

BRISTOL MYERS SQUIBB CO
Form 10-Q
October 27, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q
(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934 FOR THE TRANSITION PERIOD FROM TO
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 (I.R.S. Employer
incorporation or organization) Identification No.)

345 Park Avenue, New York, N.Y. 10154
(Address of principal executive offices) (Zip Code)

(212) 546-4000
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 the 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

At September 30, 2016, there were 1,671,229,946 shares outstanding of the Registrant's \$0.10 par value common stock.

BRISTOL-MYERS SQUIBB COMPANY
INDEX TO FORM 10-Q
SEPTEMBER 30, 2016

PART I—FINANCIAL INFORMATION

Item 1.

Financial Statements:

Consolidated Statements of Earnings and Comprehensive Income 3

Consolidated Balance Sheets 4

Consolidated Statements of Cash Flows 5

Notes to Consolidated Financial Statements 6

Item 2.

Management’s Discussion and Analysis of Financial Condition and Results of Operations 22

Item 3.

Quantitative and Qualitative Disclosure About Market Risk 34

Item 4.

Controls and Procedures 34

PART II—OTHER INFORMATION

Item 1.

Legal Proceedings 34

Item 1A.

Risk Factors 34

Item 2.

Issuer Purchases of Equity Securities 35

Item 6.

Exhibits 36

Signatures 37

PART I—FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

BRISTOL-MYERS SQUIBB COMPANY

CONSOLIDATED STATEMENTS OF EARNINGS

Dollars in Millions, Except Per Share Data

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
EARNINGS				
Net product sales	\$4,492	\$3,552	\$12,888	\$10,183
Alliance and other revenues	430	517	1,296	2,090
Total Revenues	4,922	4,069	14,184	12,273
Cost of products sold	1,305	1,097	3,563	2,957
Marketing, selling and administrative	1,144	1,176	3,450	3,340
Research and development	1,138	1,132	3,540	4,004
Other (income)/expense	(224)	(323)	(1,198)	(515)
Total Expenses	3,363	3,082	9,355	9,786
Earnings Before Income Taxes	1,559	987	4,829	2,487
Provision for Income Taxes	344	257	1,220	668
Net Earnings	1,215	730	3,609	1,819
Net Earnings Attributable to Noncontrolling Interest	13	24	46	57
Net Earnings Attributable to BMS	\$1,202	\$706	\$3,563	\$1,762
Earnings per Common Share				
Basic	\$0.72	\$0.42	\$2.13	\$1.06
Diluted	\$0.72	\$0.42	\$2.12	\$1.05
Cash dividends declared per common share	\$0.38	\$0.37	\$1.14	\$1.11

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Dollars in Millions

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
COMPREHENSIVE INCOME				
Net Earnings	\$1,215	\$730	\$3,609	\$1,819
Other Comprehensive Income/(Loss), net of taxes and reclassifications to earnings:				
Derivatives qualifying as cash flow hedges	4	(46)	(126)	(49)
Pension and postretirement benefits	72	(131)	(213)	131
Available-for-sale securities	(8)	(16)	46	(22)
Foreign currency translation	1	(29)	26	(30)
Other Comprehensive Income/(Loss)	69	(222)	(267)	30

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

Comprehensive Income	1,284	508	3,342	1,849
Comprehensive Income Attributable to Noncontrolling Interest	13	24	46	57
Comprehensive Income Attributable to BMS	\$1,271	\$484	\$3,296	\$1,792

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

3

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED BALANCE SHEETS

Dollars in Millions, Except Share and Per Share Data(UNAUDITED)

	September 30, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,432	\$ 2,385
Marketable securities	2,128	1,885
Receivables	5,597	4,299
Inventories	1,482	1,221
Prepaid expenses and other	565	625
Total Current Assets	13,204	10,415
Property, plant and equipment	4,790	4,412
Goodwill	6,875	6,881
Other intangible assets	1,377	1,419
Deferred income taxes	3,528	2,844
Marketable securities	3,035	4,660
Other assets	918	1,117
Total Assets	\$ 33,727	\$ 31,748

LIABILITIES

Current Liabilities:

Short-term borrowings and current portion of long-term debt	\$ 990	\$ 139
Accounts payable	1,407	1,565
Accrued liabilities	4,964	4,738
Deferred income	1,323	1,003
Income taxes payable	312	572
Total Current Liabilities	8,996	8,017
Deferred income	567	586
Income taxes payable	905	742
Pension and other liabilities	1,642	1,429
Long-term debt	5,836	6,550
Total Liabilities	17,946	17,324

Commitments and contingencies (Note 18)

EQUITY

Bristol-Myers Squibb Company Shareholders' Equity:

Preferred stock, \$2 convertible series, par value \$1 per share: Authorized 10 million shares; 4,161 issued	—	—
and outstanding in both 2016 and 2015, 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 2016 and 2015	221	221
Capital in excess of par value of stock	1,650	1,459
Accumulated other comprehensive loss	(2,735)	(2,468)
Retained earnings	33,272	31,613
Less cost of treasury stock – 537 million common shares in 2016 and 539 million in 2015	(16,795)	(16,559)
Total Bristol-Myers Squibb Company Shareholders' Equity	15,613	14,266

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

Noncontrolling interest	168	158
Total Equity	15,781	14,424
Total Liabilities and Equity	\$ 33,727	\$ 31,748

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

4

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED STATEMENTS OF CASH FLOWS

Dollars in Millions
(UNAUDITED)

	Nine Months Ended September 30,	
	2016	2015
Cash Flows From Operating Activities:		
Net earnings	\$3,609	\$1,819
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Depreciation and amortization, net	260	300
Deferred income taxes	(500)	51
Stock-based compensation	149	176
Impairment charges	75	24
Pension settlements and amortization	122	178
Divestiture gains and royalties	(1,082)	(565)
Asset acquisition charges	274	813
Other adjustments	(56)	(17)
Changes in operating assets and liabilities:		
Receivables	(896)	(586)
Inventories	(107)	231
Accounts payable	(142)	(1,218)
Deferred income	445	153
Income taxes payable	(262)	77
Other	(467)	(215)
Net Cash Provided by Operating Activities	1,422	1,221
Cash Flows From Investing Activities:		
Sale and maturities of marketable securities	3,674	2,449
Purchase of marketable securities	(2,248)	(2,283)
Capital expenditures	(844)	(535)
Divestiture and other proceeds	1,193	673
Acquisition and other payments	(311)	(892)
Net Cash Provided by/(Used in) Investing Activities	1,464	(588)
Cash Flows From Financing Activities:		
Short-term borrowings, net	102	54
Issuance of long-term debt	—	1,268
Repayment of long-term debt	—	(1,957)
Interest rate swap contract terminations	42	(2)
Issuance of common stock	144	231
Repurchase of common stock	(231)	—
Dividends	(1,912)	(1,859)
Net Cash Used in Financing Activities	(1,855)	(2,265)
Effect of Exchange Rates on Cash and Cash Equivalents	16	36
Increase/(Decrease) in Cash and Cash Equivalents	1,047	(1,596)
Cash and Cash Equivalents at Beginning of Period	2,385	5,571
Cash and Cash Equivalents at End of Period	\$3,432	\$3,975

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

Note 1. BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING STANDARDS

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS or the Company) prepared these unaudited consolidated financial statements following the requirements of the Securities and Exchange Commission (SEC) and United States (U.S.) generally accepted accounting principles (GAAP) for interim reporting. Under those rules, certain footnotes and other financial information that are normally required for annual financial statements can be condensed or omitted. The Company is responsible for the consolidated financial statements included in this Form 10-Q, which include all adjustments necessary for a fair presentation of the financial position at September 30, 2016 and December 31, 2015, the results of operations for the three and nine months ended September 30, 2016 and 2015, and cash flows for the nine months ended September 30, 2016 and 2015. All intercompany balances and transactions have been eliminated. These financial statements and the related notes should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2015 included in the Annual Report on Form 10-K.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Accordingly, the results and trends in these unaudited consolidated financial statements may not be indicative of full year operating results. 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; estimated selling prices used in multiple element arrangements; and pension and postretirement benefits. Actual results may differ from estimates.

Certain prior period amounts were reclassified to conform to the current period presentation. The reclassifications provide a more concise financial statement presentation and additional information is disclosed in the notes if material.

	Prior Presentation	Current Presentation
Consolidated Statements of Earnings	Advertising and product promotion	Included in Marketing, selling and administrative expenses
	Assets held-for-sale	Included in Prepaid expenses and other
	Accrued expenses	Combined as Accrued liabilities
	Accrued rebates and returns	
Consolidated Balance Sheets	Dividends payable	Combined as Pension and other liabilities
	Pension, postretirement and postemployment liabilities	
	Other liabilities	
	Net earnings attributable to noncontrolling interest	Included in Other adjustments
Consolidated Statements of Cash Flows	Divestiture gains and royalties included in Other adjustments	Divestiture gains and royalties
	Asset acquisition charges included in Other adjustments	Asset acquisition charges

In October 2016, the Financial Accounting Standards Board (FASB) issued amended guidance on income tax accounting for intra-entity transfers of assets other than inventory. The amended guidance requires that the tax consequences of transfers of assets between members of a consolidated group be recognized in the period the transfer takes place (excluding inventory). The guidance is effective beginning with interim periods in 2018 with early adoption permitted in the first quarter of 2017 on a modified retrospective approach. The Company is assessing the potential impact of the new standard.

In June 2016, the FASB issued amended guidance for the measurement of credit losses on financial instruments. Entities will be required to use a forward-looking estimated loss model. Available-for-sale debt security credit losses will be recognized as allowances rather than a reduction in amortized cost. The guidance is effective beginning with interim periods in 2020 with early adoption permitted in 2019 on a modified retrospective approach. The Company is assessing the potential impact of the new standard.

In March 2016, the FASB issued amended guidance for share-based payment transactions. Excess tax benefits and deficiencies will be recognized in the consolidated statement of earnings rather than capital in excess of par value of stock on a prospective basis. A policy election will be available to account for forfeitures as they occur, with the cumulative effect of the change recognized as an adjustment to retained earnings at the date of adoption. Excess tax benefits within the consolidated statement of cash flows will be presented as an operating activity (prospective or retrospective application) and cash payments to tax authorities in connection with shares withheld for statutory tax withholding requirements will be presented as a financing activity (retrospective application). The guidance is effective beginning with interim periods in 2017 with early adoption permitted. The Company is assessing the potential impact of the new standard.

In February 2016, the FASB issued amended guidance on lease accounting. The amended guidance requires the recognition of a right-of-use asset and a lease liability, initially measured at the present value of the lease payments for leases with a term longer than 12 months. The guidance is effective beginning with interim periods in 2019 with early adoption permitted on a modified retrospective approach. The Company is assessing the potential impact of the new standard.

In January 2016, the FASB issued amended guidance for the recognition, measurement, presentation and disclosures of financial instruments effective January 1, 2018 with early adoption not permitted. The new guidance requires that fair value adjustments for equity securities with readily determinable fair values currently classified as available-for-sale be reported through earnings. The new guidance also requires a qualitative impairment assessment for equity investments without a readily determinable fair value and a charge through earnings if an impairment exists. The Company is assessing the potential impact of the new standard.

In May 2014, the FASB issued a new standard related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2018. Early adoption is permitted no earlier than 2017. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application in retained earnings. The Company is assessing the potential impact of the new standard and has not yet selected a transition method.

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 responsible for the discovery, development, manufacturing and supply of products. Regional commercial organizations market, distribute and sell the products. The business is also supported by global corporate staff functions. Segment information is consistent with the financial information regularly reviewed by the chief executive officer for purposes of evaluating performance, allocating resources, setting incentive compensation targets and planning and forecasting future periods.

Product revenues were as follows:

Dollars in Millions	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Oncology				
Empliciti (elotuzumab)	\$41	\$—	\$103	\$—
Erbitux* (cetuximab)	—	167	—	501
Opdivo (nivolumab)	920	305	2,464	467
Sprycel (dasatinib)	472	411	1,330	1,191
Yervoy (ipilimumab)	285	240	789	861
Cardiovascular				
Eliquis (apixaban)	884	466	2,395	1,258
Immunoscience				
Orencia (abatacept)	572	484	1,640	1,345
Virology				
Baraclude (entecavir)	306	320	896	1,003
Hepatitis C Franchise	379	402	1,352	1,145
Reyataz (atazanavir sulfate) Franchise	238	270	706	867
Sustiva (efavirenz) Franchise	275	333	819	940
Neuroscience				
Abilify* (aripiprazole)	29	46	97	707
Mature Products and All Other	521	625	1,593	1,988
Total Revenues	\$4,922	\$4,069	\$14,184	\$12,273

* Indicates brand names of products which are trademarks not owned or wholly owned by BMS. Specific trademark ownership information is included at the end of this quarterly report on Form 10-Q.

The composition of total revenues was as follows:

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,	30,	September 30,	30,
Dollars in Millions	2016	2015	2016	2015
Net product sales	\$4,492	\$3,552	\$12,888	\$10,183
Alliance revenues	402	496	1,229	2,003
Other revenues	28	21	67	87
Total Revenues	\$4,922	\$4,069	\$14,184	\$12,273

7

Note 3. ALLIANCES

BMS enters into collaboration arrangements with third parties for the development and commercialization of certain products. Although each of these arrangements is unique in nature, both parties are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities. BMS may either in-license intellectual property owned by the other party or out-license its intellectual property to the other party. These arrangements also typically include research, development, manufacturing and/or commercial activities and can cover a single investigational compound or commercial product or multiple compounds and/or products in various life cycle stages. The rights and obligations of the parties can be global or limited to geographic regions. We refer to these collaborations as alliances and our partners as alliance partners. Products sold through alliance arrangements in certain markets include Empliciti, Erbitux*, Opdivo, Sprycel, Yervoy, Eliquis, Orencia, Sustiva (Atripla*), Abilify* and certain mature and other brands.

Selected financial information pertaining to our alliances was as follows, including net product sales when BMS is the principal in the third-party customer sale for products subject to the alliance. Expenses summarized below do not include all amounts attributed to the activities for the products in the alliance, but only the payments between the alliance partners or the related amortization if the payments were deferred or capitalized.

Dollars in Millions	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues from alliances:				
Net product sales	\$1,465	\$981	\$4,031	\$3,203
Alliance revenues	402	496	1,229	2,003
Total Revenues	\$1,867	\$1,477	\$5,260	\$5,206
Payments to/(from) alliance partners:				
Cost of products sold	\$572	\$445	\$1,543	\$1,257
Marketing, selling and administrative	(3)	4	(10)	26
Research and development	(7)	89	23	277
Other (income)/expense	(160)	(173)	(864)	(622)
Noncontrolling interest, pre-tax	3	17	13	45

Selected Alliance Balance Sheet information:

Dollars in Millions	September 30, 2016	December 31, 2015
Receivables - from alliance partners	\$ 1,085	\$ 958
Accounts payable - to alliance partners	550	542
Deferred income from alliances	1,414	1,459

Specific information pertaining to each of our significant alliances is discussed in our 2015 Form 10-K, including their nature and purpose, the significant rights and obligations of the parties and specific accounting policy elections.

Note 4. ACQUISITIONS AND DIVESTITURES

Acquisitions

In July 2016, BMS acquired all of the outstanding shares of Cormorant Pharmaceuticals (Cormorant), a private pharmaceutical company focused on the development of therapies for cancer and rare diseases. The acquisition

provides BMS with full rights to Cormorant's lead candidate HuMax-IL8, a Phase I/II monoclonal antibody that represents a potentially complementary immuno-oncology mechanism of action to T-cell directed antibodies and co-stimulatory molecules. The consideration includes an upfront payment of \$35 million and contingent development and regulatory milestone payments of up to \$485 million. No significant Cormorant processes were acquired, therefore the transaction was accounted for as an asset acquisition because Cormorant was determined not to be a business as that term is defined in ASC 805 - Business Combinations. The consideration was allocated to HuMax-IL8 resulting in \$35 million of research and development expenses.

In April 2016, BMS acquired all of the outstanding shares of Padlock Therapeutics, Inc. (Padlock), a private biotechnology company dedicated to creating new medicines to treat destructive autoimmune diseases. The acquisition provides BMS with full rights to Padlock's Protein/Peptidyl Arginine Deiminase (PAD) inhibitor discovery program focused on the development of potentially transformational treatment approaches for patients with rheumatoid arthritis. Padlock's PAD discovery program may have additional utility in treating systemic lupus erythematosus and other autoimmune diseases. The consideration includes an upfront payment of \$150 million and contingent development and regulatory milestone payments of up to \$450 million. No significant Padlock processes were acquired, therefore the transaction was accounted for as an asset acquisition because Padlock was determined not to be a business. The consideration was allocated to the PAD discovery program resulting in \$139 million of research and development expenses and to net operating losses and tax credit carryforwards resulting in \$11 million of deferred tax assets.

Divestitures

In May 2016, BMS sold the business comprising an alliance with Reckitt Benckiser Group plc (Reckitt) for proceeds of \$317 million, resulting in a gain of \$277 million. Reckitt initially exercised its option to acquire the business in July 2015, which included several over-the-counter products sold primarily in Mexico and Brazil, as well as a manufacturing facility and related employees.

In February 2016, BMS sold its investigational HIV medicines business to ViiV Healthcare which includes a number of programs at different stages of discovery, preclinical and clinical development. The transaction excluded BMS's HIV marketed medicines. BMS will provide certain R&D and other services over a transitional period. In February 2016, BMS received an upfront payment of \$350 million, resulting in a gain of \$272 million. BMS will also receive from ViiV Healthcare contingent development and regulatory milestone payments of up to \$1.1 billion, sales-based milestone payments of up to \$4.3 billion and future tiered royalties if the products are approved and commercialized.

Assets held-for-sale from the businesses discussed above were \$134 million at December 31, 2015 and included in prepaid expenses and other. The amount consisted primarily of allocated goodwill relating to the businesses. The allocation of goodwill was determined using the relative fair value of the applicable businesses to the Company's reporting unit. Revenues and pretax earnings related to these businesses were not material in 2016 and 2015 (excluding the divestiture gains).

Note 5. OTHER (INCOME)/EXPENSE

	Three Months		Nine Months	
	Ended		Ended	
Dollars in Millions	September 30,	September 30,	September 30,	September 30,
	2016	2015	2016	2015
Interest expense	\$42	\$41	\$127	\$141
Investment income	(32)	(18)	(81)	(74)
Provision for restructuring	19	10	41	50
Litigation and other settlements	(1)	(2)	48	14
Equity in net income of affiliates	(19)	(19)	(65)	(67)
Divestiture gains	(21)	(208)	(574)	(370)
Royalties and licensing income	(158)	(63)	(579)	(258)
Transition and other service fees	(57)	(37)	(184)	(91)
Pension charges	19	48	66	111
Out-licensed intangible asset impairment	—	—	15	13
Equity investment impairment	—	—	45	—
Written option adjustment	—	(87)	—	(123)
Loss on debt redemption	—	—	—	180

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

Other	(16)	12	(57)	(41)
Other (income)/expense	\$(224)	\$(323)	\$(1,198)	\$(515)

9

Note 6. INCOME TAXES

	Three Months		Nine Months	
	Ended September		Ended September	
Dollars in Millions	30,	30,	30,	30,
	2016	2015	2016	2015
Earnings Before Income Taxes	\$ 1,559	\$ 987	\$ 4,829	\$ 2,487
Provision for Income Taxes	344	257	1,220	668
Effective tax rate	22.1	% 26.0	% 25.3	% 26.9

The effective tax rate is lower than the U.S. statutory rate of 35% primarily attributable to undistributed earnings of certain foreign subsidiaries in low tax jurisdictions that have been considered or are expected to be indefinitely reinvested offshore. These undistributed earnings primarily relate to operations in Switzerland, Ireland and Puerto Rico. If these undistributed earnings are repatriated to the U.S. in the future, or if it were determined that such earnings are to be remitted in the foreseeable future, additional tax provisions would be required. 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 would have to be provided. Reforms to U.S. tax laws related to foreign earnings have been proposed and if adopted, may increase taxes, which could reduce the results of operations and cash flows. BMS operates under a favorable tax grant in Puerto Rico not scheduled to expire prior to 2023.

The jurisdictional tax rates and other tax impacts attributed to research and development charges, divestiture transactions and other discrete items increased the effective tax rate by 3.1% and 4.4% in the nine months ended September 30, 2016 and 2015, respectively. The taxes attributed to these items were impacted by non-deductible R&D charges for Padlock, Flexus Biosciences, Inc. (Flexus) and Cormorant in 2016 and Flexus in 2015, higher non-deductible goodwill allocated to business divestitures in 2016 and higher valuation allowances attributed to capital loss carryforwards released in 2015. The tax impact for discrete items are reflected immediately and are not considered in estimating the annual effective tax rate.

To a lesser extent, unfavorable earnings mix between high and low tax jurisdictions and favorable R&D tax credits also impacted the effective tax rates. The R&D tax credit legislation was permanently extended in December 2015 and was included in estimating the annual effective tax rate in 2016. The R&D tax credit was not extended as of September 30, 2015, therefore the tax credit was not considered in estimating the annual effective tax rate in 2015.

BMS is currently under examination by a number of tax authorities which have proposed or are considering proposing material adjustments to tax positions for issues such as transfer pricing, certain tax credits and the deductibility of certain expenses. It is reasonably possible that the total amount of unrecognized tax benefits at September 30, 2016 could decrease in the range of approximately \$265 million to \$325 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 may result in the payment of additional taxes, adjustment of certain deferred taxes and/or recognition of tax benefits. It is also reasonably possible that new issues will be raised by tax authorities which may require adjustments to the amount of unrecognized tax benefits; however, an estimate of such adjustments cannot reasonably be made at this time.

Note 7. EARNINGS PER SHARE

	Three Months		Nine Months	
	Ended		Ended	
Amounts in Millions, Except Per Share Data	September	September	September	September
	30,	30,	30,	30,
	2016	2015	2016	2015
Net Earnings Attributable to BMS used for Basic and Diluted EPS Calculation	\$ 1,202	\$ 706	\$ 3,563	\$ 1,762

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

Weighted-average common shares outstanding – basic	1,671	1,668	1,670	1,666
Incremental shares attributable to share-based compensation plans	8	10	9	11
Weighted-average common shares outstanding – diluted	1,679	1,678	1,679	1,677

Earnings per Common Share:

Basic	\$0.72	\$0.42	\$2.13	\$1.06
Diluted	\$0.72	\$0.42	\$2.12	\$1.05

10

Note 8. FINANCIAL INSTRUMENTS AND FAIR VALUE MEASUREMENTS

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

Dollars in Millions	September 30, 2016		December 31, 2015	
	Level 1	Level 2 Total	Level 1	Level 2 Total
Cash and cash equivalents - Money market and other securities	\$—	\$2,835	\$—	\$1,825
Marketable securities:				
Certificates of deposit	—469	469	—804	804
Commercial paper	—540	540	—	—
Corporate debt securities	—4,046	4,046	—5,638	5,638
Equity funds	—101	101	—92	92
Fixed income funds	—7	7	—11	11
Derivative assets:				
Interest rate swap contracts	—8	8	—31	31
Forward starting interest rate swap contracts	—	—	—15	15
Foreign currency forward contracts	—20	20	—50	50
Equity investments	34	34	60	60
Derivative liabilities:				
Interest rate swap contracts	—	—	—(1)	(1)
Forward starting interest rate swap contracts	—(102)	(102)	—(7)	(7)
Foreign currency forward contracts	—(42)	(42)	—(10)	(10)

As further described in "Note 10. Financial Instruments and Fair Value Measurements" in our 2015 Form 10-K, our fair value estimates use inputs that are either (1) quoted prices for identical assets or liabilities in active markets (Level 1 inputs), (2) observable prices for similar assets or liabilities in active markets or for identical or similar assets or liabilities in markets that are not active (Level 2 inputs) or (3) unobservable inputs (Level 3 inputs). There were no Level 3 financial assets or liabilities as of September 30, 2016 and December 31, 2015.

Available-for-sale Securities

The following table summarizes available-for-sale securities:

Dollars in Millions	Amortized Cost	Gross Unrealized Gain in Accumulated OCI	Gross Unrealized Loss in Accumulated OCI	Fair Value
September 30, 2016				
Certificates of deposit	\$ 469	\$ —	\$ —	\$469
Commercial paper	540	—	—	540
Corporate debt securities	4,011	36	(1)	4,046
Equity investments	31	4	(1)	34
Total	\$ 5,051	\$ 40	\$ (2)	\$5,089
December 31, 2015				
Certificates of deposit	\$ 804	\$ —	\$ —	\$804
Corporate debt securities	5,646	15	(23)	5,638
Equity investments	74	10	(24)	60
Total	\$ 6,524	\$ 25	\$ (47)	\$6,502

Dollars in Millions

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

	September 30, December 31,	
	2016	2015
Current marketable securities ^(a)	\$ 2,128	\$ 1,885
Non-current marketable securities ^(b)	3,035	4,660
Other assets	34	60
Available-for-sale securities	\$ 5,197	\$ 6,605

The fair value option for financial assets was elected for investments in equity and fixed income funds. The fair (a) value of these investments were \$108 million at September 30, 2016 and \$103 million at December 31, 2015 and were included in current marketable securities.

(b) All non-current marketable securities mature within five years as of September 30, 2016 and December 31, 2015.

Qualifying Hedges and Non-Qualifying Derivatives

The following table summarizes the fair value of outstanding derivatives:

Dollars in Millions	Balance Sheet Location	September 30, 2016		December 31, 2015	
		Notional	Fair Value	Notional	Fair Value
Derivatives designated as hedging instruments:					
Interest rate swap contracts	Other assets	\$ 1,250	\$ 8	\$ 1,100	\$ 31
Interest rate swap contracts	Pension and other liabilities	—	—	650	(1)
Forward starting interest rate swap contracts	Other assets	—	—	500	15
Forward starting interest rate swap contracts	Accrued liabilities	750	(102)	—	—
Forward starting interest rate swap contracts	Pension and other liabilities	—	—	250	(7)
Foreign currency forward contracts	Prepaid expenses and other	415	18	1,016	50
Foreign currency forward contracts	Accrued liabilities	748	(40)	342	(5)
Derivatives not designated as hedging instruments:					
Foreign currency forward contracts	Prepaid expenses and other	188	2	—	—
Foreign currency forward contracts	Accrued liabilities	360	(2)	445	(5)

Cash Flow Hedges — The notional amount of outstanding foreign currency forward contracts was primarily attributed to the euro (\$517 million) and Japanese yen (\$360 million) at September 30, 2016.

Net Investment Hedges — Non-U.S. dollar borrowings of €950 million (\$1,066 million) are designated to hedge euro currency exposures of the net investment in certain foreign affiliates.

Fair Value Hedges — The notional amount of fixed-to-floating interest rate swap contracts terminated was \$500 million in 2016 and \$147 million in 2015 generating proceeds of \$43 million in 2016 and \$28 million in 2015 (including accrued interest).

Debt Obligations

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

Dollars in Millions	September 30, 2016	December 31, 2015
Principal Value	\$ 6,367	\$ 6,339
Adjustments to Principal Value:		
Fair value of interest rate swap contracts	8	30
Unamortized basis adjustment from swap terminations	294	272
Unamortized bond discounts and issuance costs	(84)	(91)
Total	\$ 6,585	\$ 6,550
Current portion of long-term debt	\$ 749	\$ —
Long-term debt	\$ 5,836	\$ 6,550

The fair value of debt was \$7,493 million at September 30, 2016 and \$6,909 million at December 31, 2015 valued using Level 2 inputs. Interest payments were \$140 million and \$158 million for the nine months ended September 30, 2016 and 2015, respectively, net of amounts related to interest rate swap contracts.

The following summarizes the issuance and redemption of long-term debt obligations in 2015 (none in 2016) and related termination of interest rate swap contracts:

Amounts in Millions	2015	
	Euro	U.S. dollars
Principal Value:		
1.000% Euro Notes due 2025	€75	\$643
1.750% Euro Notes due 2035	575	643
Total	€1,150	\$1,286
Proceeds net of discount and deferred loan issuance costs	€1,133	\$1,268

Forward starting interest rate swap contracts terminated:

Notional amount	€00	\$559
Unrealized loss	(16)	(18)
Dollars in Millions	2015	
Principal amount	\$1,624	
Carrying value	1,795	
Debt redemption price	1,957	
Notional amount of interest rate swap contracts terminated	735	
Interest rate swap contract termination payments	11	
Loss on debt redemption ^(a)	180	

(a) Including acceleration of debt issuance costs, loss on interest rate lock contract and other related fees.

Note 9. RECEIVABLES

Dollars in Millions	September 30, December 31,	
	2016	2015
Trade receivables	\$ 3,963	\$ 3,070
Less allowances	(150)	(122)
Net trade receivables	3,813	2,948
Alliance receivables	1,085	958
Prepaid and refundable income taxes	444	182
Other	255	211
Receivables	\$ 5,597	\$ 4,299

Non-U.S. receivables sold on a nonrecourse basis were \$470 million and \$327 million for the nine months ended September 30, 2016 and 2015, respectively. Receivables from our three largest pharmaceutical wholesalers in the U.S. represented 63% and 53% of total trade receivables at September 30, 2016 and December 31, 2015, respectively.

Note 10. INVENTORIES

Dollars in Millions	September 30, December 31,	
	2016	2015
Finished goods	\$ 416	\$ 381
Work in process	952	868
Raw and packaging materials	265	199
Total inventories	\$ 1,633	\$ 1,448
Inventories	\$ 1,482	\$ 1,221

Other assets 151 227

Other assets include inventory pending regulatory approval of \$80 million at September 30, 2016 and \$85 million at December 31, 2015 and other amounts expected to remain on-hand beyond one year.

13

Note 11. PROPERTY, PLANT AND EQUIPMENT

Dollars in Millions	September 30, December 31,	
	2016	2015
Land	\$ 107	\$ 107
Buildings	4,724	4,515
Machinery, equipment and fixtures	3,194	3,347
Construction in progress	906	662
Gross property, plant and equipment	8,931	8,631
Less accumulated depreciation	(4,141)	(4,219)
Property, plant and equipment	\$ 4,790	\$ 4,412

Depreciation expense was \$319 million and \$393 million for the nine months ended September 30, 2016 and 2015, respectively.

Note 12. OTHER INTANGIBLE ASSETS

Dollars in Millions	September 30, December 31,	
	2016	2015
Licenses	\$ 554	\$ 574
Developed technology rights	2,357	2,357
Capitalized software	1,393	1,302
In-process research and development	120	120
Gross other intangible assets	4,424	4,353
Less accumulated amortization	(3,047)	(2,934)
Other intangible assets	\$ 1,377	\$ 1,419

Amortization expense was \$134 million and \$140 million for the nine months ended September 30, 2016 and 2015, respectively.

Note 13. ACCRUED LIABILITIES

Dollars in Millions	September 30, December 31,	
	2016	2015
Accrued rebates and returns	\$ 1,636	\$ 1,324
Employee compensation and benefits	715	904
Dividends payable	642	655
Accrued research and development	586	553
Royalties	189	161
Litigation and other settlements	123	189
Restructuring	60	89
Pension and postretirement benefits	47	47
Other	966	816
Accrued liabilities	\$ 4,964	\$ 4,738

Note 14. DEFERRED INCOME

Dollars in Millions	September 30, 2016	December 31, 2015
Alliances	\$ 1,414	\$ 1,459
Other	476	130
Total deferred income	\$ 1,890	\$ 1,589
Current portion	\$ 1,323	\$ 1,003
Non-current portion	567	586

Alliances include unamortized upfront, milestone and other licensing proceeds, revenue deferrals attributed to Atripla* and undelivered elements of diabetes business divestiture proceeds. As of September 30, 2016, other deferred income includes approximately \$265 million of Opdivo product sale deferrals under an early access program in France which began in 2015. The amount of net product sales to be realized is subject to final price negotiations with the French government. Amortization of deferred income was \$193 million and \$233 million for the nine months ended September 30, 2016 and 2015, respectively.

Note 15. EQUITY

Dollars and Shares in Millions	Common Stock Shares	Par Value	Capital in Excess of Par Value of Stock	Retained Earnings	Treasury Stock Share	Cost	Noncontrolling Interest
Balance at January 1, 2015	2,208	\$ 221	\$ 1,507	\$32,541	547	\$(16,992)	\$ 131
Net earnings	—	—	—	1,762	—	—	73
Cash dividends declared	—	—	—	(1,857)	—	—	—
Employee stock compensation plans	—	—	(94)	—	(7)	384	—
Debt conversion	—	—	—	—	—	2	—
Distributions	—	—	—	—	—	—	(10)
Balance at September 30, 2015	2,208	\$ 221	\$ 1,413	\$32,446	540	\$(16,606)	\$ 194
Balance at January 1, 2016	2,208	\$ 221	\$ 1,459	\$31,613	539	\$(16,559)	\$ 158
Net earnings	—	—	—	3,563	—	—	46
Cash dividends declared	—	—	—	(1,904)	—	—	—
Stock repurchase program	—	—	—	—	4	(231)	—
Employee stock compensation plans	—	—	191	—	(6)	(5)	—
Distributions	—	—	—	—	—	—	(36)
Balance at September 30, 2016	2,208	\$ 221	\$ 1,650	\$33,272	537	\$(16,795)	\$ 168

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

As of September 30, 2016, \$1.1 billion of common stock repurchase capacity remains under prior approved programs. In October 2016, the Board of Directors approved a new share repurchase program authorizing the repurchase of an additional \$3.0 billion of common stock. 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.

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

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

	2016			2015		
	Pretax	Tax	After tax	Pretax	Tax	After tax
Three Months Ended September 30,						
Derivatives qualifying as cash flow hedges: ^(a)						
Unrealized losses	\$(14)	\$4	\$ (10)	\$(34)	\$14	\$ (20)
Reclassified to net earnings	21	(7)	14	(39)	13	(26)
Derivatives qualifying as cash flow hedges	7	(3)	4	(73)	27	(46)
Pension and postretirement benefits:						
Actuarial gains/(losses)	72	(26)	46	(272)	96	(176)
Amortization ^(b)	20	(7)	13	20	(6)	14
Curtailments and settlements ^(c)	19	(6)	13	48	(17)	31
Pension and postretirement benefits	111	(39)	72	(204)	73	(131)
Available-for-sale securities:						
Unrealized losses	(8)	4	(4)	(24)	8	(16)
Realized gains	(4)	—	(4)	—	—	—
Available-for-sale securities	(12)	4	(8)	(24)	8	(16)
Foreign currency translation	(2)	3	1	(34)	5	(29)
	\$104	\$(35)	\$ 69	\$(335)	\$113	\$(222)

Nine Months Ended September 30,

Derivatives qualifying as cash flow hedges: ^(a)						
Unrealized gains/(losses)	\$(199)	\$66	\$ (133)	\$36	\$(16)	\$ 20
Reclassified to net earnings	12	(5)	7	(102)	33	(69)
Derivatives qualifying as cash flow hedges	(187)	61	(126)	(66)	17	(49)
Pension and postretirement benefits:						
Actuarial gains/(losses)	(453)	160	(293)	20	(7)	13
Amortization ^(b)	56	(19)	37	67	(21)	46
Curtailments and settlements ^(c)	66	(23)	43	111	(39)	72
Pension and postretirement benefits	(331)	118	(213)	198	(67)	131
Available-for-sale securities:						
Unrealized gains/(losses)	29	(13)	16	(31)	9	(22)
Realized losses	30	—	30	—	—	—
Available-for-sale securities	59	(13)	46	(31)	9	(22)
Foreign currency translation	20	6	26	(14)	(16)	(30)
	\$(439)	\$172	\$(267)	\$87	\$(57)	\$ 30

(a)Included in cost of products sold

(b)Included in cost of products sold, research and development and marketing, selling and administrative expenses

(c)Included in other (income)/expense

The accumulated balances related to each component of other comprehensive loss, net of taxes, were as follows:

Dollars in Millions	September 30, December 31,	
	2016	2015
Derivatives qualifying as cash flow hedges	\$ (92)	\$ 34
Pension and other postretirement benefits	(2,293)	(2,080)
Available-for-sale securities	23	(23)
Foreign currency translation	(373)	(399)
Accumulated other comprehensive loss	\$ (2,735)	\$ (2,468)

Note 16. PENSION AND POSTRETIREMENT BENEFIT PLANS

The net periodic benefit cost/(credit) of defined benefit pension and postretirement benefit plans includes:

	Three Months Ended				Nine Months Ended			
	September 30,		September 30,		September 30,		September 30,	
	Pension	Other	Pension	Other	Pension	Other	Pension	Other
	Benefits	Benefits	Benefits	Benefits	Benefits	Benefits	Benefits	Benefits
Dollars in Millions	2016	2015	2016	2015	2016	2015	2016	2015
Service cost – benefits earned during the year	\$6	\$6	\$1	\$1	\$19	\$18	\$3	\$3
Interest cost on projected benefit obligation	45	60	2	3	145	181	7	9
Expected return on plan assets	(104)	(102)	(6)	(7)	(314)	(307)	(18)	(20)
Amortization of prior service credits	(1)	—	—	(1)	(3)	(2)	(2)	(4)
Amortization of net actuarial (gain)/loss	22	20	(1)	1	62	70	(1)	3
Curtailments and settlements	19	48	—	—	66	111	—	—
Special termination benefits	—	—	—	—	1	—	—	—
Net periodic benefit cost/(credit)	\$(13)	\$32	\$(4)	\$(3)	\$(24)	\$71	\$(11)	\$(9)

Pension settlement charges were recognized after determining that the annual lump sum payments will likely exceed the annual interest and service costs for certain pension plans, including the primary U.S. pension plan. The charges included the acceleration of a portion of unrecognized actuarial losses.

Non-current pension liabilities were \$1,067 million at September 30, 2016 and \$765 million at December 31, 2015. The increase resulted primarily from a lower discount rate assumed in the remeasurement of U.S. plan benefit obligations.

Defined contribution plan expense in the U.S. was \$49 million and \$53 million for the three months ended September 30, 2016 and 2015, respectively, and \$141 million and \$142 million for the nine months ended September 30, 2016 and 2015, respectively.

Note 17. EMPLOYEE STOCK BENEFIT PLANS

Stock-based compensation expense was as follows:

	Three		Nine	
	Months	Months	Months	Months
	Ended	Ended	Ended	Ended
	September	September	September	September
	30,	30,	30,	30,
Dollars in Millions	2016	2015	2016	2015
Restricted stock units	\$ 23	\$ 20	\$66	\$62
Market share units	9	9	27	27
Performance share units	16	34	56	87
Total stock-based compensation expense	\$ 48	\$ 63	\$149	\$176
Income tax benefit	\$ 16	\$ 20	\$50	\$58

The number of units granted and the weighted-average fair value on the grant date were as follows:

	Nine Months Ended
	September 30, 2016
Units in Millions	Units

		Weighted-Average Fair Value
Restricted stock units	2.2	\$ 61.26
Market share units	0.7	65.26
Performance share units	1.1	64.87

Unrecognized compensation cost related to nonvested awards of \$380 million is expected to be recognized over a weighted-average period of 2.5 years.

17

Note 18. 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. These claims or proceedings can involve various types of parties, including governments, competitors, customers, suppliers, service providers, licensees, employees, or shareholders, among others. The resolution of these matters often develops over a long period of time and expectations can change as a result of new findings, rulings, appeals or settlement arrangements. 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, contractual rights, licensing obligations, 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 revenues 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 sought by Apotex. The Australian government has intervened in this matter and is also seeking damages for alleged losses experienced during the period when the injunction was in place. The Company and Apotex have settled the Apotex case, and the case has been dismissed. The Australian government's claim is still pending and a trial has been scheduled for August 2017. It is not possible at this time to predict the outcome of the Australian government's claim or its impact on the Company.

Sprycel - European Union

In May 2013, Apotex, Actavis Group PTC ehf, Generics [UK] Limited (Mylan) and an unnamed company filed oppositions in the European Patent Office (EPO) seeking revocation of European Patent No. 1169038 (the '038 patent) covering dasatinib, the active ingredient in Sprycel. The '038 patent is scheduled to expire in April 2020 (excluding potential term extensions). On January 20, 2016, the Opposition Division of the EPO revoked the '038 patent. In May 2016, the Company appealed the EPO's decision to the EPO Board of Appeal. The '038 patent will remain in force

pending the outcome of our appeal of the EPO's decision, and we intend to pursue legal options to defend our intellectual property rights from any future infringement. Orphan drug exclusivity and data exclusivity for Sprycel in the EU expire in November 2016. The decision does not affect the validity of our other Sprycel patents within and outside Europe, including a different patent that covers the monohydrate form of dasatinib. In the U.S., the Company entered into a settlement agreement with Apotex in 2013 regarding a patent infringement suit whereby Apotex can launch its generic dasatinib monohydrate product in September 2024, or earlier in certain circumstances.

18

Anti-PD-1 Antibody Patent Oppositions and Litigation

There are a number of ongoing patent litigations against Merck & Co., Inc. (Merck) around the world with respect to patents directed to 1) methods of treating cancer using a PD-1 antibody (the Honjo patent filing) and 2) a class of anti-PD-1 antibodies (the Korman patent filing).

Europe

Under our alliance with Ono Pharmaceutical Co., Ltd. (Ono), BMS has exclusive rights to the Honjo patent filing, including European patent (EP 1 537 878) (the '878 patent). In 2011, Merck filed an opposition in the European Patent Office (EPO) seeking revocation of the '878 patent. In June 2014, the Opposition Division of the EPO maintained the validity of the claims in the '878 patent. Merck has appealed this decision.

In May 2014, Merck filed a lawsuit in the United Kingdom (UK) seeking revocation of the UK national version of the '878 patent. In July 2014, BMS and Ono sued Merck for patent infringement. A trial was held in the UK in July 2015. In October 2015, the court issued its judgment, finding the '878 patent valid and infringed. Merck has appealed this judgment and the appeal hearing is scheduled for March 2017.

In February 2015, Merck filed a lawsuit in the Netherlands seeking revocation of the Dutch national version of the '878 patent, and BMS and Ono subsequently sued Merck for patent infringement. A trial regarding the validity and infringement of the '878 patent was held in January 2016. In June 2016, the Dutch court found the '878 patent valid and infringed by Merck. Merck has appealed the judgment.

In December 2015, BMS and Ono filed lawsuits with respect to national versions of the '878 patent in several other European countries, including France, Germany, Ireland, Spain and Switzerland. BMS and Ono can file patent infringement actions against Merck in other national courts in Europe at or around the time Merck launches Keytruda*. If any of the above-mentioned national courts determine Merck infringes a valid claim in the '878 patent, BMS and Ono may be entitled to monetary damages, including royalties on future sales of Keytruda*. BMS and Ono are not seeking an injunction to prevent Merck from marketing Keytruda* in these litigations unless an appropriate financial remedy cannot be agreed upon or awarded by the court.

In April 2014, Merck and three other companies opposed a European patent (EP 2 161 336) (the '336 patent) which is based on the Korman patent filing. In February 2015, BMS and Ono submitted a request to amend the claims of the '336 patent. Oral proceedings before the Opposition Division of the EPO occurred in July 2016. The Opposition Division of the EPO maintained the validity of the '336 patent claims.

United States

In September 2014, BMS and Ono filed a lawsuit in the United States alleging that Merck's marketing of Keytruda* infringes U.S. Patent No. 8,728,474 (the '474 patent) which is based on the Honjo patent filing. The trial in this matter is currently scheduled to begin in April 2017. In June and July 2015, BMS and Ono filed lawsuits in the United States alleging that Merck's marketing of Keytruda* infringes U.S. Patent Nos. 9,067,999 (the '999 patent) and 9,073,994 (the '994 patent), respectively, which are based on the Honjo patent filing. In these lawsuits, BMS and Ono are not seeking to prevent or stop the marketing of Keytruda* in the United States unless an appropriate financial remedy cannot be agreed upon or awarded by the court.

In September 2015, Dana-Farber Cancer Institute (Dana-Farber) filed a complaint in Massachusetts federal court seeking to correct the inventorship of five related U.S. patents based on the Honjo patent filing. Specifically, Dana-Farber is seeking to add two scientists as inventors to these patents. Three of these patents (the '474, '999, and '994 patents) are currently subject to patent infringement proceedings filed by BMS and Ono against Merck in Delaware federal court, as specified above.

In April 2016, Merck filed an action in New Jersey federal court seeking a declaratory judgment that U.S. Patent Nos. 8,777,105 (the '105 patent) and 9,084,776 (the '776 patent), which are based on the Korman patent filing, are invalid and not infringed by Keytruda*.

In July 2016, Merck filed Petitions for Inter Partes Review of the '999 and '994 patents. The petitions request that the Patent Trial and Appeal Board (PTAB) review the validity of the '999 and '994 patents. The Company intends to respond and oppose the petitions by October 2016.

Rest of World

In September 2014, Merck filed a lawsuit in Australia seeking the revocation of Australian Patent No. 2011203119, which is based on the Korman patent filing. In March 2015, BMS and Ono countersued Merck for patent infringement. Ono and BMS have similar and other patents and applications pending in the United States and other countries. A trial has been scheduled for September 2017.

PRICING, SALES AND PROMOTIONAL PRACTICES LITIGATION

Plavix* State Attorneys General Lawsuits

The Company and certain affiliates of Sanofi are defendants in consumer protection and/or false advertising actions brought by several states relating to the sales and promotion of Plavix*. It is not possible at this time to reasonably assess the outcome of these lawsuits or their potential impact on the Company.

PRODUCT LIABILITY LITIGATION

The Company is a party to various product liability lawsuits. Plaintiffs in these cases seek damages and other relief on various grounds for alleged personal injury and economic loss. 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, over 5,300 claims involving injury plaintiffs as well as claims by spouses and/or other beneficiaries, are filed in state and federal courts in various states including California, New Jersey, Delaware and New York. In February 2013, the Judicial Panel on Multidistrict Litigation granted the Company and Sanofi's motion to establish a multi-district litigation (MDL) to coordinate Federal pretrial proceedings in Plavix* product liability and related cases in New Jersey Federal Court. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

Byetta*

Amylin, a former subsidiary of the Company, and Lilly are co-defendants in product liability litigation related to Byetta*. To date, there are over 500 separate lawsuits pending on behalf of almost 2,300 active plaintiffs (including pending settlements), which include injury plaintiffs as well as claims by spouses and/or other beneficiaries, in various courts in the U.S. The Company has agreed in principle to resolve over 137 of these claims. The majority of these cases have been brought by individuals who allege personal injury sustained after using Byetta*, primarily pancreatic cancer and pancreatitis, and, in some cases, claiming alleged wrongful death. The majority of cases were pending in Federal Court in San Diego in an MDL or in a coordinated proceeding in California Superior Court in Los Angeles (JCCP). In November 2015, the defendants' motion for summary judgment based on federal preemption was granted in both the MDL and the JCCP. The plaintiffs in the MDL have appealed to the U.S. Court of Appeals for the Ninth Circuit and the JCCP plaintiffs have appealed to the California Court of Appeal. Amylin has product liability insurance covering a substantial number of claims involving Byetta* and any additional liability to Amylin with respect to Byetta* is expected to be shared between the Company and AstraZeneca. It is not possible to reasonably predict the outcome of any lawsuit, claim or proceeding or the potential impact on the Company.

Abilify*

The Company and Otsuka Pharmaceutical Co. Ltd. (Otsuka) are co-defendants in product liability litigation related to Abilify. Plaintiffs allege Abilify caused them to engage in compulsive gambling and other impulse control disorders. There have been approximately 60 cases filed in state and federal courts and two cases are pending in Canada. The Judicial Panel on Multidistrict Litigation has consolidated the federal court cases for pretrial purposes in the United States District Court for the Northern District of Florida.

SHAREHOLDER DERIVATIVE LITIGATION

Since December 2015, three shareholder derivative lawsuits were filed in New York state court against certain officers and directors of the Company. The plaintiffs allege, among other things, breaches of fiduciary duty surrounding the Company's previously disclosed October 2015 civil settlement with the Securities and Exchange Commission of alleged Foreign Corrupt Practices Act violations in China in which the Company agreed to a payment of approximately \$14.7 million in disgorgement, penalties and interest. In May 2016, the Company filed motions to dismiss two of the shareholder derivative lawsuits.

GOVERNMENT INVESTIGATIONS

Like other pharmaceutical companies, the Company and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the U.S. and other countries in which BMS operates. As a result, the Company, from time to time, is subject to various governmental inquiries and investigations. It is possible that criminal charges, substantial fines and/or civil penalties, could result from government investigations. The most significant investigations conducted by government agencies, of which the Company is aware, are listed below.

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 (Coalition) investigating whether certain Abilify* marketing practices violated those respective states' consumer protection statutes. The Company and the Executive Committee of the Coalition have reached a settlement in principle in this matter, which remains subject to approval by each individual state and the District of Columbia in the Coalition.

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 \$61 million at September 30, 2016, 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). The \$61 million includes the estimated costs for any additional probable loss associated with the previously disclosed North Brunswick Township High School Remediation Site.

Item 2. 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 specialty biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We have transitioned to a specialty biopharmaceutical company, with a strategy designed to leverage both the reach and resources of a major pharmaceutical company as well as the entrepreneurial spirit and agility of a biotech firm. Our four strategic priorities are to drive business performance, maintain our leadership in immuno-oncology, maintain a diversified portfolio both within and outside of immuno-oncology and continue our disciplined approach to capital allocation, with business development as a priority.

In August 2016, the Company disclosed the negative top line results of CheckMate-026, a Phase III trial investigating the use of Opdivo as a first-line monotherapy in patients with previously untreated advanced non-small cell lung cancer (NSCLC) whose tumors expressed PD-L1 at $\geq 5\%$. In October 2016, the final primary results were presented at the European Society for Medical Oncology Congress. While the Company was disappointed by the negative results of CheckMate-026 given the performance of Opdivo in previous studies, the results of the study provided important information for the scientific community. The Company continues to investigate Opdivo in other comprehensive development programs for first-line NSCLC, including combination therapies with Yervoy and other anti-cancer agents. The Company's overall strategy remains unchanged and we continue to believe that the breadth and depth of our immuno-oncology portfolio positions us well for the future.

The Company announced an evolution to its operating model to drive the Company's continued success in the near- and long-term through a more focused investment in commercial opportunities against key brands and markets, a competitive and more agile research and development (R&D) organization that can accelerate the pipeline, streamlined operations and realigned manufacturing capabilities that broaden biologics capabilities to reflect the current and future portfolio. The new operating model will enable the Company to deliver the strategic, financial and operational flexibility necessary to invest in the highest priorities across the Company. Restructuring and other pre-tax charges to implement the evolution are expected to be approximately \$1.5 billion to \$2.0 billion of which 40% to 50% would require cash outlays. Charges are expected to begin in the fourth quarter of 2016 and continue during the next few years as certain plans are finalized and recognition criteria met. The majority of the costs are expected to be incurred by 2020. Although GAAP operating expenses may increase initially as we incur restructuring and other charges, the Company expects non-GAAP operating expenses to be roughly flat with 2016 levels through 2020.

Our revenues increased by 16% for the nine months ended September 30, 2016 as a result of higher Opdivo and Eliquis product sales. These impacts were partially offset by the expiration of U.S. commercialization rights to Abilify*, the transfer of Erbitux* rights in North America and increased competition for Reyataz, Sustiva and Baraclude in certain markets.

The increase in GAAP earnings per share (EPS) from \$1.05 in 2015 to \$2.12 in 2016 was due to higher revenues, divestiture gains and royalties as well as lower R&D asset acquisition charges partially offset by higher Eliquis profit sharing and Opdivo related expenses. The tax impact of specified items and earnings mix contributed to the change in the effective tax rate. After adjusting for divestiture gains, R&D asset acquisition charges and other specified items, non-GAAP EPS increased from \$1.63 in 2015 to \$2.20 in 2016.

	Three Months Ended September 30,		Nine Months Ended September 30,	
Dollars in Millions, except per share data	2016	2015	2016	2015

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

Total Revenues	\$4,922	\$4,069	\$14,184	\$12,273
Total Expenses	3,363	3,082	9,355	9,786
Earnings Before Income Taxes	1,559	987	4,829	2,487
Provision for Income Taxes	344	257	1,220	668
Effective tax rate	22.1	% 26.0	% 25.3	% 26.9
Net Earnings Attributable to BMS				
GAAP	1,202	706	3,563	1,762
Non-GAAP	1,287	648	3,686	2,731
Diluted Earnings Per Share				
GAAP	0.72	0.42	2.12	1.05
Non-GAAP	0.77	0.39	2.20	1.63
Cash, Cash Equivalents and Marketable Securities			8,595	10,040

22

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 refer to “—Non-GAAP Financial Measures.”

Significant Product and Pipeline Approvals

The following is a summary of significant approvals received in 2016.

Product	Date	Approval
Opdivo	August 2016	Japanese Ministry of Health, Labour and Welfare manufacturing and marketing approval for the treatment of unresectable or metastatic renal cell carcinoma (RCC), received by our alliance partner, Ono Pharmaceutical Co., Ltd. (Ono).
	May 2016	U.S. Food and Drug Administration (FDA) approval for the treatment of patients with classical Hodgkin lymphoma (cHL) who have relapsed or progressed after autologous hematopoietic stem cell transplantation (auto-HSCT) and post-transplantation brentuximab vedotin.
	April 2016	European Commission (EC) approval for the treatment of previously treated RCC.
	April 2016	EC approval for the treatment of previously treated patients with metastatic non-squamous (NSQ) NSCLC.
Opdivo+ Yervoy	January 2016	FDA expanded the use of Opdivo as a single agent to include previously untreated BRAF mutation positive advanced melanoma patients.
	May 2016	EC approval for the treatment of unresectable or metastatic melanoma, regardless of BRAF mutational status.
Empliciti	January 2016	FDA approval for the treatment of patients with BRAF V600 wild-type and BRAF V600 mutation positive unresectable or metastatic melanoma.
	September 2016	Japanese Ministry of Health, Labour and Welfare manufacturing and marketing approval in combination with Revlimid* and dexamethasone for the treatment of multiple myeloma.
Hepatitis C Portfolio - Daklinza	May 2016	EC approval for the treatment of multiple myeloma as combination therapy with Revlimid* and dexamethasone in patients who have received at least one prior therapy.
	February 2016	FDA approval for use with sofosbuvir for the treatment of chronic hepatitis C (HCV) in genotypes 1 and 3 in three additional patient populations.
	January 2016	EC approval for use with sofosbuvir for the treatment of chronic HCV in three new patient populations.

Refer to “—Product and Pipeline Developments” for all of the developments in our marketed products and late-stage pipeline in 2016.

Acquisition and Licensing Arrangements

Acquisition and licensing transactions allow us to focus our resources behind our growth opportunities that drive the greatest long-term value. We are focused on the following core therapeutic areas: oncology, immuno-oncology, immunoscience, cardiovascular diseases, fibrosis and genetically defined diseases. Significant transactions entered into in 2016 are summarized below:

Cormorant Pharmaceuticals (Cormorant)

In July 2016, BMS acquired all of the outstanding shares of Cormorant, a private pharmaceutical company focused on the development of therapies for cancer and rare diseases. The acquisition provides BMS with full rights to Cormorant's lead candidate HuMax-IL8, a Phase I/II monoclonal antibody that represents a potentially complementary immuno-oncology mechanism of action to T-cell directed antibodies and co-stimulatory molecules.

Padlock Therapeutics, Inc. (Padlock)

In April 2016, BMS acquired all of the outstanding shares of Padlock, a private biotechnology company dedicated to creating new medicines to treat destructive autoimmune diseases. The acquisition provides BMS with full rights to Padlock's Protein/Peptidyl Arginine Deiminase (PAD) inhibitor discovery program focused on the development of potentially transformational treatment approaches for patients with rheumatoid arthritis. Padlock's PAD discovery program may have additional utility in treating systemic lupus erythematosus and other autoimmune diseases.

Portola Pharmaceuticals, Inc. (Portola)

In February 2016, BMS and Pfizer, Inc. (Pfizer) entered into a collaboration and license agreement with Portola to develop and commercialize the investigational agent andexanet alfa in Japan. Andexanet alfa is designed to reverse the anticoagulant activity of Factor Xa inhibitors, including Eliquis. BMS and Pfizer will be responsible for all development and regulatory activities for andexanet alfa in Japan and for exclusively commercializing the agent in Japan. Portola retains the rights to andexanet alfa outside of Japan and will be responsible for the manufacturing supply.

In addition to the above transactions, in the third quarter of 2016, BMS provided a notice of termination to the California Institute for Biomedical Research (Calibr) pertaining to a research collaboration agreement for the development of anti-fibrotic preclinical compounds.

RESULTS OF OPERATIONS

Total Revenues

	Three Months Ended September 30,				Nine Months Ended September 30,			
	Total Revenues		2016 vs. 2015		Total Revenues		2016 vs. 2015	
Dollars in Millions	2016	2015	Total Change	Foreign Exchange ^(b)	2016	2015	Total Change	Foreign Exchange ^(b)
United States	\$2,790	\$2,044	36 %	—	\$8,015	\$5,925	35 %	—
Europe	946	813	16 %	(2) %	2,855	2,569	11 %	(2) %
Rest of the World	1,069	1,027	4 %	(3) %	2,922	3,170	(8) %	(4) %
Other ^(a)	117	185	(37) %	N/A	392	609	(36) %	N/A
Total	\$4,922	\$4,069	21 %	(1) %	\$14,184	\$12,273	16 %	(1) %

(a) Other revenues include royalties and alliance-related revenues for products not sold by our regional commercial organizations.

(b) Foreign exchange impacts were derived by applying the prior period average currency rates to the current period sales.

U.S. revenues increased in both periods primarily due to higher demand for Opdivo and Eliquis and the launch of Daklinza in July 2015, partially offset by the transfer of Erbitux* rights in North America. The nine months ended September 30, 2016 was also negatively impacted by the expiration of commercialization rights to Abilify*. Average U.S. net selling prices, including related gross-to-net adjustments, increased by approximately 5% for the three and nine months ended September 30, 2016. Refer to “—Product Revenues” below for additional information.

Europe revenues increased in both periods due to higher demand for Opdivo and Eliquis partially offset by lower demand for Yervoy. The nine months ended September 30, 2015 included the recognition of \$170 million of previously deferred Daklinza revenue in France.

Rest of the World revenues decreased in the nine months ended September 30, 2016 due to increased competition for the Hepatitis C Franchise in Japan and unfavorable foreign exchange partially offset by higher demand for Opdivo and Eliquis. Rest of the World revenues increased in the three months ended September 30, 2016 as the growth in Opdivo and Eliquis sales exceeded the decline in the Hepatitis C Franchise sales.

The decrease in Other revenues in both periods resulted from the expiration of certain supply arrangements.

No single country outside the U.S. contributed more than 10% of total revenues during the nine months ended September 30, 2016 and 2015 except for Japan which contributed 10% of total revenues in 2015. Our business is typically not seasonal.

The reconciliation of gross product sales (which excludes alliance and other revenues such as Abilify* and Atrippla*) to net product sales by each significant category of gross-to-net adjustments was as follows:

	Three Months Ended			Nine Months Ended		
	September 30,		% Change	September 30,		% Change
Dollars in Millions	2016	2015		2016	2015	
Gross product sales	\$5,698	\$4,358	31 %	\$16,252	\$12,373	31 %
Gross-to-Net Adjustments:						
Charge-backs and cash discounts	(427)	(308)	39 %	(1,174)	(747)	57 %
Medicaid and Medicare rebates	(397)	(226)	76 %	(1,018)	(556)	83 %

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

Other rebates, returns, discounts and adjustments	(382)	(272)	40 %	(1,172)	(887)	32 %
Total Gross-to-Net Adjustments	(1,206)	(806)	50 %	(3,364)	(2,190)	54 %
Net product sales	\$4,492	\$3,552	26 %	\$12,888	\$10,183	27 %

Reductions to provisions for product sales made in prior periods resulting from changes in estimates were \$143 million and \$117 million in the nine months ended September 30, 2016 and 2015, respectively. Changes in the gross-to-net adjustments are primarily a function of changes in sales volume and payer channel mix, contractual and legislative discounts and rebates. Net U.S. product sales, excluding alliance and other revenues, increased by approximately 45% in the three months ended September 30, 2016 and approximately 60% in the nine months ended September 30, 2016.

Charge-backs and cash discounts increased in both periods primarily due to higher Opdivo and Eliquis product sales. Medicaid and Medicare rebates increased in both periods primarily due to higher Eliquis product sales.

Other rebates, returns, discounts and adjustments increased in both periods primarily due to additional rebates worldwide for Eliquis and Daklinza product sales. The nine months ended September 30, 2015 includes additional rebates for Daklinza of approximately \$180 million for amounts previously deferred in France.

Product Revenues

Dollars in Millions	Three Months Ended September 30,				Nine Months Ended September 30,				
	2016	2015	% Change	% Change Attributable to Foreign Exchange	2016	2015	% Change	% Change Attributable to Foreign Exchange	
Oncology									
Empliciti (elotuzumab)	\$41	\$ —	N/A	N/A	\$103	\$ —	N/A	N/A	
U.S.	36	—	N/A	—	97	—	N/A	—	
Non-U.S.	5	—	N/A	N/A	6	—	N/A	N/A	
Erbitux* (cetuximab)	—	167	(100)%	—	—	501	(100)%	—	
U.S.	—	165	(100)%	—	—	487	(100)%	—	
Non-U.S.	—	2	(100)%	—	—	14	(100)%	—	
Opdivo (nivolumab)	920	305	**	N/A	2,464	467	**	N/A	
U.S.	712	268	**	—	1,949	413	**	—	
Non-U.S.	208	37	**	N/A	515	54	**	N/A	
Sprycel (dasatinib)	472	411	15	% (1)%	1,330	1,191	12	% (1)%	
U.S.	259	215	20	% —	702	601	17	% —	
Non-U.S.	213	196	9	% (1)%	628	590	6	% (3)%	
Yervoy (ipilimumab)	285	240	19	% (4)%	789	861	(8)%	(2)%	
U.S.	222	121	83	% —	600	438	37	% —	
Non-U.S.	63	119	(47)%	(8)%	189	423	(55)%	(5)%	
Cardiovascular									
Eliquis (apixaban)	884	466	90	% 3	% 2,395	1,258	90	% 1	%
U.S.	512	245	**	—	1,424	688	**	—	
Non-U.S.	372	221	68	% 5	% 971	570	70	% 2	%
Immunoscience									
Orencia (abatacept)	572	484	18	% —	1,640	1,345	22	% (1)%	
U.S.	387	330	17	% —	1,109	899	23	% —	
Non-U.S.	185	154	20	% 1	% 531	446	19	% (2)%	
Virology									
Baraclude (entecavir)	306	320	(4)%	1	% 896	1,003	(11)%	(1)%	
U.S.	17	25	(32)%	—	49	108	(55)%	—	
Non-U.S.	289	295	(2)%	1	% 847	895	(5)%	(1)%	
Hepatitis C Franchise (daclatasvir and asunaprevir)	379	402	(6)%	(1)%	1,352	1,145	18	% (2)%	
U.S.	192	111	73	% —	745	111	**	—	
Non-U.S.	187	291	(36)%	(1)%	607	1,034	(41)%	(2)%	
Reyataz (atazanavir sulfate) Franchise	238	270	(12)%	(3)%	706	867	(19)%	(4)%	

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

U.S.	125	149	(16)%	—		367	449	(18)%	—
Non-U.S.	113	121	(7)%	(8)%		339	418	(19)%	(8)%
Sustiva (efavirenz) Franchise	275	333	(17)%	—		819	940	(13)%	—
U.S.	234	280	(16)%	—		689	772	(11)%	—
Non-U.S.	41	53	(23)%	—		130	168	(23)%	—
Neuroscience									
Abilify* (aripiprazole)	29	46	(37)%	—		97	707	(86)%	—
U.S.	—	18	(100)%	—		—	593	(100)%	—
Non-U.S.	29	28	4 %	4 %		97	114	(15)%	(4)%
Mature Products and All Other	521	625	(17)%	(4)%		1,593	1,988	(20)%	(4)%
U.S.	94	117	(20)%	—		284	366	(22)%	—
Non-U.S.	427	508	(16)%	(5)%		1,309	1,622	(19)%	(4)%

** Change in excess of 100%

Empliciti — a humanized monoclonal antibody for the treatment of multiple myeloma.

Empliciti was launched in the U.S. in December 2015 and in the European Union (EU) in May 2016.

Erbitux* — a monoclonal antibody for the treatment of certain types of metastatic colorectal cancer and squamous cell carcinoma of the head and neck (SCCHN).

BMS transferred its rights to Erbitux* in North America to Eli Lilly and Company in October 2015.

Opdivo — a fully human monoclonal antibody that binds to the programmed death receptor-1 (PD-1) on T and natural killer T (NKT) cells that has been approved and continues to be investigated as an anti-cancer treatment. Refer to "—Significant Product and Pipeline Approvals" for further discussion on the Opdivo approvals in 2016 and the 2015 Form 10-K for the 2015 approvals.

U.S. and international revenues increased in both periods due to higher demand resulting from the rapid commercial acceptance for several indications.

Sprycel — an oral inhibitor of multiple tyrosine kinase indicated 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*.

U.S. revenues increased in both periods due to higher demand and average net selling prices.

International revenues increased in both periods due to higher demand.

Yervoy — a monoclonal antibody for the treatment of patients with unresectable or metastatic melanoma.

U.S. revenues increased in both periods due to higher demand as a result of the approvals for adjuvant treatment and the Opdivo+Yervoy regimen for patients with metastatic melanoma.

International revenues decreased in both periods due to lower demand resulting from the introduction of other immuno-oncology products being used to treat patients with melanoma, including Opdivo.

Eliquis — an oral Factor Xa inhibitor, targeted at stroke prevention in adult patients with non-valvular atrial fibrillation and the prevention and treatment of venous thromboembolic disorders.

U.S. and international revenues increased in both periods due to higher demand resulting from increased commercial acceptance of novel oral anticoagulants and market share gains.

Orencia — a fusion protein indicated for adult patients with moderate to severe active rheumatoid arthritis (RA) and is also indicated for reducing signs and symptoms in certain pediatric patients with moderately to severely active polyarticular juvenile idiopathic arthritis.

U.S. revenues increased in both periods due to higher average net selling prices and demand.

International revenues increased in both periods due to higher demand.

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

U.S. revenues continued to decrease in both periods due to the loss of exclusivity in September 2014.

International revenues continued to decrease in both periods following the loss of exclusivity in South Korea in October 2015.

Hepatitis C Franchise — Daklinza - an NS5A replication complex inhibitor; Sunvepra - an NS3 protease inhibitor.

Daklinza was launched in the U.S. in July 2015. U.S. revenues are expected to significantly decline in the remainder of 2016 due to lower demand resulting from increased competition.

International revenues decreased in both periods and are expected to continue to significantly decline in 2016 from the prior year comparable periods due to lower demand resulting from increased competition, primarily in Japan. The nine months ended September 30, 2015 includes the recognition of \$170 million of previously deferred Daklinza revenue in France.

Reyataz Franchise — Includes Reyataz - a protease inhibitor for the treatment of human immunodeficiency virus (HIV) and Evotaz (atazanavir 300 mg and cobicistat 150 mg) - a combination therapy containing Reyataz and Tybost*.

U.S. revenues continued to decrease in both periods due to lower demand resulting from increased competition.

International revenues continued to decrease in both periods due to lower demand resulting from increased competition and unfavorable foreign exchange. The decrease in the three months ended September 30, 2016 was partially offset by the timing of government purchases in certain countries.

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*.

U.S. revenues continued to decrease in both periods due to lower demand resulting from increased competition. International revenues continued to decrease in both periods due to Sustiva's loss of exclusivity in Europe in November 2013.

26

Abilify* — an antipsychotic agent for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder.

BMS's U.S. commercialization rights to Abilify* expired in April 2015.

Mature Products and All Other — includes all other products, including those which have lost exclusivity in major markets, the diabetes alliance products, over-the-counter brands and royalty revenue.

U.S. revenues for the three and nine months ended September 30, 2015 were favorably impacted by a reduction in the sales return reserve for Plavix* of \$25 million and \$63 million, respectively.

International revenues decreased in both periods due to the expiration of certain supply arrangements, lower sales due to the divestiture of certain mature and other products and unfavorable foreign exchange. The decrease in the nine months ended September 30, 2016 was also impacted by increased competition for over-the counter products.

Estimated End-User Demand

Pursuant to the Securities and Exchange Commission (SEC) Consent Order described in our 2015 Annual Report on Form 10-K, we monitor inventory levels 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 the following products were not material to our results of operations as of the dates indicated. No U.S. products had estimated levels of inventory in the distribution channel in excess of one month on hand at September 30, 2016. Below are international products that had estimated levels of inventory in the distribution channel in excess of one month at June 30, 2016.

Dafalgan, an analgesic product sold principally in Europe, had 1.2 months of inventory on hand internationally at direct customers compared to 1.1 months of inventory on hand at March 31, 2016. The level of inventory on hand was primarily due to the ordering patterns of pharmacists in France.

Efferalgan, an analgesic product sold principally in Europe, had 1.2 months of inventory on hand internationally at direct customers compared to 1.3 months of inventory on hand at March 31, 2016. The level of inventory on hand was primarily due to the ordering patterns of pharmacists in France.

Fervex, a cold and flu product, had 4.2 months of inventory on hand at direct customers compared to 5.1 months of inventory on hand at March 31, 2016. The level of inventory on hand was primarily in France to support product seasonality.

Perfalgan, an analgesic product, had 2.9 months of inventory on hand internationally at direct customers compared to 2.1 months of inventory on hand at March 31, 2016. The level of inventory on hand was primarily in the Gulf Countries and Saudi Arabia due to extended delivery lead time.

In the U.S., we generally determine our months on hand estimates using inventory levels of product on hand and the amount of out-movement provided by our three largest wholesalers and our distributors. Our three largest wholesalers account for approximately 95% of total gross sales of U.S. products. Factors that may influence our estimates include generic competition, 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.

Our non-U.S. businesses have significantly more direct customers. Information on available direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information varies widely. We limit our direct customer sales channel inventory reporting to where we can influence demand. When this information does not exist or is otherwise not available, we have developed a variety of methodologies to estimate such data, including using historical sales made to direct customers and third-party market research data related to prescription trends and end-user demand. Given the difficulties inherent in estimating third-party demand information, we evaluate our methodologies to estimate direct customer product level inventory and to calculate months on hand on an ongoing basis and make changes as necessary. Factors that may affect our estimates include generic competition, seasonality of products, 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 a result, all of the information required to estimate months on hand in the direct customer distribution channel for non-U.S. businesses for the quarter ended September 30, 2016 is not available prior to the filing of this quarterly report on Form 10-Q. We will disclose any product with inventory levels in excess of one month on hand or expected demand for the current quarter, subject to a de minimis exception, in the next annual report on Form 10-K.

Expenses

Dollars in Millions	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2016	2015	% Change	2016	2015	% Change
Cost of products sold	\$1,305	\$1,097	19 %	\$3,563	\$2,957	20 %
Marketing, selling and administrative	1,144	1,176	(3) %	3,450	3,340	3 %
Research and development	1,138	1,132	1 %	3,540	4,004	(12) %
Other (income)/expense	(224)	(323)	(31) %	(1,198)	(515)	**
Total Expenses	\$3,363	\$3,082	9 %	\$9,355	\$9,786	(4) %

** Change in excess of 100%

Cost of products sold increased in both periods primarily due to higher Eliquis profit sharing (\$200 million and \$540 million for the three and nine months ended September 30, 2016, respectively), lower hedge settlement gains and higher Puerto Rico excise tax.

Marketing, selling and administrative expenses increased in the nine months ended September 30, 2016 due to higher advertising and promotion and additional sales-related activities supporting Opdivo. The decrease for the three months ended September 30, 2016 was primarily due to lower advertising and promotion and sales related activities supporting certain brands, including the Hepatitis C Franchise partially offset by increased spending for Opdivo.

Research and development expenses decreased in the nine months ended September 30, 2016 due to lower license and asset acquisition charges in the first half of the year partially offset by the acceleration and expansion of Opdivo development programs and capabilities. Charges related to asset acquisitions include \$139 million for Padlock in 2016 and \$800 million for Flexus Biosciences, Inc. (Flexus) in 2015. Refer to "—Non-GAAP Financial Measures - Specified Items" for license and asset acquisition charges included in each period.

Other income increased in the nine months ended September 30, 2016 due to higher divestiture gains, royalties and licensing income combined with a debt redemption loss in 2015 partially offset by written option adjustments in 2015. The decrease for the three months ended September 30, 2016 was due to lower divestiture gains and written option adjustments. Refer to "Item 1. Financial Statements—Note 5. Other (Income)/Expense and Note 8. Financial Instruments and Fair Value Measurements" and "—Non-GAAP Financial Measures - Specified Items" for further information.

The significant divestiture gains were related to over-the-counter product and investigational HIV medicines businesses in 2016, the Mount Vernon, Indiana manufacturing facility, Ixempra* and mature and other over-the-counter product businesses in 2015. The higher royalties were related to the sale of the diabetes and Erbitux* businesses, including \$124 million in the nine months ended September 30, 2016 from the transfer of certain future royalty rights pertaining to Amylin product sales. The written option adjustments resulted from the change in fair value of the written option liability attributed to the Reckitt Benckiser Group plc alliance (\$87 million and \$123 million for the three and nine months ended September 30, 2015, respectively).

Income Taxes

Dollars in Millions	Three Months		Nine Months	
	Ended September		Ended September	
	30,	30,	30,	30,
	2016	2015	2016	2015
Earnings Before Income Taxes	\$1,559	\$987	\$4,829	\$2,487
Provision for Income Taxes	344	257	1,220	668
Effective tax rate	22.1 %	26.0 %	25.3 %	26.9 %

The jurisdictional tax rates and other tax impacts attributed to research and development charges, divestiture transactions and other specified items increased the effective tax rate by 3.1% and 4.4% in the nine months ended September 30, 2016 and 2015, respectively.

Refer to "Item 1. Financial Statements—Note 6. Income Taxes" for further discussion.

28

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 are evaluated on an individual basis. These items are adjusted after considering their quantitative and qualitative aspects and typically have one or more of the following characteristics, such as being highly variable, difficult to project, unusual in nature, significant to the results of a particular period or not indicative of future operating results. Similar charges or gains were recognized in prior periods and will likely reoccur in future periods including restructuring costs, accelerated depreciation and impairment of property, plant and equipment and intangible assets, R&D charges in connection with the acquisition or licensing of third party intellectual property rights, divestiture gains or losses, pension, legal and other contractual settlement charges and debt redemption gains or losses, among other items. Deferred and current income taxes attributed to these items are also adjusted for considering their individual impact to the overall tax expense, deductibility and jurisdictional tax rates.

Non-GAAP information is intended to portray the results of our baseline performance, supplement or enhance management, analysts and investors overall understanding of our underlying financial performance and facilitate comparisons among current, past and future periods. 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.

Specified items were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Dollars in Millions	2016	2015	2016	2015
Cost of products sold ^(a)	\$7	\$15	\$15	\$74
Marketing, selling and administrative	—	2	—	6
License and asset acquisition charges	45	94	309	1,125
Other	14	15	40	17
Research and development	59	109	349	1,142
Provision for restructuring	19	10	41	50
Divestiture gains	(13)	(198)	(559)	(358)
Pension charges	19	48	66	111
Written option adjustment	—	(87)	—	(123)
Litigation and other settlements	(3)	—	40	15
Out-licensed intangible asset impairment	—	—	15	13
Loss on debt redemption	—	—	—	180
Other (income)/expense	22	(227)	(397)	(112)
Increase/(decrease) to pretax income	88	(101)	(33)	1,110
Income taxes on items above	(3)	43	156	(141)

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

Increase/(decrease) to net earnings \$85 \$(58) \$123 \$969

(a) Specified items in cost of products sold are accelerated depreciation, asset impairment and other shutdown costs.

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

Dollars in Millions, except per share data	Three Months		Nine Months	
	Ended	Ended	Ended	Ended
	September 30,	September 30,	September 30,	September 30,
	2016	2015	2016	2015
Net Earnings Attributable to BMS used for Diluted EPS Calculation – GAAP	\$1,202	\$706	\$3,563	\$1,762
Specified Items	85	(58)	123	969
Net Earnings used for Diluted EPS Calculation – Non-GAAP	\$1,287	\$648	\$3,686	\$2,731
Average Common Shares Outstanding – Diluted	1,679	1,678	1,679	1,677
Diluted Earnings Per Share – GAAP	\$0.72	\$0.42	\$2.12	\$1.05
Diluted EPS Attributable to Specified Items	0.05	(0.03)	0.08	0.58
Diluted Earnings Per Share – Non-GAAP	\$0.77	\$0.39	\$2.20	\$1.63

FINANCIAL POSITION, LIQUIDITY, AND CAPITAL RESOURCES

Our net cash position was as follows:

Dollars in Millions	September 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 3,432	\$ 2,385
Marketable securities – current	2,128	1,885
Marketable securities – non-current	3,035	4,660
Cash, cash equivalents and marketable securities	8,595	8,930
Short-term borrowings and current portion of long-term debt	(990)	(139)
Long-term debt	(5,836)	(6,550)
Net cash position	\$ 1,769	\$ 2,241

Cash, cash equivalents and marketable securities held in the U.S. were approximately \$1.1 billion at September 30, 2016. Most of the remaining \$7.5 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 believe that our existing cash, cash equivalents and marketable securities together with cash generated from operations and issuance of commercial paper in the U.S. will be sufficient to satisfy our normal cash requirements for at least the next few years, including dividends, capital expenditures, milestone payments and working capital. Management continuously evaluates the Company's capital structure to ensure the Company is financed efficiently, which may result in the repurchase of common stock and debt securities, termination of interest rate swap contracts prior to maturity and issuance of debt securities. The Company's common stock repurchase capacity was increased to \$4.1 billion during October 2016 and share repurchases may begin later in the fourth quarter of 2016. Refer to "Item 1. Financial Statements—Note 15. Equity" for further information.

Dividend payments were \$1.9 billion in 2016 and 2015. Dividends declared per common share were \$1.14 in 2016 and \$1.11 in 2015. Dividend decisions are made on a quarterly basis by our Board of Directors. Capital expenditures were approximately \$800 million in 2015 and are expected to increase to approximately \$1.3 billion in 2016 and \$1.0 billion in 2017. The higher spending is expected as a result of expanding our biologics manufacturing capabilities and other facility-related activities. For example, we are constructing a new large-scale biologics manufacturing facility in Ireland that will produce multiple therapies for our growing biologics portfolio when completed in 2019. Long-term debt with a principal value of \$750 million matures in August 2017.

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. Our investment policy establishes limits on the amount and duration 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. Refer to "Item 1. Financial Statements—Note 8. Financial Instruments and Fair Value Measurements" for further information.

We currently have two separate \$1.5 billion revolving credit facilities from a syndicate of lenders. The facilities provide for customary terms and conditions with no financial covenants and were extended to October 2020 and July 2021. Each facility is extendable annually by one year on the anniversary date with the consent of the lenders. No borrowings were outstanding under either revolving credit facility at September 30, 2016 and December 31, 2015.

Additional regulations in the U.S. could be passed in the future, which may reduce our results of operations, operating cash flow, liquidity and financial flexibility. We continue to monitor the potential impact of the economic conditions in certain European and other countries and the related impact on prescription trends, pricing discounts and creditworthiness of our customers. We believe these economic conditions will not have a material impact on our

liquidity, cash flow or financial flexibility.

The United Kingdom (UK) voted to depart from the EU during June 2016. Similar to other companies in our industry, certain regulatory, trade, labor and other aspects of our business will likely be affected over time. However, we currently do not believe that these matters and other related financial effects will have a material impact on our consolidated results of operations, financial position or liquidity. Our sales in the UK represent less than 2% of our consolidated sales.

30

Credit Ratings

BMS's long-term and short-term credit ratings assigned by Moody's Investors Service are A2 and Prime-1, respectively, with a stable long-term credit outlook. BMS's long-term and short-term credit ratings assigned by Standard & Poor's are A+ and A-1+, respectively, with a stable long-term credit outlook. BMS's long-term and short-term credit ratings assigned by Fitch are A- and F2, respectively, with a stable long-term credit outlook. Our long-term ratings reflect the agencies' opinion 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 reflect the agencies' opinion that we have good to extremely strong capacity for timely repayment. Any credit rating downgrade may affect the interest rate of any debt we may incur, the fair market value of existing debt and our ability to access the capital markets generally.

Cash Flows

The following is a discussion of cash flow activities:

Dollars in Millions	Nine Months Ended September 30,	
	2016	2015
Cash flow provided by/(used in):		
Operating activities	\$1,422	\$1,221
Investing activities	1,464	(588)
Financing activities	(1,855)	(2,265)
Operating Activities		

Cash flow from operating activities represents the cash receipts and disbursements from all of our activities other than investing 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; customer discounts and rebates; and tax payments in the ordinary course of business. For example, annual employee bonuses are typically paid in the first quarter of the subsequent year. In addition, cash collections continue to be impacted by longer payment terms for certain biologic products in the U.S., primarily our newer oncology products including Opdivo, Yervoy and Empliciti (120 days to 150 days). The longer payment terms are used to more closely align with the insurance reimbursement timing for physicians and cancer centers following administration to the patients.

The \$201 million increase in cash provided by operating activities compared to 2015 was primarily attributable to:

- Higher operating cash flow attributed to increased sales and the timing of cash collections and payments in the ordinary course of business including the wind-down of the Abilify* alliance in 2015.

Partially offset by:

- Higher income tax payments of approximately \$1.5 billion.

Investing Activities

Cash requirements from investing activities include cash used for acquisitions, manufacturing and facility-related capital expenditures and purchases of marketable securities with maturities greater than 90 days reduced by proceeds from business divestitures (including royalties) and the sale and maturity of marketable securities.

The \$2.1 billion decrease in cash used in investing activities compared to 2015 was primarily attributable to:

Higher net redemptions of marketable securities of approximately \$1.3 billion in 2016 to meet short-term liquidity requirements;

Lower asset acquisition payments of approximately \$600 million. Asset acquisitions include Cormorant and Padlock in 2016 and Flexus in 2015; and

Higher business divestiture proceeds of approximately \$500 million. These amounts include royalties and other contingent consideration received subsequent to the divestiture. Divestitures include over-the-counter product and investigational HIV businesses in 2016 and the Mount Vernon, Indiana manufacturing facility, Ixempra* and mature and other over-the-counter product businesses in 2015.

Partially offset by:

Higher capital expenditures of approximately \$300 million.

Financing Activities

Cash requirements from financing activities include cash used to pay dividends, repurchase common stock and repay long-term debt and other borrowings reduced by proceeds from the exercise of stock options and issuance of long-term debt and other borrowings.

The \$410 million decrease in cash used in financing activities compared to 2015 was primarily attributable to:

Long-term net debt repayment of approximately \$700 million in 2015 (none in 2016).

Partially offset by:

Repurchase of common stock of approximately \$200 million in 2016 (none in 2015).

Product and Pipeline Developments

We manage our R&D programs on a portfolio basis, investing resources in each stage 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- 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 programs include both investigational compounds in Phase III development for initial indications and marketed products in Phase III development for additional indications or formulations. The following are the recent significant developments in our marketed products and our late-stage pipeline:

Opdivo - a fully human monoclonal antibody that binds to the PD-1 receptor on T and NKT cells that has been approved and continues to be investigated as an anti-cancer treatment. Opdivo is part of our alliance with Ono.

NSCLC

In October 2016, the Company announced updated results from two pivotal Phase III studies, CheckMate-057 and CheckMate-017, which showed more than one-third of previously treated metastatic NSCLC patients in both trials experienced ongoing responses with Opdivo, compared to no ongoing responses in the docetaxel arm. In CheckMate-057, patients with PD-L1 $\geq 1\%$ had a median duration of response of 17.2 months and in patients with PD-L1 $< 1\%$, it was 18.3 months. In both studies, durability of response was observed in both PD-L1 expressors and non-expressors, and in CheckMate-057, one out of the four complete responses occurred in a patient with $< 1\%$ PD-L1 expression. There were no new safety signals identified for Opdivo in the pooled safety analysis from both studies. In October 2016, the Company presented the final primary analysis of CheckMate-026, a Phase III trial investigating the use of Opdivo as a first-line monotherapy in patients with advanced NSCLC whose tumors expressed PD-L1 $\geq 1\%$. The study was powered to assess progression-free survival (PFS) for patients with $\geq 5\%$ PD-L1 expression. The top line results from this study were previously disclosed in August 2016 and showed CheckMate-026 did not meet the primary endpoint of superior PFS compared to chemotherapy. The median PFS was 4.2 months with Opdivo and 5.9 months with platinum-based doublet chemotherapy (stratified hazard ratio [HR]=1.15 [95% CI: 0.91, 1.45, p=0.25]). Median overall survival (OS) was 14.4 months for Opdivo versus 13.2 months for chemotherapy, (HR=1.02 [95% CI: 0.80, 1.30]), and 60% of patients on the chemotherapy arm received subsequent Opdivo use after progression either through crossover or commercial access.

Other indications

In October 2016, the Company announced new results from CheckMate-205, a multi-cohort, single-arm, Phase II trial evaluating Opdivo in patients with cHL. These results from cohort C of the trial included patients with cHL who had received brentuximab vedotin before and/or after auto-HSCT. After a median follow-up of 8.8 months, Opdivo demonstrated an objective response rate (ORR) as assessed by an independent radiologic review committee of 73% overall and median PFS of 11.2 months. The safety profile of Opdivo was consistent with previously reported data in this tumor type, and no new clinically meaningful safety signals were identified.

In October 2016, the Company announced the FDA accepted a supplemental Biologics License Application, which seeks to expand the use of Opdivo to adult patients with locally advanced unresectable or metastatic urothelial carcinoma (mUC) after failure of prior platinum-containing therapy. The FDA granted the application a priority review and previously granted Opdivo Breakthrough Therapy Designation for mUC in June 2016. The FDA action date is March 2, 2017.

In October 2016, the Company announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of Opdivo for the treatment of adult patients with relapsed or refractory cHL after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin. The CHMP recommendation will now be reviewed by the EC, which has the authority to approve medicines for the EU.

In October 2016, the Company announced updated results from the Phase I CheckMate-016 trial, which evaluated the safety and tolerability of the Opdivo+Yervoy regimen in previously treated and treatment-naïve patients with metastatic RCC. The overall response rate for the combination regimen was 40%. The safety profile of the Opdivo+Yervoy combination in metastatic RCC patients is consistent with previous reports of the regimen in other studies.

In October 2016, the Company announced new data from the Phase III CheckMate-141 trial evaluating Opdivo in patients with recurrent or metastatic SCCHN after platinum therapy compared to investigator's choice of therapy (methotrexate, docetaxel or cetuximab). Outcome assessments showed Opdivo stabilized patients' symptoms and functioning, including physical, role and social functioning across three separate instruments. Both PD-L1 expressors and non-expressors treated with investigator's choice of therapy experienced statistically significant worsening of patient-reported outcomes from baseline to week 15 versus Opdivo. In addition, Opdivo more than doubled the time to deterioration for most functional domains measured and significantly delayed the time to worsening symptoms of fatigue, dyspnea and insomnia, compared to investigator's choice of therapy.

32

In October 2016, the Company announced results from the Phase II CheckMate-275 trial, in which Opdivo had a confirmed ORR, the primary endpoint, of 19.6% (95% CI: 15.0 – 24.9) in platinum-refractory patients with mUC. Responses were observed in both PD-L1 expressors and non-expressors. The confirmed ORR in patients expressing PD-L1 $\geq 1\%$ was 23.8% (95% CI: 16.5 – 32.3) and 16.1% (95% CI: 10.5 – 23.1) in patients expressing PD-L1 $<1\%$. In patients expressing PD-L1 $\geq 5\%$, the confirmed ORR was 28.4% (95% CI: 18.9 – 39.5) and 15.8% (95% CI: 10.8 – 21.8) in patients expressing PD-L1 $<5\%$. The safety profile of Opdivo in this study was consistent with the safety profile of Opdivo in other tumor types.

In September 2016, the Company announced the EMA validated its type II variation application, which seeks to extend the current indications for Opdivo to include the treatment of locally advanced mUC in adults after failure of prior platinum-containing therapy. Validation of the application confirms the submission is complete and begins the EMA's centralized review process.

In August 2016, the Company and Ono announced that Ono received manufacturing and marketing approval for Opdivo in Japan for the treatment of unresectable or metastatic RCC.

In July 2016, the Company announced the FDA accepted for priority review, the EMA validated, and in Japan BMS's partner Ono submitted applications for Opdivo for patients with previously treated recurrent or metastatic SCCHN. The three submissions were based on CheckMate-141, a pivotal Phase III open-label, randomized study, that evaluated the OS of Opdivo in patients with SCCHN after platinum therapy compared to investigator's choice of therapy (methotrexate, docetaxel or cetuximab). This study was stopped early in January 2016 because an assessment conducted by the independent Data Monitoring Committee concluded the study met its primary endpoint of OS. The projected FDA action date is November 11, 2016.

Empliciti - a humanized monoclonal antibody for the treatment of multiple myeloma. Empliciti is part of our alliance with AbbVie Inc. (AbbVie).

In September 2016, the Company and AbbVie announced manufacturing and marketing approval in Japan for Empliciti in combination with Revlimid* and dexamethasone for the treatment of relapsed or refractory multiple myeloma.

Yervoy - a monoclonal antibody for the treatment of patients with unresectable or metastatic melanoma.

In October 2016, the Company announced superior efficacy with Yervoy 10mg/kg versus placebo on all survival endpoints in the Phase III trial CA184-029 (EORTC 18071) evaluating stage III melanoma patients who are at high risk of recurrence following complete surgical resection. In the study, Yervoy compared with placebo significantly improved OS (HR=0.72 [95.1% CI: 0.58-0.88; p=0.001]), a secondary endpoint, with five-year OS rates at 65.4% in the Yervoy group and 54.4% in the placebo group.

Orencia - a fusion protein indicated for adult patients with moderate to severe active RA and is also indicated for reducing signs and symptoms in certain pediatric patients with moderately to severely active polyarticular juvenile idiopathic arthritis.

In September 2016, the Company announced the EC approved Orencia intravenous infusion and subcutaneous injection, in combination with methotrexate (MTX), for the treatment of highly active and progressive disease in adult patients with RA not previously treated with MTX. With this approval, Orencia is the first biologic therapy with an indication in the EU specifically applicable to the treatment of MTX-naive RA patients with highly active and progressive disease. This approval allows for the expanded marketing of Orencia in all 28 Member States of the EU.

In July 2016, the Company announced the commercial launch of the Orencia ClickJect Autoinjector, a new self-administered autoinjector for adults with moderate to severe RA.

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. For a discussion of our critical

accounting policies, refer to “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2015 Annual Report on Form 10-K. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2016.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q (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 and expression 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 report and in the 2015 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of our market risk, refer to “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our 2015 Annual Report on Form 10-K.

Item 4. CONTROLS AND PROCEDURES

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Chief Executive Officer and Chief Financial Officer have concluded that such disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) are effective.

There were no changes in the Company’s internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Information pertaining to legal proceedings can be found in “Item 1. Financial Statements—Note 18. Legal Proceedings and Contingencies,” to the interim consolidated financial statements, and is incorporated by reference herein.

Item 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in the Company's 2015 Annual Report on Form 10-K.

34

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The following table summarizes the surrenders of our equity securities during the nine months ended September 30, 2016:

Period	Total Number of Shares Purchased ^(a)	Average Price Paid per Share ^(a)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs ^(b)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs ^(b)
Dollars in Millions, Except Per Share Data				
January 1 to 31, 2016	29,768	\$ 68.96	—	\$ 1,368
February 1 to 29, 2016	1,334,226	\$ 62.45	1,193,017	\$ 1,294
March 1 to 31, 2016	4,008,710	\$ 64.12	2,464,576	\$ 1,137
Three months ended March 31, 2016	5,372,704		3,657,593	
April 1 to 30, 2016	7,807	\$ 64.78	—	\$ 1,137
May 1 to 31, 2016	13,948	\$ 71.50	—	\$ 1,137
June 1 to 30, 2016	10,311	\$ 71.96	—	\$ 1,137
Three months ended June 30, 2016	32,066		—	
July 1 to 31, 2016	15,069	\$ 73.72	—	\$ 1,137
August 1 to 31, 2016	6,223	\$ 75.10	—	\$ 1,137
September 1 to 30, 2016	5,702	\$ 57.36	—	\$ 1,137
Three months ended September 30, 2016	26,994		—	
Nine months ended September 30, 2016	5,431,764		3,657,593	

The total number of shares purchased and the total number of shares purchased as part of publicly announced (a) programs are different because shares of common stock are surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of awards under our long-term incentive program.

In May 2010, the Board of Directors authorized the 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. As of September (b) 30, 2016, \$1.1 billion of common stock repurchase capacity remains under these programs. In October 2016, the Board of Directors approved a new share repurchase program authorizing the repurchase of an additional \$3.0 billion of common stock. The stock repurchase program does not have an expiration date.

Item 6. EXHIBITS

Exhibits (listed by number corresponding to the Exhibit Table of Item 601 in Regulation S-K).

Exhibit No. Description

12. Computation of Earnings to Fixed Charges.

31a. Section 302 Certification Letter.

31b. Section 302 Certification Letter.

32a. Section 906 Certification Letter.

32b. Section 906 Certification Letter.

The following financial statements from the Bristol-Myers Squibb Company Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in Extensible Business Reporting Language (XBRL):

101. (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.

* Indicates, in this Form 10-Q, brand names of products, which are registered trademarks not solely owned by the Company or its subsidiaries. Abilify is a trademark of Otsuka Pharmaceutical Co., Ltd.; Atripla is a trademark of Bristol-Myers Squibb and Gilead Sciences, LLC; Byetta is a trademark of Amylin Pharmaceuticals, LLC; Erbitux is a trademark of ImClone LLC; Gleevec is a trademark of Novartis AG; Ixempra is a trademark of R-Pharm US Operating, LLC; Keytruda is a trademark of Merck Sharp & Dohme Corp.; Plavix is a trademark of Sanofi; Revlimid is a trademark of Celgene Corporation and Tybost is a trademark of Gilead Sciences Ireland UC. Brand names of products that are in all italicized letters, without an asterisk, are registered trademarks of BMS and/or one of its subsidiaries.

SIGNATURES

Pursuant to the requirements 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)**

Date: October 27, 2016 By: /s/ Giovanni Caforio
Giovanni Caforio
Chief Executive Officer

Date: October 27, 2016 By: /s/ Charles Bancroft
Charles Bancroft
Chief Financial Officer