

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, 2014

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)

22-0790350
(IRS Employer
Identification No.)

345 Park Avenue, New York, N.Y. 10154
(Address of principal executive offices)
Telephone: (212) 546-4000

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.10 Par Value	New York Stock Exchange

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

<u>Title of each class</u>
\$2 Convertible Preferred Stock, \$1 Par Value

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 1,655,998,321 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, 2014) was approximately \$80,332,478,552. Bristol-Myers Squibb has no non-voting common equity. At February 2, 2015, there were 1,662,118,446 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the Proxy Statement for the registrant's Annual Meeting of Stockholders to be held May 5, 2015 are incorporated by reference into Part III of this Annual Report on Form 10-K.

BMS 2009
SEAL BMS

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.

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 six foreign countries.

The percentage of revenues by significant region/country were as follows:

Dollars in Millions	Year Ended December 31,		
	2014	2013	2012
United States	49%	51%	59%
Europe	23%	24%	21%
Japan	6%	5%	4%
China	4%	4%	3%
Total Revenues	\$ 15,879	\$ 16,385	\$ 17,621

Acquisitions and Divestitures

We continue to transform BMS into a leading-edge biopharmaceutical company focused exclusively on discovering, developing, and delivering innovative medicines that address serious unmet medical needs. This transformation has encompassed all areas of our business and operations. As part of this strategy, we have divested our diabetes and non-pharmaceutical businesses, implemented our acquisition and licensing strategy, and executed our productivity transformation initiative (PTI). Our divestitures included our diabetes business in February 2014, Mead Johnson in December 2009, ConvaTec in August 2008 and Medical Imaging in January 2008. As part of our acquisition and licensing strategy, we acquired iPierian, Inc. (iPierian) in April 2014, Amylin Pharmaceuticals, Inc. (Amylin) in August 2012, Inhibitex, Inc. (Inhibitex) in February 2012, Amira Pharmaceuticals, Inc. (Amira) in September 2011, ZymoGenetics, Inc. (ZymoGenetics) in October 2010 and Medarex, Inc. (Medarex) in September 2009 and entered into several license and other collaboration arrangements. These transactions have allowed and continue to allow us to focus our resources behind our growth opportunities that drive the greatest long-term value. From a disease standpoint, we are focused on the following core therapeutic areas: oncology, virology, immunology, specialty cardiovascular disease, fibrosis and genetically defined diseases.

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: virology, including human immunodeficiency virus (HIV) infection; oncology; neuroscience; immunoscience; and cardiovascular.

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.

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 China. We also sell our pharmaceutical products in other countries; however, data is not provided on a country-by-country basis because individual country revenues are not significant outside the U.S., the EU, Japan and China. 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 purpose 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 revenues of our key products and estimated basic exclusivity loss in the U.S., EU, Japan and China:

Dollars in Millions	Total Revenues by Product			Past or Currently Estimated Year of Basic Exclusivity Loss			
	2014	2013	2012	U.S.	EU ^(a)	Japan	China
Virology							
<i>Baraclude</i>	\$ 1,441	\$ 1,527	1,388	2014 ^(c)	2011-2016	2016	--
Hepatitis C Franchise ^(b)	256	—	—	++	2027	2027	++
<i>Reyataz</i>	1,362	1,551	1,521	2017	2017-2019 ^(d)	2019	2017
<i>Sustiva Franchise</i>	1,444	1,614	1,527	2017 ^(e)	2013 ^(f)	++	++
Oncology							
<i>Erbitux*</i>	723	696	702	2016 ^(g)	++	2016 ^(h)	++
<i>Opdivo</i>	6	—	—	2027	++	2026	++
<i>Sprycel</i>	1,493	1,280	1,019	2020	2020	2021	2020
<i>Yervoy</i>	1,308	960	706	2023 ^(h)	2021 ^(h)	++	++
Neuroscience							
<i>Abilify*</i>	2,020	2,289	2,827	2015 ⁽ⁱ⁾	2014 ⁽ⁱ⁾	++	++
Immunoscience							
<i>Orencia</i>	1,652	1,444	1,176	2019	2017 ^(h)	2018 ^(h)	++
Cardiovascular							
<i>Eliquis</i>	774	146	2	2023	2022	2022	^

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 by BMS. Specific trademark ownership information is included in the Exhibit Index.

++ 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.

^ There is uncertainty about China's exclusivity laws.

- References to the EU throughout this Form 10-K include all member states of the European Union during the year ended December 31, 2014. Basic patent applications have not been filed in all 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.
- Exclusivity period relates to the *Daklinza* (daclatasvir) brand.
- In September 2014, Teva Pharmaceuticals launched a generic version of *Baraclude* (entecavir). These actions follow a decision in June 2014 by the U.S. Court of Appeals for the Federal Circuit to uphold a lower court decision invalidating *Baraclude*'s patent in February 2013. A petition for a rehearing en banc was also denied in October 2014. The Company filed a petition for writ of certiorari with the U.S. Supreme Court in January 2015.
- Data exclusivity in the EU expired in 2014 and market exclusivity expires between 2017 and 2019.
- Exclusivity period relates to the *Sustiva* (efavirenz) brand and does not include exclusivity related to any combination therapy. The composition of matter patent for efavirenz in the U.S. expired in 2013 and the method of use patent for the treatment of HIV infection expired in September 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. In October 2014, the Company announced that it has successfully resolved all outstanding U.S. patent litigation relating to efavirenz and that loss of exclusivity in the U.S. for efavirenz is not expected to occur until December 2017.
- Exclusivity period relates to the *Sustiva* brand and does not include exclusivity related to any combination therapy. Market exclusivity for *Sustiva* expired in November 2013 in countries in the EU. Data exclusivity for *Sustiva* expired in the EU in 2009.
- 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.

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 and Japan.

Baraclude *Baraclude* (entecavir) is a potent and selective inhibitor of hepatitis B virus that was approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic hepatitis B virus infection. *Baraclude* was discovered and developed internally.

In September 2014, Teva Pharmaceuticals launched a generic version of *Baraclude* (entecavir) and we have experienced a rapid and significant negative impact on U.S. net product sales of *Baraclude* beginning in the fourth quarter of 2014. These actions follow a decision in June by the U.S. Court of Appeals for the Federal Circuit to uphold a lower court decision invalidating *Baraclude*'s patent in February 2013. A petition for rehearing en banc was also denied in October 2014. The Company filed a petition for writ of certiorari requesting U.S. Supreme Court review in January 2015. For more information about this patent litigation matter, see "Item 8. Financial Statements—Note 22. Legal Proceedings and Contingencies."

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

Bulk active entecavir is manufactured by both the company and a third party. The product is then finished in our facilities.

Hepatitis C Franchise *Daklinza* (Daclatasvir (DCV)) is an oral small molecule NS5A replication complex inhibitor for the treatment of hepatitis C virus infection (HCV) and was approved in combination with other medicinal products in the EU across multiple genotypes in August 2014. The dual regimen with *Sunvepra* was also approved in Japan in July 2014. It is currently in the registration process in the U.S. We own a patent covering daclatasvir as a composition of matter that expires in 2028 in the U.S.

Sunvepra (Asunaprevir (ASV)) is an oral small molecule NS3 protease inhibitor for the treatment of HCV, and was approved as a dual regimen of DCV+ASV in Japan in July 2014. In October 2014, we announced that we would not pursue FDA approval of the dual regimen and we have withdrawn our New Drug Application (NDA) for asunaprevir.

We manufacture our bulk requirements of daclatasvir and finish the product in our facilities. We obtain bulk requirements for asunaprevir from a third-party manufacturer and finish the product at a third-party facility.

Reyataz Franchise *Reyataz* (atazanavir sulfate) is a protease inhibitor for the treatment of HIV. The *Reyataz Franchise* includes *Reyataz* and combination therapy *Evotaz* (atazanavir 300 mg and cobicistat 150 mg), a once-daily single tablet two drug regimen combining *Reyataz* and Gilead Sciences, Inc.'s (Gilead) *Tybost** (cobicistat) for the treatment of HIV-1 infection in adults.

We developed atazanavir under a worldwide license from Novartis Pharmaceutical Corporation (Novartis) for which a royalty is paid based on a percentage of net product sales. We are entitled to promote *Reyataz* for use in combination with *Norvir** (ritonavir) under a non-exclusive license agreement with AbbVie Inc. (AbbVie), as amended, for which a royalty is paid based on a percentage of net product sales. We have a licensing agreement with Gilead for *Evotaz*, which was approved in January 2015.

Market exclusivity for *Reyataz* is expected to expire in 2017 in the U.S. and China and 2019 in the major EU member countries and Japan. Data exclusivity in the EU expired 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, 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). For more information about our arrangement with Gilead, see "—Alliances" below and "Item 8. Financial Statements—Note 3. Alliances."

Rights to market efavirenz in the U.S., Canada, the UK, France, Germany, Ireland, Italy and Spain are licensed from Merck & Co., Inc. (Merck) for a royalty based on a percentage of revenues. Efavirenz is marketed by another company in Japan.

The composition of matter patent for efavirenz in the U.S. expired in 2013 and a method of use patent for the treatment of HIV infection expired in September 2014, with an additional six month period of pediatric exclusivity added to the term of these patents. In October 2014, the Company announced that it has successfully resolved all outstanding U.S. patent litigation relating to efavirenz and that loss of exclusivity in the U.S. for efavirenz is not expected to occur until December 2017.

Market exclusivity for *Sustiva* expired in November 2013 in countries in the EU. Data exclusivity for *Sustiva* expired in the EU in 2009.

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.

*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 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 approved *Erbix** 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.

Exclusive distribution rights in North America for cetuximab were granted to the Company by ImClone Systems Incorporated (ImClone), the predecessor company of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company (Lilly) and is part of our alliance with Lilly. For more information about our alliance with Lilly, see “—Alliances” below and “Item 8. Financial Statements—Note 3. Alliances”

Data exclusivity for *Erbix** in the U.S. expires in 2016. There is no patent that specifically claims the composition of matter of cetuximab, the active molecule in *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 5-Fluorouracil (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). This use patent was challenged by Yeda Research and Development Company Ltd. (Yeda). Pursuant to a December 2007 worldwide settlement agreement, Sanofi and Yeda granted ImClone a non-exclusive worldwide license under the use patent. Data exclusivity in Japan expires in 2016.

Yeda has the right to license the use patent to third parties and has granted Amgen, Inc. (Amgen) a license. Amgen received FDA approval to market an EGFR-product that competes with *Erbix**. Yeda's license of the patent to third parties could result in product competition for *Erbix** that might not otherwise occur and we are unable to assess the potential impact of such competition.

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.

Opdivo

Opdivo (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 jointly own a patent with Ono Pharmaceutical Co., LTD. (Ono) covering *Opdivo* as a composition of matter that expires in 2027 in the U.S. (excluding potential patent term extension). In December 2014, the FDA approved *Opdivo* for unresectable (inoperable) or metastatic melanoma, and disease progression following *Yervoy* and, if BRAF V600 mutation positive, a BRAF inhibitor. *Opdivo* was also approved in Japan in July 2014 for the same indication. The FDA has granted Fast Track designation for *Opdivo* in three tumor types: non-small cell lung cancer, renal cell carcinoma and metastatic melanoma, and it is in the registrational process for melanoma and non-small cell lung cancer in the U.S. and Europe. The FDA granted Breakthrough Therapy designation for Hodgkin Lymphoma in 2014.

We obtain our bulk requirements for *Opdivo* from a third party and finish the product in our facilities.

Sprycel

Sprycel (dasatinib) is a multi-targeted tyrosine kinase inhibitor approved for the first-line treatment of adults with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase and 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). *Gleevec** is a trademark of Novartis.

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