense	138	134	128
Royalty expense	78	72	62
Reimbursement of operating expenses to/(from) Otsuka	(49)	(47)	(101)
Amortization (income)/expense extension payment	66	66	66
Amortization (income)/expense upfront, milestone and other licensing payments	5	6	6

Dollars in Millions	December 31,	
	2012	2011
Other assets extension payment	\$ 153	\$ 219

Other intangible assets    upfront, milestone and other licensing payments

5

**Lilly**

BMS has an Epidermal Growth Factor Receptor (EGFR) commercialization agreement with Eli Lilly and Company (Lilly) through Lilly's 2008 acquisition of ImClone Systems Incorporated (ImClone) for the codevelopment and promotion of *Erbix*\* and necitumumab (IMC-11F8) in the U.S., which expires as to *Erbix*\* in September 2018. BMS also has codevelopment and copromotion rights to both products in Canada and Japan. *Erbix*\* is indicated for use in the treatment of patients with metastatic colorectal cancer and for use in the treatment of squamous cell carcinoma of the head and neck. Under the EGFR agreement, with respect to *Erbix*\* 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.



In 2007, BMS and ImClone amended their codevelopment agreement with Merck KGaA (Merck) to provide for cocommercialization of *Erbix*\* in Japan. The rights under this agreement expire in 2032; however, Lilly has the ability to terminate the agreement after 2018 if it determines that it is commercially unreasonable for Lilly to continue. *Erbix*\* received marketing approval in Japan in 2008 for the use of *Erbix*\* in treating patients with advanced or recurrent colorectal cancer. BMS receives 50% of the pre-tax profit from Merck sales of *Erbix*\* in Japan which is further shared equally with Lilly.

BMS is amortizing \$500 million of license acquisition costs in costs of products sold through 2018.

In 2010, BMS and Lilly restructured the EGFR commercialization agreement described above between BMS and ImClone as it relates to necitumumab, a novel targeted cancer therapy currently in Phase III development for non-small cell lung cancer. Both companies share in the cost of developing and potentially commercializing necitumumab in the U.S., Canada and Japan. Lilly maintains exclusive rights to necitumumab in all other markets.

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 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.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Net sales	\$ 702	\$ 691	\$ 662
Distribution fees and royalty expense	291	287	275
Research and development expense reimbursement to Lilly necitumumab	14	12	12
Amortization (income)/expense upfront, milestone and other licensing payments	38	37	37
Commercialization expense reimbursements to/(from) Lilly	(20)	(18)	(16)
Japan commercialization profit sharing (income)/expense, net	(37)	(34)	(39)

Dollars in Millions	December 31,	
	2012	2011
Other intangible assets upfront, milestone and other licensing payments	\$ 211	\$ 249

BMS acquired Amylin Pharmaceuticals, Inc. (Amylin) on August 8, 2012 (see Note 4. Acquisitions for further information). Amylin had previously entered into a settlement and termination agreement with Lilly regarding their collaboration for the global development and commercialization of *Byetta*\* and *Bydureon*\* (exenatide products) under which the parties agreed to transition full responsibility of these products to Amylin. Although the transition of the U.S. operations was completed, Lilly had not yet transitioned the non-U.S. operations to Amylin. In September 2012, BMS provided notification to Lilly that BMS will assume essentially all non-U.S. operations of the exenatide products during the first half of 2013 and therefore terminate Lilly's exclusive right to non-U.S. commercialization of the exenatide products, subject to certain regulatory and other conditions. BMS is responsible for any non-U.S. losses incurred by Lilly during 2012 and 2013 up to a maximum of \$60 million and is entitled to tiered royalties until the transition is complete. Promissory notes assumed in the acquisition of Amylin aggregating \$1.4 billion were repaid to Lilly during 2012.

### Gilead

BMS and Gilead Sciences, Inc. (Gilead) have a joint venture to develop and commercialize *Atripla*\* (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg), a once-daily single tablet three-drug regimen for the treatment of human immunodeficiency virus (HIV) infection, combining *Sustiva*, a product of BMS, and *Truvada*\* (emtricitabine and tenofovir disoproxil fumarate), a product of Gilead, in the U.S., Canada and Europe. BMS accounts for its participation in the U.S. joint venture under the equity method of accounting.

Net sales of the bulk efavirenz component of *Atripla*\* are deferred until the combined product is sold to third-party customers. Net sales for the efavirenz component are based on the relative ratio of the average respective net selling prices of *Truvada*\* and *Sustiva*.

Summarized financial information related to this alliance is as follows:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Net sales	\$ 1,267	\$ 1,204	\$ 1,053
Equity in net loss of affiliates	(18)	(16)	(12)

**AstraZeneca**

In 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 (*Bydureon\**, *Byetta\**, *Symlin\** and metformin, which is currently in development). The arrangement is based on the framework of the existing diabetes alliance agreements discussed further below, 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 including \$73 million included in accrued expenses that is expected to be reimbursed back to AstraZeneca in 2013. The remaining \$3.5 billion is accounted for as deferred income and 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.

In addition, BMS continues to maintain two worldwide diabetes codevelopment and cocommercialization agreements with AstraZeneca for *Onglyza*, *Kombiglyze XR* (saxagliptin and metformin hydrochloride extended-release), *Komboglyze* (saxagliptin and metformin immediate-release marketed in the EU) and *Forxiga* (dapagliflozin). The agreements for saxagliptin exclude Japan. In this document unless specifically noted, we refer to both *Kombiglyze* and *Komboglyze* as *Kombiglyze*. *Forxiga* was approved in the EU in November 2012. *Onglyza* and *Forxiga* were discovered by BMS. *Kombiglyze* was codeveloped with AstraZeneca. Both companies jointly develop the clinical and marketing strategy and share commercialization expenses and profits and losses equally on a global basis and also share in development costs, with the exception of *Forxiga* development costs in Japan, which are borne by AstraZeneca. BMS manufactures both products. BMS has opted to decline involvement in cocommercialization for both products in certain countries not in the BMS global commercialization network and instead receives compensation based on net sales recorded by AstraZeneca in these countries.

BMS received \$300 million in upfront, milestone and other licensing payments related to saxagliptin to date and could receive up to an additional \$300 million for sales-based milestones. BMS also received \$250 million in upfront, milestone and other licensing payments related to dapagliflozin to date, including \$80 million received in January 2013, and could potentially receive up to an additional \$150 million for development and regulatory milestones and up to an additional \$390 million for sales-based milestones. BMS is entitled to reimbursements for 50% of capital expenditures related to Amylin.

Summarized financial information related to these alliances is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Net sales	\$ 972	\$ 473	\$ 158
Profit sharing expense	425	207	67
Commercialization expense reimbursements to/(from) AstraZeneca	(141)	(40)	(33)
Research and development expense reimbursements to/(from) AstraZeneca	(18)	40	19
Amortization (income)/expense			
upfront, milestone and other licensing payments recognized in:			
Cost of products sold	(126)		
Other (income)/expense	(38)	(38)	(28)
Upfront, milestone and other licensing payments received:			
Amylin-related products	3,547		
Saxagliptin			50
Dapagliflozin		120	
Dollars in Millions		December 31,	
		2012	2011
Deferred income			
upfront, milestone and other licensing payments:			

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Amylin-related products	\$ 3,423	\$
Saxagliptin	208	230
Dapagliflozin	206	142

**Pfizer**

BMS and Pfizer Inc. (Pfizer) maintain a worldwide codevelopment and cocommercialization agreement for *Eliquis*, an anticoagulant discovered by BMS for the prevention and treatment of atrial fibrillation and other arterial thrombotic conditions. *Eliquis* was approved in the US and Japan in December 2012. Pfizer funds 60% of all development costs under the initial development plan effective January 1, 2007. The companies jointly develop the clinical and marketing strategy and share commercialization expenses and profits equally on a global basis. In certain countries not in the BMS global commercialization network, Pfizer will commercialize *Eliquis* alone and will pay compensation to BMS based on a percentage of net sales. BMS manufactures the product.

BMS received \$654 million in upfront, milestone and other licensing payments for *Eliquis* to date, including \$95 million received in February 2013 and could receive up to an additional \$230 million for development and regulatory milestones. These payments are deferred and amortized over the estimated useful life of the products in other income.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Net sales	\$ 2	\$	\$
Commercialization expense reimbursements to/(from) Pfizer	(18)	(10)	(8)
Research and development reimbursements to/(from) Pfizer	7	(65)	(190)
Amortization (income)/expense upfront, milestone and other licensing payments	(37)	(33)	(31)
Upfront, milestone and other licensing payments received	20	65	10

Dollars in Millions	December 31,	
	2012	2011
Deferred income upfront, milestone and other licensing payments	\$ 397	\$ 434

**Valeant**

In 2012, BMS and PharmaSwiss SA, a wholly-owned subsidiary of Valeant Pharmaceuticals International Inc. (Valeant) entered into a collaboration for certain mature brand products in Europe. In connection with the collaboration, Valeant is responsible for the marketing, promotion, distribution and sale of the products and related regulatory matters in the covered territory, and BMS is responsible for the maintenance of the products intellectual property and supply of the products. The collaboration expires December 31, 2014 at which time Valeant has the right to purchase the trademarks and intellectual property at a price determined based on a multiple of sales. If the right is not exercised, all rights transferred to Valeant during the collaboration period revert back to BMS.

As consideration for entering into the collaboration, BMS received \$79 million at the start of the collaboration period which was allocated to the license and other rights transferred to Valeant (\$61 million) and the option to purchase the remaining assets at the end of the collaboration (\$18 million). The allocation was based on the estimated fair value of the option and other elements after considering various market factors, including an analysis of any estimated excess of the fair value of the mature brands business over the potential purchase price if the option to purchase the trademarks and intellectual property is exercised at December 31, 2014. The fair value of the option was recorded as a liability, and changes in the estimated fair value of the option liability will be recognized in the results of operations. The remaining \$61 million will be recognized as alliance revenue throughout the term of the collaboration. BMS will also recognize revenue during the collaboration period for the supply of the product, and provide certain information technology, regulatory, order processing, distribution and other transitional services in exchange for a fee during the first six months of the collaboration.

**Note 4. ACQUISITIONS***Amylin Pharmaceuticals, Inc. Acquisition*

On August 8, 2012, BMS completed its acquisition of the outstanding shares of Amylin, a biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines to treat diabetes and other metabolic diseases. Acquisition costs of \$29 million were included in other expenses.

BMS obtained full U.S. commercialization rights to Amylin's two primary commercialized assets, *Bydureon*\*, a once-weekly diabetes treatment and *Byetta*\*, a daily diabetes treatment, both of which are glucagon-like peptide-1 (GLP-1) receptor agonists approved in certain countries to improve glycemic control in adults with type 2 diabetes. BMS also obtained full commercialization rights to *Symmlin*\* (pramlintide acetate), an

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

amylinomimetic approved in the U.S. for adjunctive therapy to mealtime insulin to treat diabetes. Goodwill generated from this acquisition was primarily attributed to the expansion of our diabetes franchise.

IPRD was attributed to metreleptin, an analog of the human hormone leptine being studied and developed for the treatment of diabetes and/or hypertriglyceridemia in pediatric and adult patients with inherited or acquired lipodystrophy. The estimated useful life and the cash flows utilized to value metreleptin assumed initial positive cash flows to commence shortly after the expected receipt of regulatory approvals, subject to trial results.

#### *Inhibitex, Inc. Acquisition*

On February 13, 2012, BMS completed its acquisition of the outstanding shares of Inhibitex, Inc. (Inhibitex), a clinical-stage biopharmaceutical company focused on developing products to prevent and treat serious infectious diseases. Acquisition costs of \$12 million were included in other expense.

BMS obtained Inhibitex's lead asset, INX-189, an oral nucleotide polymerase (NS5B) inhibitor in Phase II development for the treatment of chronic hepatitis C virus infections. Goodwill generated from this acquisition was primarily attributed to the potential to offer a full portfolio of therapy choices for hepatitis virus infections as well as to provide additional levels of sustainability to BMS's virology pipeline.

IPRD was primarily attributed to INX-189. INX-189 was expected to be most effective when used in combination therapy and it was assumed all market participants would inherently maintain franchise synergies attributed to maximizing the cash flows of their existing virology pipeline assets. The cash flows utilized to value INX-189 included such synergies and also assumed initial positive cash flows to commence shortly after the expected receipt of regulatory approvals, subject to trial results.

In August 2012, the Company discontinued development of INX-189 in the interest of patient safety. As a result, the Company recognized a non-cash, pre-tax impairment charge of \$1.8 billion related to the IPRD intangible asset in the third quarter of 2012. For further information discussion of the impairment charge, see Note 13. Goodwill and Other Intangible Assets.

#### *Amira Pharmaceuticals, Inc. Acquisition*

On September 7, 2011, BMS completed its acquisition of the outstanding shares of Amira Pharmaceuticals, Inc. (Amira) for \$325 million in cash plus three separate, contingent \$50 million payments due upon achievement of certain development and sales-based milestones. The first contingent payment was made in the fourth quarter of 2011. The purchase price of Amira includes the estimated fair value of the total contingent consideration of \$58 million, which was recorded in other liabilities. Acquisition costs of \$1 million were included in other expense. Amira was a privately-held biotechnology company primarily focused on the discovery and development of therapeutic products for the treatment of cardiovascular and fibrotic inflammatory diseases. The acquisition provides BMS with: 1) full rights to develop and commercialize AM152 which has completed Phase I clinical studies and the remainder of the Amira lysophosphatidic acid 1 receptor antagonist program; 2) researchers with fibrotic expertise; and 3) a pre-clinical autotaxin program. Goodwill generated from the acquisition was primarily attributed to acquired scientific expertise in fibrotic diseases allowing for expansion into a new therapeutic class.

The contingent liability was estimated utilizing a model that assessed the probability of achieving each milestone and discounted the amount of each potential payment based on the expected timing. Estimates used in evaluating the contingent liability were consistent with those used in evaluating the acquired IPRD. The discount rate for each payment was consistent with market debt yields for the non-callable, publicly-traded bonds of BMS with similar maturities to each of the estimated potential payment dates. This fair value measurement was based on significant inputs not observable in the market and therefore represents a Level 3 measurement.

#### *ZymoGenetics, Inc. Acquisition*

On October 8, 2010, BMS completed its acquisition of the outstanding shares of common stock of ZymoGenetics, Inc. (ZymoGenetics) in October 2010. Acquisition costs of \$10 million were included in other expense. ZymoGenetics is focused on developing and commercializing therapeutic protein-based products for the treatment of human diseases. The companies collaborated on the development of peginterferon lambda, a novel interferon in Phase IIb development at the acquisition date, for the treatment of hepatitis C virus infection. The acquisition provides the Company with full rights to develop and commercialize peginterferon lambda and also brings proven capabilities with therapeutic proteins and revenue from *Recothrom*, an FDA approved specialty surgical biologic. Goodwill generated from the acquisition was primarily attributed to full ownership rights to peginterferon lambda.

The final purchase price allocation for ZymoGenetics, Amira and Inhibitex and the preliminary purchase price allocation (pending final valuation of intangible assets and deferred income taxes) for Amylin were as follows:

Dollars in Millions

<b>Identifiable net assets:</b>	<b>Amylin</b>	<b>Inhibitex</b>	<b>Amira</b>	<b>ZymoGenetics</b>
Cash	\$ 179	\$ 46	\$ 15	\$ 56
Marketable securities	108	17		91
Inventory	173			98
Property, plant and equipment	742			
Developed technology rights	6,340			230
IPRD	120	1,875	160	448
Other assets	136			29
Debt obligations	(2,020)	(23)		
Other liabilities	(339)	(10)	(16)	(91)
Deferred income taxes	(1,057)	(579)	(41)	9
<b>Total identifiable net assets</b>	<b>4,382</b>	<b>1,326</b>	<b>118</b>	<b>870</b>
<b>Goodwill</b>	<b>836</b>	<b>1,213</b>	<b>265</b>	<b>15</b>
<b>Purchase price to be allocated</b>	<b>\$ 5,218</b>	<b>\$ 2,539</b>	<b>\$ 383</b>	<b>\$ 885</b>

Cash paid for the acquisition of Amylin included payments of \$5,093 million to its outstanding common stockholders and \$219 million to holders of its stock options and restricted stock units (including \$94 million attributed to accelerated vesting that was accounted for as stock compensation expense in the third quarter of 2012).

The results of operations from acquired companies are included in the consolidated financial statements as of the acquisition date.

Revisions to goodwill from preliminary estimates at September 30, 2012 for Amylin relate primarily to an adjustment of the preliminary amount allocated to the fair value of acquired IPRD (decrease of \$250 million) based on additional information obtained related to future cash flow projections, net of the resulting deferred tax adjustment (\$99 million).

Pro forma supplemental financial information is not provided as the impacts of the acquisitions were not material to operating results in the year of acquisition. Goodwill, IPRD and all intangible assets valued in these acquisitions are non-deductible for tax purposes.

#### Note 5. OTHER (INCOME)/EXPENSE

Other (income)/expense includes:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Interest expense	\$ 182	\$ 145	\$ 145
Investment income	(106)	(91)	(75)
Provision for restructuring (See Note 6)	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)

**Note 6. RESTRUCTURING**

The following is the provision for restructuring:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Employee termination benefits	\$ 145	\$ 85	\$ 102
Other exit costs	29	31	11
<b>Provision for restructuring</b>	<b>\$ 174</b>	<b>\$ 116</b>	<b>\$ 113</b>

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Restructuring charges included termination benefits for workforce reductions of manufacturing, selling, administrative, and research and development personnel across all geographic regions of approximately 1,205 in 2012, 822 in 2011 and 995 in 2010.

The following table represents the activity of employee termination and other exit cost liabilities:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Liability at January 1	\$ 77	\$ 126	\$ 173
Charges	178	128	121
Change in estimates	(4)	(12)	(8)
Provision for restructuring	174	116	113
Foreign currency translation	(1)	2	(5)
Amylin acquisition	26		
Spending	(109)	(167)	(155)
Liability at December 31	\$ 167	\$ 77	\$ 126

**Note 7. INCOME TAXES**

The provision/(benefit) for income taxes consisted of:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
<b>Current:</b>			
U.S.	\$ 627	\$ 864	\$ 797
Non-U.S.	442	442	339
Total Current	1,069	1,306	1,136
<b>Deferred:</b>			
U.S.	(1,164)	406	438
Non-U.S.	(66)	9	(16)
Total Deferred	(1,230)	415	422
Total Provision/(Benefit)	\$ (161)	\$ 1,721	\$ 1,558

Effective Tax Rate

The reconciliation of the effective tax rate to the U.S. statutory Federal income tax rate was:

Dollars in Millions	% of Earnings Before Income Taxes		
	2012	2011	2010
Earnings before income taxes:			
U.S.	\$ (271)	\$ 4,336	\$ 3,833
Non-U.S.	2,611	2,645	2,238
Total	\$ 2,340	\$ 6,981	\$ 6,071

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

U.S. statutory rate	819	35.0 %	2,443	35.0 %	2,125	35.0 %
Non-tax deductible annual pharmaceutical company fee	90	3.8 %	80	1.2 %		
Tax effect of foreign subsidiaries earnings previously considered indefinitely reinvested offshore					207	3.4 %
Foreign tax effect of certain operations in Ireland, Puerto Rico and Switzerland	(688)	(29.4)%	(593)	(8.5)%	(694)	(11.4)%
State and local taxes (net of valuation allowance)	20	0.9 %	33	0.5 %	43	0.7 %
U.S. Federal, state and foreign contingent tax matters	66	2.8 %	(161)	(2.3)%	(131)	(2.1)%
U.S. Federal research and development tax credit			(69)	(1.0)%	(61)	(1.0)%
U.S. tax effect of capital losses	(392)	(16.7)%				
Foreign and other	(76)	(3.3)%	(12)	(0.2)%	69	1.1 %
	\$ (161)	(6.9)%	\$ 1,721	24.7 %	\$ 1,558	25.7 %

The change in the 2012 effective tax rate from 2011 was due to:

A tax benefit of \$392 million attributable to a capital loss deduction resulting from the tax insolvency of Inhibitex; and

Favorable earnings mix between high and low tax jurisdictions 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.

Partially offset by:

Contingent tax matters which resulted in a \$66 million charge in 2012 and \$161 million benefit in 2011;

An unfavorable impact on the current year rate from the delay in the legal enactment of the research and development tax credit, which was not extended as of December 31, 2012; and

Changes in prior period estimates upon finalizing U.S. tax returns resulting in a \$54 million benefit in 2011. The change in the 2011 effective tax rate from 2010 was due to:

A \$207 million charge recognized in the fourth quarter of 2010, which resulted primarily from additional U.S. taxable income from earnings of foreign subsidiaries previously considered to be indefinitely reinvested offshore;

Changes in prior period estimates upon finalizing U.S. tax returns resulting in a \$54 million benefit in 2011 and a \$30 million charge in 2010; and

Higher tax benefits from contingent tax matters primarily related to the effective settlements and remeasurements of uncertain tax positions (\$161 million in 2011 and \$131 million in 2010).

Partially offset by:

Unfavorable earnings mix between high and low tax jurisdictions compared to the prior year;

The non-tax deductible annual pharmaceutical company fee effective January 1, 2011 (tax impact of \$80 million); and

An out-of-period tax adjustment of \$59 million in 2010 for previously unrecognized net deferred tax assets primarily attributed to deferred profits related to certain alliances as of December 31, 2009 (not material to any prior periods).

The American Taxpayer Relief Act of 2012 (the Act) was signed into law on January 2, 2013. Among the provisions of the Act, was the retroactive reinstatement of the R&D tax credit and look thru exception for 2012 and 2013. As a result, the 2012 R&D tax credit and look thru exception benefit will be recognized in the first quarter of 2013.

*Deferred Taxes and Valuation Allowance*

The components of current and non-current deferred income tax assets/(liabilities) were as follows:

Dollars in Millions	December 31,	
	2012	2011
<b>Deferred tax assets</b>		
Foreign net operating loss carryforwards	\$ 3,722	\$ 3,674
Milestone payments and license fees	550	574
Deferred income	2,083	573
U.S. capital losses	794	

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

U.S. Federal net operating loss carryforwards	170	251
Pension and postretirement benefits	693	755
State net operating loss and credit carryforwards	346	344
Intercompany profit and other inventory items	288	331
U.S. Federal tax credit carryforwards	31	109
Other foreign deferred tax assets	197	112
Share-based compensation	111	111
Legal settlements	45	46
Repatriation of foreign earnings	86	
Other	344	233
<b>Total deferred tax assets</b>	<b>9,460</b>	<b>7,113</b>
Valuation allowance	(4,404)	(3,920)
<b>Net deferred tax assets</b>	<b>5,056</b>	<b>3,193</b>
<b>Deferred tax liabilities</b>		
Depreciation	(147)	(118)
Repatriation of foreign earnings		(31)
Acquired intangible assets	(2,768)	(593)
Other	(734)	(676)
<b>Total deferred tax liabilities</b>	<b>(3,649)</b>	<b>(1,418)</b>
<b>Deferred tax assets, net</b>	<b>\$ 1,407</b>	<b>\$ 1,775</b>
Recognized as:		
Deferred income taxes current	\$ 1,597	\$ 1,200
Deferred income taxes non-current	203	688
U.S. and foreign income taxes payable current	(10)	(6)
Deferred income taxes non-current	(383)	(107)
<b>Total</b>	<b>\$ 1,407</b>	<b>\$ 1,775</b>

The U.S. Federal net operating loss carryforwards were \$486 million at December 31, 2012. These carryforwards were acquired as a result of certain acquisitions and are subject to limitations under Section 382 of the Internal Revenue Code. The net operating loss carryforwards expire in varying amounts beginning in 2022. The U.S. Federal tax credit carryforwards expire in varying amounts beginning in 2017. The realization of the U.S. Federal tax credit carryforwards is dependent on generating sufficient domestic-sourced taxable income prior to their expiration. The capital loss available of \$2,200 million can be carried back to 2009 and carried forward to 2017. The foreign and state net operating loss carryforwards expire in varying amounts beginning in 2013 (certain amounts have unlimited lives).

Management has established a valuation allowance when a deferred tax asset is more likely than not to be realized. At December 31, 2012, a valuation allowance of \$4,404 million was established for the following items: \$3,659 million primarily for foreign net operating loss and tax credit carryforwards, \$338 million for state deferred tax assets including net operating loss and tax credit carryforwards, \$15 million for U.S. Federal net operating loss carryforwards and \$392 million for U.S. Federal capital losses.

In 2011, foreign holding companies net operating losses and their corresponding valuation allowances included an increase of \$2,027 million as a result of statutory impairment charges that are not required in consolidated net earnings. These foreign holding companies had a higher asset basis for statutory purposes than the basis used in the consolidated financial statements due to an internal reorganization of certain legal entities in prior periods.

Changes in the valuation allowance were as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Balance at beginning of year	\$ 3,920	\$ 1,863	\$ 1,791
Provision	494	2,410	92
Utilization	(145)	(135)	(22)
Foreign currency translation	39	(222)	(6)
Acquisitions	96	4	8
Balance at end of year	\$ 4,404	\$ 3,920	\$ 1,863

Income tax payments were \$676 million in 2012, \$597 million in 2011 and \$672 million in 2010. The current tax benefit realized as a result of stock related compensation credited to capital in excess of par value of stock was \$71 million in 2012, \$47 million in 2011 and \$10 million in 2010.

U.S. taxes have not been provided on approximately \$21 billion of undistributed earnings of foreign subsidiaries as these undistributed earnings are indefinitely invested offshore at December 31, 2012. Additional tax provisions will be required if these earnings are repatriated in the future to the U.S. or if such earnings are determined to be remitted in the foreseeable future. Due to complexities in the tax laws and assumptions that would have to be made, it is not practicable to estimate the amounts of income taxes that will have to be provided. As a result, BMS has favorable tax rates in Ireland and Puerto Rico under grants not scheduled to expire prior to 2023.

An internal reorganization of certain legal entities resulted in a \$207 million charge in 2010. It is possible that U.S. tax authorities could assert additional material tax liabilities arising from the reorganization. BMS would vigorously challenge any such assertion, were it to occur, and believes it would prevail; however, there can be no assurance of such a result.

Business is conducted in various countries throughout the world and is subject to tax in numerous jurisdictions. A significant number of tax returns are filed and subject to examination by various Federal, state and local tax authorities. Tax examinations are often complex, as tax authorities may disagree with the treatment of items reported requiring several years to resolve. Liabilities are established for possible assessments by tax authorities resulting from known tax exposures including, but not limited to, transfer pricing matters, tax credits and deductibility of certain expenses. Such liabilities represent a reasonable provision for taxes ultimately expected to be paid and may need to be adjusted over time as more information becomes known. The effect of changes in estimates related to contingent tax liabilities is included in the effective tax rate reconciliation above.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Balance at beginning of year	\$ 628	\$ 845	\$ 968
Gross additions to tax positions related to current year	46	44	46
Gross additions to tax positions related to prior years	66	105	177
Gross additions to tax positions assumed in acquisitions	31	1	11
Gross reductions to tax positions related to prior years	(57)	(325)	(196)
Settlements	(54)	(30)	(153)
Reductions to tax positions related to lapse of statute	(19)	(7)	(7)
Cumulative translation adjustment	1	(5)	(1)
Balance at end of year	\$ 642	\$ 628	\$ 845

Additional information regarding unrecognized tax benefits is as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Unrecognized tax benefits that if recognized would impact the effective tax rate	\$ 633	\$ 570	\$ 818
Accrued interest	59	51	51
Accrued penalties	32	25	23
Interest expense/(benefit)	14	10	(12)
Penalty expense/(benefit)	16	7	(4)

Uncertain tax benefits reduce deferred tax assets to the extent the uncertainty directly related to that asset; otherwise, they are recognized as either current or non-current U.S. and foreign income taxes payable. Accrued interest and penalties payable for unrecognized tax benefits are included in either current or non-current U.S. and foreign income taxes payable. Interest and penalties related to unrecognized tax benefits are included in income tax expense.

BMS is currently under examination by a number of tax authorities, including but not limited to the major tax jurisdictions listed in the table below, which have proposed adjustments to tax for issues such as transfer pricing, certain tax credits and the deductibility of certain expenses. BMS estimates that it is reasonably possible that the total amount of unrecognized tax benefits at December 31, 2012 will decrease in the range of approximately \$370 million to \$400 million in the next twelve months as a result of the settlement of certain tax audits and other events. The expected change in unrecognized tax benefits, primarily settlement related, will involve the payment of additional taxes, the adjustment of certain deferred taxes and/or the recognition of tax benefits. BMS also anticipates that it is reasonably possible that new issues will be raised by tax authorities which may require increases to the balance of unrecognized tax benefits; however, an estimate of such increases cannot reasonably be made at this time. BMS believes that it has adequately provided for all open tax years by tax jurisdiction.

The following is a summary of major tax jurisdictions for which tax authorities may assert additional taxes based upon tax years currently under audit and subsequent years that will likely be audited:

U.S.	2008 to 2012
Canada	2005 to 2012
France	2010 to 2012
Germany	2007 to 2012
Italy	2003 to 2012
Mexico	2006 to 2012

**Note 8. EARNINGS PER SHARE**

Amounts in Millions, Except Per Share Data	Year Ended December 31,		
	2012	2011	2010
Net Earnings Attributable to BMS	\$ 1,960	\$ 3,709	\$ 3,102
Earnings attributable to unvested restricted shares	(1)	(8)	(12)
Net Earnings Attributable to BMS common shareholders	\$ 1,959	\$ 3,701	\$ 3,090
Earnings per share - basic	\$ 1.17	\$ 2.18	\$ 1.80
Weighted-average common shares outstanding - basic	1,670	1,700	1,713
Contingently convertible debt common stock equivalents	1	1	1
Incremental shares attributable to share-based compensation plans	17	16	13
Weighted-average common shares outstanding - diluted	1,688	1,717	1,727



Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Earnings per share - diluted	\$	1.16	\$	2.16	\$	1.79
Anti-dilutive weighted-average equivalent shares - stock incentive plans		2		13		51

---

**Note 9. FINANCIAL INSTRUMENTS**

Financial instruments include cash and cash equivalents, marketable securities, accounts receivable and payable, debt instruments and derivatives. The carrying amount of receivables and accounts payable approximates fair value due to their short term maturity.

Changes in currency exchange rates and interest rates create exposure to market risk. Certain derivative financial instruments are used when available on a cost-effective basis to hedge the underlying economic exposure. These instruments qualify as cash flow, net investment and fair value hedges upon meeting certain criteria, including effectiveness of offsetting hedged exposures. Changes in fair value of derivatives that do not qualify for hedge accounting are recognized in earnings as they occur. Derivative financial instruments are not used for trading purposes.

Financial instruments are subject to counterparty credit risk which is considered as part of the overall fair value measurement. Counterparty credit risk is monitored on an ongoing basis and mitigated by limiting amounts outstanding with any individual counterparty, utilizing conventional derivative financial instruments and only entering into agreements with counterparties that meet high credit quality standards. The consolidated financial statements would not be materially impacted if any counterparty failed to perform according to the terms of its agreement. Collateral is not required by any party whether derivatives are in an asset or liability position under the terms of the agreements.

*Fair Value Measurements* The fair values of financial instruments are classified into one of the following categories:

Level 1 inputs utilize non-binding quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs. These instruments include U.S. treasury securities.

Level 2 inputs utilize observable prices for similar instruments, non-binding quoted prices for identical or similar instruments in markets that are not active, and other observable inputs that can be corroborated by market data for substantially the full term of the assets or liabilities. These instruments include corporate debt securities, commercial paper, Federal Deposit Insurance Corporation (FDIC) insured debt securities, certificates of deposit, money market funds, foreign currency forward contracts, interest rate swap contracts, equity funds, fixed income funds and long-term debt. Additionally, certain corporate debt securities utilize a third-party matrix pricing model that uses significant inputs corroborated by market data for substantially the full term of the assets. Equity and fixed income funds are primarily invested in publicly traded securities and are valued at the respective net asset value of the underlying investments. There were no significant unfunded commitments or restrictions on redemptions related to equity and fixed income funds as of December 31, 2012. Level 2 derivative instruments are valued using London Interbank Offered Rate (LIBOR) and Euro Interbank Offered Rate (EURIBOR) yield curves, less credit valuation adjustments, and observable forward foreign exchange rates at the reporting date. Valuations of derivative contracts may fluctuate considerably from period-to-period due to volatility in underlying foreign currencies and underlying interest rates, which are driven by market conditions and the duration of the contract. Credit adjustment volatility may have a significant impact on the valuation of interest rate swaps due to changes in counterparty credit ratings and credit default swap spreads.

Level 3 unobservable inputs are used when little or no market data is available. Valuation models for the Auction Rate Security (ARS) and Floating Rate Security (FRS) portfolio are based on expected cash flow streams and collateral values including assessments of counterparty credit quality, default risk underlying the security, discount rates and overall capital market liquidity. The fair value of the ARS was determined using an internally developed valuation which was based in part on indicative bids received on the underlying assets of the security and other evidence of fair value. The ARS is a private placement security rated BBB- by Standard and Poor's as of December 31, 2012 and represents interests in insurance securitizations. Due to the current lack of an active market for FRS and the general lack of transparency into their underlying assets, other qualitative analysis is relied upon to value FRS including discussions with brokers and fund managers, default risk underlying the security and overall capital markets liquidity.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Available-For-Sale Securities and Cash Equivalents

The following table summarizes available-for-sale securities at December 31, 2012 and 2011:

Dollars in Millions	Amortized Cost	Unrealized Gain in Accumulated OCI	Unrealized Loss in Accumulated OCI	Gain/(Loss) in Income	Fair Value	Level 1	Fair Value Level 2	Level 3
<b>December 31, 2012</b>								
Marketable Securities:								
Certificates of Deposit	\$ 34	\$	\$	\$	\$ 34	\$	\$ 34	\$
Corporate Debt Securities	4,305	72			4,377		4,377	
U.S. Treasury Securities	150				150	150		
Equity Funds	52			5	57		57	
Fixed Income Funds	47				47		47	
ARS	8	3			11			11
FRS	21		(1)		20			20
Total Marketable Securities	\$ 4,617	\$ 75	\$ (1)	\$ 5	\$ 4,696	\$ 150	\$ 4,515	\$ 31
<b>December 31, 2011</b>								
Marketable Securities:								
Certificates of Deposit	\$ 1,051	\$	\$	\$	\$ 1,051	\$	\$ 1,051	\$
Corporate Debt Securities	2,908	60	(3)		2,965		2,965	
Commercial Paper	1,035				1,035		1,035	
U.S. Treasury Securities	400	2			402	402		
FDIC Insured Debt Securities	302	1			303		303	
ARS	80	12			92			92
FRS	21		(3)		18			18
Total Marketable Securities	\$ 5,797	\$ 75	\$ (6)	\$	\$ 5,866	\$ 402	\$ 5,354	\$ 110

The following table summarizes the classification of available-for-sale securities in the consolidated balance sheet:

Dollars in Millions	December 31,	
	2012	2011
Current Marketable Securities	\$ 1,173	\$ 2,957
Non-current Marketable Securities	3,523	2,909
Total Marketable Securities	\$ 4,696	\$ 5,866

Money market funds and other securities aggregating \$1,288 million and \$5,469 million at December 31, 2012 and 2011, respectively, were included in cash and cash equivalents and valued using Level 2 inputs. Cash and cash equivalents maintained in foreign currencies were \$493 million at December 31, 2012 and are subject to currency rate risk.

At December 31, 2012, \$3,512 million of non-current available for sale corporate debt securities and FRS mature within five years. All auction rate securities mature beyond 10 years.

The change in fair value for the investments in equity and fixed income funds are recognized in other income/expense and are designed to offset the changes in fair value of certain employee retirement benefits.

The following table summarizes the activity for financial assets utilizing Level 3 fair value measurements:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Dollars in Millions	2012	2011
Fair value at January 1	\$ 110	\$ 110
Sales	(81)	
Unrealized gains	2	
Fair value at December 31	\$ 31	\$ 110

Qualifying Hedges and Non-Qualifying Derivatives

The following summarizes the fair value of outstanding derivatives:

Dollars in Millions	Balance Sheet Location	December 31, 2012		December 31, 2011	
		Notional	Fair Value (Level 2)	Notional	Fair Value (Level 2)
<i>Derivatives designated as hedging instruments:</i>					
Interest rate swap contracts	Other assets	\$ 573	\$ 146	\$ 579	\$ 135
Foreign currency forward contracts	Other assets	735	59	1,347	88
Foreign currency forward contracts	Accrued expenses	916	(30)	480	(29)

*Cash Flow Hedges* Foreign currency forward contracts are primarily utilized to hedge forecasted intercompany inventory purchase transactions in certain foreign currencies. These forward contracts are designated as cash flow hedges with the effective portion of changes in fair value being temporarily reported in accumulated OCI and recognized in earnings when the hedged item affects earnings. The notional amount of outstanding foreign currency forward contracts was primarily attributed to the Euro (\$929 million) and Japanese yen (\$413 million) at December 31, 2012.

The net gains on foreign currency forward contracts qualifying for cash flow hedge accounting are expected to be reclassified to cost of products sold within the next two years, including \$25 million of pre-tax gains to be reclassified within the next 12 months. Cash flow hedge accounting is discontinued when the forecasted transaction is no longer probable of occurring on the originally forecasted date, or 60 days thereafter, or when the hedge is no longer effective. Assessments to determine whether derivatives designated as qualifying hedges are highly effective in offsetting changes in the cash flows of hedged items are performed at inception and on a quarterly basis. Any ineffective portion of the change in fair value is included in current period earnings. The earnings impact related to discontinued cash flow hedges and hedge ineffectiveness was not significant during all periods presented.

*Net Investment Hedges* Non-U.S. dollar borrowings of 541 million (\$714 million) are designated to hedge the foreign currency exposures of the net investment in certain foreign affiliates. These borrowings are designated as net investment hedges and recognized in long term debt. The effective portion of foreign exchange gains or losses on the remeasurement of the debt is recognized in the foreign currency translation component of accumulated OCI with the related offset in long term debt.

*Fair Value Hedges* Fixed-to-floating interest rate swap contracts are designated as fair value hedges and are used as part of an interest rate risk management strategy to create an appropriate balance of fixed and floating rate debt. The swaps and underlying debt for the benchmark risk being hedged are recorded at fair value. The effective interest rate paid on fixed-to-floating interest rate swaps is one-month LIBOR (0.210% as of December 31, 2012) plus an interest rate spread ranging from 1.3% to 2.9%. When the underlying swap is terminated prior to maturity, the fair value basis adjustment to the underlying debt instrument is amortized into earnings as a reduction to interest expense over the remaining life of the debt.

During 2011, fixed-to-floating interest rate swap contracts of \$1.6 billion notional amount and 1.0 billion notional amount were terminated generating total proceeds of \$356 million (including accrued interest of \$66 million). During 2010, fixed-to-floating interest rate swap contracts of \$237 million notional amount and 500 million notional amount were terminated generating total proceeds of \$116 million (including accrued interest of \$18 million).

*Non-Qualifying Foreign Exchange Contracts* Foreign currency forward contracts are used to offset exposure to foreign currency-denominated monetary assets, liabilities and earnings. The primary objective of these contracts is to protect the U.S. dollar value of foreign currency-denominated monetary assets, liabilities and earnings from the effects of volatility in foreign exchange rates that might occur prior to their receipt or settlement in U.S. dollars. These contracts are not designated as hedges and are adjusted to fair value through other (income)/expense as they occur, and substantially offset the change in fair value of the underlying foreign currency denominated monetary asset, liability or earnings. The effect of non-qualifying hedges on earnings was not significant for all periods presented.

*Debt Obligations*

Short-term borrowings and the current portion of long-term debt includes:

December 31,

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Dollars in Millions	2012	2011
Bank drafts	\$ 162	\$ 113
Other short-term borrowings		2
Current portion of long-term debt	664	
Total	\$ 826	\$ 115

Long-term debt and the current portion of long term debt includes:

Dollars in Millions	December 31,	
	2012	2011
<b>Principal Value:</b>		
0.875% Notes due 2017	\$ 750	\$
2.000% Notes due 2022	750	
4.375% Euro Notes due 2016	659	652
4.625% Euro Notes due 2021	659	652
5.875% Notes due 2036	625	638
5.25% Notes due 2013	597	597
5.45% Notes due 2018	582	600
3.250% Notes due 2042	500	
6.125% Notes due 2038	480	500
6.80% Debentures due 2026	330	332
7.15% Debentures due 2023	304	304
6.88% Debentures due 2097	260	287
0% - 5.75% Other - maturing 2013 - 2030	135	107
<b>Subtotal</b>	<b>6,631</b>	<b>4,669</b>
<b>Adjustments to Principal Value:</b>		
Fair value of interest rate swaps	146	135
Unamortized basis adjustment from swap terminations	509	594
Unamortized bond discounts	(54)	(22)
<b>Total</b>	<b>\$ 7,232</b>	<b>\$ 5,376</b>

<b>Current portion of long-term debt</b>	<b>\$ 664</b>	<b>\$</b>
Long-term debt	6,568	5,376

Included in the current portion of long-term debt is \$50 million of Floating Rate Convertible Senior Debentures due 2023 which can be redeemed by the holders at par on September 15, 2013 and 2018, or if a fundamental change in ownership occurs. The Debentures are callable at par at any time by the Company. The Debentures have a current conversion price of \$39.99, equal to a conversion rate of 25.0047 shares for each \$1,000 principal amount, subject to certain anti-dilutive adjustments.

During the third quarter 2012, \$2.0 billion of senior unsecured notes were issued: \$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 in a registered public offering. Interest on the notes will be paid semi-annually. The notes rank equally in right of payment with all of BMS's existing and future senior unsecured indebtedness. BMS may redeem the notes, in whole or in part, at any time at a predetermined redemption price. The net proceeds of the note issuances were \$1,950 million, which is net of a discount of \$36 million and deferred loan issuance costs of \$14 million.

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.

Substantially all of the \$2.0 billion debt obligations assumed in the acquisition of Amylin were repaid during the third quarter of 2012, including a promissory note with Lilly with respect to a revenue sharing obligation and Amylin senior notes due 2014.

The principal value of long-term debt obligations was \$6,631 million at December 31, 2012, of which \$648 million is due in 2013, \$27 million is due in 2014, \$659 million is due in 2016, \$750 million is due in 2017 and the remaining \$4,547 million is due in 2018 or thereafter. The fair value of long-term debt was \$8,285 million and \$6,406 million at December 31, 2012 and 2011, respectively, and was estimated based upon the quoted market prices for the same or similar debt instruments. The fair value of short-term borrowings approximates the carrying value due to the short maturities of the debt instruments.

Debt repurchase activity was as follows:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Dollars in Millions	2012	2011	2010
Principal amount	\$ 2,052	\$ 71	\$ 750
Carrying value	2,081	88	849
Repurchase price	2,108	78	855
Notional amount of interest rate swaps terminated	6	34	319
Swap termination proceeds	2	6	48
Total (gain)/loss	27	(10)	6



Interest payments were \$241 million in 2012, \$171 million in 2011 and \$178 million in 2010 net of amounts related to interest rate swap contracts.

BMS currently has two separate \$1.5 billion five-year revolving credit facilities from a syndicate of lenders, including a new facility received in July 2012. There are no financial covenants under either facility. No borrowings were outstanding under either revolving credit facility at December 31, 2012 or 2011.

At December 31, 2012, \$249 million of financial guarantees were provided in the form of stand-by letters of credit and performance bonds. The stand-by letters of credit are issued through financial institutions in support of guarantees made by BMS and its affiliates for various obligations. The performance bonds were issued to support a range of ongoing operating activities, including sale of products to hospitals and foreign ministries of health, bonds for customs, duties and value added tax and guarantees related to miscellaneous legal actions. A significant majority of the outstanding financial guarantees will expire within the year and are not expected to be funded.

#### Note 10. RECEIVABLES

Receivables include:

Dollars in Millions	December 31,	
	2012	2011
Trade receivables	\$ 1,812	\$ 2,397
Less allowances	(104)	(147)
Net trade receivables	1,708	2,250
Alliance partners receivables	857	1,081
Prepaid and refundable income taxes	319	256
Miscellaneous receivables	199	156
Receivables	\$ 3,083	\$ 3,743

Receivables are netted with deferred income related to alliance partners until recognition of income. As a result, alliance partner receivables and deferred income were reduced by \$1,056 million and \$901 million at December 31, 2012 and 2011, respectively. For additional information regarding alliance partners, see Note 3. Alliances and Collaborations. Non-U.S. receivables sold on a nonrecourse basis were \$956 million in 2012, \$1,077 million in 2011, and \$932 million in 2010. In the aggregate, receivables from three pharmaceutical wholesalers in the U.S. represented 37% and 55% of total trade receivables at December 31, 2012 and 2011, respectively.

Changes to the allowances for bad debt, charge-backs and cash discounts were as follows:

Dollars in Millions	Year Ended December 31,		
	2012	2011	2010
Balance at beginning of year	\$ 147	\$ 107	\$ 103
Provision	832	1,094	864
Utilization	(875)	(1,054)	(860)
Balance at end of year	\$ 104	\$ 147	\$ 107

#### Note 11. INVENTORIES

Inventories include:

Dollars in Millions	December 31,	
	2012	2011

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Finished goods	\$ 572	\$ 478
Work in process	814	646
Raw and packaging materials	271	260
Inventories	\$ 1,657	\$ 1,384

Inventories expected to remain on-hand beyond one year were \$424 million at December 31, 2012 and \$260 million at December 31, 2011 and included in non-current assets.

**Note 12. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment includes:

Dollars in Millions	December 31,	
	2012	2011
Land	\$ 114	\$ 137
Buildings	4,963	4,545
Machinery, equipment and fixtures	3,695	3,437
Construction in progress	611	262
Gross property, plant and equipment	9,383	8,381
Less accumulated depreciation	(4,050)	(3,860)
Property, plant and equipment	\$ 5,333	\$ 4,521

Depreciation expense was \$382 million in 2012, \$448 million in 2011 and \$473 million in 2010.

**Note 13. GOODWILL AND OTHER INTANGIBLE ASSETS**

Changes in the carrying amount of goodwill were as follows:

Dollars in Millions	December 31,	
	2012	2011
Carrying amount of goodwill at January 1	\$ 5,586	\$ 5,233
Acquisitions:		
Amira		265
Inhibitex	1,213	
Amylin	836	
Other		88
Carrying amount of goodwill at December 31	\$ 7,635	\$ 5,586

Other includes an out-of-period adjustment to correct the purchase price allocation for the September 2009 Medarex acquisition and a \$24 million contingent milestone payment from a prior acquisition. The Medarex purchase price adjustment decreased other intangible assets by \$98 million and increased deferred tax assets by \$34 million and goodwill by \$64 million. The effect of this adjustment was not material for the current or any prior periods.

Other intangible assets include:

Dollars in Millions	Estimated Useful Lives	December 31, 2012			December 31, 2011		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Licenses	5 15 years	\$ 1,160	\$ 534	\$ 626	\$ 1,218	\$ 443	\$ 775
Developed technology rights	7 15 years	8,827	1,604	7,223	2,608	1,194	1,414
Capitalized software	3 10 years	1,200	939	261	1,147	857	290
Total finite-lived intangible assets		11,187	3,077	8,110	4,973	2,494	2,479

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

IPRD	668	668	645	645		
Total other intangible assets	\$ 11,855	\$ 3,077	\$ 8,778	\$ 5,618	\$ 2,494	\$ 3,124

Changes in other intangible assets were as follows:

Dollars in Millions	2012	2011	2010
Other intangible assets carrying amount at January 1	\$ 3,124	\$ 3,370	\$ 2,865
Capitalized software and other additions	60	75	107
Acquisitions	8,335	160	678
Amortization expense	(607)	(353)	(271)
Impairment charges	(2,134)	(30)	(10)
Other		(98)	1
Other intangible assets, net carrying amount at December 31	\$ 8,778	\$ 3,124	\$ 3,370

Annual amortization expense of other intangible assets is expected to be approximately \$850 million in 2013, \$850 million in 2014, \$750 million in 2015, \$750 million in 2016, \$700 million in 2017 and \$4,210 million thereafter.

BMS announced the discontinued development of BMS-986094 (formerly known as INX-189), a nucleotide polymerase (NS5B) inhibitor that was in Phase II development for the treatment of the hepatitis C virus infection on August 23, 2012. The decision was made in the interest of patient safety, based on a rapid, thorough and ongoing assessment of patients in a Phase II study that was voluntarily suspended on August 1, 2012. BMS acquired BMS-986094 with its acquisition of Inhibitex in February 2012. As a result of the termination of this development program, a \$1,830 million pre-tax impairment charge was recognized for the IPRD intangible asset.

An impairment charge of \$120 million was recognized in 2012 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. The developed technology impairment charge resulted from continued competitive pricing pressures.

#### Note 14. ACCRUED EXPENSES

Accrued expenses include:

Dollars in Millions	December 31,	
	2012	2011
Employee compensation and benefits	\$ 844	\$ 783
Royalties	152	571
Accrued research and development	418	450
Restructuring - current	120	58
Pension and postretirement benefits	49	46
Accrued litigation	162	65
Other	828	818
Total accrued expenses	\$ 2,573	\$ 2,791

#### Note 15. SALES REBATES AND RETURN ACCRUALS

Reductions to trade receivables and accrued rebates and returns liabilities are as follows:

Dollars in Millions	December 31,	
	2012	2011
Charge-backs related to government programs	\$ 41	\$ 51
Cash discounts	13	28
Reductions to trade receivables	\$ 54	\$ 79
Managed healthcare rebates and other contract discounts	\$ 175	\$ 417
Medicaid rebates	351	411
Sales returns	345	161
Other adjustments	183	181
Accrued rebates and returns	\$ 1,054	\$ 1,170

#### Note 16. DEFERRED INCOME

Deferred income includes:

Dollars in Millions	December 31,	
	2012	2011
Upfront, milestone and other licensing receipts	\$ 4,346	\$ 882

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

<i>Atripla</i> * deferred revenue	339	113
Gain on sale-leaseback transactions	99	120
Other	65	88
<b>Total deferred income</b>	<b>\$ 4,849</b>	<b>\$ 1,203</b>
Current portion	\$ 825	\$ 337
Non-current portion	4,024	866

Upfront, milestone and other licensing receipts are amortized over the expected life of the product. See Note 3. Alliances and Collaborations for information pertaining to revenue recognition and other transactions including \$3.5 billion of proceeds received from AstraZeneca related to the Amylin collaboration during the 2012. Deferred gains on several sale-leaseback transactions are amortized over the remaining lease terms of the related facilities through 2018. Deferred income amortization was \$308 million in 2012, \$173 million in 2011 and \$137 million in 2010.

**Note 17. EQUITY**

Dollars and Shares in Millions	Common Stock		Capital in Excess of Par	Retained Earnings	Treasury Stock		Non-Controlling Interest
	Shares	Par Value	Value of Stock		Shares	Cost	
Balance at January 1, 2010	2,205	\$ 220	\$ 3,768	\$ 30,760	491	\$ (17,364)	\$ (58)
Net earnings				3,102			2,091
Cash dividends declared				(2,226)			
Stock repurchase program					23	(587)	
Employee stock compensation plans			(86)		(13)	497	
Distributions							(2,108)
Balance at December 31, 2010	2,205	220	3,682	31,636	501	(17,454)	(75)
Net earnings				3,709			2,333
Cash dividends declared				(2,276)			
Stock repurchase program					42	(1,226)	
Employee stock compensation plans			(568)		(28)	1,278	
Other comprehensive income attributable to noncontrolling interest							7
Distributions							(2,354)
Balance at December 31, 2011	2,205	220	3,114	33,069	515	(17,402)	(89)
Net earnings				1,960			850
Cash dividends declared				(2,296)			
Stock repurchase program					73	(2,407)	
Employee stock compensation plans	3	1	(420)		(18)	986	
Other comprehensive income attributable to noncontrolling interest							(6)
Distributions							(740)
Balance at December 31, 2012	2,208	\$ 221	\$ 2,694	\$ 32,733	570	\$ (18,823)	\$ 15

Treasury stock is recognized at the cost to reacquire the shares. Shares issued from treasury are recognized utilizing the first-in first-out method.

In May 2010, the Board of Directors authorized a repurchase of up to \$3.0 billion of common stock and in June 2012 increased its authorization for the repurchase of common stock by an additional \$3.0 billion. Repurchases may be made either in the open market or through private transactions, including under repurchase plans established in accordance with Rule 10b5-1 under the Securities Exchange Act of 1934. The stock repurchase program does not have an expiration date and may be suspended or discontinued at any time.

Noncontrolling interest is primarily related to the *Plavix*\* and *Avapro*\*/*Avalide*\* partnerships with Sanofi for the territory covering the Americas. Net earnings attributable to noncontrolling interest are presented net of taxes of \$317 million in 2012, \$792 million in 2011 and \$683 million in 2010 with a corresponding increase to the provision for income taxes. Distribution of the partnership profits to Sanofi and Sanofi's funding of ongoing partnership operations occur on a routine basis. The above activity includes the pre-tax income and distributions related to these partnerships.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The components of other comprehensive income/(loss) (OCI) were as follows:

Dollars in Millions	Pretax	Tax	After Tax
<b>Year ended December 31, 2010</b>			
Derivatives qualifying as cash flow hedges: <sup>(a)</sup>			
Unrealized gains	\$ 18	\$ (3)	\$ 15
Realized gains	(10)	5	(5)
Derivatives qualifying as cash flow hedges	8	2	10
Pension and other postretirement benefits: <sup>(b)</sup>			
Actuarial losses	(154)	66	(88)
Amortization	102	(35)	67
Settlements and curtailments	25	(9)	16
Pension and other postretirement benefits	(27)	22	(5)
Available for sale securities, unrealized gains	47	(3)	44
Foreign currency translation	121		121
	\$ 149	\$ 21	\$ 170
<b>Year ended December 31, 2011</b>			
Derivatives qualifying as cash flow hedges: <sup>(a)</sup>			
Unrealized gains	\$ 28	\$ (4)	\$ 24
Realized gains	52	(20)	32
Derivatives qualifying as cash flow hedges	80	(24)	56
Pension and other postretirement benefits: <sup>(b)</sup>			
Actuarial losses	(1,251)	421	(830)
Amortization	115	(34)	81
Settlements and curtailments	11	(4)	7
Pension and other postretirement benefits	(1,125)	383	(742)
Available for sale securities, unrealized gains	35	(7)	28
Foreign currency translation	(16)		(16)
	\$ (1,026)	\$ 352	\$ (674)
<b>Year ended December 31, 2012</b>			
Derivatives qualifying as cash flow hedges: <sup>(a)</sup>			
Unrealized gains	\$ 26	\$ (17)	\$ 9
Realized gains	(56)	20	(36)
Derivatives qualifying as cash flow hedges	(30)	3	(27)
Pension and other postretirement benefits: <sup>(b)</sup>			
Actuarial losses	(432)	121	(311)
Amortization	133	(43)	90
Settlements and curtailments	159	(56)	103
Pension and other postretirement benefits	(140)	22	(118)
Available for sale securities:			
Unrealized gains	20	(8)	12
Realized gains	(11)	2	(9)
Available for sale securities <sup>(c)</sup>	9	(6)	3
Foreign currency translation	(15)		(15)



Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

\$ (176)      \$ 19      \$ (157)

- (a) Realized (gains)/losses on derivatives qualifying as effective hedges are recognized in costs of products sold.
- (b) See Item 8. Financial Statements Note 18. Pension, Postretirement and Postemployment Liabilities for further detail.
- (c) Realized (gains)/losses on available for sale securities are recognized in other (income)/expense.

The accumulated balances related to each component of other comprehensive income/(loss) (OCI), net of taxes, were as follows:

Dollars in Millions	December 31,	
	2012	2011
Derivatives qualifying as cash flow hedges	\$ 9	\$ 36
Pension and other postretirement benefits	(3,023)	(2,905)
Available for sale securities	65	62
Foreign currency translation	(253)	(238)
<b>Accumulated other comprehensive income/(loss)</b>	<b>\$ (3,202)</b>	<b>\$ (3,045)</b>

**Note 18. PENSION, POSTRETIREMENT AND POSTEMPLOYMENT LIABILITIES**

The Company and certain of its subsidiaries sponsor defined benefit pension plans, defined contribution plans and termination indemnity plans for regular full-time employees. The principal defined benefit pension plan is the Bristol-Myers Squibb Retirement Income Plan, which covers most U.S. employees and represents approximately 70% of the consolidated pension plan assets and obligations. The funding policy is to contribute at least the minimum amount required by the Employee Retirement Income Security Act of 1974 (ERISA). Plan benefits are based primarily on the participant's years of credited service and final average compensation. Plan assets consist principally of equity and fixed-income securities.

Comprehensive medical and group life benefits are provided for substantially all U.S. retirees who elect to participate in comprehensive medical and group life plans. The medical plan is contributory. Contributions are adjusted periodically and vary by date of retirement. The life insurance plan is noncontributory. Plan assets consist principally of equity and fixed-income securities. Similar plans exist for employees in certain countries outside of the U.S.

The net periodic benefit cost of defined benefit pension and postretirement benefit plans includes:

Dollars in Millions	Pension Benefits			Other Benefits		
	2012	2011	2010	2012	2011	2010
Service cost – benefits earned during the year	\$ 32	\$ 43	\$ 44	\$ 8	\$ 8	\$ 6
Interest cost on projected benefit obligation	319	337	347	22	26	30
Expected return on plan assets	(508)	(464)	(453)	(25)	(26)	(24)
Amortization of prior service cost/(benefit)	(3)	(1)		(2)	(3)	(3)
Amortization of net actuarial loss	129	112	95	10	7	10
Curtailments	(1)	(3)	5		(1)	
Settlements	160	15	22			
Special termination benefits			1			
<b>Total net periodic benefit cost</b>	<b>\$ 128</b>	<b>\$ 39</b>	<b>\$ 61</b>	<b>\$ 13</b>	<b>\$ 11</b>	<b>\$ 19</b>

A \$151 million 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.

Net actuarial loss and prior service cost of \$147 million is expected to be amortized from accumulated OCI into net periodic benefit cost for pension and postretirement benefit plans in 2013.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Changes in defined benefit and postretirement benefit plan obligations, assets, funded status and amounts recognized in the consolidated balance sheets were as follows:

Dollars in Millions	Pension Benefits		Other Benefits	
	2012	2011	2012	2011
Benefit obligations at beginning of year	\$ 7,499	\$ 6,704	\$ 582	\$ 589
Service cost benefits earned during the year	32	43	8	8
Interest cost	319	337	22	26
Plan participants contributions	2	3	24	25
Curtailements	(19)	(3)		(1)
Settlements	(260)	(41)		(2)
Plan amendments	(8)	(40)		(1)
Actuarial losses/(gains)	838	876	(107)	6
Retiree Drug Subsidy			6	12
Benefits paid	(227)	(386)	(76)	(79)
Exchange rate losses/(gains)	24	6	1	(1)
Benefit obligations at end of year	\$ 8,200	\$ 7,499	\$ 460	\$ 582
Fair value of plan assets at beginning of year	\$ 5,842	\$ 5,766	\$ 305	\$ 315
Actual return on plan assets	761	66	41	10
Employer contributions	396	432	11	24
Plan participants contributions	2	3	24	25
Settlements	(260)	(41)		(2)
Retiree Drug Subsidy			6	12
Benefits paid	(227)	(386)	(76)	(79)
Exchange rate gains/(losses)	28	2		
Fair value of plan assets at end of year	\$ 6,542	\$ 5,842	\$ 311	\$ 305
Funded status	\$ (1,658)	\$ (1,657)	\$ (149)	\$ (277)
Assets/Liabilities recognized:				
Other assets	\$ 22	\$ 39	\$ 12	\$
Accrued expenses	(37)	(33)	(12)	(12)
Pension and other postretirement liabilities	(1,643)	(1,663)	(149)	(265)
Funded status	\$ (1,658)	\$ (1,657)	\$ (149)	\$ (277)
Recognized in accumulated other comprehensive loss:				
Net actuarial loss	\$ 4,572	\$ 4,297	\$ 34	\$ 166
Net obligation at adoption	1	1		
Prior service cost/(benefit)	(44)	(39)	(6)	(8)
Total	\$ 4,529	\$ 4,259	\$ 28	\$ 158

The accumulated benefit obligation for all defined benefit pension plans was \$8,068 million and \$7,322 million at December 31, 2012 and 2011, respectively.

Additional information related to pension plans was as follows:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Dollars in Millions	<b>2012</b>	<b>2011</b>
<b>Pension plans with projected benefit obligations in excess of plan assets:</b>		
Projected benefit obligation	\$ 8,112	\$ 7,236
Fair value of plan assets	6,432	5,540
<b>Pension plans with accumulated benefit obligations in excess of plan assets:</b>		
Accumulated benefit obligation	\$ 7,987	\$ 6,867
Fair value of plan assets	6,432	5,327
<b>Actuarial Assumptions</b>		

Weighted-average assumptions used to determine benefit obligations at December 31 were as follows:

	<b>Pension Benefits</b>		<b>Other Benefits</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Discount rate	3.7%	4.4%	3.0%	4.1%
Rate of compensation increase	2.3%	2.3%	2.0%	2.0%

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Weighted-average actuarial assumptions used to determine net periodic benefit cost for the years ended December 31 were as follows:

	Pension Benefits			Other Benefits		
	2012	2011	2010	2012	2011	2010
Discount rate	4.4%	5.2%	5.6%	4.1%	4.8%	5.5%
Expected long-term return on plan assets	8.2%	8.3%	8.3%	8.8%	8.8%	8.8%
Rate of compensation increase	2.3%	2.4%	3.7%	2.0%	2.0%	3.5%

The yield on high quality corporate bonds that matches the duration of the benefit obligations is used in determining the discount rate. The Citigroup Pension Discount curve is used in developing the discount rate for the U.S. plans.

Several factors are considered in developing the expected return on plan assets, including long-term historical returns and input from external advisors. Individual asset class return forecasts were developed based upon market conditions, for example, price-earnings levels and yields and long-term growth expectations. The expected long-term rate of return is the weighted-average of the target asset allocation of each individual asset class. Historical long-term actual annualized returns for U.S. pension plans were as follows:

	2012	2011	2010
10 years	8.5%	5.6%	4.7%
15 years	6.5%	7.0%	7.9%
20 years	8.5%	8.1%	9.3%

Pension and postretirement liabilities were increased by \$459 million at December 31, 2012 with a corresponding charge to other comprehensive income as a result of actuarial losses attributed to the benefit obligation (\$731 million) partially offset by higher than expected return on plan assets (\$272 million). These actuarial losses resulted from prevailing equity and fixed income market conditions and a reduction in interest rates in 2012.

The expected return on plan assets was determined using the expected rate of return and a calculated value of assets, referred to as the market-related value which approximates the fair value of plan assets at December 31, 2012. Differences between the assumed and actual returns are amortized to the market-related value on a straight-line basis over a three-year period.

Gains and losses have resulted from changes in actuarial assumptions (such as changes in the discount rate) and from differences between assumed and actual experience (such as differences between actual and expected return on plan assets). These gains and losses (except those differences being amortized to the market-related value) are only amortized to the extent they exceed 10% of the higher of the market-related value or the projected benefit obligation for each respective plan. As a result, approximately \$840 million related to pension benefits is not expected to be amortized during 2013. The majority of the remaining actuarial losses are amortized over the life expectancy of the plans participants for U.S. plans (30 years) and expected remaining service periods for most other plans into cost of products sold, research and development, and marketing, selling and administrative expenses as appropriate.

Assumed healthcare cost trend rates at December 31 were as follows:

	2012	2011	2010
Healthcare cost trend rate assumed for next year	6.8%	7.4%	7.9%
Rate to which the cost trend rate is assumed to decline (the ultimate trend rate)	4.5%	4.5%	4.5%
Year that the rate reaches the ultimate trend rate	2018	2018	2018

Assumed healthcare cost trend rates have an effect on the amounts reported for the healthcare plans. A one-percentage-point change in assumed healthcare cost trend rates would have the following effects:

Dollars in Millions	1-Percentage-Point Increase	1-Percentage-Point Decrease
Effect on total of service and interest cost	\$ 1	\$ (1)
Effect on postretirement benefit obligation	25	(25)



**Plan Assets**

The fair value of pension and postretirement plan assets by asset category at December 31, 2012 and 2011 was as follows:

Dollars in Millions	December 31, 2012				December 31, 2011			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Equity Securities	\$ 2,196	\$	\$	\$ 2,196	\$ 1,679	\$	\$	\$ 1,679
Equity Funds	410	1,555		1,965	236	1,559	4	1,799
Fixed Income Funds	234	401		635	203	419		622
Corporate Debt Securities		453	3	456		315	10	325
Venture Capital and Limited Partnerships			381	381			408	408
Government Mortgage Backed Securities		350	8	358		372	8	380
U.S. Treasury and Agency Securities		259		259		304		304
Short-Term Investment Funds		189		189		306		306
Insurance Contracts			132	132			125	125
Event Driven Hedge Funds		92		92		86		86
Collateralized Mortgage Obligation Bonds		50	6	56		63	7	70
State and Municipal Bonds		44	3	47		34		34
Asset Backed Securities		23	3	26		17	4	21
Real Estate	3			3		12		12
Cash and Cash Equivalents	58			58	(24)			(24)
Total plan assets at fair value	\$ 2,901	\$ 3,416	\$ 536	\$ 6,853	\$ 2,094	\$ 3,487	\$ 566	\$ 6,147

The investment valuation policies per investment class are as follows:

Level 1 inputs utilize quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs. These instruments include equity securities, equity funds, and fixed income funds publicly traded on a national securities exchange, U.S. treasury and agency securities, and cash and cash equivalents. Cash and cash equivalents are highly liquid investments with original maturities of three months or less at the time of purchase and are recognized at cost, which approximates fair value. Pending trade sales and purchases are included in cash and cash equivalents until final settlement.

Level 2 inputs include observable prices for similar instruments, quoted prices for identical or similar instruments in markets that are not active, and other observable inputs that can be corroborated by market data for substantially the full term of the assets or liabilities. Equity funds, fixed income funds, event driven hedge funds and short-term investment funds classified as Level 2 within the fair value hierarchy are valued at the net asset value of their shares held at year end. There were no significant unfunded commitments or restrictions on redemptions related to investments valued at NAV as of December 31, 2012. Corporate debt securities, government mortgage backed securities, collateralized mortgage obligation bonds, asset backed securities, U.S. treasury and agency securities, state and municipal bonds, and real estate interests classified as Level 2 within the fair value hierarchy are valued utilizing observable prices for similar instruments and quoted prices for identical or similar instruments in markets that are not active.

Level 3 unobservable inputs are used when little or no market data is available. Equity funds and venture capital and limited partnership investments classified as Level 3 within the fair value hierarchy are valued at estimated fair value. The estimated fair value is based on the fair value of the underlying investment values or cost plus or minus accumulated earnings or losses which approximates fair value. Insurance contract interests are carried at contract value, which approximates the estimated fair value and is based on the fair value of the underlying investment of the insurance company. Insurance contracts are held by certain foreign pension plans. Valuation models for corporate debt securities, collateralized mortgage obligation bonds and asset backed securities classified as Level 3 within the fair value hierarchy are based on estimated bids from brokers or other third-party vendor sources that utilize expected cash flow streams and collateral values including assessments of counterparty credit quality, default risk, discount rates and overall capital market liquidity.

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The following summarizes the activity for financial assets utilizing Level 3 fair value measurements:

Dollars in Millions	Venture Capital and Limited Partnerships	Insurance Contracts	Other	Total
Fair value at January 1, 2011	\$ 415	\$ 144	\$ 39	\$ 598
Purchases	53	8	5	66
Sales	(5)	(31)	(3)	(39)
Settlements	(48)		(4)	(52)
Realized (losses)/gains	56		3	59
Unrealized gains/(losses)	(63)	4	(7)	(66)
Fair value at December 31, 2011	408	125	33	566
Purchases	43	5		48
Sales	(8)	(7)	(10)	(25)
Settlements	(51)		(2)	(53)
Realized (losses)/gains	53		(4)	49
Unrealized gains/(losses)	(64)	9	6	(49)
Fair value at December 31, 2012	\$ 381	\$ 132	\$ 23	\$ 536

The investment strategy emphasizes equities in order to achieve higher expected returns and lower expenses and required cash contributions over the long-term. A target asset allocation of 70% public equity (58% U.S. and 12% international), 8% private equity and 22% fixed income is maintained for the U.S. pension plans. Investments are well diversified within each of the three major asset categories. Approximately 81% of the U.S. pension plans equity investments are actively managed. Venture capital and limited partnerships are typically valued on a three month lag. BMS Company common stock represents less than 1% of the plan assets at December 31, 2012 and 2011.

*Contributions*

Contributions to the U.S. pension plans were \$335 million in 2012, \$343 million in 2011 and \$341 million in 2010.

Contributions to the international pension plans were \$61 million in 2012, \$88 million in 2011 and \$90 million in 2010. Aggregate contributions to the U.S. and international plans are expected to be \$100 million in 2013.

*Estimated Future Benefit Payments*

Dollars in Millions	Pension Benefits	Other Benefits
2013	\$ 385	\$ 47
2014	398	44
2015	401	42
2016	415	40
2017	422	37
Years 2018 - 2022	2,109	151

*Savings Plan*

The principal defined contribution plan is the Bristol-Myers Squibb Savings and Investment Program. The contribution is based on employee contributions and the level of Company match. The expense related to the plan was \$190 million in 2012, \$181 million in 2011 and \$188 million in 2010.

*Post Employment Benefit Plan*

Post-employment liabilities for long-term disability benefits were \$90 million and \$92 million at December 31, 2012 and 2011, respectively. The expense related to these benefits was \$17 million in 2012 and \$18 million in both 2011 and 2010.



*Termination Indemnity Plans*

Statutory termination obligations are recognized on an undiscounted basis assuming employee termination at each measurement date. The liability recognized for these obligations was \$29 million and \$25 million at December 31, 2012 and 2011, respectively.

**Note 19. EMPLOYEE STOCK BENEFIT PLANS**

On May 1, 2012, the shareholders approved the 2012 Stock Award and Incentive Plan (the 2012 Plan), which replaced the 2007 Stock Incentive Plan. Shares of common stock reserved for issuance pursuant to stock plans, options and conversions of preferred stock were 283 million at December 31, 2012. Shares available to be granted for the active plans, adjusted for the combination of plans, were 116 million at December 31, 2012. Shares for the stock option exercise and share unit vesting are issued from treasury stock. Only shares actually delivered to participants in connection with an award after all restrictions have lapsed will reduce the number of shares reserved. Shares tendered in a prior year to pay the purchase price of options and shares previously utilized to satisfy withholding tax obligations upon exercise continue to be available and reserved.

Executive officers and key employees may be granted options to purchase common stock at no less than the market price on the date the option is granted. Options generally become exercisable ratably over 4 years and have a maximum term of 10 years. Additionally, the plan provides for the granting of stock appreciation rights whereby the grantee may surrender exercisable rights and receive common stock and/or cash measured by the excess of the market price of the common stock over the option exercise price.

Common stock may be granted to key employees, subject to restrictions as to continuous employment. Restrictions expire over a four year period from date of grant. Compensation expense is recognized over the vesting period. A stock unit is a right to receive stock at the end of the specified vesting period but has no voting rights.

Market share units were granted to certain executives beginning in 2010. Vesting is conditioned upon continuous employment until vesting date and the payout factor equals at least 60%. The payout factor is the share price on vesting date divided by share price on award date, with a maximum of 200%. The share price used in the payout factor is calculated using an average of the closing prices on the grant or vest date, and the nine trading days immediately preceding the grant or vest date. Vesting occurs ratably over four years.

Long-term performance awards have a three year cycle and are delivered in the form of a target number of performance share units. The number of shares ultimately issued is calculated based on actual performance compared to earnings targets and other performance criteria established at the beginning of the performance period. The awards have annual goals with a maximum payout of 167.5%. If threshold targets are not met for a performance period, no payment is made under the plan for that annual period. Vesting occurs at the end of the three year period.

Stock-based compensation expense is based on awards ultimately expected to vest and is recognized over the vesting period. The acceleration of unvested stock options and restricted stock units in connection with the acquisition of Amylin resulted in stock-based compensation expense in 2012. Forfeitures are estimated based on historical experience at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense was as follows:

Dollars in Millions	Years Ended December 31,		
	2012	2011	2010
Stock options	\$ 7	\$ 27	\$ 50
Restricted stock	64	79	83
Market share units	23	23	13
Long-term performance awards	60	32	47
Amylin stock options and restricted stock units (see Note 4)	94		
Total stock-based compensation expense	\$ 248	\$ 161	\$ 193
Income tax benefit	\$ 82	\$ 56	\$ 63

Share-based compensation activities were as follows:

Stock Options	Restricted Stock Units		Market Share Units		Long-Term Performance Awards	
	Weighted-Average	Number of	Weighted-Average	Number of	Weighted-Average	Number of

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Shares in Thousands	Number of Options Outstanding	Exercise Price of Shares	Nonvested Awards	Grant-Date Fair Value	Nonvested Awards	Grant-Date Fair Value	Nonvested Awards	Grant-Date Fair Value
Balance at January 1, 2012	70,224	\$ 27.04	8,416	\$ 23.10	1,982	\$ 25.39	3,411	\$ 23.53
Granted			3,036	32.71	1,076	31.85	1,717	32.33
Released/Exercised	(16,560)	24.18	(3,341)	22.13	(562)	25.29	(1,087)	19.63
Adjustments for actual payout					(166)	25.29	225	32.55
Forfeited/Cancelled	(11,699)	44.85	(543)	25.96	(126)	27.38	(170)	28.90
Balance at December 31, 2012	41,965	23.21	7,568	27.18	2,204	28.46	4,096	28.44
Vested or expected to vest	41,875	23.22	6,826	27.18	1,988	28.46	3,694	28.44

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Total compensation costs related to share-based payment awards not yet recognized and the weighted-average period over which such awards are expected to be recognized at December 31, 2012 were as follows:

Dollars in Millions	Stock Options	Restricted Stock Units	Market Share Units	Long-Term Performance Awards
Unrecognized compensation cost	\$ 2	\$ 146	\$ 31	\$ 32
Expected weighted-average period in years of compensation cost to be recognized	0.2	2.6	2.7	1.4

Additional information related to share-based compensation awards is summarized as follows:

Amounts in Millions, except per share data	2012	2011	2010
Weighted-average grant date fair value (per share):			
Restricted stock units	32.71	26.04	24.80
Market share units	31.85	25.83	24.69
Long-term performance awards	32.33	25.30	23.65
Fair value of options or awards that vested during the year:			
Stock options	\$ 23	\$ 45	\$ 73
Restricted stock units	74	75	79
Market share units	18	8	
Long-term performance awards	56	21	56
Total intrinsic value of stock options exercised during the year	\$ 153	\$ 154	\$ 47

The following table summarizes significant ranges of outstanding and exercisable options at December 31, 2012 (amounts in millions, except per share data):

Range of Exercise Prices	Options Outstanding Weighted-				Options Exercisable Weighted-			
	Number Outstanding (in thousands)	Life (in years)	Price Per Share	Intrinsic Value	Number Exercisable	Life (in years)	Price Per Share	Intrinsic Value
\$1 - \$20	10,344	6.16	\$ 17.51	\$ 156	7,184	6.16	\$ 17.49	\$ 109
\$20 - \$30	31,606	3.00	25.06	238	31,585	3.00	25.07	238
\$30 - \$40	15	4.49	31.62		15	4.49	31.62	
	41,965	3.78	23.21	\$ 394	38,784	3.58	23.67	\$ 347

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on the closing stock price of \$32.59 on December 31, 2012.

*Fair Value Assumptions*

The fair value of restricted stock units and long-term performance awards is determined based on the closing trading price of the Company's common stock on the grant date. Beginning in 2010, the fair value of performance share units granted was not discounted because they participate in dividends. The fair value of performance share units granted prior to 2010 was discounted using the risk-free interest rate on the date of grant because they do not participate in dividends.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The fair value of the market share units was estimated on the date of grant using a model applying multiple input variables that determine the probability of satisfying market conditions. The model uses the following input variables:

	2012	2011	2010
Expected volatility	24.1%	24.3%	24.8%
Risk-free interest rate	0.6%	1.8%	1.9%
Dividend yield	4.4%	4.9%	5.8%

Expected volatility is based on the four year historical volatility levels on the Company's common stock and the current implied volatility. The four-year risk-free interest rate was derived from the Federal Reserve, based on the market share units' contractual term. Expected dividend yield is based on historical dividend payments.

**Note 20. LEASES**

Minimum rental commitments for non-cancelable operating leases (primarily real estate and motor vehicles) in effect at December 31, 2012, were as follows:

Years Ending December 31,	Dollars in Millions
2013	\$ 167
2014	152
2015	130
2016	123
2017	76
Later years	108
<b>Total minimum rental commitments</b>	<b>\$ 756</b>

Operating lease expense was \$142 million in 2012, \$136 million in 2011 and \$145 million in 2010. Sublease income was not material for all periods presented.

**Note 21. LEGAL PROCEEDINGS AND CONTINGENCIES**

The Company and certain of its subsidiaries are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. The Company recognizes accruals for such contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. These matters involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage. Legal proceedings that are material or that the Company believes could become material are described below.

Although the Company believes it has substantial defenses in these matters, there can be no assurance that there will not be an increase in the scope of pending matters or that any future lawsuits, claims, government investigations or other legal proceedings will not be material. Unless otherwise noted, the Company is unable to assess the outcome of the respective litigation nor is it able to provide an estimated range of potential loss. Furthermore, failure to enforce our patent rights would likely result in substantial decreases in the respective product sales from generic competition.

**INTELLECTUAL PROPERTY*****Plavix*\* Australia**

As previously disclosed, Sanofi was notified that, in August 2007, GenRx Proprietary Limited (GenRx) obtained regulatory approval of an application for clopidogrel bisulfate 75mg tablets in Australia. GenRx, formerly a subsidiary of Apotex Inc. (Apotex), has since changed its name to Apotex. In August 2007, Apotex filed an application in the Federal Court of Australia (the Federal Court) seeking revocation of Sanofi's Australian Patent No. 597784 (Case No. NSD 1639 of 2007). Sanofi filed counterclaims of infringement and sought an injunction. On September 21, 2007, the Federal Court granted Sanofi's injunction. A subsidiary of the Company was subsequently added as a party to the proceedings. In February 2008, a second company, Spirit Pharmaceuticals Pty. Ltd., also filed a revocation suit against the same patent. This case was consolidated with the Apotex case and a trial occurred in April 2008. On August 12, 2008, the Federal Court of Australia held that claims of Patent No. 597784 covering clopidogrel bisulfate, hydrochloride, hydrobromide, and taurocholate salts were valid. The Federal Court also held that the process claims, pharmaceutical composition claims, and claim directed to clopidogrel and its pharmaceutically acceptable salts were invalid. The Company and Sanofi filed notices of appeal in the Full Court of the Federal Court of Australia (Full Court) appealing the holding of invalidity of the claim covering clopidogrel and its pharmaceutically acceptable salts, process claims, and pharmaceutical composition claims which have stayed the Federal Court's ruling. Apotex filed a notice of appeal appealing the holding of validity of the clopidogrel bisulfate, hydrochloride, hydrobromide, and taurocholate claims. A hearing on the appeals occurred in February 2009. On September 29, 2009, the Full Court held all of the claims of Patent No. 597784 invalid. In November 2009, the Company and Sanofi applied to the High Court of Australia (High Court) for special leave to appeal the judgment of the Full Court. In March 2010, the High Court denied the Company and Sanofi's request to hear the appeal of the Full Court decision. The case has been remanded to the Federal Court for further proceedings related to damages. It is expected the amount of damages will not be material to the Company.



**Plavix\* EU**

As previously disclosed, in 2007, YES Pharmaceutical Development Services GmbH (YES Pharmaceutical) filed an application for marketing authorization in Germany for an alternate salt form of clopidogrel. This application relied on data from studies that were originally conducted by Sanofi and BMS for *Plavix\** and were still the subject of data protection in the EU. Sanofi and BMS have filed an action against YES Pharmaceutical and its partners in the administrative court in Cologne objecting to the marketing authorization. This matter is currently pending, although these specific marketing authorizations now have been withdrawn from the market. The resolution of this lawsuit is not expected to have a material impact on the Company.

**Plavix\* Canada (Apotex, Inc.)**

On April 22, 2009, Apotex filed an impeachment action against Sanofi in the Federal Court of Canada alleging that Sanofi's Canadian Patent No. 1,336,777 (the 777 Patent) is invalid. On June 8, 2009, Sanofi filed its defense to the impeachment action and filed a suit against Apotex for infringement of the 777 Patent. The trial was completed in June 2011 and in December 2011, the Federal Court of Canada issued a decision that the 777 Patent is invalid. Sanofi has appealed this decision though generic companies have since entered the market and a decision is expected later this year.

**Abilify\***

As previously disclosed, Otsuka has filed patent infringement actions against Teva, Barr Pharmaceuticals, Inc. (Barr), Sandoz Inc. (Sandoz), Synthron Laboratories, Inc (Synthron), Sun Pharmaceuticals (Sun), Zydus Pharmaceuticals USA, Inc. (Zydus), and Apotex relating to U.S. Patent No. 5,006,528, ( 528 Patent) which covers aripiprazole and expires in April 2015 (including the additional six-month pediatric exclusivity period). Aripiprazole is comarketed by the Company and Otsuka in the U.S. as *Abilify\**. A non-jury trial in the U.S. District Court for the District of New Jersey (NJ District Court) against Teva/Barr and Apotex was completed in August 2010. In November 2010, the NJ District Court upheld the validity and enforceability of the 528 Patent, maintaining the main patent protection for *Abilify\** in the U.S. until April 2015. The NJ District Court also ruled that the defendants' generic aripiprazole product infringed the 528 Patent and permanently enjoined them from engaging in any activity that infringes the 528 Patent, including marketing their generic product in the U.S. until after the patent (including the six-month pediatric extension) expires. Sandoz, Synthron, Sun and Zydus are also bound by the NJ District Court's decision. In December 2010, Teva/Barr and Apotex appealed this decision to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). In May 2012, the Federal Circuit affirmed the NJ District Court's decision. In June 2012, Apotex filed a petition for rehearing *en banc* which was denied. In December 2012, the United States Supreme Court denied Apotex's Petition for a Writ of Certiorari requesting an appeal of the Federal Circuit decision, which concluded the matter.

**Atripla\***

In April 2009, Teva filed an abbreviated New Drug Application (aNDA) to manufacture and market a generic version of *Atripla\**. *Atripla\** is a single tablet three-drug regimen combining the Company's *Sustiva* and Gilead's *Truvada\**. As of this time, the Company's U.S. patent rights covering *Sustiva*'s composition of matter and method of use have not been challenged. Teva sent Gilead a Paragraph IV certification letter challenging two of the fifteen Orange Book-listed patents for *Atripla\**. *Atripla\** is the product of a joint venture between the Company and Gilead. In May 2009, Gilead filed a patent infringement action against Teva in the U.S. District Court for the Southern District of New York (SDNY). In January 2010, the Company received a notice that Teva has amended its aNDA and is challenging eight additional Orange Book-listed patents for *Atripla\**. In March 2010, the Company and Merck, Sharp & Dohme Corp. (Merck) filed a patent infringement action against Teva also in the SDNY relating to two U.S. Patents which claim crystalline or polymorph forms of efavirenz. In March 2010, Gilead filed two patent infringement actions against Teva in the SDNY relating to six Orange Book-listed patents for *Atripla\**. Trial is expected in 2013. It is not possible at this time to reasonably assess the outcome of these lawsuits or their impact on the Company.

**Baraclude**

In August 2010, Teva filed an aNDA to manufacture and market generic versions of Baraclude. The Company received a Paragraph IV certification letter from Teva challenging the one Orange Book-listed patent for Baraclude, U.S. Patent No. 5,206,244 (the 244 Patent). In September 2010, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware (Delaware District Court) against Teva for infringement. In February 2013, the Delaware District Court ruled against the Company and invalidated the 244 Patent. The Company will appeal the Delaware District Court's decision and is evaluating all other legal options. Upon final FDA approval of its aNDA, Teva could launch its generic product. There could be a rapid and significant negative impact on U.S. sales of Baraclude beginning in 2013. U.S. net sales of Baraclude were \$241 million in 2012.

In June 2012, the Company filed a patent infringement lawsuit against Sandoz following the receipt of a Paragraph IV certification letter challenging the same Orange-Book listed patent. The parties have requested that the case be dismissed. In February 2013, the parties filed a



stipulation of dismissal and the case has been dismissed.

***Sprycel***

In September 2010, Apotex filed an aNDA to manufacture and market generic versions of *Sprycel*. The Company received a Paragraph IV certification letter from Apotex challenging the four Orange Book listed patents for *Sprycel*, including the composition of matter patent. In November 2010, the Company filed a patent infringement lawsuit in the NJ District Court against Apotex for infringement of the four Orange Book listed patents covering *Sprycel*, which triggered an automatic 30-month stay of approval of Apotex's aNDA. In October 2011, the Company received a Paragraph IV notice letter from Apotex informing the Company that it is seeking approval of generic versions of the 80 mg and 140 mg dosage strengths of *Sprycel* and challenging the same four Orange Book listed patents. In November 2011, BMS filed a patent infringement suit against Apotex on the 80 mg and 140 mg dosage strengths in the NJ District Court. This case has been consolidated with the suit filed in November 2010. Trial is currently scheduled for September 2013. Discovery in this matter is ongoing. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

***Sustiva* EU**

In January 2012, Teva obtained a European marketing authorization for Efavirenz Teva 600 mg tablets. In February 2012, the Company and Merck filed lawsuits and requests for injunctions against Teva in the Netherlands, Germany and the U.K. for infringement of Merck's European Patent No. 0582455 and Supplementary Protection Certificates expiring in November 2013. As of December 2012, requests for injunctions have been granted in the U.K. and denied in the Netherlands and Germany. The Company and Merck are appealing the denial of the request for injunction in the Netherlands. It is not possible at this time to reasonably assess the outcome of these lawsuits or their impact on the Company.

**GENERAL COMMERCIAL LITIGATION****Clayworth Litigation**

As previously disclosed, the Company, together with a number of other pharmaceutical manufacturers, was named as a defendant in an action filed in California Superior Court in Oakland, *James Clayworth et al. v. Bristol-Myers Squibb Company, et al.*, alleging that the defendants conspired to fix the prices of pharmaceuticals by agreeing to charge more for their drugs in the U.S. than they charge outside the U.S., particularly Canada, and asserting claims under California's Cartwright Act and unfair competition law. The plaintiffs sought trebled monetary damages, injunctive relief and other relief. In December 2006, the Court granted the Company and the other manufacturers' motion for summary judgment based on the pass-on defense, and judgment was then entered in favor of defendants. In July 2008, judgment in favor of defendants was affirmed by the California Court of Appeals. In July 2010, the California Supreme Court reversed the California Court of Appeal's judgment and the matter was remanded to the California Superior Court for further proceedings. In March 2011, the defendants' motion for summary judgment was granted and judgment was entered in favor of the defendants. The plaintiffs appealed that decision and the California Court of Appeals affirmed summary judgment for the defendants. In October 2012, the plaintiffs filed a petition seeking review by the California Supreme Court which was denied in November 2012.

**Remaining Apotex Matters Related to *Plavix*\***

As previously disclosed, in November 2008, Apotex filed a lawsuit in New Jersey Superior Court entitled, *Apotex Inc., et al. v. sanofi-aventis, et al.*, seeking payment of \$60 million, plus interest calculated at the rate of 1% per month from the date of the filing of the lawsuit, until paid, related to the break-up of a March 2006 proposed settlement agreement relating to the then pending *Plavix*\* patent litigation against Apotex. In April 2011, the New Jersey Superior Court granted the Company's cross-motion for summary judgment motion and denied Apotex's motion for summary judgment. Apotex appealed these decisions and the New Jersey Appellate Division reversed the grant of summary judgments. The case has been remanded back to the Superior Court for additional proceedings. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

In January 2011, Apotex filed a lawsuit in Florida State Court, Broward County, alleging breach of contract relating to the May 2006 proposed settlement agreement with Apotex relating to the then pending *Plavix*\* patent litigation. Apotex is seeking damages for the amount of profits it alleges it would have received from selling its generic clopidogrel bisulfate for somewhere between 8 and 11.5 months had the May 2006 agreement been approved by regulators. Discovery has concluded. The Company moved for summary judgment which was denied in November 2012. The case is now scheduled for a trial beginning in March 2013. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

**PRICING, SALES AND PROMOTIONAL PRACTICES LITIGATION AND INVESTIGATIONS*****Abilify*\* Federal Subpoena**

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

In January 2012, the Company received a subpoena from the United States Attorney's Office for the Southern District of New York requesting information related to, among other things, the sales and marketing of *Abilify*\*. It is not possible at this time to assess the outcome of this matter or its potential impact on the Company.

### **Abilify\* State Attorneys General Investigation**

In March 2009, the Company received a letter from the Delaware Attorney General's Office advising of a multi-state coalition investigating whether certain *Abilify\** marketing practices violated those respective states' consumer protection statutes. It is not possible at this time to reasonably assess the outcome of this investigation or its potential impact on the Company.

### **Abilify\* Co-Pay Assistance Litigation**

In March 2012, the Company and its partner Otsuka were named as co-defendants in a putative class action lawsuit filed by union health and welfare funds in the SDNY. Plaintiffs are challenging the legality of the *Abilify\** co-pay assistance program under the Federal Antitrust and the Racketeer Influenced and Corrupt Organizations laws, and seeking damages. The Company and Otsuka have filed a motion to dismiss the complaint. It is not possible at this time to reasonably assess the outcome of this litigation or its potential impact on the Company.

### **AWP Litigation**

As previously disclosed, the Company, together with a number of other pharmaceutical manufacturers, has been a defendant in a number of private class actions as well as suits brought by the attorneys general of various states. In these actions, plaintiffs allege that defendants caused the Average Wholesale Prices (AWPs) of their products to be inflated, thereby injuring government programs, entities and persons who reimbursed prescription drugs based on AWPs. The Company remains a defendant in two state attorneys general suits pending in state courts around the country having settled the lawsuits brought by the Mississippi and Louisiana Attorneys General. Beginning in August 2010, the Company was the defendant in a trial in the Commonwealth Court of Pennsylvania (Commonwealth Court), brought by the Commonwealth of Pennsylvania. In September 2010, the jury issued a verdict for the Company, finding that the Company was not liable for fraudulent or negligent misrepresentation; however, the Commonwealth Court judge issued a decision on a Pennsylvania consumer protection claim that did not go to the jury, finding the Company liable for \$28 million and enjoining the Company from contributing to the provision of inflated AWPs. The Company has moved to vacate the decision and the Commonwealth has moved for a judgment notwithstanding the verdict, which the Commonwealth Court denied. The Company has appealed the decision to the Pennsylvania Supreme Court.

### **Qui Tam Litigation**

In March 2011, the Company was served with an unsealed qui tam complaint filed by three former sales representatives in California Superior Court, County of Los Angeles. The California Department of Insurance has elected to intervene in the lawsuit. The complaint alleges the Company paid kickbacks to California providers and pharmacies in violation of California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7. Discovery is ongoing. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

## **PRODUCT LIABILITY LITIGATION**

The Company is a party to various product liability lawsuits. As previously disclosed, in addition to lawsuits, the Company also faces unfiled claims involving its products.

### ***Plavix\****

As previously disclosed, the Company and certain affiliates of Sanofi are defendants in a number of individual lawsuits in various state and federal courts claiming personal injury damage allegedly sustained after using *Plavix\**. Currently, more than 2,000 claims are filed in state and federal courts in various states including California, Illinois, New Jersey, and New York. The defendants terminated the previously disclosed tolling agreement effective as of September 1, 2012. In February 2013, the Judicial Panel on Multidistrict Litigation granted the Company and Sanofi's motion to establish a multidistrict litigation to coordinate federal pretrial proceedings in *Plavix\** product liability and related cases. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

### ***Reglan\****

The Company is one of a number of defendants in numerous lawsuits, on behalf of approximately 2,700 plaintiffs, claiming personal injury allegedly sustained after using *Reglan\** or another brand of the generic drug metoclopramide, a product indicated for gastroesophageal reflux and certain other gastrointestinal disorders. The Company, through its generic subsidiary, Apothecon, Inc., distributed metoclopramide tablets manufactured by another party between 1996 and 2000. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company. The resolution of these pending lawsuits is not expected to have a material impact on the Company.



---

## Hormone Replacement Therapy

The Company is one of a number of defendants in a mass-tort litigation in which plaintiffs allege, among other things, that various hormone therapy products, including hormone therapy products formerly manufactured by the Company (*Estrace\**, Estradiol, *Delestrogen\** and *Ovcon\**) cause breast cancer, stroke, blood clots, cardiac and other injuries in women, that the defendants were aware of these risks and failed to warn consumers. The Company has agreed to resolve the claims of approximately 400 plaintiffs. As of February 2013, the Company remains a defendant in approximately 35 actively pending lawsuits in federal and state courts throughout the U.S. All of the Company's hormone therapy products were sold to other companies between January 2000 and August 2001. The resolution of these remaining lawsuits is not expected to have a material impact on the Company.

### *Byetta\** and *Bydureon\**

Amylin, now a wholly-owned subsidiary of the Company (see Note 4. Acquisitions), and Lilly are co-defendants in product liability litigation related to *Byetta\** and *Bydureon\**. As of February 2013, there were approximately 120 separate lawsuits pending on behalf of approximately 575 plaintiffs in various courts in the U.S. The vast majority of these cases have been brought by individuals who allege personal injury sustained after using *Byetta\**, primarily pancreatitis, and, in some cases, claiming alleged wrongful death. Of these, the Company has agreed in principle to resolve the claims of over 300 plaintiffs. The majority of cases are pending in California state court, where the Judicial Council has granted Amylin's petition for a coordinated proceeding for all California state court cases alleging harm from the alleged use of *Byetta\**. Amylin and Lilly are currently scheduled for trial in one single-plaintiff case in the second quarter of 2013. We cannot reasonably predict the outcome of any lawsuit, claim or proceeding. However, given that Amylin has product liability insurance coverage for existing claims and future related claims involving *Byetta\**, it is expected the amount of damages, if any, will not be material to the Company.

### BMS-986094

In August 2012, the Company announced that it had discontinued development of BMS-986094, an investigational compound which was being tested in clinical trials to treat the hepatitis C virus infection due to the emergence of a serious safety issue. To date, five lawsuits have been filed against the Company in Texas State Court by plaintiffs, which have been removed to Federal Court, alleging that they participated in the Phase II study of BMS-986094 and suffered injuries as a result thereof. We have an agreement in principle to resolve four of the five filed claims and the vast majority of claims that have surfaced to date in this matter. In total, slightly fewer than 300 patients were administered the compound at various doses and durations as part of the clinical trials. The resolution of the remaining lawsuit and any other potential future lawsuits is not expected to have a material impact on the Company.

## ENVIRONMENTAL PROCEEDINGS

As previously reported, the Company is a party to several environmental proceedings and other matters, and is responsible under various state, federal and foreign laws, including the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), for certain costs of investigating and/or remediating contamination resulting from past industrial activity at the Company's current or former sites or at waste disposal or reprocessing facilities operated by third-parties.

### CERCLA Matters

With respect to CERCLA matters for which the Company is responsible under various state, federal and foreign laws, the Company typically estimates potential costs based on information obtained from the U.S. Environmental Protection Agency, or counterpart state or foreign agency and/or studies prepared by independent consultants, including the total estimated costs for the site and the expected cost-sharing, if any, with other potentially responsible parties, and the Company accrues liabilities when they are probable and reasonably estimable. The Company estimated its share of future costs for these sites to be \$72 million at December 31, 2012, which represents the sum of best estimates or, where no best estimate can reasonably be made, estimates of the minimal probable amount among a range of such costs (without taking into account any potential recoveries from other parties).

### New Brunswick Facility Environmental & Personal Injury Lawsuits

Since May 2008, over 250 lawsuits have been filed against the Company in New Jersey Superior Court by or on behalf of current and former residents of New Brunswick, New Jersey who live or have lived adjacent to the Company's New Brunswick facility. The complaints either allege various personal injuries damages resulting from alleged soil and groundwater contamination on their property stemming from historical operations at the New Brunswick facility, or are claims for medical monitoring. A portion of these complaints also assert claims for alleged property damage. In October 2008, the New Jersey Supreme Court granted Mass Tort status to these cases and transferred them to the New Jersey Superior Court in Atlantic County for centralized case management purposes. The Company intends to defend itself vigorously in this litigation. Discovery is ongoing. Since October 2011, over 100 additional cases have been filed in New Jersey Superior Court and removed by

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

the Company to United States District Court, District of New Jersey. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

### **North Brunswick Township Board of Education**

As previously disclosed, in October 2003, the Company was contacted by counsel representing the North Brunswick, NJ Board of Education (BOE) regarding a site where waste materials from E.R. Squibb and Sons may have been disposed from the 1940 s through the 1960 s. Fill material containing industrial waste and heavy metals in excess of residential standards was discovered during an expansion project at the North Brunswick Township High School, as well as at a number of neighboring residential properties and adjacent public park areas. In January 2004, the New Jersey Department of Environmental Protection (NJDEP) sent the Company and others an information request letter about possible waste disposal at the site, to which the Company responded in March 2004. The BOE and the Township, as the current owners of the school property and the park, are conducting and jointly financing soil remediation work and ground water investigation work under a work plan approved by the NJDEP, and have asked the Company to contribute to the cost. The Company is actively monitoring the clean-up project, including its costs. To date, neither the school board nor the Township has asserted any claim against the Company. Instead, the Company and the local entities have negotiated an agreement to attempt to resolve the matter by informal means, and avoid litigation. A central component of the agreement is the provision by the Company of interim funding to help defray cleanup costs and assure the work is not interrupted. The Company transmitted interim funding payments in December 2007 and November 2009. The parties commenced mediation in late 2008; however, those efforts were not successful and the parties moved to a binding allocation process. The parties are expected to conduct fact and expert discovery, followed by formal evidentiary hearings and written argument. Hearings likely will be scheduled for mid-to-late 2013. In addition, in September 2009, the Township and BOE filed suits against several other parties alleged to have contributed waste materials to the site. The Company does not currently believe that it is responsible for any additional amounts beyond the two interim payments totaling \$4 million already transmitted. Any additional possible loss is not expected to be material.

### **OTHER PROCEEDINGS**

#### **Italy Investigation**

In July 2011, the Public Prosecutor in Florence, Italy (Italian Prosecutor) initiated a criminal investigation against the Company s subsidiary in Italy (BMS Italy). The allegations against the Company relate to alleged activities of a former employee who left the Company in the 1990s. The Italian Prosecutor also had requested interim measures that a judicial administrator be appointed to temporarily run the operations of BMS Italy. In October 2012, the parties reached an agreement to resolve the request for interim measures which resulted in the Italian Prosecutor withdrawing the request and this request was accepted by the Florence Court. It is not possible at this time to assess the outcome of the underlying investigation or its potential impact on the Company.

#### **SEC Germany Investigation**

In October 2006, the SEC informed the Company that it had begun a formal inquiry into the activities of certain of the Company s German pharmaceutical subsidiaries and its employees and/or agents. The SEC s inquiry encompasses matters formerly under investigation by the German prosecutor in Munich, Germany, which have since been resolved. The Company understands the inquiry concerns potential violations of the Foreign Corrupt Practices Act (FCPA). The Company is cooperating with the SEC.

#### **FCPA Investigation**

In March 2012, the Company received a subpoena from the SEC. The subpoena, issued in connection with an investigation under the FCPA, primarily relates to sales and marketing practices in various countries. The Company is cooperating with the government in its investigation of these matters.



**Note 22. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

Dollars in Millions, except per share data 2012	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year
Net Sales	\$ 5,251	\$ 4,443	\$ 3,736	\$ 4,191	\$ 17,621
Gross Margin	3,948	3,198	2,749	3,116	13,011
Net Earnings/(Loss)	1,482	808	(713)	924	2,501
Net Earnings/(Loss) Attributable to:					
Noncontrolling Interest	381	163	(2)	(1)	541
BMS	1,101	645	(711)	925	1,960
Earnings/(Loss) per Share - Basic <sup>(1)</sup>	\$ 0.65	\$ 0.38	\$ (0.43)	\$ 0.56	\$ 1.17
Earnings/(Loss) per Share - Diluted <sup>(1)</sup>	\$ 0.64	\$ 0.38	\$ (0.43)	\$ 0.56	\$ 1.16
Cash dividends declared per common share	\$ 0.34	\$ 0.34	\$ 0.34	\$ 0.35	\$ 1.37
Cash and cash equivalents	\$ 2,307	\$ 2,801	\$ 1,503	\$ 1,656	\$ 1,656
Marketable securities <sup>(2)</sup>	6,307	5,968	5,125	4,696	4,696
Total Assets	32,408	31,667	36,044	35,897	35,897
Long-term debt <sup>(3)</sup>	5,270	5,209	7,227	7,232	7,232
Equity	16,246	15,812	13,900	13,638	13,638

Dollars in Millions, except per share data 2011	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year
Net Sales	\$ 5,011	\$ 5,434	\$ 5,345	\$ 5,454	\$ 21,244
Gross Margin	3,668	3,953	3,938	4,087	15,646
Net Earnings	1,367	1,307	1,355	1,231	5,260
Net Earnings Attributable to:					
Noncontrolling Interest	381	405	386	379	1,551
BMS	986	902	969	852	3,709
Earnings per Share - Basic <sup>(1)</sup>	\$ 0.58	\$ 0.53	\$ 0.57	\$ 0.50	\$ 2.18
Earnings per Share - Diluted <sup>(1)</sup>	\$ 0.57	\$ 0.52	\$ 0.56	\$ 0.50	\$ 2.16
Cash dividends declared per common share	\$ 0.33	\$ 0.33	\$ 0.33	\$ 0.34	\$ 1.33
Cash and cash equivalents	\$ 3,405	\$ 3,665	\$ 4,471	\$ 5,776	\$ 5,776
Marketable securities <sup>(2)</sup>	6,453	6,739	6,541	5,866	5,866
Total Assets	30,851	31,833	32,014	32,970	32,970
Long-term debt	5,276	5,332	5,437	5,376	5,376
Equity	15,901	16,145	16,436	15,867	15,867

(1) Earnings per share for the quarters may not add to the amounts for the year, as each period is computed on a discrete basis.

(2) Marketable securities includes current and non-current assets.

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

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

The following specified items affected the comparability of results in 2012 and 2011:

**2012**

Dollars in Millions	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year
Accelerated depreciation, asset impairment and other shutdown costs	\$	\$ 147	\$	\$	\$ 147
Amortization of acquired Amylin intangible assets			91	138	229
Amortization of Amylin collaboration proceeds			(46)	(68)	(114)
Amortization of Amylin inventory adjustment			9	14	23
Stock compensation from accelerated vesting of Amylin awards			94		94
Process standardization implementation costs	8	5	3	2	18
Upfront, milestone and other licensing payments			21	16	37
IPRD impairment	58	45		39	142
Impairment charge for BMS-986094 intangible asset			1,830		1,830
Provision for restructuring	22	20	29	103	174
Pension curtailments and settlements				151	151
Gain on sale of product lines, businesses and assets				(51)	(51)
Litigation charges/(recoveries)	(172)	22	50	55	(45)
Acquisition-related expenses	12	1	29	1	43
Out-licensed intangible asset impairment	38				38
Loss on debt repurchases	19		8		27
<b>Total</b>	<b>(15)</b>	<b>240</b>	<b>2,118</b>	<b>400</b>	<b>2,743</b>
Income tax/(tax benefit) on items above	8	(77)	(722)	(156)	(947)
Specified tax benefit*				(392)	(392)
<b>(Increase)/Decrease to Net Earnings</b>	<b>\$ (7)</b>	<b>\$ 163</b>	<b>\$ 1,396</b>	<b>\$ (148)</b>	<b>\$ 1,404</b>

**2011**

Dollars in Millions	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year
Accelerated depreciation, asset impairment and other shutdown costs	\$ 23	\$ 18	\$ 19	\$ 15	\$ 75
Pension curtailments and settlements				13	13
Process standardization implementation costs	4	10	5	10	29
Provision for restructuring	44	40	8	24	116
Litigation charges/(recoveries)	(76)		10	75	9
Gain on sale of product lines, businesses and assets			(12)		(12)
Upfront, milestone and other licensing payments/(receipts)	88	50	69	(20)	187
IPRD impairment	15		13		28
<b>Total</b>	<b>98</b>	<b>118</b>	<b>112</b>	<b>117</b>	<b>445</b>
Income tax benefit on items above	(28)	(34)	(37)	(37)	(136)
Specified tax benefit*	(56)	(15)		(26)	(97)
<b>Decrease to Net Earnings</b>	<b>\$ 14</b>	<b>\$ 69</b>	<b>\$ 75</b>	<b>\$ 54</b>	<b>\$ 212</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.

**Note 23. SUBSEQUENT EVENTS**

**Collaboration with The Medicines Company**

In February 2013, BMS and The Medicines Company entered into a global license and two year collaboration regarding *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). Net sales of *Recothrom* were \$67 million in 2012. In connection with the collaboration, The Medicines Company will be responsible for all sales, distribution, marketing and certain regulatory matters relating to *Recothrom*, and BMS will be responsible for the exclusive supply of the product. Certain assets were transferred to The Medicines Company at the start of the collaboration period, primarily the *Recothrom* Business License Agreement and other regulatory assets. BMS retained all other assets related to *Recothrom* including the patents, trademarks and inventory.

The collaboration expires in 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 cost of any remaining inventory held by BMS at that time). If the option is not exercised, all assets previously transferred to The Medicines Company during the collaboration period revert back to BMS.

BMS received \$115 million at the start of the collaboration period, which will be allocated to the license and other rights transferred to The Medicines Company and the written option, which will be recorded as an option liability at fair value. The allocation will be based on the estimated fair value of the elements after considering various market factors and the estimated excess of the fair value of the business over the potential purchase price if the option to purchase is exercised. Changes in the estimated fair value of the option liability will be recognized in the results of operations. The remaining amount of proceeds received upon entering into the collaboration will be recognized as alliance revenue throughout the term of the collaboration. BMS will also recognize alliance revenue during the collaboration period for tiered royalties and supply of product. BMS will provide certain information technology, regulatory, order processing, distribution and other transitional services in exchange for a fee during a period up to six months commencing at the start of the collaboration.

**Agreement to enter into Collaboration with Reckitt Benckiser Group plc**

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. Net sales of these products were approximately \$100 million in 2012.

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. Certain limited assets are expected to be transferred to RBL at the start of the collaboration period, primarily the market authorization, as well as the employees directly attributed to the business. BMS will retain all other assets related to the business including the patents, trademarks and inventory during the collaboration period.

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). 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, which will be recorded as an option liability at fair value. The allocation will be based on the estimated fair value of the elements after considering various market factors. Changes in the estimated fair value of the option liability will be recognized in the results of operations. The remaining amount of proceeds received upon entering into the collaboration will be recognized as alliance revenue throughout the term of the collaboration. BMS will also recognize alliance revenue during the collaboration period for tiered royalties and supply of product. BMS will also provide certain information technology, regulatory, order processing, distribution and other transitional services in exchange for a fee during a period up to six months commencing at the start of the collaboration.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Bristol-Myers Squibb Company

We have audited the accompanying consolidated balance sheets of Bristol-Myers Squibb Company and subsidiaries (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of earnings, comprehensive income, and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Bristol-Myers Squibb Company and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 15, 2013 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

February 15, 2013

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**Item 9A. CONTROLS AND PROCEDURES**  
**Evaluation of Disclosure Controls and Procedures**

As of December 31, 2012, management carried out an evaluation, under the supervision and with the participation of its chief executive officer and chief financial officer, of the effectiveness of the design and operation of its disclosure controls and procedures as such term is defined under Exchange Act Rule 13a-15(e). Based on this evaluation, management has concluded that as of December 31, 2012, such disclosure controls and procedures were effective.

**Management's Report on Internal Control Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision and with the participation of management, including the chief executive officer and chief financial officer, management assessed the effectiveness of internal control over financial reporting as of December 31, 2012 based on the framework in "Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. As permitted by SEC guidance, we excluded Amylin from management's assessment of internal control over financial reporting as of December 31, 2012. Amylin's financial statement amounts constituted 23% of total assets (including \$6.2 billion of acquired developed technology rights and in-process research and development) and 1% of total net sales of the Company's consolidated financial statement amounts and a pre-tax loss of \$270 million as of and for the year ended December 31, 2012. Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective at December 31, 2012 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes in accordance with United States generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Deloitte & Touche LLP, an independent registered public accounting firm, has audited the Company's financial statements included in this report on Form 10-K and issued its report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2012, which is included herein.

**Changes in Internal Control Over Financial Reporting**

In August 2012, Bristol-Myers Squibb Company (the Company) completed its acquisition of Amylin Pharmaceuticals, Inc. (Amylin) which represents a material change in the internal control over financial reporting since management's last assessment of effectiveness. Amylin's operations utilize separate information and accounting systems and processes and it was not possible to complete an evaluation and review of the internal controls over financial reporting since the completion of the acquisition. Management intends to complete its assessment of the effectiveness of internal control over financial reporting for Amylin within one year of the acquisition date. There were no changes in our internal control over financial reporting in the fourth quarter of 2012 that have or are reasonably likely to materially affect the Company's internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

---

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Bristol-Myers Squibb Company

We have audited the internal control over financial reporting of Bristol-Myers Squibb Company and subsidiaries (the Company) as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management's Report on Internal Control Over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Amylin Pharmaceuticals, Inc. (Amylin), which was acquired on August 8, 2012 and whose financial statement amounts constitute 23% of total assets (including \$6.2 billion of acquired developed technology rights and in-process research and development) and 1% of total net sales of the Company's consolidated financial statement amounts and a pre-tax loss of \$270 million as of and for the year ended December 31, 2012. Accordingly, our audit did not include the internal control over financial reporting at Amylin. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2012 of the Company and our report dated February 15, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

February 15, 2013

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.**

- (a) Reference is made to the 2013 Proxy Statement to be filed on or about March 21, 2013 with respect to the Directors of the Registrant, which is incorporated herein by reference and made a part hereof in response to the information required by Item 10.
- (b) The information required by Item 10 with respect to the Executive Officers of the Registrant has been included in Part IA of this Form 10-K in reliance on General Instruction G of Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K.

**Item 11. EXECUTIVE COMPENSATION.**

Reference is made to the 2013 Proxy Statement to be filed on or about March 21, 2013 with respect to Executive Compensation, which is incorporated herein by reference and made a part hereof in response to the information required by Item 11.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

Reference is made to the 2013 Proxy Statement to be filed on or about March 21, 2013 with respect to the security ownership of certain beneficial owners and management, which is incorporated herein by reference and made a part hereof in response to the information required by Item 12.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.**

Reference is made to the 2013 Proxy Statement to be filed on or about March 21, 2013 with respect to certain relationships and related transactions, which is incorporated herein by reference and made a part hereof in response to the information required by Item 13.

**Item 14. AUDITOR FEES.**

Reference is made to the 2013 Proxy Statement to be filed on or about March 21, 2013 with respect to auditor fees, which is incorporated herein by reference and made a part hereof in response to the information required by Item 14.



**PART IV**

**Item 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULE.**

(a)

	<b>Page Number</b>
1. Consolidated Financial Statements	
<u>Consolidated Statements of Earnings</u>	64
<u>Consolidated Statements of Comprehensive Income</u>	65
<u>Consolidated Balance Sheets</u>	66
<u>Consolidated Statements of Cash Flows</u>	67
<u>Notes to Consolidated Financial Statements</u>	68-108
<u>Report of Independent Registered Public Accounting Firm</u>	109

All other schedules not included with this additional financial data are omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

2. <u>Exhibits Required to be filed by Item 601 of Regulation S-K</u>	115-119
---	---------

The information called for by this Item is incorporated herein by reference to the Exhibit Index in this Form 10-K.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BRISTOL-MYERS SQUIBB COMPANY

(Registrant)

By **/s/ LAMBERTO ANDREOTTI**  
**Lamberto Andreotti**  
*Chief Executive Officer*

Date: February 15, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ LAMBERTO ANDREOTTI (Lamberto Andreotti)	Chief Executive Officer and Director (Principal Executive Officer)	February 15, 2013
/s/ CHARLES BANCROFT (Charles Bancroft)	Chief Financial Officer (Principal Financial Officer)	February 15, 2013
/s/ JOSEPH C. CALDARELLA (Joseph C. Caldarella)	Senior Vice President and Corporate Controller (Principal Accounting Officer)	February 15, 2013
/s/ JAMES M. CORNELIUS (James M. Cornelius)	Chairman of the Board of Directors	February 15, 2013
/s/ LEWIS B. CAMPBELL (Lewis B. Campbell)	Director	February 15, 2013
/s/ LOUIS J. FREEH (Louis J. Freeh)	Director	February 15, 2013
/s/ LAURIE H. GLIMCHER, M.D. (Laurie H. Glimcher, M.D.)	Director	February 15, 2013
/s/ MICHAEL GROBSTEIN (Michael Grobstein)	Director	February 15, 2013
/s/ ALAN J. LACY (Alan J. Lacy)	Director	February 15, 2013
/s/ VICKI L. SATO, PH.D. (Vicki L. Sato, Ph.D.)	Director	February 15, 2013
/s/ ELLIOTT SIGAL, M.D., PH.D. (Elliott Sigal, M.D., Ph.D.)	Director	February 15, 2013
/s/ GERALD L. STORCH	Director	February 15, 2013

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

(Gerald L. Storch)

/s/ TOGO D. WEST, JR.  
(Togo D. West, Jr.)

Director

February 15, 2013

/s/ R. SANDERS WILLIAMS, M.D.  
(R. Sanders Williams, M.D.)

Director

February 15, 2013

**EXHIBIT INDEX**

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by two asterisks (\*\*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15. An asterisk (\*) in the Page column indicates that the Exhibit has been previously filed with the Commission and is incorporated herein by reference. Unless otherwise indicated, all Exhibits are part of Commission File Number 1-1136.

<b>Exhibit No.</b>	<b>Description</b>	<b>Page No.</b>
2a.	Agreement and Plan of Merger by and among Bristol-Myers Squibb Company, B&R Acquisition Company and Amylin Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 2.1 to the Form 8-K dated July, 2012 and filed on July 3, 2012).	*
3a.	Amended and Restated Certificate of Incorporation of Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 3a to the Form 10-Q for the quarterly period ended June 30, 2005).	*
3b.	Certificate of Correction to the Amended and Restated Certificate of Incorporation, effective as of December 24, 2009 (incorporated herein by reference to Exhibit 3b to the Form 10-K for the fiscal year ended December 31, 2010).	*
3c.	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, effective as of May 7, 2010 (incorporated herein by reference to Exhibit 3a to the Form 8-K dated May 4, 2010 and filed on May 10, 2010).	*
3d.	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, effective as of May 7, 2010 (incorporated herein by reference to Exhibit 3b to the Form 8-K dated May 4, 2010 and filed on May 10, 2010).	*
3e.	Bylaws of Bristol-Myers Squibb Company, as amended as of May 4, 2010 (incorporated herein by reference to Exhibit 3.1 to the Form 8-K dated May 4, 2010 and filed on May 10, 2010).	*
4a.	Letter of Agreement dated March 28, 1984 (incorporated herein by reference to Exhibit 4 to the Form 10-K for the fiscal year ended December 31, 1983).	*
4b.	Indenture, dated as of June 1, 1993, between Bristol-Myers Squibb Company and JPMorgan Chase Bank (as successor trustee to The Chase Manhattan Bank (National Association)) (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated May 27, 1993 and filed on June 3, 1993).	*
4c.	Form of 7.15% Debenture due 2023 of Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 4.2 to the Form 8-K dated May 27, 1993 and filed on June 3, 1993).	*
4d.	Form of 6.80% Debenture due 2026 of Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 4e to the Form 10-K for the fiscal year ended December 31, 1996).	*
4e.	Form of 6.875% Debenture due 2097 of Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 4f to the Form 10-Q for the quarterly period ended September 30, 1997).	*
4f.	Third Supplemental Indenture, dated August 18, 2003, between Bristol-Myers Squibb Company and JPMorgan Chase Bank, as Trustee, to the indenture dated June 1, 1993 (incorporated herein by reference to Exhibit 4k to the Form 10-Q for the quarterly period ended September 30, 2003).	*
4g.	Form of 5.25% Senior Note due 2013 (incorporated herein by reference to Exhibit 4o to the Form 10-Q for the quarterly period ended September 30, 2003).	*
4h.	Indenture, dated October 1, 2003, between Bristol-Myers Squibb Company, as Issuer, and JPMorgan Chase Bank, as Trustee (incorporated herein by reference to Exhibit 4q to the Form 10-Q for the quarterly period ended September 30, 2003).	*
4i.	Form of Floating Rate Convertible Senior Debenture due 2023 (incorporated herein by reference to Exhibit 4s to the Form 10-Q for the quarterly period ended September 30, 2003).	*
4j.	Specimen Certificate of Common Stock (incorporated herein by reference to Exhibit 4s to the Form 10-K for the fiscal year ended December 31, 2003).	*
4k.	Specimen Certificate of Convertible Preferred Stock (incorporated herein by reference to Exhibit 4s to the Form 10-K for the fiscal year ended December 31, 2003).	*

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

- 4l. Form of Fourth Supplemental Indenture between Bristol-Myers Squibb Company and The Bank of New York, as Trustee, to the indenture dated June 1, 1993 (incorporated herein by reference to Exhibit 4r to the Form 8-K dated November 20, 2006 and filed November 27, 2006). \*
- 4m. Form of Fifth Supplemental Indenture between Bristol-Myers Squibb Company and The Bank of New York, as Trustee, to the indenture dated June 1, 1993 (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated May 1, 2008 and filed on May 7, 2008). \*
- 4n. Form of Sixth Supplemental Indenture between Bristol-Myers Squibb Company and The Bank of New York, as Trustee, to the indenture dated June 1, 1993 (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated July 26, 2012 and filed on July 31, 2012). \*
- 4o. Form of 5.875% Notes due 2036 (incorporated herein by reference to Exhibit 4s to the Form 8-K dated November 20, 2006 and filed November 27, 2006). \*
- 4p. Form of 4.375% Notes due 2016 (incorporated herein by reference to Exhibit 4t to the Form 8-K dated November 20, 2006 and filed November 27, 2006). \*

4q.	Form of 4.625% Notes due 2021 (incorporated herein by reference to Exhibit 4u to the Form 8-K dated November 20, 2006 and filed November 27, 2006).	*
4r.	Form of 5.45% Notes due 2018 (incorporated herein by reference to Exhibit 4.2 to the Form 8-K dated May 1, 2008 and filed on May 7, 2008).	*
4s.	Form of 6.125% Notes due 2038 (incorporated herein by reference to Exhibit 4.3 to the Form 8-K dated May 1, 2008 and filed on May 7, 2008).	*
4t.	Form of 0.875% Notes Due 2017 (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated July 26, 2012 and filed on July 31, 2012).	*
4u.	Form of 2.000% Notes Due 2022 (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated July 26, 2012 and filed on July 31, 2012).	*
4v.	Form of 3.250% Notes Due 2042 (incorporated herein by reference to Exhibit 4.1 to the Form 8-K dated July 26, 2012 and filed on July 31, 2012).	*
10a.	\$1,500,000,000 Five Year Competitive Advance and Revolving Credit Facility Agreement dated as of September 29, 2011 among Bristol-Myers Squibb Company, the borrowing subsidiaries, the lenders named in the agreement, BNP Paribas and The Royal Bank of Scotland plc, as documentation agents, Bank of America N.A., as syndication agent, and JPMorgan Chase Bank, N.A. and Citibank, N.A., as administrative agents (incorporated herein by reference to Exhibit 10.1 to the Form 8-K dated September 29, 2011 and filed on October 4, 2011).	*
10b.	\$1,500,000,000 Five Year Competitive Advance and Revolving Credit Facility Agreement dated as of July 31, 2012 among Bristol-Myers Squibb Company, the borrowing subsidiaries, the lenders named in the agreement, Bank of America N.A., Barclays Bank plc, Deutsche Bank Securities Inc., and Wells Fargo Bank, National Association as documentation agents, Citibank, N.A. and JPMorgan Chase Bank, N.A., as administrative agents (incorporated herein by reference to Exhibit 10.1 to the Form 8-K dated July 26, 2012 and filed on July 31, 2012).	*
10c.	SEC Consent Order (incorporated herein by reference to Exhibit 10s to the Form 10-Q for the quarterly period ended September 30, 2004).	*
10d.	Bylaws (Statuts) of Sanofi Pharma Bristol-Myers Squibb, a partnership (societe en nom collectif) organized under French law, dated as of June 6, 1997. English Translation (incorporated by reference herein to Exhibit 10.1 to the Form 8-K filed on August 17, 2009).	*
10e.	Internal Regulation (Reglement Interieur) of Sanofi Pharma Bristol-Myers Squibb dated as of June 6, 1997 and effective as of January 1, 1997. English Translation (incorporated by reference herein to Exhibit 10.2 to the Form 8-K filed on August 17, 2009).	*
10f.	Partnership Agreement of Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership between Sanofi Pharmaceuticals, Inc. and Bristol-Myers Squibb Company Investco, Inc. dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.3 to the Form 8-K filed on August 17, 2009).	*
10g.	Territory A Alliance Support Agreement between Sanofi and Bristol-Myers Squibb Company dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.4 to the Form 8-K filed on August 17, 2009).	*
10h.	Amendment No. 1 to the Territory A Alliance Support Agreement between Sanofi-Synthelabo and Bristol-Myers Squibb Company dated as of October 17, 2001 (incorporated by reference herein to Exhibit 10.5 to the Form 8-K filed on August 17, 2009).	*
10i.	Territory B Alliance Support Agreement between Sanofi and Bristol-Myers Squibb Company dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.6 to the Form 8-K filed on August 17, 2009).	*
10j.	Amendment No. 1 to the Territory B Alliance Support Agreement between Sanofi-Synthelabo and Bristol-Myers Squibb Company dated as of October 17, 2001 (incorporated by reference herein to Exhibit 10.7 to the Form 8-K filed on August 17, 2009).	*
10k.	Clopidogrel Intellectual Property License and Supply Agreement between Sanofi and Sanofi Pharma Bristol-Myers Squibb dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.8 to the Form 8-K filed on August 17, 2009).	*
10l.	Clopidogrel Intellectual Property License and Supply Agreement between Sanofi and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership dated as of January 1, 1997 (incorporated by reference herein to	*

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

Exhibit 10.9 to the Form 8-K filed on August 17, 2009).

- 10m. Product Know-How License Agreement among Sanofi, Bristol-Myers Squibb Company and Sanofi Pharma Bristol-Myers Squibb dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.10 to the Form 8-K filed on August 17, 2009). \*
- 10n. Product Know-How License Agreement among Sanofi, Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership dated as of January 1, 1997 (incorporated by reference herein to Exhibit 10.11 to the Form 8-K filed on August 17, 2009). \*
- 10o. Master Restructuring Agreement between Bristol-Myers Squibb Company and Sanofi dated as of September 27, 2012 (incorporated by reference herein to Exhibit 10a to the Form 10-Q for the quarterly period ended September 30, 2012). \*

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

10p.	Side Letter to Master Restructuring Agreement between Bristol-Myers Squibb Company and Sanofi dated as of January 1, 2013 (filed herewith).	E-10-1
10q.	Amended and Restated Articles of Association (Statuts) of Sanofi Pharma Bristol-Myers Squibb, a partnership (societe en nom collectif) organized under French law, dated as of January 1, 2013. English Translation (filed herewith).	E-10-2
10r.	Amended and Restated Internal Regulation (Reglement Interieur) of Sanofi Pharma Bristol-Myers Squibb dated as of dated as of January 1, 2013. English Translation (filed herewith).	E-10-3
10s.	Amendment to the Partnership Agreement of Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership between sanofi-aventis U.S. LLC (as successor-in-interest to Sanofi Pharmaceuticals, Inc.) and Bristol-Myers Squibb Company Investco, Inc. dated as of January 1, 2013 (filed herewith).	E-10-4
10t.	Termination Agreement of Territory A Alliance Support Agreement between Sanofi and Bristol-Myers Squibb Company dated as of January 1, 2013 (filed herewith).	E-10-5
10u.	Amendment No.4 to the Territory B Alliance Support Agreement between Sanofi and Bristol-Myers Squibb Company dated as of January 1, 2013 (filed herewith).	E-10-6
10v.	Amended and Restated Clopidogrel Intellectual Property License Agreement between Sanofi and Sanofi Pharma Bristol-Myers Squibb dated as of January 1, 2013 (filed herewith).	E-10-7
10w.	Amended and Restated Clopidogrel Intellectual Property License Agreement between Sanofi and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership dated as of January 1, 2013 (filed herewith).	E-10-8
10x.	Amended and Restated Territory A Product Know-How License Agreement among Sanofi, Bristol-Myers Squibb Company and Sanofi Pharma Bristol-Myers Squibb dated as of January 1, 2013 (filed herewith).	E-10-9
10y.	Amended and Restated Territory B Product Know-How License Agreement among Sanofi, Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership dated as of January 1, 2013 (filed herewith).	E-10-10
10z.	Amended and Restated Territory B1 Product Know-How License Agreement among Sanofi, Bristol-Myers Squibb Company and Sanofi-Aventis U.S. LLC dated as of January 1, 2013 (filed herewith).	E-10-11
10aa.	Assignment Agreement among Sanofi, Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership dated as of January 1, 2013 (filed herewith).	E-10-12
10bb.	Restated Development and Commercialization Collaboration Agreement between Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Company dated as of October 23, 2001 (incorporated by reference herein to Exhibit 10.12 to the Form 8-K filed on August 17, 2009).	*
10cc.	Amendment No. 3 to the Restated Development and Commercialization Collaboration Agreement between Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Company dated as of September 25, 2006 (incorporated by reference herein to Exhibit 10.13 to the Form 8-K filed on August 17, 2009).	*
10dd.	Amendment No. 5 to the Restated Development and Commercialization Collaboration Agreement between Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Company effective as of April 4, 2009 (incorporated by reference herein to Exhibit 10.14 to the Form 8-K filed on August 17, 2009).	*
10ee.	Amendment No. 9 to the Restated Development and Commercialization Collaboration Agreement between Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Company effective as of October 29, 2012 (filed herewith).	E-10-13
**10ff.	Bristol-Myers Squibb Company 2002 Stock Incentive Plan, effective as of May 7, 2002 and as amended effective June 10, 2008 (incorporated herein by reference to Exhibit 10.1 to the Form 10-Q for the quarterly period ended September 30, 2008).	*
**10gg.	Bristol-Myers Squibb Company 2012 Stock Award and Incentive Plan, effective as of May 1, 2012 (incorporated herein by reference to Exhibit B to the 2012 Proxy Statement dated March 20, 2012).	*
**10hh.	Bristol-Myers Squibb Company 2007 Stock Award and Incentive Plan, effective as of May 1, 2007 and as amended effective June 10, 2008 (incorporated herein by reference to Exhibit 10.2 to the Form 10-Q for the quarterly period ended September 30, 2008).	*
**10ii.	Bristol-Myers Squibb Company TeamShare Stock Option Plan, as amended and restated effective September 10, 2002 (incorporated herein by reference to Exhibit 10c to the Form 10-K for the fiscal year ended December 31,	*



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

2002).

**10jj.	Form of Non-Qualified Stock Option Agreement under the 2002 Stock Award and Incentive Plan (incorporated herein by reference to Exhibit 10s to the Form 10-K for the fiscal year ended December 31, 2005).	*
**10kk.	Form of Non-Qualified Stock Option Agreement under the 2007 Stock Award and Incentive Plan (incorporated herein by reference to Exhibit 10s to the Form 10-Q for the quarterly period ended March 31, 2007).	*
**10ll.	Form of Performance Share Units Agreement for the 2010-2012 Performance Cycle (incorporated herein by reference to Exhibit 10aa to the Form 10-K for the fiscal year ended December 31, 2009).	*
**10mm.	Form of Performance Share Units Agreement for the 2011-2013 Performance Cycle (incorporated herein by reference to Exhibit 10aa to the Form 10-K for the fiscal year ended December 31, 2010).	*
**10nn.	Form of Performance Share Units Agreement for the 2012-2014 Performance Cycle (incorporated by reference to Exhibit 10z to the Form 10-K for the fiscal year ended December 31, 2011).	*
**10oo.	Form of Performance Share Units Agreement for the 2013-2015 Performance Cycle (filed herewith).	E-10-14

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

**10pp.	Form of Restricted Stock Units Agreement with five year vesting under the 2012 Stock Award and Incentive Plan (filed herewith).	E-10-15
**10qq.	Form of Restricted Stock Units Agreement with four year vesting under the 2012 Stock Award and Incentive Plan (filed herewith).	E-10-16
**10rr.	Form of Market Share Units Agreement under the 2012 Stock Award and Incentive Plan (filed herewith).	E-10-17
**10ss.	Bristol-Myers Squibb Company Performance Incentive Plan, as amended (as adopted, incorporated herein by reference to Exhibit 2 to the Form 10-K for the fiscal year ended December 31, 1978; as amended as of January 8, 1990, incorporated herein by reference to Exhibit 19b to the Form 10-K for the fiscal year ended December 31, 1990; as amended on April 2, 1991, incorporated herein by reference to Exhibit 19b to the Form 10-K for the fiscal year ended December 31, 1991; as amended effective January 1, 1994, incorporated herein by reference to Exhibit 10d to the Form 10-K for the fiscal year ended December 31, 1993; and as amended effective January 1, 1994, incorporated herein by reference to Exhibit 10d to the Form 10-K for the fiscal year ended December 31, 1994).	*
**10tt.	Bristol-Myers Squibb Company Executive Performance Incentive Plan effective January 1, 1997 (incorporated herein by reference to Exhibit 10b to the Form 10-K for the fiscal year ended December 31, 1996).	*
**10uu.	Bristol-Myers Squibb Company Executive Performance Incentive Plan effective January 1, 2003 and as amended effective June 10, 2008 (incorporated herein by reference to Exhibit 10.3 to the Form 10-Q for the quarterly period ended September 30, 2008).	*
**10vv.	Bristol-Myers Squibb Company 2007 Senior Executive Performance Incentive Plan (as amended and restated effective June 8, 2010 and incorporated herein by reference to Exhibit 10a. to the Form 10-Q for the quarterly period ended June 30, 2010).	*
**10ww.	Bristol-Myers Squibb Company Benefit Equalization Plan Retirement Income Plan, as amended and restated effective as of January 1, 2012, (filed herewith).	E-10-18
**10xx.	Bristol-Myers Squibb Company Benefit Equalization Plan Savings and Investment Program, as amended and restated effective as of January 1, 2012 (filed herewith).	E-10-19
**10yy.	Squibb Corporation Supplementary Pension Plan, as amended (as previously amended and restated, incorporated herein by reference to Exhibit 19g to the Form 10-K for the fiscal year ended December 31, 1991; as amended as of September 14, 1993, and incorporated herein by reference to Exhibit 10g to the Form 10-K for the fiscal year ended December 31, 1993).	*
**10zz.	Senior Executive Severance Plan, effective as of April 26, 2007 and as amended effective February 16, 2012 (incorporated by reference to Exhibit 10ll to the Form 10-K for the fiscal year ended December 31, 2011).	*
**10aaa.	Form of Agreement entered into between the Registrant and each of the named executive officers and certain other executives effective January 1, 2009 (incorporated herein by reference to Exhibit 10bb to the Form 10-K for the fiscal year ended December 31, 2008).	*
**10bbb.	Form of Corrective Amendment between the Registrant and each of the named executive officers and certain other executives effective January 1, 2009 (incorporated herein by reference to Exhibit 10b to the Form 10-Q for the quarterly period ended June 30, 2012).	*
**10ccc.	Employment Letter Agreement effective as of February 11, 2011, between Beatrice Cazala and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10a to the Form 10-Q for the quarterly period ended March 30, 2012).	*
**10ddd.	Bristol-Myers Squibb Company Retirement Income Plan for Non-Employee Directors, as amended March 5, 1996 (incorporated herein by reference to Exhibit 10k to the Form 10-K for the fiscal year ended December 31, 1996).	*
**10eee.	Bristol-Myers Squibb Company 1987 Deferred Compensation Plan for Non-Employee Directors, as amended December 17, 2009 (incorporated herein by reference to Exhibit 10tt to the Form 10-K for the fiscal year ended December 31, 2009).	*
**10fff.	Bristol-Myers Squibb Company Non-Employee Directors Stock Option Plan, as amended (as approved by the Stockholders on May 1, 1990, incorporated herein by reference to Exhibit 28 to Registration Statement No. 33-38587 on Form S-8; as amended May 7, 1991, incorporated herein by reference to Exhibit 19c to the Form 10-K for the fiscal year ended December 31, 1991), as amended January 12, 1999 (incorporated herein by reference to Exhibit 10m to the Form 10-K for the fiscal year ended December 31, 1998).	*

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-K

- \*\*10ggg. Bristol-Myers Squibb Company Non-Employee Directors Stock Option Plan, as amended (as approved by the Stockholders on May 2, 2000, incorporated herein by reference to Exhibit A to the 2000 Proxy Statement dated March 20, 2000). \*
- \*\*10hhh. Squibb Corporation Deferral Plan for Fees of Outside Directors, as amended (as adopted, incorporated herein by reference to Exhibit 10e Squibb Corporation 1991 Form 10-K for the fiscal year ended December 31, 1987, File No. 1-5514; as amended effective December 31, 1991 incorporated herein by reference to Exhibit 10m to the Form 10-K for the fiscal year ended December 31, 1992). \*

**10iii.	Amendment to all of the Company's plans, agreements, legal documents and other writings, pursuant to action of the Board of Directors on October 3, 1989, to reflect the change of the Company's name to Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10v to the Form 10-K for the fiscal year ended December 31, 1989).	*
12	Statement re computation of ratios (filed herewith).	E-12-1
21	Subsidiaries of the Registrant (filed herewith).	E-21-1
23	Consent of Deloitte & Touche LLP (filed herewith).	E-23-1
31a.	Section 302 Certification Letter (filed herewith).	E-31-1
31b.	Section 302 Certification Letter (filed herewith).	E-31-1
32a.	Section 906 Certification Letter (filed herewith).	E-32-1
32b.	Section 906 Certification Letter (filed herewith).	E-32-2
101.	The following financial statements from the Bristol-Myers Squibb Company Annual Report on Form 10-K for the years ended December 31, 2012, 2011 and 2010, formatted in Extensible Business Reporting Language (XBRL): (i) consolidated statements of earnings, (ii) consolidated statements of comprehensive income, (iii) consolidated balance sheets, (iv) consolidated statements of cash flows, and (v) the notes to the consolidated financial statements.	

Confidential treatment has been granted for certain portions which are omitted in the copy of the exhibit electronically filed with the Commission.

Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Commission. The omitted information has been filed separately with the Commission pursuant to the Company's application for confidential treatment.

\* Indicates, in this Form 10-K, brand names of products, which are registered trademarks not solely owned by the Company or its subsidiaries. *Byetta*, *Bydureon*, and *Symlin* are trademarks of Amylin Pharmaceuticals, LLC and AstraZeneca Pharmaceuticals LP; *Erbix* is a trademark of ImClone LLC; *Avapro/Avalide* (known in the EU as *Aprovel/Karvea*), *Iscover*, *Karvezide*, *Coaprovel* and *Plavix* are trademarks of Sanofi; *Abilify* is a trademark of Otsuka Pharmaceutical Co., Ltd.; *Truvada* is a trademark of Gilead Sciences, Inc.; *Gleevec* is a trademark of Novartis AG; *Atripla* is a trademark of Bristol-Myers Squibb and Gilead Sciences, LLC; *Norvir* is a trademark of Abbott Laboratories; *Estrace* and *Ovcon* are trademarks of Warner-Chilcott Company, LLC; *Delestrogen* is a trademark of JHP Pharmaceuticals, LLC; *Reglan* is a trademark of ANIP Acquisition Company and *Humira* is a trademark of AbbVie Biotechnology LTD. Brand names of products that are in all italicized letters, without an asterisk, are registered trademarks of BMS and/or one of its subsidiaries.