BRISTOL MYERS SQUIBB CO
Form 10-K
February 14, 2014

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, 2013
Commission File Number 1-1136

BRISTOL-MYERS SQUIBB COMPANY
(Exact name of registrant as specified in its charter)

Delaware	22-0790350
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	Name of each exchange on which registered
Common Stock, $0.10 Par Value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:
Title of each class
$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 x 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 x
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 x 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 x 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. x

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 x 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 x

The aggregate market value of the 1,644,046,930 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, 2013) was approximately $73,472,457,302. Bristol-Myers Squibb has no non-voting common equity. At February 1, 2014, there were 1,650,232,566 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 6, 2014 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.

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 were as follows:

	Year Ended December 31,					
Dollars in Millions	2013		2012		2011	
United States	51	%	59	%	66	%
Europe	24	%	21	%	18	%
Japan	5	%	4	%	3	%
China	4	%	3	%	2	%
Total Revenues	16,385		17,621		21,244	

Acquisitions and Divestitures

Since 2007, we have been transforming BMS into a leading-edge biopharmaceutical company focused exclusively on discovering, developing, and delivering innovative medicines that address serious unmet medical needs. This transformation 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 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 four core therapeutic areas: oncology, virology, immunology, and specialty cardiovascular disease.

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; metabolics; 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 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 revenues of our key products and estimated basic exclusivity loss in the U.S., EU, Japan and China:

	Total Revenues by Product			Past or Currently Estimated Year of Basic Exclusivity Loss							
Dollars in Millions	2013	2012	2011	U.S.		EU[a]		Japan		China	
Key Products											
Virology											
Baraclude	$1,527	$1,388	$1,196	2014	(b)	2011-2016		2016		--	
Reyataz	1,551	1,521	1,569	2017		2017-2019	(c)	2019		2017	
Sustiva Franchise	1,614	1,527	1,485	2015	(d)	2013	(e)	++		++	
Oncology											
Erbitux*	696	702	691	2016	(f)	++		2016	(g)	++	
Sprycel	1,280	1,019	803	2020		2020		2021		2020	
Yervoy	960	706	360	2023	(g)	2021	(g)	++		++	
Neuroscience											
Abilify*	2,289	2,827	2,758	2015	(h)	2014	(i)	++		++	
Metabolics[m]											
Bydureon*	298	78	N/A	2025	(j)	2021	(j)	2020	(g)	++	
Byetta*	400	149	N/A	2016	(k)	2016	(g)	2018	(g)	++	
Forxiga/Xigduo	23	—	N/A	2020		2023		++		++	
Onglyza/Kombiglyze	877	709	473	2023		2021		++		2016	
Immunoscience											
Nulojix	26	11	3	2023		2021		++		++	
Orencia	1,444	1,176	917	2019		2017	(g)	2018	(g)	++	
Cardiovascular											
Avapro*/Avalide*	231	503	952	2012		2007-2013		++		--	
Eliquis	146	2	—	2023		2022		2022		++	
Plavix*	258	2,547	7,087	2012		2008	(l)	++		++	

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 123.

++ 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 member states of the European Union during the year ended December 31, 2013. 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.

(b) In February 2013, the U.S. District Court for the District of Delaware invalidated the composition of matter patent covering Baraclude (entecavir), which was scheduled to expire in 2015, including granted pediatric exclusivity. An appeal is pending and a decision is expected in 2014. We may face generic competition with this product beginning in 2014. The Company is prepared to take legal action in the event that Teva Pharmaceutical Industries Ltd. (Teva) chooses to launch its generic product prior to the resolution of the Company's appeal.

(c) Data exclusivity in the EU expires in 2014 and market exclusivity expires between 2017 and 2019.

(d) 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. expired in 2013, but a method of use patent for the treatment of HIV infection expires 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.

(e) Exclusivity period relates to the Sustiva (efavirenz) 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.

(f) 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.

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

(h) Our rights to commercialize Abilify* (aripiprazole) in the U.S. terminate in 2015.

(i) Our rights to commercialize Abilify* in the EU terminate in June 2014.

(j) Exclusivity period is based on formulation patents.

(k) Exclusivity period is based on method of use patent.

(l) Data exclusivity in the EU expired in July 2008. In most of the major markets within Europe, the product has national patents, expired in 2013, which specifically claim the bisulfate form of clopidogrel. Generic and alternate salt forms of clopidogrel bisulfate are marketed and compete with Plavix* throughout the EU.

(m) In February 2014, BMS sold to AstraZeneca PLC (AstraZeneca) the diabetes business of BMS which comprised our global alliance with them, including all rights and ownership to Onglyza/Kombiglyze, Forxiga/Xigduo, Bydureon*, Byetta*, and Symlin*.

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 infection. Baraclude was discovered and developed internally.

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. An appeal is pending and a decision is expected in 2014. We may face generic competition with this product beginning in 2014. In December 2013, the FDA granted pediatric exclusivity for Baraclude. In the event that the Company is successful in its appeal, the composition of matter patent including the pediatric extension will expire in August 2015. The Company is prepared to take legal action in the event that Teva chooses to launch its generic product prior to the resolution of the Company's appeal. 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.

Entecavir is manufactured by both the company and a third party. The product is then finished in our 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 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 Sciences, Inc. (Gilead) to develop and commercialize a fixed-dose combination containing atazanavir and one of Gilead’s compounds in development.

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 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). For more information about our arrangement with Gilead, see "—Strategic 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, but a method of use patent for the treatment of HIV infection expires in September 2014, with an additional six month period of pediatric exclusivity added to the term of these patents.

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

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.

Erbitux*	Erbitux* (cetuximab) is an IgG1 monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor (EGFR), which is expressed on the surface of certain cancer cells in multiple tumor types as well as some normal cells. Erbitux*, a biological product, is approved 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 Erbitux* 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 Erbitux* for first-line recurrent locoregional or metastatic head and neck cancer in combination with platinum-based chemotherapy with 5-Fluorouracil.

Erbitux* is marketed in North America by us under an agreement with ImClone Systems Incorporated (ImClone), the predecessor company of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company (Lilly). We share copromotion rights to Erbitux* with Merck KGaA in Japan under a codevelopment and cocommercialization agreement signed in October 2007 with ImClone, Merck KGaA and Merck Serono Japan. Erbitux* received marketing approval in Japan in July 2008 for use in treating patients with advanced or recurrent colorectal cancer and in December 2012 for head and neck cancer. For a description of our alliance with ImClone, see "—Strategic Alliances" below and "Item 8. Financial Statements—Note 3. Alliances"

Data exclusivity for Erbitux*in the U.S. expires in 2016. There is no patent that specifically claims the composition of matter of cetuximab, the active molecule in Erbitux*. Erbitux* has been approved by the FDA and other health authorities for monotherapy, for which there is no use patent. The use of Erbitux* in combination with 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). 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 expires 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 Erbitux* that might not otherwise occur. We are unable to assess whether and to what extent any such competitive impact will occur or to quantify any such impact. However, Yeda has granted Amgen Inc. (Amgen) a license under the use patent. Amgen received FDA approval to market an EGFR-product that competes with Erbitux*.

We obtain our finished goods requirements for cetuximab for use in North America from Lilly. Lilly manufactures bulk requirements for cetuximab in its own facilities and 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 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).

Sprycel was internally discovered and is part of our strategic alliance with Otsuka. For more information about our alliance with Otsuka, see "—Strategic Alliances" below and "Item 8. Financial Statements—Note 3. Alliances"

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. In 2013, the Company entered into a settlement agreement with Apotex regarding

a patent infringement suit covering the monohydrate form of dasatinib whereby Apotex can launch its generic dasatinib monohydrate aNDA product in September 2024, or earlier in certain circumstances. In the U.S., orphan drug exclusivity expired in 2013, which protected 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 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. Yervoy 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). 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 in our facilities and at a third-party facility.

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), excluding Japan, China and certain other Asian countries. For more information about our arrangement with Otsuka, see "—Strategic Alliances" below and "Item 8. Financial Statements—Note 3. Alliances."

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 major EU countries. The original expiration date of 2009 has been extended to 2014 by grant of a supplementary protection certificate in most EU countries. Data exclusivity and the rights to commercialize in the EU expire in June 2014.

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

Bydureon*

Bydureon* (exenatide extended-release for injectable suspension) is a once-weekly glucagon-like peptide-1 (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, a former wholly-owned subsidiary of the Company. Prior to the sale of our diabetes business in February 2014, we had a worldwide development and commercialization agreement with AstraZeneca for Bydureon*. For more information about our arrangement with and the sale of our diabetes business to AstraZeneca, see "Item 8. Financial Statements—Note 3. Alliances" and "Item 8. Financial Statements—Note 5. Assets Held-For-Sale."

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

Prior to the sale of the diabetes business, we obtained the bulk requirements for exenatide from third parties and the microspheres manufacturing process required for the extended release formulation was performed by the Company. Following the sale of the diabetes business, AstraZeneca assumed all manufacturing and finishing responsibilities.

Byetta*

Byetta*(exenatide) is a twice daily 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, a former wholly-owned subsidiary of the Company. Prior to the sale of our diabetes business in February 2014, we had a worldwide development and commercialization agreement with AstraZeneca for Byetta*. For more information about our arrangement with and the sale of our diabetes business to AstraZeneca, see "Item 8. Financial Statements—Note 3. Alliances" and "Item 8. Financial Statements—Note 5. Assets Held-For-Sale."

The method of use patent expires in 2016 in the U.S. Data exclusivity expires in 2016 in Europe and 2018 in Japan.

Prior to the sale of the diabetes business, we obtained the bulk requirements for exenatide from third parties. Manufacturing and finishing also took place in third-party facilities. Following the sale of the diabetes business, AstraZeneca assumed all manufacturing and finishing responsibilities.

Forxiga

Forxiga (dapagliflozin) is an oral sodium-glucose cotransporter 2 (SGLT2) for the treatment of type 2 diabetes mellitus. Forxiga is marketed as Farxiga in the U.S. In this document unless specifically noted, we refer to both Forxiga and Farxiga as Forxiga.

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It was approved in the U.S. in January 2014 and in the EU in November 2012 for use in adults with type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise. For further discussion, See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Product and Pipeline Developments.” Forxiga was internally discovered. Prior to the sale of our diabetes business in February 2014, we had a worldwide development and commercialization agreement with AstraZeneca for Forxiga. For more information about our arrangement with and the sale of our diabetes business to AstraZeneca, see “Item 8. Financial Statements—Note 3. Alliances” and “Item 8. Financial Statements—Note 5. Assets Held-For-Sale.”

The composition of matter patent covering dapagliflozin expires in October 2020 in the U.S. and May 2023 in the EU. Prior to the sale of the diabetes business, we manufactured the bulk requirements for dapagliflozin and finished the product in our own facilities. Following the sale of the diabetes business, BMS will continue to manufacture the bulk requirement and finish the product pursuant to a supply arrangement that was agreed upon in connection with the sale of the diabetes business to AstraZeneca.

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. Prior to the sale of our diabetes business in February 2014, we had a worldwide (except Japan) codevelopment and cocommercialization agreement with AstraZeneca for saxagliptin. For more information about our arrangement with and the sale of our diabetes business to AstraZeneca and for our arrangement with Otsuka for Japan, see “—Strategic Alliances” below, “Item 8. Financial Statements—Note 3. Alliances” and “Item 8. Financial Statements—Not Assets Held-For-Sale.”

The composition of matter patent covering saxagliptin expires in July 2023 (including granted patent term extension) in the U.S. and expires in the EU in March 2021. In the EU, supplementary protection certificates have been granted for Onglyza in the majority of European countries which expire in October 2024. Supplementary protection certifications for Kombiglyze have been applied for and have been granted in France, Italy and Spain and the application is pending in a number of other European countries. Market exclusivity in China expires in 2016.

Following the sale of the diabetes business, BMS will continue to manufacture the bulk requirement and finish the product pursuant to a supply arrangement that was agreed upon in connection with the sale of the diabetes business to AstraZeneca.

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.

Orencia

Orencia (abatacept), a biological product, is a fusion protein with novel immunosuppressive activity targeted initially at adult patients with moderately to severely active 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 and has since been approved in the EU and other regions.

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 EU, the

composition of matter patent covering abatacept expired in 2012. In the majority of the EU countries, we have applied for supplementary protection certificates and also pediatric extension of the supplementary

protection certificates for protection until 2017. Most of these protection certificates have been granted. Data exclusivity expires in 2017 in the U.S. and the EU and 2018 in Japan.

Bulk abatacept is manufactured by both the Company and a third party. We finish both formulations of the product in our own facilities.

See "—Strategic Alliances" below for further discussion of our collaborations with Ono Pharmaceutical Co., LTD. (Ono) for Orencia in Japan.

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" below and "Item 8. Financial Statements—Note 3. Alliances."

The composition of matter patent expired in the U.S. in March 2012 and in most countries in the EU in 2012 and 2013. Data exclusivity in the EU expired in August 2007 for Avapro* and in October 2008 for Avalide*.

Both the Company and Sanofi manufacture bulk requirements for irbesartan and finishing is performed by Sanofi. 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. 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."

The composition of matter patent covering apixaban in the U.S. expires in February 2023 (excluding potential patent term extensions) and in the EU and 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.

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

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" below and "Item 8. Financial Statements—Note 3. Alliances."

The composition of matter patent in the U.S. expired in May 2012. In the EU, regulatory data exclusivity protection expired in July 2008. In Europe, national patents, which specifically claim the bisulfate form of clopidogrel, expired in 2013. Plavix faces generic competition globally.

We obtain our bulk requirements for clopidogrel bisulfate from Sanofi. Prior to January 1, 2013, both the Company and Sanofi finished the product in their own respective facilities. Effective January 1, 2013, the Company no longer finishes clopidogrel bisulfate in our 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 New Jersey and Connecticut. 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 which help us bring new products into the pipeline. 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 research and development efforts in the following disease areas with significant unmet medical needs: oncology, Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS), hepatitis, immunologic disorders, cardiovascular 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 volunteers 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 fourteen years or longer, with approximately three years often spent in Phase III, or late-stage, development. We consider our R&D programs in Phase III 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 2008-2012, 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 49%.

Total research and development expenses include the costs of discovery research, preclinical development, early- and late-stage 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 $3.7 billion in 2013, $3.9 billion in 2012 and $3.8 billion in 2011 and includes payments under third-party collaborations and contracts. At the end of 2013, 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 represented approximately 30-45% of our annual R&D expenses in the last three years. 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 or under regulatory review for at least one potential indication. Whether or not any of these or our other investigational compounds ultimately becomes one of our marketed products depends on the results of clinical studies, the competitive landscape of the potential product's market and the manufacturing processes necessary to produce the potential product on a commercial scale, among other factors. However, as noted above, there can be no assurance that we will seek regulatory approval of any of these compounds or that, if such approval is sought, it will be obtained. There is also no assurance that a compound that is approved will be commercially successful. At this stage of development, we cannot determine all intellectual property issues or all the patent protection that may, or may not, be available for these investigational compounds. The patent coverage highlighted below includes patent terms and 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, and is currently in the registrational process in Japan. We own a patent covering asunaprevir as a composition of matter that expires in 2023 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 and is currently in the registrational process in Japan and the EU. We own a patent covering daclatasvir as a composition of matter that expires in 2028 in the U.S.
BMS-791325	BMS-791325 is an oral small molecule non-nucleoside NS5B inhibitor in Phase III development (which commenced in 2013) for the treatment of hepatitis C virus infection. We own a patent covering BMS-791235 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 jointly own a patent with Ono covering nivolumab as a composition of matter that expires in 2027 in the U.S. The FDA has granted Fast Track designation for nivolumab in three tumor types: non-small-cell lung cancer, renal cell carcinoma and advanced melanoma.

In February 2014, BMS sold to AstraZeneca the diabetes business of BMS which comprised our global alliance with them, including all rights and ownership to metreleptin. Metreleptin is a protein in development for the treatment of lipodystrophy and is currently in the registrational process.

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:

Key marketed product	Potential indication and/or formulation
Baraclude	Pediatric extension (EU)
Reyataz	Pediatric extension Fixed dose combination with cobicistat in additional formulations
Erbitux*	Additional indication in esophageal cancer
Yervoy	Additional indications in adjuvant melanoma, prostate cancer, non-small-cell lung cancer and small cell lung cancer Additional indication in melanoma in combination with nivolumab
Orencia	Additional indications in lupus nephritis and psoriatic arthritis
Eliquis	Additional indication for VTE treatment and VTE prevention (U.S.)

The following key developments are currently expected to occur during 2014 with respect to our significant pipeline programs. The outcome and timing of these expected developments are dependent upon a number of factors