

BRISTOL MYERS SQUIBB CO  
Form 10-Q  
October 25, 2018

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, 2018

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.)

430 E. 29th Street, 14FL, New York, N.Y. 10016  
(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  Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, there were 1,632,198,774 shares outstanding of the Registrant's \$0.10 par value common stock.

---

BRISTOL-MYERS SQUIBB COMPANY  
INDEX TO FORM 10-Q  
SEPTEMBER 30, 2018

PART I—FINANCIAL INFORMATION

Item 1.

Financial Statements:

<u>Consolidated Statements of Earnings and Comprehensive Income</u>	<u>3</u>
<u>Consolidated Balance Sheets</u>	<u>4</u>
<u>Consolidated Statements of Cash Flows</u>	<u>5</u>
<u>Notes to Consolidated Financial Statements</u>	<u>6</u>

Item 2.

<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>27</u>
--	-----------

Item 3.

<u>Quantitative and Qualitative Disclosure About Market Risk</u>	<u>41</u>
--	-----------

Item 4.

<u>Controls and Procedures</u>	<u>41</u>
--------------------------------	-----------

PART II—OTHER INFORMATION

Item 1.

<u>Legal Proceedings</u>	<u>42</u>
--------------------------	-----------

Item 1A.

<u>Risk Factors</u>	<u>42</u>
---------------------	-----------

Item 2.

<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>42</u>
--	-----------

Item 6.

<u>Exhibits</u>	<u>43</u>
-----------------	-----------

<u>Summary of Abbreviated Terms</u>	<u>44</u>
-------------------------------------	-----------

<u>Signatures</u>	<u>45</u>
-------------------	-----------

\* Indicates brand names of products which are trademarks not owned by BMS. Specific trademark ownership information is included in the Exhibit Index.

## 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		Nine Months	
	Ended		Ended September	
	September 30,		30,	
EARNINGS	2018	2017	2018	2017
Net product sales	\$5,433	\$4,862	\$15,866	\$14,212
Alliance and other revenues	258	392	722	1,115
Total Revenues	5,691	5,254	16,588	15,327
Cost of products sold	1,648	1,579	4,857	4,413
Marketing, selling and administrative	1,104	1,163	3,215	3,435
Research and development	1,280	1,561	4,965	4,543
Other income (net)	(508 )	(232 )	(912 )	(1,497 )
Total Expenses	3,524	4,071	12,125	10,894
Earnings Before Income Taxes	2,167	1,183	4,463	4,433
Provision for Income Taxes	255	327	674	1,129
Net Earnings	1,912	856	3,789	3,304
Noncontrolling Interest	11	11	29	(31 )
Net Earnings Attributable to BMS	\$1,901	\$845	\$3,760	\$3,335
Earnings per Common Share				
Basic	\$1.16	\$0.52	\$2.30	\$2.02
Diluted	1.16	0.51	2.30	2.02
Cash dividends declared per common share	\$0.40	\$0.39	\$1.20	\$1.17

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Dollars in Millions

(UNAUDITED)

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
COMPREHENSIVE INCOME	2018	2017	2018	2017
Net Earnings	\$1,912	\$856	\$3,789	\$3,304
Other Comprehensive Income/(Loss), net of taxes and reclassifications to earnings:				
Derivatives qualifying as cash flow hedges	5	(1 )	71	(61 )
Pension and postretirement benefits	22	18	194	74
Available-for-sale securities	2	22	(31 )	41
Foreign currency translation	(21 )	7	(237 )	28
Other Comprehensive Income/(Loss)	8	46	(3 )	82

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

Comprehensive Income	1,920	902	3,786	3,386
Noncontrolling Interest	11	11	29	(31 )
Comprehensive Income Attributable to BMS	\$1,909	\$891	\$3,757	\$3,417

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

3

---

BRISTOL-MYERS SQUIBB COMPANY  
CONSOLIDATED BALANCE SHEETS

Dollars in Millions  
(UNAUDITED)

ASSETS	September 30, 2018	December 31, 2017
Current Assets:		
Cash and cash equivalents	\$ 5,408	\$ 5,421
Marketable securities	1,422	1,391
Receivables	5,871	6,300
Inventories	1,282	1,166
Prepaid expenses and other	886	576
Total Current Assets	14,869	14,854
Property, plant and equipment	5,092	5,001
Goodwill	6,686	6,863
Other intangible assets	1,107	1,210
Deferred income taxes	1,627	1,610
Marketable securities	2,017	2,480
Other assets	2,336	1,533
Total Assets	\$ 33,734	\$ 33,551

LIABILITIES

Current Liabilities:		
Short-term debt obligations	\$ 1,620	\$ 987
Accounts payable	1,773	2,248
Accrued liabilities	5,853	6,014
Deferred income	93	83
Income taxes payable	355	231
Total Current Liabilities	9,694	9,563
Deferred income	486	454
Income taxes payable	3,112	3,548
Pension and other liabilities	1,005	1,164
Long-term debt	5,687	6,975
Total Liabilities	19,984	21,704

Commitments and contingencies

EQUITY

Bristol-Myers Squibb Company Shareholders' Equity:		
Preferred stock	—	—
Common stock	221	221
Capital in excess of par value of stock	2,029	1,898
Accumulated other comprehensive loss	(2,326)	(2,289)
Retained earnings	33,292	31,160
Less cost of treasury stock	(19,576)	(19,249)
Total Bristol-Myers Squibb Company Shareholders' Equity	13,640	11,741
Noncontrolling interest	110	106
Total Equity	13,750	11,847
Total Liabilities and Equity	\$ 33,734	\$ 33,551

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,	
	2018	2017
Cash Flows From Operating Activities:		
Net earnings	\$3,789	\$3,304
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Depreciation and amortization, net	465	592
Deferred income taxes	(161 )	283
Stock-based compensation	168	149
Impairment charges	110	223
Pension settlements and amortization	145	148
Divestiture gains and royalties	(822 )	(546 )
Asset acquisition charges	85	510
Loss/(gain) on equity investments	244	(17 )
Other adjustments	(43 )	125
Changes in operating assets and liabilities:		
Receivables	(222 )	(539 )
Inventories	(152 )	7
Accounts payable	(186 )	63
Deferred income	84	(91 )
Income taxes payable	199	400
Other	(192 )	(453 )
Net Cash Provided by Operating Activities	3,511	4,158
Cash Flows From Investing Activities:		
Sale and maturities of marketable securities	1,453	4,296
Purchase of marketable securities	(1,062 )	(4,434 )
Capital expenditures	(661 )	(801 )
Divestiture and other proceeds	947	526
Acquisition and other payments	(1,215 )	(672 )
Net Cash Used in Investing Activities	(538 )	(1,085 )
Cash Flows From Financing Activities:		
Short-term debt obligations, net	(617 )	1,198
Issuance of long-term debt	—	1,488
Repayment of long-term debt	(5 )	(1,224 )
Repurchase of common stock	(320 )	(2,220 )
Dividends	(1,960 )	(1,938 )
Other	(55 )	(29 )
Net Cash Used in Financing Activities	(2,957 )	(2,725 )
Effect of Exchange Rates on Cash and Cash Equivalents	(29 )	59
Net (Decrease)/Increase in Cash and Cash Equivalents	(13 )	407
Cash and Cash Equivalents at Beginning of Period	5,421	4,237
Cash and Cash Equivalents at End of Period	\$5,408	\$4,644

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 prepared these unaudited consolidated financial statements following the requirements of the SEC and U.S. 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 Quarterly Report on Form 10-Q, which include all adjustments necessary for a fair presentation of the financial position at September 30, 2018 and December 31, 2017, the results of operations for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. 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, 2017 included in the 2017 Form 10-K. Refer to the Summary of Abbreviated Terms at the end of this Quarterly Report on Form 10-Q for terms used throughout the document.

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, judgments and assumptions. The most significant assumptions are estimates used in determining sales rebate and return accruals; legal contingencies; income taxes; and pension and postretirement benefits. Actual results may differ from estimates.

Certain prior period amounts were reclassified to conform to the current period presentation. Loss/(gain) on equity investments previously presented in Other adjustments in the consolidated statements of cash flows is now presented separately.

Recently Adopted Accounting Standards

Revenue from Contracts with Customers

Amended guidance for revenue recognition was adopted in the first quarter of 2018 using the modified retrospective method with the cumulative effect of the change recognized in Retained earnings. The new guidance, referred to as ASC 606, 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 and replaces most of the existing revenue recognition standards in U.S. GAAP. A five-step model is utilized to achieve the core principle: (1) identify the customer contract; (2) identify the contract's performance obligation; (3) determine the transaction price; (4) allocate the transaction price to the performance obligation; and (5) recognize revenue when or as a performance obligation is satisfied.

The timing of recognizing revenue for typical net product sales to our customers did not significantly change. However, transaction prices are no longer required to be fixed or determinable and certain variable consideration might be recognized prior to the occurrence or resolution of the contingent event. As a result, certain revenue previously deferred under the prior standard because the transaction price was not fixed or determinable is now accounted for as variable consideration and might be recognized earlier provided such terms are sufficient to reliably estimate the ultimate price expected to be realized.

Estimated future royalties and contingent fees related to certain arrangements are now recognized prior to the third party sale or event occurring to the extent it is probable that a significant reversal in the amount of estimated cumulative revenue will not occur. The new guidance pertaining to the separation of licensing rights and related fee recognition did not significantly change the timing of recognizing revenue in our existing alliance arrangements that are currently generating revenue. The timing of royalties, sales-based milestones and other forms of contingent consideration resulting from the divestiture of businesses as well as royalties and sales-based milestones from licensing arrangements did not change.

The cumulative effect of the accounting change resulted in recognizing contract assets of \$214 million and a \$168 million increase in Retained earnings net of tax. The cumulative effect was primarily attributed to royalties and licensing rights reacquired by alliance partners that are expected to be received in the future and are not eligible for the licensing exclusion. As a result of the new guidance and cumulative effect adjustment, revenue was approximately \$53 million and \$151 million lower in the three and nine months ended September 30, 2018, respectively, compared to what would have been reported under the previous guidance. Refer to "—Note 3. Revenue" for further information.

### Gains and Losses from the Derecognition of Nonfinancial Assets

Amended guidance for gains and losses from the derecognition of nonfinancial assets (ASC 610) was adopted in the first quarter of 2018 using the modified retrospective method. The amendments clarify the scope of asset derecognition guidance, add guidance for partial sales of nonfinancial assets and clarify recognizing gains and losses from the transfer of nonfinancial assets in contracts with noncustomers. Certain transactions such as the sale or transfer of product rights that do not constitute a business will require accounting similar to ASC 606 including the potential recognition of variable consideration. The amended guidance may result in earlier recognition of variable consideration depending on the facts and circumstances of each transaction.

The cumulative effect of the accounting change resulted in recognizing contract assets of \$167 million and a \$130 million increase in Retained earnings net of tax. The cumulative effect was primarily attributed to royalties and termination fees for licensing rights reacquired by third parties that are expected to be received in the future and are not eligible for the licensing exclusion. As a result of the new guidance and cumulative effect adjustment, Other income (net) was approximately \$4 million and \$16 million lower in the three and nine months ended September 30, 2018, respectively, compared to what would have been reported under the previous guidance.

### Presentation of Net Periodic Pension and Postretirement Benefits

Amended guidance requiring all net periodic benefit components for defined benefit pension and other postretirement plans other than service costs to be recorded outside of income from operations (other income) was adopted in the first quarter of 2018 on a retrospective basis. Cost of products sold; Marketing, selling and administrative; and Research and development expenses increased in the aggregate with a corresponding offset in Other income (net).

As adjusted amounts upon adoption of the new guidance are as follows:

Dollars in Millions	Three Months		Nine Months	
	Ended September		Ended September	
	30, 2017		30, 2017	
	As	As	As	As
	Previously	Previously	Previously	
	Reported	Adjusted	Reported	Adjusted
Cost of products sold	\$1,572	\$ 1,579	\$4,393	\$ 4,413
Marketing, selling and administrative	1,147	1,163	3,388	3,435
Research and development	1,543	1,561	4,490	4,543
Other income (net)	(191 )	(232 )	(1,377 )	(1,497 )

### Definition of a Business

Amended guidance which revises the definition of a business was adopted prospectively in the first quarter of 2018. The amendment provides an initial screen that when substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single identifiable asset or a group of similar identifiable assets, an integrated set of assets and activities would not represent a business. If the screen is not met, the set must include an input and a substantive process that together significantly contributes to the ability to create outputs for the set to represent a business. The amendment also narrows the definition of the term "output" and requires the transfer of an organized work force when outputs do not exist. The amended guidance may result in more transactions being accounted for as assets in the future with the impact to our results of operations dependent on the individual facts and circumstances of each transaction.

### Recognition and Measurement of Financial Assets and Liabilities

Amended guidance for the recognition, measurement, presentation and disclosure of financial instruments was adopted using the modified retrospective method in the first quarter of 2018. The new guidance requires that fair value adjustments for equity investments with readily determinable fair values be reported through earnings. The new guidance also requires a qualitative impairment assessment for equity investments without a readily determinable fair value based upon observable price changes and a charge through earnings if an impairment exists. The cumulative effect of the accounting change resulted in a \$36 million reduction to Other Comprehensive Income/(Loss) and a corresponding \$34 million increase to Retained earnings, net of tax. Refer to "— Note 6. Other Income (Net) for further information and the impact on the results of operations.

Accounting for Hedging Activities

Amended guidance for derivatives and hedging was adopted using the modified retrospective method in the first quarter of 2018. The amended guidance revises and expands items eligible for hedge accounting, simplifies hedge effectiveness testing and changes the timing of recognition and presentation for certain hedged items. Certain disclosure requirements were also modified for hedging activities on a prospective basis. The adoption of the amended standard did not have a material impact on the Company's results of operations.

7

---

### Recently Issued Accounting Standards Not Yet Adopted

#### Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

In February 2018, the FASB issued amended guidance on income tax accounting. The amended guidance permits the reclassification of the income tax effect on amounts recorded within Other comprehensive income impacted by the Tax Cuts and Jobs Act into Retained earnings. The amended guidance is effective for periods ending after December 15, 2018 and applies only to those amounts remaining in Other comprehensive income at the date of enactment of the Act. The amended guidance may be adopted on either a retrospective basis or at the beginning of the period of adoption. The Company is assessing the potential impact of the amended standard.

In addition, the following recently issued accounting standards have not been adopted. Refer to the 2017 Form 10-K for additional information and their potential impacts.

Accounting Standard Update	Effective Date
Leases	January 1, 2019
Financial Instruments - Measurement of Credit Losses	January 1, 2020
Goodwill Impairment Testing	January 1, 2020

### 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. The determination of a single segment 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. For further information on product and regional revenues, see "—Note 3. Revenue."

### Note 3. REVENUE

The following table summarizes the disaggregation of revenue by nature:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Dollars in Millions				
Net product sales	\$5,433	\$4,862	\$15,866	\$14,212
Alliance revenues	177	232	483	694
Other revenues	81	160	239	421
Total Revenues	\$5,691	\$5,254	\$16,588	\$15,327

Net product sales represent more than 90% of the Company's total revenues during the three and nine months ended September 30, 2018 and 2017. Products are sold principally to wholesalers or distributors and to a lesser extent, directly to retailers, hospitals, clinics, government agencies and pharmacies. Customer orders are generally fulfilled within a few days of receipt resulting in minimal order backlog. Contractual performance obligations are usually limited to transfer of control of the product to the customer. The transfer occurs either upon shipment or upon receipt of the product in certain non-U.S. countries after considering when the customer obtains legal title to the product and

when the Company obtains a right of payment. At these points, customers are able to direct the use of and obtain substantially all of the remaining benefits of the product.

8

---

Wholesalers are initially invoiced at contractual list prices. Payment terms are typically 30 to 90 days based on customary practices in each country with the exception of certain biologic products in the U.S., including Opdivo, Yervoy and Empliciti (90 days to 120 days). Revenue is reduced from wholesaler list price at the time of recognition for expected charge-backs, discounts, rebates, sales allowances and product returns, which are referred to as gross-to-net (GTN) adjustments. These reductions are attributed to various commercial arrangements, managed healthcare organizations and government programs such as Medicare, Medicaid and the 340B Drug Pricing Program containing various pricing implications such as mandatory discounts, pricing protection below wholesaler list price or other discounts when Medicare Part D beneficiaries are in the coverage gap. In addition, non-U.S. government programs include different pricing schemes such as cost caps, volume discounts, outcome-based pricing and pricing claw-backs determined on sales of individual companies or an aggregation of companies participating in a specific market. Charge-backs and cash discounts are reflected as a reduction to receivables and settled through the issuance of credits to the customer, typically within one month. All other rebates, discounts and adjustments, including Medicaid and Medicare, are reflected as a liability and settled through cash payments to the customer, typically within various time periods ranging from a few months to one year.

Significant judgment is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

The following table summarizes GTN adjustments:

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,		30,	
Dollars in Millions	2018	2017	2018	2017
Gross product sales	\$7,681	\$6,555	\$21,891	\$18,723
GTN adjustments <sup>(a)</sup>				
Charge-backs and cash discounts	(711 )	(583 )	(1,957 )	(1,521 )
Medicaid and Medicare rebates	(847 )	(573 )	(2,169 )	(1,474 )
Other rebates, returns, discounts and adjustments	(690 )	(537 )	(1,899 )	(1,516 )
Total GTN adjustments	(2,248 )	(1,693 )	(6,025 )	(4,511 )
Net product sales	\$5,433	\$4,862	\$15,866	\$14,212

Includes adjustments to provisions for product sales made in prior periods resulting from changes in estimates of (a) \$(7) million and \$11 million in the three months ended September 30, 2018 and 2017 and \$103 million and \$65 million in the nine months ended September 30, 2018 and 2017, respectively.

Alliance and other revenues consist primarily of amounts related to collaborations and out-licensing arrangements. Each of these arrangements are evaluated for whether they represent contracts that are within the scope of the revenue recognition guidance in their entirety or contain aspects that are within the scope of the guidance, either directly or by reference based upon the application of the guidance related to the derecognition of nonfinancial assets (ASC 610).

Performance obligations are identified and separated when the other party can benefit directly from the rights, goods or services either on their own or together with other readily available resources and when the rights, goods or services are not highly interdependent or interrelated.

Transaction prices for these arrangements may include fixed up-front amounts as well as variable consideration such as contingent development and regulatory milestones, sales-based milestones and royalties. The most likely amount method is used to estimate contingent development, regulatory and sales-based milestones because the ultimate outcomes are binary in nature. The expected value method is used to estimate royalties because a broad range of potential outcomes exist, except for instances in which such royalties relate to a license. Variable consideration is



included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. Significant judgment is required in estimating the amount of variable consideration to recognize when assessing factors outside of BMS's influence such as likelihood of regulatory success, limited availability of third party information, expected duration of time until resolution, lack of relevant past experience, historical practice of offering fee concessions and a large number and broad range of possible amounts. To the extent arrangements include multiple performance obligations that are separable, the transaction price assigned to each distinct performance obligation is reflective of the relative stand-alone selling price and recognized at a point in time upon the transfer of control.

Three types of out-licensing arrangements are typically utilized: 1) arrangements when we out-license intellectual property to another party and have no further performance obligations; 2) arrangements that include a license and an additional performance obligation to supply product upon the request of the third party; and 3) collaboration arrangements, which include transferring a license to a third party to jointly develop and commercialize a product.

Most out-licensing arrangements consist of a single performance obligation that is satisfied upon execution of the agreement when the development and commercialization rights are transferred to a third party. Up-front fees are recognized immediately and included in other income. Although contingent development and regulatory milestone amounts are assessed each period for the likelihood of achievement, they are typically constrained and recognized when the uncertainty is subsequently resolved for the full amount of the milestone and included in other income. Sales-based milestones and royalties are recognized when the milestone is achieved or the subsequent sales occur. Sales-based milestones are included in other income and royalties are included in alliance and other revenue.

Certain out-licensing arrangements may also include contingent performance obligations to supply commercial product to the third party upon its request. The license and supply obligations are accounted for as separate performance obligations as they are considered distinct because the third party can benefit from the license either on its own or together with other supply resources readily available to it and the obligations are separately identifiable from other obligations in the contract in accordance with the revenue recognition guidance. After considering the standalone selling prices in these situations, up-front fees, contingent development and regulatory milestone amounts and sales-based milestone and royalties are allocated to the license and recognized in the manner described above. Consideration for the supply obligation is usually based upon stipulated cost-plus margin contractual terms which represent a standalone selling price. The supply consideration is recognized at a point in time upon transfer of control of the product to the third party and included in alliance and other revenue. The above fee allocation between the license and the supply represents the amount of consideration that the Company expects to be entitled to for the satisfaction of the separate performance obligations.

Although collaboration arrangements are unique in nature, both parties are active participants in the operating activities and are exposed to significant risks and rewards depending on the commercial success of the activities. Performance obligations inherent in these arrangements may include the transfer of certain development or commercialization rights, ongoing development and commercialization services and product supply obligations. Except for certain product supply obligations which are considered distinct and accounted for as separate performance obligations similar to the manner discussed above, all other performance obligations are not considered distinct and are combined into a single performance obligation since the transferred rights are highly integrated and interrelated to our obligation to jointly develop and commercialize the product with the third party. As a result, up-front fees are recognized over time throughout the expected period of the collaboration activities and included in other income as the license is combined with other development and commercialization obligations. Contingent development and regulatory milestones that are no longer constrained are recognized in a similar manner on a prospective basis. Royalties and profit sharing are recognized when the underlying sales and profits occur and are included in alliance and other revenue. Refer to "-Note 4. Alliances" for further information.

The following table summarizes the disaggregation of revenue by product and region:

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,		30,	
Dollars in Millions	2018	2017	2018	2017
Prioritized Brands				
Opdivo	\$1,793	\$1,265	\$4,931	\$3,587
Eliquis	1,577	1,232	4,733	3,509
Orencia	675	632	1,979	1,817
Sprycel	491	509	1,464	1,478
Yervoy	382	323	946	975
Empliciti	59	60	178	168
Established Brands				
Baraclude	175	264	579	819

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

Sustiva Franchise	72	183	229	555
Reyataz Franchise	87	174	328	555
Hepatitis C Franchise (2 )	73	13	347	
Other Brands	382	539	1,208	1,517
Total Revenues	\$5,691	\$5,254	\$16,588	\$15,327

United States	\$3,235	\$2,864	\$9,243	\$8,467
Europe	1,365	1,262	4,179	3,596
Rest of World	932	970	2,728	2,858
Other	159	158	438	406
Total Revenues	\$5,691	\$5,254	\$16,588	\$15,327

10

---

The following table summarizes contract assets as of September 30, 2018 and January 1, 2018:

Dollars in Millions	September 30, January	
	2018	1, 2018
Prepaid expenses and other	\$ 193	\$ 349
Other assets	23	32
Total Contract Assets	\$ 216	\$ 381

Contract assets are primarily estimated future royalties and termination fees not eligible for the licensing exclusion and therefore recognized upon the adoption of ASC 606 and ASC 610. Contract assets are reduced and receivables are increased in the period the underlying sales occur. Contingent development and regulatory milestones from out-licensing arrangements of \$1.4 billion were constrained and not recognized after considering the likelihood of a significant reversal of cumulative amount of revenue occurring. Cumulative catch-up adjustments to revenue affecting contract assets or contract liabilities were not material during the three and nine months ended September 30, 2018. Revenue recognized from performance obligations satisfied in prior periods was \$97 million and \$398 million in the three and nine months ended September 30, 2018, consisting primarily of royalties for out-licensing arrangements and revised estimates for gross-to-net adjustments related to prior period sales.

Sales commissions and other incremental costs of obtaining customer contracts are expensed as incurred as the amortization periods would be less than one year.

#### Note 4. 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 prioritized products and certain 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. Certain prior period amounts included below were revised to exclude amounts for arrangements that no longer meet the criteria for collaboration arrangements.

Dollars in Millions	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues from alliances:				
Net product sales	\$2,037	\$1,754	\$6,135	\$5,017
Alliance revenues	177	232	483	694
Total Revenues	\$2,214	\$1,986	\$6,618	\$5,711
Payments to/(from) alliance partners:				
Cost of products sold	\$838	\$678	\$2,528	\$1,965

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

Marketing, selling and administrative	(26 )	(18 )	(76 )	(41 )
Research and development	(2 )	(13 )	1,060	(14 )
Other income (net)	(14 )	(9 )	(44 )	(29 )

Selected Alliance Balance Sheet information:

Dollars in Millions	September 30, December 31,	
	2018	2017
Receivables - from alliance partners	\$ 354	\$ 322
Accounts payable - to alliance partners	835	875
Deferred income from alliances <sup>(a)</sup>	510	467

(a) Includes unamortized up-front, milestone and other licensing proceeds. Amortization of deferred income (primarily related to alliances) was \$16 million and \$20 million in the three months ended September 30, 2018 and 2017 and \$48 million and \$59 million in the nine months ended September 30, 2018 and 2017, respectively.

The nature and purpose, significant rights and obligations of the parties and specific accounting policy elections for each of our significant alliances are discussed in our 2017 Form 10-K. Significant developments and updates related to alliances during 2018 are set forth below.

#### Nektar

In the second quarter of 2018, BMS and Nektar commenced a worldwide license and collaboration for the development and commercialization of NKTR-214, Nektar's investigational immuno-stimulatory therapy designed to selectively expand specific cancer-fighting T cells and natural killer cells directly in the tumor micro-environment. The Opdivo and NKTR-214 combination therapy is currently in Phase II clinical studies for multiple cancer indications and in a Phase III clinical study for melanoma. A joint development plan agreed by the parties contemplates development in various indications and tumor types with each party responsible for the supply of their own product. BMS's share of the development costs associated with therapies comprising a BMS medicine used in combination with NKTR-214 is 67.5%, subject to certain cost caps for Nektar. The parties will also jointly commercialize the therapies, subject to regulatory approval. BMS's share of global NKTR-214 profits and losses will be 35% subject to certain annual loss caps for Nektar.

BMS paid Nektar \$1.85 billion for the rights discussed above and 8.3 million shares of Nektar common stock representing a 4.8% ownership interest. BMS's equity ownership is subject to certain lock-up, standstill and voting provisions for a five-year period. The amount of the up-front payment allocated to the equity investment was \$800 million after considering Nektar's stock price on the date of closing and current limitations on trading the securities. The remaining \$1.05 billion of the up-front payment was allocated to the rights discussed above and included in research and development expense in the second quarter of 2018. BMS will also pay up to \$1.8 billion upon the achievement of contingent development, regulatory and sales-based milestones over the life of the alliance period.

#### Ono

In the third quarter of 2018, BMS provided Ono with a right to accept NKTR-214 into their alliance upon completion of a Phase I clinical study of Opdivo and NKTR-214 in the Ono Territory. If the right is exercised, Ono will partially reimburse BMS for development costs incurred with the study and share in certain future development costs, contingent milestone payments, profits and losses under the collaboration with Nektar.

#### Promedior

In the third quarter of 2018, BMS notified Promedior that it would not exercise its warrant to purchase all outstanding shares of Promedior.

### Note 5. DIVESTITURES AND LICENSING ARRANGEMENTS

#### Divestitures

The following table summarizes proceeds, gains and royalty income resulting from divestitures. Revenues and pretax earnings related to all divestitures were not material in all periods presented (excluding divestiture gains).

	Three Months Ended September 30,					
	Proceeds <sup>(a)</sup>		Divestiture Gains		Royalty Income	
Dollars in Millions	2018	2017	2018	2017	2018	2017
Manufacturing Operations	\$—	\$—	\$—	\$—	\$—	\$—
Diabetes Business	165	82	—	—	(170 )	(78 )
Erbix <sup>*</sup> Business	59	54	—	—	(48 )	(56 )
Mature Brands and Other	140	1	(108 )	1	1	(2 )
	\$364	\$137	\$(108)	\$ 1	\$(217)	\$(136)
	Nine Months Ended September 30,					
	Proceeds <sup>(a)</sup>		Divestiture Gains		Royalty Income	

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

Dollars in Millions	2018	2017	2018	2017	2018	2017
Manufacturing Operations	\$159	\$—	\$—	\$—	\$—	\$—
Diabetes Business	408	333	—	(100 )	(497 )	(252 )
Erbix* Business	168	162	—	—	(145 )	(164 )
Mature Brands and Other	212	31	(178 )	(26 )	(2 )	(4 )
	\$947	\$526	\$(178)	\$(126)	\$(644)	\$(420)

(a) Includes royalties received subsequent to the related sale of the asset or business.

12

---

### Manufacturing Operations

In the fourth quarter of 2017, BMS sold its small molecule active pharmaceutical ingredient manufacturing operations in Swords, Ireland to SK Biotek for approximately \$165 million, subject to certain adjustments. The transaction was accounted for as the sale of a business. SK Biotek will provide certain manufacturing services for BMS through 2022.

### Diabetes Business

In the first quarter of 2017, BMS received \$100 million from AstraZeneca as additional contingent consideration for the diabetes business divestiture upon achievement of a regulatory approval milestone, which was included in Other income (net).

### Mature Brands and Other

Divestitures include several brands sold to Cheplapharm resulting in proceeds of \$153 million and divestiture gains of \$127 million in 2018.

### Licensing Arrangements

#### Biogen

In the second quarter of 2017, BMS out-licensed to Biogen exclusive rights to develop and commercialize BMS-986168, an anti-eTau compound in development for Progressive Supranuclear Palsy. Biogen paid \$300 million to BMS which was included in Other income (net). BMS is also entitled to contingent development, regulatory and sales-based milestone payments of up to \$410 million if achieved and future royalties. BMS originally acquired the rights to this compound in 2014 through its acquisition of iPierian. Biogen assumed all of BMS's remaining obligations to the former stockholders of iPierian.

#### Roche

In the second quarter of 2017, BMS out-licensed to Roche exclusive rights to develop and commercialize BMS-986089, an anti-myostatin adnectin in development for Duchenne Muscular Dystrophy. Roche paid \$170 million to BMS which was included in Other income (net). BMS is also entitled to contingent development and regulatory milestone payments of up to \$205 million if achieved and future royalties.

### Note 6. OTHER INCOME (NET)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
Dollars in Millions	2018	2017	2018	2017
Interest expense	\$44	\$48	\$135	\$145
Investment income	(44 )	(32 )	(118 )	(87 )
Loss/(gain) on equity investments	(97 )	(5 )	244	(17 )
Provision for restructuring	45	28	102	207
Litigation and other settlements	11	—	10	(489 )
Equity in net income of affiliates	(22 )	(21 )	(73 )	(59 )
Divestiture (gains)/losses	(108 )	1	(178 )	(126 )
Royalties and licensing income	(338 )	(209 )	(1,058)	(1,093 )
Transition and other service fees	—	(12 )	(5 )	(32 )
Pension and postretirement	(10 )	(19 )	(40 )	(29 )
Intangible asset impairment	—	—	64	—
Loss on debt redemption	—	—	—	109
Other	11	(11 )	5	(26 )
Other income (net)	\$(508)	\$(232)	\$(912)	\$(1,497)

Loss/(gain) on equity investments includes a \$100 million increase and \$307 million decrease in fair value adjustments for the equity investment in Nektar in the three and nine months ended September 30, 2018, respectively.



Litigation and other settlements includes BMS's share of a patent-infringement litigation settlement of \$481 million related to Merck's PD-1 antibody Keytruda\* in the first quarter of 2017.  
Royalties and licensing income includes up-front licensing fees of \$470 million from Biogen and Roche in the second quarter of 2017.

## Note 7. RESTRUCTURING

In October 2016, the Company announced a restructuring plan to evolve and streamline its operating model. The majority of the charges are expected to be incurred through 2020, range between \$1.5 billion to \$2.0 billion and consist of employee termination benefit costs, contract termination costs, plant and equipment accelerated depreciation and impairment charges and other shutdown costs associated with early manufacturing and R&D site exits. Cash outlays in connection with these actions are expected to be approximately 40% to 50% of the total charges. Charges of approximately \$1.0 billion have been recognized for these actions since the announcement (\$200 million and \$534 million for the nine months ended September 30, 2018 and 2017, respectively). Restructuring charges are recognized upon meeting certain criteria, including finalization of committed plans, reliable estimates and discussions with local works councils in certain markets.

Employee workforce reductions were approximately 600 and 1,200 for the nine months ended September 30, 2018 and 2017, respectively.

The following tables summarize the charges and activity related to the restructuring actions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Dollars in Millions	2018	2017	2018	2017
Employee termination costs	\$ 37	\$ 18	\$ 72	\$ 190
Other termination costs	8	10	30	17
Provision for restructuring	45	28	102	207
Accelerated depreciation	30	64	82	216
Asset impairments	—	1	10	144
Other shutdown costs	1	—	6	3
Total charges	\$ 76	\$ 93	\$ 200	\$ 570

  

	Three Months Ended September 30,		Nine Months Ended September 30,	
Dollars in Millions	2018	2017	2018	2017
Cost of products sold	\$ 12	\$ 1	\$ 39	\$ 131
Marketing, selling and administrative	1	—	2	—
Research and development	18	64	57	232
Other income (net)	45	28	102	207
Total charges	\$ 76	\$ 93	\$ 200	\$ 570

  

	Nine Months Ended September 30,	
Dollars in Millions	2018	2017
Liability at January 1	\$ 186	\$ 114
Charges	108	233
Change in estimates	(6 )	(26 )

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

Provision for restructuring	102	207
Foreign currency translation	2	17
Payments	(171 )	(179 )
Liability at September 30	\$119	\$159

14

---

## Note 8. INCOME TAXES

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
Dollars in Millions	2018	2017	2018	2017
Earnings Before Income Taxes	\$2,167	\$1,183	\$4,463	\$4,433
Provision for Income Taxes	255	327	674	1,129
Effective Tax Rate	11.8	% 27.6	% 15.1	% 25.5

New tax reform legislation in the U.S. was enacted on December 22, 2017 known as the Tax Cuts and Jobs Act of 2017 (the Act). The Act moves from a worldwide tax system to a quasi-territorial tax system and comprises broad and complex changes to the U.S. tax code including, but not limited to, (1) reducing the U.S. tax rate from 35% to 21%; (2) adding a deemed repatriation transition tax on certain foreign earnings and profits; (3) generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; (4) including certain income of controlled foreign companies in U.S. taxable income; (5) creating a new minimum tax referred to as a base erosion anti-abuse income tax; (6) limiting certain research-based credits; and (7) eliminating the domestic manufacturing deduction.

Although many aspects of the Act were not effective until 2018, additional tax expense of \$2.9 billion was recognized in the fourth quarter of 2017 upon its enactment, including a \$2.6 billion one-time deemed repatriation transition tax on previously untaxed post-1986 foreign earnings and profits (including related tax reserves). The accounting for the \$2.6 billion was and continues to be incomplete as we do not have all of the necessary information available, prepared and analyzed to complete the accounting. However, a reasonable estimate of this tax was recorded as a provisional amount. The provisional amount was reduced by \$49 million in 2018, and may continue to change until completed in the fourth quarter of 2018 if additional interpretations of the relevant tax code are released.

The provisional adjustment discussed above, jurisdictional tax rates and other tax impacts attributed to non-deductible R&D charges, Nektar equity investment fair value adjustments and other specified items decreased the effective tax rate by 1.5% and 0.8% in the three and nine months ended September 30, 2018, and increased the effective tax rate by 4.7% and 3.7% in the three and nine months ended September 30, 2017, respectively. The tax impact of these discrete items are reflected immediately and are not considered in estimating the annual effective tax rate. In addition to the ongoing impact of U.S. tax reform discussed above, a \$49 million tax reserve release, a higher Puerto Rico excise tax credit and unfavorable changes in earnings mix resulted in a reduction to the effective tax rates of 9.6% and 5.9% in the three and nine months ended September 30, 2018 from prior year comparable periods, respectively. Additional changes to the effective tax rate may occur in future periods due to various reasons including pretax earnings mix, tax reserves, cash repatriations and revised interpretations of the relevant tax code.

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 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.

It is also reasonably possible that the total amount of unrecognized tax benefits at September 30, 2018 could decrease in the range of approximately \$305 million to \$355 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.

## Note 9. EARNINGS PER SHARE

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

	Three Months		Nine Months	
	Ended September 30,	Ended September 30,	Ended September 30,	Ended September 30,
Amounts in Millions, Except Per Share Data	2018	2017	2018	2017
Net Earnings Attributable to BMS used for Basic and Diluted EPS Calculation	\$1,901	\$845	\$3,760	\$3,335
Weighted-average common shares outstanding - basic	1,632	1,639	1,633	1,648
Incremental shares attributable to share-based compensation plans	4	6	4	7
Weighted-average common shares outstanding - diluted	1,636	1,645	1,637	1,655
Earnings per share - basic	\$1.16	\$0.52	\$2.30	\$2.02
Earnings per share - diluted	1.16	0.51	2.30	2.02

15

---

## Note 10. 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, 2018		December 31, 2017	
	Level 1	Level 2	Level 1	Level 2
Cash and cash equivalents - money market and other investments	\$4,861	\$—	\$4,728	\$—
Marketable securities				
Certificates of deposit	—	15	—	141
Commercial paper	—	608	—	50
Corporate debt securities	—	2,675	—	3,548
Equity investments	—	141	—	132
Derivative assets	—	47	—	13
Equity investments	10,494	—	67	—
Derivative liabilities	(24)	—	(52)	—

As further described in "—Note 9. Financial Instruments and Fair Value Measurements" in our 2017 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, 2018 and December 31, 2017.

## Available-for-sale Securities

The following table summarizes available-for-sale securities:

Dollars in Millions	September 30, 2018			December 31, 2017			
	Gross		Fair Value	Gross			Fair Value
	Amortized Cost	Unrealized Gains/Losses		Amortized Cost	Unrealized Gains	Unrealized Losses	
Certificates of deposit	\$15	\$—	\$15	\$141	\$—	\$—	\$141
Commercial paper	608	—	608	50	—	—	50
Corporate debt securities	2,720	(45)	2,675	3,555	3	(10)	3,548
Equity investments <sup>(a)</sup>	—	—	—	31	37	(1)	67
	\$3,343	\$(45)	\$3,298	\$3,777	\$40	\$(11)	\$3,806
Equity investments <sup>(b)</sup>			739				132
Total			\$4,037				\$3,938

Dollars in Millions	September 30, 2018	December 31, 2017
Current marketable securities	\$ 1,422	\$ 1,391
Non-current marketable securities <sup>(c)</sup>	2,017	2,480
Other assets <sup>(a)</sup>	598	67
Total	\$ 4,037	\$ 3,938

<sup>(a)</sup> Includes equity investments with readily determinable fair values not measured using the fair value option as of December 31, 2017.

<sup>(b)</sup> Includes equity and fixed income funds measured using the fair value option at December 31, 2017. Refer to "—Note.1 Basis of Presentation and Recently Issued Accounting Standards" for more information.

<sup>(c)</sup> All non-current marketable securities mature within five years as of September 30, 2018 and December 31, 2017.

Equity investments not measured at fair value and excluded from the above table were limited partnerships and other equity method investments of \$109 million at September 30, 2018 and \$66 million at December 31, 2017 and other equity investments without readily determinable fair values of \$193 million at September 30, 2018 and \$152 million at December 31, 2017. These amounts are included in Other assets. Adjustments to equity investments without readily determinable fair values for the nine months ended September 30, 2018 were \$18 million resulting from observable price changes for similar securities of the same issuer and were recorded in Other income (net).

The following table summarizes net loss recorded for equity investments with readily determinable fair values held as of September 30, 2018:

Dollars in Millions	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Net gain/(loss) recognized	\$ 97	\$ (262 )
Less: Net gain/(loss) recognized for equity investments sold	—	—
Net unrealized gain/(loss) on equity investments held	\$ 97	\$ (262 )

Qualifying Hedges and Non-Qualifying Derivatives

The following table summarizes the fair value of outstanding derivatives:

Dollars in Millions	September 30, 2018		December 31, 2017	
	Asset <sup>(a)</sup> Fair Notional Value	Liability <sup>(b)</sup> Fair Notional Value	Asset <sup>(a)</sup> Fair Notional Value	Liability <sup>(b)</sup> Fair Notional Value
Derivatives designated as hedging instruments:				
Interest rate swap contracts	\$—	—\$755 (\$19 )	\$—	—\$755 \$ (6 )
Cross-currency interest rate swap contracts	172	125 (1 )	—	—
Foreign currency forward contracts	1,446	22 —	942	489 (9 )

Derivatives not designated as hedging instruments:

Foreign currency forward contracts	412	157 (4 )	206	1,369 (37 )
------------------------------------	-----	----------	-----	-------------

(a) Included in prepaid expenses and other and other assets.

(b) Included in accrued liabilities and pension and other liabilities.

The following table summarizes the financial statement classification and amount of gain/(loss) recognized on hedging instruments:

Dollars in Millions	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
	Cost of products sold Other income (net)	Cost of products sold Other income (net)
Interest rate swap contracts	\$ —\$ 5	\$ —\$ 18
Cross-currency interest rate swap contracts	— 2	— 6
Foreign currency forward contracts	13 10	(20) 17

Dollars in Millions	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2017
	Cost of products (net)	Cost of products (net)



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

	sold	sold
Interest rate swap contracts	\$ —\$ 7	\$ —\$ 23
Foreign currency forward contracts	3 (19 )	38 (42 )

17

---

The following table summarizes the effect of derivative and non-derivative instruments designated as hedging instruments in Other Comprehensive Income/(Loss):

Dollars in Millions	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Derivatives qualifying as cash flow hedges		
Foreign currency forward contracts gain/(loss):		
Recognized in Other Comprehensive Income/(Loss) <sup>(a)</sup>	\$ 18	\$ 63
Reclassified to Cost of products sold	(13 )	20

Derivatives qualifying as net investment hedges  
Cross-currency interest rate swap contracts gain/(loss):

Recognized in Other Comprehensive Income/(Loss)	5	1
---	---	---

Non-derivatives qualifying as net investment hedges

Non U.S. dollar borrowings gain/(loss):

Recognized in Other Comprehensive Income/(Loss)	(6 )	10
---	------	----

(a) The amount is expected to be reclassified into earnings in the next 12 months.

Cash Flow Hedges — Foreign currency forward contracts are used to hedge certain forecasted intercompany inventory purchase transactions and certain foreign currency transactions. The fair value for contracts designated as cash flow hedges is temporarily reported in Accumulated other comprehensive loss and included in earnings when the hedged item affects earnings. Upon adoption of the amended guidance for derivatives and hedging, the entire change in fair value of the hedging instrument included in the assessment of hedge effectiveness is recorded in the derivatives qualifying as cash flow hedges component of Other Comprehensive Income/(Loss). The net gain or loss on foreign currency forward contracts is expected to be reclassified to net earnings (primarily included in cost of products sold) within the next twelve months. The notional amount of outstanding foreign currency forward contracts was primarily attributed to the euro (\$861 million) and Japanese yen (\$393 million) at September 30, 2018.

The earnings impact related to discontinued cash flow hedges and hedge ineffectiveness was not significant during all periods presented. Cash flow hedge accounting is discontinued when the forecasted transaction is no longer probable of occurring within 60 days after the originally forecasted date or when the hedge is no longer effective. Assessments to determine whether derivatives designated as qualifying hedges are highly effective in offsetting changes in the cash flows of hedged items are performed at inception and on a quarterly basis. Foreign currency forward contracts not designated as hedging instruments are used to offset exposures in certain foreign currency denominated assets, liabilities and earnings. Changes in the fair value of these derivatives are recognized in earnings as they occur.

Net Investment Hedges — Non-U.S. dollar borrowings of €950 million (\$1.1 billion) are designated to hedge euro currency exposures of the net investment in certain foreign affiliates. These borrowings are designated as net investment hedges and recognized in long-term debt. The effective portion of foreign exchange gain or loss on the remeasurement of euro debt was \$10 million in 2018 and \$132 million in 2017 and was recorded in the foreign currency translation component of Other Comprehensive Income/(Loss) with a related offset in long-term debt.

In January 2018, BMS entered into \$300 million of cross-currency interest rate swap contracts maturing in December 2022 designated to hedge Japanese yen currency exposures of the Company's net investment in its Japan subsidiary. Contract fair value changes are recorded in the foreign currency translation component of Other Comprehensive

Income/(Loss) with a related offset in Pension and other liabilities.

Fair Value Hedges — Fixed to floating interest rate swap contracts are designated as fair value hedges and used as an interest rate risk management strategy to create an appropriate balance of fixed and floating rate debt. The contracts and underlying debt for the hedged benchmark risk are recorded at fair value. Gains or losses resulting from changes in fair value of the underlying debt attributable to the hedged benchmark interest rate risk are recorded in interest expense with an associated offset to the carrying value of debt. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, all changes in fair value of the swap are recorded in interest expense with an associated offset to the derivative asset or liability on the consolidated balance sheet. As a result, there was no net impact in earnings. When the underlying swap is terminated prior to maturity, the fair value adjustment to the underlying debt is amortized as a reduction to interest expense over the remaining term of the debt.

18

---

## Debt Obligations

Short-term debt obligations include:

Dollars in Millions	September 30, December 31,	
	2018	2017
Commercial paper	\$ —	\$ 299
Non-U.S. short-term borrowings	312	512
Current portion of long-term debt	1,247	—
Other	61	176
Total	\$ 1,620	\$ 987

The average amount of commercial paper outstanding was \$25.1 million at a weighted-average rate of 1.3% during 2018. The maximum amount of commercial paper outstanding was \$300 million with no outstanding balance at September 30, 2018.

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

Dollars in Millions	September 30, December 31,	
	2018	2017
Principal Value	\$ 6,819	\$ 6,835
Adjustments to Principal Value		
Fair value of interest rate swap contracts	(19 )	(6 )
Unamortized basis adjustment from swap terminations	207	227
Unamortized bond discounts and issuance costs	(73 )	(81 )
Total	\$ 6,934	\$ 6,975
Current portion of long-term debt	\$ 1,247	\$ —
Long-term debt	5,687	6,975

In February 2017, BMS issued \$1.5 billion in senior unsecured notes in a registered public offering. Proceeds, net of discount and deferred loan issuance costs, were \$1.49 billion. The fair value of long-term debt was \$7.1 billion at September 30, 2018 and \$7.5 billion at December 31, 2017 valued using Level 2 inputs. Interest payments were \$174 million and \$172 million for the nine months ended September 30, 2018 and 2017, respectively, net of amounts related to interest rate swap contracts.

During the third quarter of 2017, the \$750 million 0.875% Notes matured and were repaid.

During the second quarter of 2017, the Company repurchased certain long-term debt obligations with interest rates ranging from 5.875% to 6.875%. The following summarizes the debt repurchase activity:

Dollars in Millions	2017
Principal amount	\$337
Carrying value	366
Debt redemption price	474
Loss on debt redemption <sup>(a)</sup>	109

(a) Including acceleration of debt issuance costs, gain on previously terminated interest rate swap contracts and other related fees.

## Note 11. RECEIVABLES

Dollars in Millions	September 30, December 31,	
	2018	2017
Trade receivables	\$ 4,873	\$ 4,599

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

Less charge-backs and cash discounts	(216	)	(209	)
Less bad debt allowances	(35	)	(43	)
Net trade receivables	4,622		4,347	
Prepaid and refundable income taxes	180		691	
Alliance, royalties, VAT and other	1,069		1,262	
Receivables	\$ 5,871		\$ 6,300	

19

---

Non-U.S. receivables sold on a nonrecourse basis were \$594 million and \$460 million for the nine months ended September 30, 2018 and 2017, respectively. Receivables from our three largest pharmaceutical wholesalers in the U.S. represented 69% and 65% of total trade receivables at September 30, 2018 and December 31, 2017, respectively.

#### Note 12. INVENTORIES

Dollars in Millions	September 30, 2018	December 31, 2017
Finished goods	\$ 429	\$ 384
Work in process	994	931
Raw and packaging materials	244	273
Total inventories	\$ 1,667	\$ 1,588

Inventories	\$ 1,282	\$ 1,166
Other assets	385	422

Other assets include inventory expected to remain on hand beyond one year in both periods.

#### Note 13. PROPERTY, PLANT AND EQUIPMENT

Dollars in Millions	September 30, 2018	December 31, 2017
Land	\$ 105	\$ 100
Buildings	5,278	4,848
Machinery, equipment and fixtures	3,223	3,059
Construction in progress	570	980
Gross property, plant and equipment	9,176	8,987
Less accumulated depreciation	(4,084 )	(3,986 )
Property, plant and equipment	\$ 5,092	\$ 5,001

Depreciation expense was \$366 million and \$509 million for the nine months ended September 30, 2018 and 2017, respectively.

#### Note 14. GOODWILL AND OTHER INTANGIBLE ASSETS

Dollars in Millions	Estimated Useful Lives	September 30, 2018	December 31, 2017
Goodwill		\$ 6,686	\$ 6,863
Other intangible assets:			
Licenses	5 – 15 years	\$ 537	\$ 567
Developed technology rights	9 – 15 years	2,357	2,357
Capitalized software	3 – 10 years	1,451	1,381
IPRD		32	32
Gross other intangible assets		4,377	4,337
Less accumulated amortization		(3,270 )	(3,127 )
Other intangible assets		\$ 1,107	\$ 1,210

An out of period adjustment was included in the nine months ended September 30, 2018 to reduce Goodwill and increase Accumulated other comprehensive loss by \$180 million attributed to goodwill from prior acquisitions of foreign entities previously not recorded in the correct local currency. The adjustment did not impact the consolidated results of operations and was not material to previously reported balance sheets.

Amortization expense was \$147 million and \$142 million for the nine months ended September 30, 2018 and 2017, respectively.

In the first quarter of 2018, a \$64 million impairment charge was recorded in Other income (net) for an out-licensed asset obtained in the 2010 acquisition of ZymoGenetics, Inc., which did not meet its primary endpoint in a Phase II clinical study.

## Note 15. ACCRUED LIABILITIES

Dollars in Millions	September 30, December 31,	
	2018	2017
Rebates and returns	\$ 2,263	\$ 2,024
Employee compensation and benefits	758	869
Research and development	778	783
Dividends	653	654
Royalties	355	285
Branded Prescription Drug Fee	147	303
Restructuring	102	155
Pension and postretirement benefits	40	40
Litigation and other settlements	41	38
Other	716	863
Accrued liabilities	\$ 5,853	\$ 6,014

## Note 16. EQUITY

The following table summarizes changes in equity for the three and nine months ended September 30, 2018:

Dollars and Shares in Millions	Common Stock		Capital in	Accumulated	Retained	Treasury Stock		Noncontrolling
	Shares	Par Value	Excess of Par Value of Stock	Other Comprehensive Loss	Earnings	Share	Cost	Interest
Balance at June 30, 2018	2,208	\$ 221	\$ 1,966	\$ (2,334)	) \$32,044	576	\$(19,580)	\$ 101
Net earnings	—	—	—	—	1,901	—	—	11
Other Comprehensive Income/(Loss)	—	—	—	8	—	—	—	—
Cash dividends declared	—	—	—	—	(653)	—	—	—
Stock repurchase program	—	—	—	—	—	—	—	—
Stock compensation	—	—	63	—	—	—	4	—
Distributions	—	—	—	—	—	—	—	(2)
Balance at September 30, 2018	2,208	\$ 221	\$ 2,029	\$ (2,326)	) \$33,292	576	\$(19,576)	\$ 110
Balance at December 31, 2017	2,208	\$ 221	\$ 1,898	\$ (2,289)	) \$31,160	575	\$(19,249)	\$ 106
Accounting change - cumulative effect <sup>(a)</sup>	—	—	—	(34)	) 332	—	—	—
Adjusted balance at January 1, 2018	2,208	\$ 221	\$ 1,898	\$ (2,323)	) \$31,492	575	\$(19,249)	\$ 106
Net earnings	—	—	—	—	3,760	—	—	29
Other Comprehensive Income/(Loss)	—	—	—	(3)	) —	—	—	—
Cash dividends declared	—	—	—	—	(1,960)	—	—	—
Stock repurchase program	—	—	—	—	—	5	(313)	—
Stock compensation	—	—	131	—	—	(4)	(14)	—
Distributions	—	—	—	—	—	—	—	(25)
Balance at September 30, 2018	2,208	\$ 221	\$ 2,029	\$ (2,326)	) \$33,292	576	\$(19,576)	\$ 110

(a) Refer to "—Note 1. Basis of Presentation and Recently Issued Accounting Standards" for additional information.





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

The following table summarizes changes in equity for the three and nine months ended September 30, 2017:

Dollars and Shares in Millions	Common Stock		Capital in	Accumulated	Retained	Treasury Stock		Noncontrolling
	Shares	Par Value	Excess of Par Value of Stock	Other Comprehensive Loss	Earnings	Share	Cost	Interest
Balance at June 30, 2017	2,208	\$ 221	\$ 1,794	\$ (2,467)	\$ 33,934	568	\$(18,783)	\$ 122
Net earnings	—	—	—	—	845	—	—	11
Other Comprehensive Income/(Loss)	—	—	—	46	—	—	—	—
Cash dividends declared	—	—	—	—	(638)	—	—	—
Stock repurchase program	—	—	—	—	—	4	(226)	—
Stock compensation	—	—	51	—	—	(1)	6	—
Distributions	—	—	—	—	—	—	—	(2)
Balance at September 30, 2017	2,208	\$ 221	\$ 1,845	\$ (2,421)	\$ 34,141	571	\$(19,003)	\$ 131
Balance at December 31, 2016	2,208	\$ 221	\$ 1,725	\$(2,503)	\$ 33,513	536	\$(16,779)	\$ 170
Accounting change - cumulative effect	—	—	—	—	(787)	—	—	—
Adjusted balance at January 1, 2017	2,208	\$ 221	\$ 1,725	\$(2,503)	\$ 32,726	536	\$(16,779)	\$ 170
Net earnings	—	—	—	—	3,335	—	—	28
Other Comprehensive Income/(Loss)	—	—	—	82	—	—	—	—
Cash dividends declared	—	—	—	—	(1,920)	—	—	—
Stock repurchase program	—	—	—	—	—	40	(2,226)	—
Stock compensation	—	—	120	—	—	(5)	2	—
Variable interest entity	—	—	—	—	—	—	—	(59)
Distributions	—	—	—	—	—	—	—	(8)
Balance at September 30, 2017	2,208	\$ 221	\$ 1,845	\$(2,421)	\$ 34,141	571	\$(19,003)	\$ 131

BMS has a stock repurchase program authorized by its Board of Directors allowing for repurchases in the open market or through private transactions, including 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. Treasury stock is recognized at the cost to reacquire the shares. Shares issued from treasury are recognized utilizing the first-in first-out method.

BMS repurchased \$2 billion of its common stock in 2017 through accelerated share repurchase agreements. The agreements were funded through a combination of debt and cash.

The components of Other Comprehensive Income/(Loss) were as follows in the three months ended September 30:

Dollars in Millions	2018			2017		
	Pretax	Tax	After tax	Pretax	Tax	After tax
Derivatives qualifying as cash flow hedges:						
Unrealized gains/(losses)	\$ 18	\$(2)	\$ 16	\$(28)	\$ 12	\$(16)
Reclassified to net earnings <sup>(a)</sup>	(13)	2	(11)	21	(6)	15
Derivatives qualifying as cash flow hedges	5	—	5	(7)	6	(1)
Pension and postretirement benefits:						
Actuarial gains/(losses)	(12)	3	(9)	(5)	2	(3)
Amortization <sup>(b)</sup>	14	(3)	11	19	(11)	8
Settlements <sup>(b)</sup>	26	(6)	20	21	(8)	13

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

Pension and postretirement benefits	28	(6 )	22	35	(17 )	18
Available-for-sale securities:						
Unrealized gains/(losses)	4	(2 )	2	27	(5 )	22
Foreign currency translation	(21 )	—	(21 )	(10 )	17	7
Total Other Comprehensive Income/(Loss)	\$16	\$(8)	\$ 8	\$45	\$1	\$ 46

22

---

The components of Other Comprehensive Income/(Loss) were as follows in the nine months ended September 30:

Dollars in Millions	2018		2017			
	Pretax	Tax	After tax	Pretax	Tax	After tax
Derivatives qualifying as cash flow hedges:						
Unrealized gains/(losses)	\$63	\$(6 )	\$ 57	\$(81)	\$31	\$( 50 )
Reclassified to net earnings <sup>(a)</sup>	20	(6 )	14	(11 )	—	(11 )
Derivatives qualifying as cash flow hedges	83	(12 )	71	(92 )	31	(61 )
Pension and postretirement benefits:						
Actuarial gains/(losses)	100	(21 )	79	(40 )	17	(23 )
Amortization <sup>(b)</sup>	50	(9 )	41	57	(22 )	35
Settlements <sup>(b)</sup>	95	(21 )	74	96	(34 )	62
Pension and postretirement benefits	245	(51 )	194	113	(39 )	74
Available-for-sale securities:						
Unrealized gains/(losses)	(36 )	5	(31 )	48	(7 )	41
Foreign currency translation	(232)	(5 )	(237 )	(8 )	36	28
Total Other Comprehensive Income/(Loss)	\$60	\$(63)	\$ (3 )	\$61	\$21	\$ 82

(a)Included in Cost of products sold.

(b)Included in Other income (net).

The accumulated balances related to each component of Other Comprehensive Income/(Loss), net of taxes, were as follows:

Dollars in Millions	September 30, 2018		December 31, 2017	
	2018	2017	2018	2017
Derivatives qualifying as cash flow hedges	\$ 52		\$ (19 )	
Pension and postretirement benefits	(1,689 )		(1,883 )	
Available-for-sale securities	(33 )		32	
Foreign currency translation	(656 )		(419 )	
Accumulated other comprehensive loss	\$ (2,326 )		\$ (2,289 )	

#### Note 17. RETIREMENT BENEFITS

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

Dollars in Millions	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
	2018	2017	2018	2017
Service cost – benefits earned during the year	\$ 6	\$ 7	\$20	\$19
Interest cost on projected benefit obligation	50	48	146	142
Expected return on plan assets	(97)	(104)	(315)	(308)
Amortization of prior service credits	(1 )	(1 )	(3 )	(3 )
Amortization of net actuarial loss	17	20	57	61
Curtailments and settlements	26	22	95	91
Net periodic pension benefit cost/(credit)	\$ 1	\$(8 )	\$—	\$2

Pension settlement charges were recognized after determining that the annual lump sum payments will likely exceed the annual interest and service costs for the primary and certain other U.S. and international pension plans. The charges included the acceleration of a portion of unrecognized actuarial losses. Non-current pension liabilities were \$383 million at September 30, 2018 and \$456 million at December 31, 2017. Defined contribution plan expense in the U.S. was \$49 million and \$134 million for the three and nine months ended September 30, 2018 and \$46 million and \$142 million for the three and nine months ended September 30, 2017, respectively. Comprehensive medical and group life benefits are provided for substantially all U.S. retirees electing to participate in comprehensive medical and group life plans and to a lesser extent certain benefits for non-U.S. employees. The net periodic benefit credits were not material in both periods.

#### 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 was remanded to the Federal Court for further proceedings related to damages sought by Apotex. The Company and Apotex have settled the Apotex case, and the case was dismissed. The Australian government has intervened in this matter and is seeking maximum damages up to 449 million AUD (\$325 million), plus interest, which would be split between the Company and Sanofi, for alleged losses experienced for paying a higher price for branded Plavix\* during the period when the injunction was in place. The Company and Sanofi have disputed that the Australian government is entitled to any damages and the Australian government's claim is still pending and a trial was concluded in September 2017. The Company is expecting a decision in 2018.

##### Sprycel - Europe

In May 2013, Apotex, Actavis Group PTC ehf, Generics [UK] Limited (Mylan) and an unnamed company filed oppositions in the EPO seeking revocation of European Patent No. 1169038 (the '038 patent) covering dasatinib, the active ingredient in Sprycel. The '038 patent was granted a six month extension in September 2018 and is now

scheduled to expire in October 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. In February 2017, the EPO Board of Appeal upheld the Opposition Division's decision, and revoked the '038 patent. Orphan drug exclusivity and data exclusivity for Sprycel in the EU expired in November 2016. The EPO Board of Appeal's decision does not affect the validity of our other Sprycel patents within and outside Europe, including different patents that cover the monohydrate form of dasatinib and the use of dasatinib to treat CML. Additionally, in February 2017, the EPO Board of Appeal reversed and remanded an invalidity decision on European Patent No. 1610780 and its claim to the use of dasatinib to treat CML, which the EPO's Opposition Division had revoked in October 2012. A decision on the remanded opposition is expected to be received following a hearing scheduled in December 2018. The Company intends to take appropriate legal actions to protect Sprycel. Generics have been approved in certain EU markets although they have not yet launched. However, we may experience a decline in European revenues in the event that generic dasatinib product enters the market.

#### Anti-PD-1 Antibody Patent Oppositions and Litigation

In September 2015, Dana-Farber Cancer Institute (Dana-Farber) filed a complaint in Massachusetts federal court seeking to correct the inventorship on up to five related U.S. patents directed to methods of treating cancer using PD-1 and PD-L1 antibodies. Specifically, Dana-Farber is seeking to add two scientists as inventors to these patents. In October 2017, Pfizer was allowed to intervene in this case alleging that one of the scientists identified by Dana-Farber was employed by a company eventually acquired by Pfizer during the relevant period. While an adverse decision in this litigation would not result in monetary liability for the Company, it could decrease potential future licensing revenue from these patents. A trial has been scheduled for February 2019.

#### Eliquis Patent Litigation - U.S.

In 2017, twenty-five generic companies sent the Company Paragraph-IV certification letters informing the Company that they had filed abbreviated new drug applications (aNDAs) seeking approval of generic versions of Eliquis. As a result, two Eliquis patents listed in the FDA Orange Book are being challenged: the composition of matter patent claiming apixaban specifically and a formulation patent. In April 2017, the Company, along with its partner Pfizer, initiated patent lawsuits under the Hatch-Waxman Act against all generic filers in federal district courts in Delaware and West Virginia. In August 2017, the United States Patent and Trademark Office granted patent term restoration to the composition of matter patent, thereby restoring the term of the Eliquis composition of matter patent, which is the Company's basis for projected LOE, from February 2023 to November 2026. The Company has settled lawsuits with a number of aNDA filers through September 2018. The settlements do not affect the Company's projected LOE for Eliquis.

#### 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\*.

#### 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.

##### 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 530 separate lawsuits pending on behalf of approximately 2,100 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 majority of these cases have been brought by individuals who allege personal injury sustained after using Byetta\*, primarily pancreatic cancer, and, in some cases, claiming alleged wrongful death. The majority of cases are 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 appealed to the U.S. Court of Appeals for the Ninth Circuit. In November 2017, the Ninth Circuit reversed the MDL summary judgment order and remanded the case for further proceedings. The JCCP plaintiffs have appealed to the California Court of Appeal and their appeal remains pending. 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.

##### Abilify\*

The Company and 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 over 2,000 cases filed in state and federal courts and additional 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. In April 2018, the parties reached a settlement to resolve the first three cases of the MDL that had been set for trial. The Company continues to actively defend the claims in this litigation.

##### Eliquis



The Company and Pfizer are co-defendants in product liability litigation related to Eliquis. Plaintiffs assert claims, including claims for wrongful death, as a result of bleeding they allege was caused by their use of Eliquis. As of October 2018, no claims remain pending in the MDL in the United States District Court for the Southern District of New York. Fewer than 10 cases remain pending in state courts and one remains pending in Canada. Over 200 cases have been dismissed with prejudice in the MDL. The claims of 23 plaintiffs are on appeal to the Second Circuit Court of Appeals.

25

---

#### Onglyza\*

The Company and AstraZeneca are co-defendants in product liability litigation related to Onglyza\*. Plaintiffs assert claims, including claims for wrongful death, as a result of heart failure or other cardiovascular injuries they allege were caused by their use of Onglyza\*. As of October 2018, claims are pending in state and federal court on behalf of over 200 individuals who allege they ingested the product and suffered an injury. A significant majority of these claims are pending in federal courts. In February 2018, the Judicial Panel on Multidistrict Litigation ordered all federal cases to be transferred to an MDL in the United States District Court for the Eastern District of Kentucky. As part of the Company's global diabetes business divestiture, the Company sold Onglyza\* to AstraZeneca in February 2014 and any potential liability with respect to Onglyza\* is expected to be shared with AstraZeneca.

#### 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. As of October 2017, all three of the lawsuits have been dismissed. The Company received a notice of appeal as to one of the dismissed lawsuits.

#### SECURITIES LITIGATION

Since February 2018, two separate putative class action complaints were filed in the U.S. District for the Northern District of California and in the U.S. District Court for the Southern District of New York against the Company, the Company's Chief Executive Officer, Giovanni Caforio, the Company's Chief Financial Officer, Charles A. Bancroft and certain former and current executives of the Company. The case in California has been voluntarily dismissed. The remaining complaint alleges violations of securities laws for the Company's disclosures related to the CheckMate-026 clinical trial in lung cancer. The Company intends to defend itself vigorously in this litigation.

#### OTHER LITIGATION

In February 2015, the Company acquired Flexus Biosciences, Inc. ("Flexus") including rights to its IDO-1 inhibitor. In September 2015, Incyte Corporation ("Incyte") sued Flexus and Flexus's founders ("Flexus Defendants") in the Superior Court of the State of Delaware. In its initial and subsequent amended complaints, Incyte alleged claims against the Flexus Defendants for the misappropriation of various trade secrets, trade libel, and conspiracy relating to the research and development of Incyte's IDO-1 inhibitor. By opinions dated August 23, 2018 and September 28, 2018, the Superior Court denied Incyte's motions for summary judgment and granted in part motions filed by Flexus and its founders. In those opinions, the court dismissed Incyte's trade libel and conspiracy to commit trade libel claims and dismissed all but two of Incyte's alleged trade secret claims. Trial on the remaining claims commenced on October 22, 2018.

#### 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.

#### 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 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 \$64 million at September 30, 2018, 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 amount includes the estimated costs for any additional probable loss associated with the previously disclosed North Brunswick Township High School Remediation Site.

26

---

## Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### EXECUTIVE SUMMARY

Bristol-Myers Squibb Company is a global specialty biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. Our strategy is to combine the resources, scale and capability of a pharmaceutical company with the speed and focus on innovation of the biotech industry. Our four strategic priorities are to drive business performance, continue to build a strong franchise in IO, maintain a diversified portfolio both within and outside of IO, and continue our disciplined approach to capital allocation, including establishing partnerships and collaborations as an essential component of successfully delivering transformational medicines to patients. Refer to the Summary of Abbreviated Terms at the end of this Quarterly Report on Form 10-Q for terms used throughout the document.

Our revenues increased by 8% for the nine months ended September 30, 2018 as a result of higher demand for Opdivo and Eliquis partially offset by increased competition for established brands. The \$0.28 increase in GAAP EPS primarily resulted from higher revenues and a lower effective tax rate partially offset by higher license and asset acquisition charges and equity investment losses primarily related to the Nektar collaboration and lower litigation settlement income. After adjusting for specified items, non-GAAP EPS increased \$0.72 due to higher revenues, royalties and licensing income and a lower effective tax rate. Cost savings resulting from our transformation initiatives continue to be redeployed in R&D and other areas of higher priorities.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Dollars in Millions, except per share data				
Total Revenues	\$5,691	\$5,254	\$16,588	\$15,327

### Diluted Earnings Per Share

GAAP	\$1.16	\$0.51	\$2.30	\$2.02
Non-GAAP	1.09	0.75	3.04	2.32

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 2018:

#### Product/Date Approval

	August 2018	Approval in Japan for patients with malignant pleural mesothelioma (MPM) which has progressed after chemotherapy.
	August 2018	Approval in Japan for adjuvant treatment of melanoma.
Opdivo	August 2018	FDA approval as the first and only IO treatment option for patients with metastatic SCLC whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy.
	July 2018	EC approval for the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
	June 2018	Approval in China for the treatment of locally advanced or metastatic NSCLC after prior platinum-based chemotherapy in adult patients without EGFR or ALK genomic tumor aberrations.



## Product Date Approval

	August 2018	Approval in Japan of Opdivo plus low-dose Yervoy for the treatment of unresectable or metastatic RCC.
Opdivo+Yervoy	July 2018	FDA approval of Opdivo plus low-dose Yervoy for the treatment of adult and pediatric patients 12 years and older with MSI-H or dMMR mCRC that has progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan.
	May 2018	Approval in Japan of Opdivo+Yervoy combination for previously untreated patients with unresectable melanoma.
	April 2018	FDA approval of Opdivo+Yervoy combination for previously untreated patients with intermediate and poor-risk advanced RCC.
Orencia	February 2018	Approval in Japan for an intravenously administered treatment of moderate to severe polyarticular JIA in patients two years of age and older.
Sprycel	July 2018	EC expanded the indication for Sprycel to include the treatment of children and adolescents aged 1 year to 18 years with chronic phase Philadelphia chromosome positive CML and to include a powder for oral suspension.
Yervoy	January 2018	EC approval of advanced (unresectable or metastatic) melanoma in pediatric patients 12 years of age and older.

Refer to "—Product and Pipeline Developments" for all of the developments in our marketed products and late-stage pipeline in 2018.

## Acquisition, Licensing and Collaboration Arrangements

Acquisition, licensing and collaboration arrangements 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, including IO, immunoscience, cardiovascular and fibrosis. Significant transactions entered into and discontinued during 2018 are summarized below. Refer to "Item 1. Financial Statements—Note 4. Alliances" for further information.

**Nektar:** In the second quarter of 2018, BMS and Nektar commenced a worldwide license and collaboration for the development and commercialization of NKTR-214, Nektar's investigational immuno-stimulatory therapy.

**Janssen:** In the second quarter of 2018, BMS and Janssen Pharmaceuticals, Inc., commenced a worldwide collaboration for the development and commercialization of a Factor XIa program including BMS's Factor XIa inhibitor, BMS-986177, an investigational anticoagulant compound being studied for the prevention and treatment of major thrombotic conditions.

**Promedior:** In the third quarter of 2018, BMS notified Promedior that the Company would not be exercising a warrant obtained in 2015 to purchase all outstanding shares of Promedior.

**Rigel:** In the third quarter of 2018, BMS notified Rigel Pharmaceuticals, Inc., that the Company would discontinue its participation in the preclinical collaboration of cancer immunotherapies based on Rigel's small molecule TGF beta receptor kinase inhibitors originally commenced in 2015.

**Bavarian Nordic:** In the fourth quarter of 2018, BMS notified Bavarian Nordic A/S that the Company will not be exercising its option to globally license and commercialize Prosvac\*, Bavarian Nordic's investigational prostate-specific antigen-targeting cancer immunotherapy.

## RESULTS OF OPERATIONS

## Regional Revenues

Dollars in Millions	Three Months Ended September 30,				Nine Months Ended September 30,			
	Total Revenues		2018 vs. 2017		Total Revenues		2018 vs. 2017	
	2018	2017	% Change	Foreign Exchange <sup>(b)</sup>	2018	2017	% Change	Foreign Exchange <sup>(b)</sup>
United States	\$3,235	\$2,864	13 %	—	\$9,243	\$8,467	9 %	—
Europe	1,365	1,262	8 %	(2 )%	4,179	3,596	16 %	7 %
Rest of the World	932	970	(4 )%	(6 )%	2,728	2,858	(5 )%	(1 )%
Other <sup>(a)</sup>	159	158	1 %	N/A	438	406	8 %	N/A
Total	\$5,691	\$5,254	8 %	(2 )%	\$16,588	\$15,327	8 %	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 were impacted by higher demand for Opdivo and Eliquis and lower demand for established brands. Average U.S. net selling prices were approximately 1% higher after discounts, charge-backs and rebates in the three and nine months ended September 30, 2018. Refer to “—Product Revenues” below for additional information.

Europe revenues were impacted by higher demand for Opdivo and Eliquis, lower demand for established brands due to increased competition and foreign exchange.

Rest of the World revenues were impacted by higher demand for Opdivo, lower demand for established brands due to increased competition, lower average net selling prices and foreign exchange.

No single country outside the U.S. contributed more than 10% of total revenues during the nine months ended September 30, 2018 or 2017. Our business is typically not seasonal.

## GTN Adjustments

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

Dollars in Millions	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Gross product sales	\$7,681	\$6,555	17 %	\$21,891	\$18,723	17 %
GTN adjustments						
Charge-backs and cash discounts	(711 )	(583 )	22 %	(1,957 )	(1,521 )	29 %
Medicaid and Medicare rebates	(847 )	(573 )	48 %	(2,169 )	(1,474 )	47 %
Other rebates, returns, discounts and adjustments	(690 )	(537 )	28 %	(1,899 )	(1,516 )	25 %
Total GTN adjustments	(2,248 )	(1,693 )	33 %	(6,025 )	(4,511 )	34 %
Net product sales	\$5,433	\$4,862	12 %	\$15,866	\$14,212	12 %
GTN adjustments percentage	29 %	26 %	3 %	28 %	24 %	4 %
U.S.	36 %	32 %	4 %	35 %	30 %	5 %
Non-U.S.	16 %	15 %	1 %	14 %	14 %	—

Reductions to provisions for product sales made in prior periods resulting from changes in estimates were \$103 million and \$65 million in the nine months ended September 30, 2018 and 2017, respectively. GTN adjustments are

primarily a function of product sales volume, regional and payer channel mix, contractual or legislative discounts and rebates. GTN adjustments are increasing at a higher rate than gross product sales due to higher U.S. Eliquis gross product sales, which has a relatively high GTN adjustment percentage as a result of competitive pressures to maintain its position on healthcare payer formularies allowing patients continued access through their medical plans.



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

Product Revenues

Dollars in Millions	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
<b>Prioritized Brands</b>						
Opdivo	\$ 1,793	\$ 1,265	42 %	\$ 4,931	\$ 3,587	37 %
U.S.	1,141	778	47 %	3,103	2,307	35 %
Non-U.S.	652	487	34 %	1,828	1,280	43 %
Eliquis	1,577	1,232	28 %	4,733	3,509	35 %
U.S.	917	717	28 %	2,781	2,119	31 %
Non-U.S.	660	515	28 %	1,952	1,390	40 %
Orencia	675	632	7 %	1,979	1,817	9 %
U.S.	474	432	10 %	1,360	1,243	9 %
Non-U.S.	201	200	1 %	619	574	8 %
Sprycel	491	509	(4 )%	1,464	1,478	(1 )%
U.S.	267	278	(4 )%	791	806	(2 )%
Non-U.S.	224	231	(3 )%	673	672	—
Yervoy	382	323	18 %	946	975	(3 )%
U.S.	278	239	16 %	668	727	(8 )%
Non-U.S.	104	84	24 %	278	248	12 %
Empliciti	59	60	(2 )%	178	168	6 %
U.S.	41	39	5 %	119	112	6 %
Non-U.S.	18	21	(14 )%	59	56	5 %
<b>Established Brands</b>						
Baraclude	175	264	(34 )%	579	819	(29 )%
U.S.	6	14	(57 )%	25	40	(38 )%
Non-U.S.	169	250	(32 )%	554	779	(29 )%
Sustiva Franchise	72	183	(61 )%	229	555	(59 )%
U.S.	5	157	(97 )%	23	471	(95 )%
Non-U.S.	67	26	**	206	84	**
Reyataz Franchise	87	174	(50 )%	328	555	(41 )%
U.S.	27	85	(68 )%	132	260	(49 )%
Non-U.S.	60	89	(33 )%	196	295	(34 )%
Hepatitis C Franchise	(2 )	73	**	13	347	(96 )%
U.S.	(4 )	24	**	(1 )	96	**
Non-U.S.	2	49	(96 )%	14	251	(94 )%
Other Brands	382	539	(29 )%	1,208	1,517	(20 )%
U.S.	83	101	(18 )%	242	286	(15 )%

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

Non-U.S.	299	438	(32 )%	966	1,231	(22 )%
Total Revenues	5,691	5,254	8 %	16,588	15,327	8 %
U.S.	3,235	2,864	13 %	9,243	8,467	9 %
Non-U.S.	2,456	2,390	3 %	7,345	6,860	7 %

\*\* Change in excess of 100%

30

---

Opdivo (nivolumab) — a fully human monoclonal antibody that binds to the PD-1 on T and NKT cells that has been approved for several anti-cancer indications including bladder, blood, colon, head and neck, kidney, liver, lung, melanoma and stomach and continues to be investigated across other tumor types and disease areas.

U.S. revenues increased due to higher demand for the treatment of adjuvant melanoma, liver cancer, and the Opdivo+Yervoy combination approval for kidney cancer.

International revenues increased due to higher demand as a result of approvals for additional indications and launches in new countries. Excluding foreign exchange impacts, revenues increased by 39% in the third quarter and year-to-date.

Eliquis (apixaban) — 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. revenues increased due to market share gains partially offset by lower average net selling prices.

International revenues increased due to higher demand attributed to market share gains and growth within the novel oral anticoagulants market. Excluding foreign exchange impacts, revenues increased by 30% in the third quarter and 34% year-to-date.

Orencia (abatacept) — a fusion protein indicated for adult patients with moderate to severe active RA and PsA 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 due to higher demand and higher average net selling prices.

International revenues were impacted by higher demand in the quarter and year-to-date periods. Excluding foreign exchange impacts, revenues increased by 5% in the third quarter and 6% year-to-date. We may experience additional competition in Europe from biosimilars of competitor products in future periods.

Sprycel (dasatinib) — an oral inhibitor of multiple tyrosine kinase indicated for the first-line treatment of patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase and the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase CML with resistance or intolerance to prior therapy, including Gleevec\* (imatinib mesylate).

U.S. revenues decreased due to inventory workdown offset by higher average net selling prices.

International revenues were impacted by lower demand from increased competition for the quarter and year-to-date periods. Excluding foreign exchange impacts, revenues remained unchanged in the third quarter and decreased 3% year-to-date.

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

U.S. revenues decreased year-to-date due to lower demand primarily from the introduction of Opdivo for the treatment of adjuvant melanoma. Third quarter revenues increased due to Opdivo+Yervoy combination approval for kidney cancer.

- International revenues increased due to higher demand. Excluding foreign exchange impacts, revenues increased by 30% in the third quarter and 9% year-to-date.

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

International revenues continued to decrease due to lower demand resulting from increased competition.

Sustiva (efavirenz) 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\*.

The LOE for Sustiva in the U.S. occurred in December 2017. Gilead terminated BMS's participation in the U.S. and Canada joint venture following the launch of a generic version of Sustiva in the U.S. As a result, BMS's share of Atripla\* revenues will further decline during the next three years.

International revenues for 2018 include \$57 million in the third quarter and \$162 million year-to-date of U.S. Atripla\* royalty revenue.

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

The LOE for Reyataz in the U.S. occurred in December 2017.

International revenues continued to decrease due to lower demand.

Hepatitis C Franchise — Daklinza (daclatasvir) - an NS5A replication complex inhibitor; Sunvepra (asunaprevir) - an NS3 protease inhibitor; and beclabuvir - an NS5B inhibitor.

U.S. and international revenues decreased due to lower demand resulting from increased competition.

Other Brands — includes all other products, including those which have lost exclusivity in major markets, OTC brands and royalty revenue.

International revenues decreased primarily due to lower Plavix\* royalties as a result of the adoption of amended revenue guidance in 2018, the December 2017 expiration of rights to Abilify\* in Canada and lower diabetes product supply sales due to the sale of the Company's manufacturing operations in Swords, Ireland.

#### Estimated End-User Demand

Pursuant to the SEC Consent Order described in our 2017 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. At September 30, 2018, Daklinza had 2.2 months of inventory on hand in the U.S. as a result of minimum required stock levels to support patient demand. We expect inventory on hand levels of Daklinza to exceed one month over the near term. Below are international products that had estimated levels of inventory in the distribution channel in excess of one month at June 30, 2018.

Dafalgan, an analgesic product sold principally in Europe, had 1.3 months of inventory on hand internationally at direct customers compared to 1.1 months of inventory on hand at March 31, 2018. 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 1.4 months of inventory on hand internationally at direct customers compared to also 1.4 months of inventory on hand at March 31, 2018. The level of inventory on hand was primarily due to the ordering patterns of pharmacists in France.

Fervex, a cold and flu product, had 1.5 months of inventory on hand at direct customers compared to 2.0 months of inventory on hand at March 31, 2018. The level of inventory on hand was primarily due to the ordering patterns of pharmacists in France.

Daklinza, a Hepatitis C product, had 1.4 months of inventory on hand internationally at direct customers compared to 1.7 months of inventory on hand at March 31, 2018. The level of inventory on hand was primarily due to a package labeling change in Thailand in the first quarter of 2018.

Perfalgan, an analgesic product, had 1.5 months of inventory on hand internationally at direct customers compared to 1.0 months of inventory on hand at March 31, 2018. The level of inventory on hand was primarily in the Gulf Countries 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, 2018 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 September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Cost of products sold	\$1,648	\$1,579	4 %	\$4,857	\$4,413	10 %
Marketing, selling and administrative	1,104	1,163	(5) %	3,215	3,435	(6) %
Research and development	1,280	1,561	(18) %	4,965	4,543	9 %
Other income (net)	(508 )	(232 )	**	(912 )	(1,497 )	(39) %
Total Expenses	\$3,524	\$4,071	(13) %	\$12,125	\$10,894	11 %

Cost of products sold increased in both periods due to higher royalties and profit sharing (\$208 million and \$703 million in the three and nine months ended September 30, 2018, respectively) resulting primarily from higher Eliquis sales partially offset by a \$70 million charge resulting from lower expected HCV demand in the third quarter of 2017, a \$127 million impairment charge to reduce the carrying value of assets held-for-sale to their estimated fair value in the second quarter of 2017, and lower product costs partially due to foreign currency.

Marketing, selling and administrative expenses decreased in both periods due to lower advertising, promotion, and marketing expenses, lower branded prescription drug fee, and lower costs attributed to transformation initiatives.

Research and development increased in the nine months ended September 30, 2018 due to the Nektar up-front payment and other significant charges listed below and higher costs of clinical development and medical support of marketed products. Research and development decreased in the three months ended September 30, 2018 due to IFM acquisition charges in 2017.

Significant charges included in R&D expense were as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Nektar	\$ —	\$ —	\$1,050 <sup>(a)</sup>	\$ —
IFM	—	310 <sup>(a)</sup>	25 <sup>(b)</sup>	310 <sup>(a)</sup>
Cormorant	—	—	60 <sup>(b)</sup>	—
CytomX	—	—	—	200 <sup>(a)</sup>
Flexus	—	—	—	93 <sup>(b)</sup>
Cardioxyl	—	—	—	100 <sup>(b)</sup>
PsiOxus	—	—	—	50 <sup>(a)</sup>
License and asset acquisition charges	—	310	1,135	753
IPRD impairments	—	—	—	75
Site exit costs and other	18	64	57	232

(a) Up-front payment

(b) Milestone payment

License and asset acquisition charges resulted from strategic transactions to acquire or license certain investigational therapies and compounds.

IPRD impairment charges were related to the discontinued development of an investigational compound in the nine months ended September 30, 2017, which was part of our alliance with F-Star Alpha Ltd.

Site exit costs and other charges resulted from the expected exit of R&D sites in the U.S. through 2020 primarily due to the reduction in the estimated useful lives of the related assets for each site.





Other income (net) decreased in the nine months ended September 30, 2018 due to a patent litigation settlement in 2017 and a higher loss on equity investments. Other income (net) increased in the three months ended September 30, 2018 due to higher royalties and licensing income and gains on divestitures and equity investments.

Items included in Other income (net) were as follows:

Dollars in Millions	Three Months		Nine Months	
	Ended	Ended	Ended	Ended
	September 30,	September 30,	September 30,	September 30,
	2018	2017	2018	2017
Interest expense	\$44	\$48	\$135	\$145
Investment income	(44 )	(32 )	(118 )	(87 )
Loss/(gain) on equity investments	(97 )	(5 )	244	(17 )
Provision for restructuring	45	28	102	207
Litigation and other settlements	11	—	10	(489 )
Equity in net income of affiliates	(22 )	(21 )	(73 )	(59 )
Divestiture (gains)/losses	(108 )	1	(178 )	(126 )
Royalties and licensing income	(338 )	(209 )	(1,058)	(1,093 )
Transition and other service fees	—	(12 )	(5 )	(32 )
Pension and postretirement	(10 )	(19 )	(40 )	(29 )
Intangible asset impairment	—	—	64	—
Loss on debt redemption	—	—	—	109
Other	11	(11 )	5	(26 )
Other income (net)	\$(508)	\$(232)	\$(912)	\$(1,497)

Loss/(gain) on equity investments includes a \$100 million increase and \$307 million decrease in fair value adjustments related to the Company's equity investment in Nektar in the three and nine months ended September 30, 2018, respectively.

Restructuring charges relate to changes to the Company's operating model to drive continued success in the near- and long-term through a more focused investment in commercial opportunities for key brands and markets, a competitive and more agile R&D organization that can accelerate the pipeline, streamline operations and realign manufacturing capabilities that broaden biologics capabilities to reflect the current and future portfolio as well as streamline and simplify our small-molecule supply network. The new operating model is expected to enable the Company to deliver the strategic, financial and operational flexibility necessary to invest in the highest priorities across the Company. Aggregate restructuring charges of approximately \$150 million are expected to be incurred in 2018 for all actions in addition to accelerated depreciation impacts resulting from early site exits.

Litigation and other settlements include \$481 million for BMS's share of a patent-infringement settlement related to Merck's PD-1 antibody Keytruda\* in the first quarter of 2017.

Divestiture (gains)/losses includes \$105 million for the divestiture of multiple mature global product lines in oncology and infectious therapy in the third quarter of 2018 and contingent consideration of \$100 million received for the diabetes business divestiture in the first quarter of 2017.

Royalties and licensing income includes additional out-licensing consideration of \$50 million for amending a royalty rate, a \$25 million sales-based milestone and higher Diabetes business divestiture and Keytruda\* royalties in 2018; and up-front licensing fees of \$470 million from Biogen and Roche in 2017.

Pension and postretirement includes the net periodic cost (credit) for pension and post-retirement benefit plans including settlement and curtailment charges.

Intangible asset impairment includes \$64 million in the first quarter of 2018 for an out-licensed asset obtained in the 2010 acquisition of ZymoGenetics, Inc., which did not meet its primary endpoint in a Phase II clinical study.

A debt redemption loss of \$109 million resulted from the early redemption of certain long-term debt obligations in the second quarter of 2017.

Refer to "Item 1. Financial Statements—Note 1. Basis of Presentation and Recently Issued Accounting Standards, Note 6. Other Income (Net), Note 7. Restructuring and Note 10. Financial Instruments and Fair Value Measurements" for further information.

34

---

## Income Taxes

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,		
	2018	2017	2018	2017	
Earnings Before Income Taxes	\$2,167	\$1,183	\$4,463	\$4,433	
Provision for Income Taxes	255	327	674	1,129	
Effective Tax Rate	11.8	% 27.6	% 15.1	% 25.5	%
Impact of Specified Items	1.5	% (4.7)	% 0.8	% (3.7)	%

As discussed in more detail in "Item 1. Financial Statements—Note 8. Income Taxes", the above tax impact of specified items primarily resulted from jurisdictional tax rates applied to specified items, including certain non-deductible R&D charges and Nektar equity investment fair value adjustments as well as changes to the provisional repatriation tax. Excluding the impact of these items, changes in the effective tax rates were primarily due to new U.S. tax reform legislation known as the Tax Cuts and Jobs Act of 2017 (the Act) enacted on December 22, 2017, a \$49 million tax reserve release, a higher Puerto Rico excise tax credit and unfavorable changes in earnings mix. The Act moves from a worldwide tax system to a quasi-territorial tax system and comprises broad and complex changes to the U.S. tax code. Additional changes to the effective tax rate may occur in future periods due to various reasons including pretax earnings mix, tax reserves, cash repatriations and revised interpretations of the relevant tax code.

## Non-GAAP Financial Measures

Our non-GAAP financial measures, such as 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, equity investment and debt redemption gains or losses; pension settlement charges; and legal and other contractual settlements, 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. We also provide international revenues for our priority products excluding the impact of foreign exchange. Reconciliations of these non-GAAP measures to the most comparable GAAP measures are included in Exhibit 99.2 to our Form 8-K filed on October 25, 2018 and are incorporated herein by reference.

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. Similarly, revenues excluding the impact of foreign exchange show the core growth or decline of our priority products outside of the U.S. These non-GAAP measures are 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 revenues, net earnings or diluted EPS prepared in accordance with GAAP.



Specified items were as follows:

Dollars in Millions	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Impairment charges	\$—	\$1	\$10	\$128
Accelerated depreciation and other shutdown costs	13	—	30	3
Cost of products sold	13	1	40	131
Marketing, selling and administrative	—	—	1	—
License and asset acquisition charges	—	310	1,135	753
IPRD impairments	—	—	—	75
Site exit costs and other	18	64	57	232
Research and development	18	374	1,192	1,060
Loss/(gain) on equity investments	(97 )	—	244	—
Provision for restructuring	45	28	102	207
Litigation and other settlements	—	—	—	(481 )
Divestiture (gains)/losses	(108 )	—	(176 )	(100 )
Royalties and licensing income	—	—	(75 )	(497 )
Pension and postretirement	27	22	95	91
Intangible asset impairment	—	—	64	—
Loss on debt redemption	—	—	—	109
Other income (net)	(133 )	50	254	(671 )
Increase/(decrease) to pretax income	(102 )	425	1,487	520
Income taxes on items above	1	(41 )	(225 )	51
Income taxes attributed to U.S. tax reform	(20 )	—	(49 )	—
Income taxes	(19 )	(41 )	(274 )	51
Increase/(decrease) to net earnings	(121 )	384	1,213	571
Noncontrolling interest	—	—	—	(59 )
Increase/(decrease) to net earnings used for Diluted Non-GAAP EPS calculation	\$(121)	\$384	\$1,213	\$512
The reconciliations from GAAP to Non-GAAP were as follows:				
	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Dollars in Millions, except per share data				
Net Earnings Attributable to BMS used for Diluted EPS Calculation – GAAP	\$1,901	\$845	\$3,760	\$3,335
Specified Items	(121 )	384	1,213	512
Net Earnings Attributable to BMS used for Diluted EPS Calculation – Non-GAAP	\$1,780	\$1,229	\$4,973	\$3,847
Average Common Shares Outstanding – Diluted	1,636	1,645	1,637	1,655
Diluted EPS Attributable to BMS – GAAP	\$1.16	\$0.51	\$2.30	\$2.02
Diluted EPS Attributable to Specified Items	(0.07 )	0.24	0.74	0.30
Diluted EPS Attributable to BMS – Non-GAAP	\$1.09	\$0.75	\$3.04	\$2.32



## FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

Our net cash position was as follows:

Dollars in Millions	September 30, December 31,	
	2018	2017
Cash and cash equivalents	\$ 5,408	\$ 5,421
Marketable securities – current	1,422	1,391
Marketable securities – non-current	2,017	2,480
Total cash, cash equivalents and marketable securities	8,847	9,292
Short-term debt obligations	(1,620 )	(987 )
Long-term debt	(5,687 )	(6,975 )
Net cash position	\$ 1,540	\$ 1,330

Cash, cash equivalents and marketable securities held in the U.S. were approximately \$3.2 billion at September 30, 2018. Most of the remaining \$5.6 billion is held primarily in low-tax jurisdictions and is subject to restrictions or withholding taxes in certain jurisdictions. We are subject to a one-time deemed repatriation transition tax of \$2.6 billion which will be payable over eight years as a result of U.S. tax reform beginning in 2018. However, we expect to have more flexibility in accessing cash and future cash that may be generated in foreign subsidiaries. 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, working capital, deemed repatriation transition tax and \$1.25 billion of long-term debt maturing in 2019.

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 repurchased \$320 million of common stock in 2018. The average amount of commercial paper outstanding was \$25.1 million at a weighted-average rate of 1.3% during 2018. The maximum amount of commercial paper outstanding was \$300 million with no outstanding balance at September 30, 2018.

Dividend payments were \$2.0 billion and \$1.9 billion in the nine months ended September 30, 2018 and 2017, respectively. Dividends declared per common share were \$1.20 and \$1.17 in the nine months ended September 30, 2018 and 2017, respectively. Dividend decisions are made on a quarterly basis by our Board of Directors. Annual capital expenditures were \$1.1 billion in 2017 and are expected to be approximately \$900 million in 2018 and 2019. We continue to expand 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. We also paid \$1.85 billion to Nektar in the second quarter of 2018 for certain collaboration rights and 8.3 million shares of its common stock representing a 4.8% ownership interest.

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 time to maturity of investments with any institution. The policy also requires that investments are only entered into with corporate and financial institutions that meet high credit quality standards. Refer to "Item 1. Financial Statements—Note 10. Financial Instruments and Fair Value Measurements" for further information.

We currently have three separate revolving credit facilities totaling \$5.0 billion from a syndicate of lenders. The facilities provide for customary terms and conditions with no financial covenants. Our 364-day \$2.0 billion facility

expires in March 2019 and our two \$1.5 billion facilities were extended to September 2022 and July 2023. Our two \$1.5 billion, five-year facilities are extendable annually by one year on the anniversary date with the consent of the lenders. No borrowings were outstanding under any revolving credit facility at September 30, 2018 or December 31, 2017.

Additional regulations in the U.S. could be passed in the future including additional healthcare reform initiatives, further changes to tax laws, additional pricing laws and potential importation restrictions 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.



## 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 rating outlook. BMS's long-term and short-term credit ratings assigned by Standard & Poor's are A+ and A-1+, respectively, with a stable rating 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,	
	2018	2017
Cash flow provided by/(used in):		
Operating activities	\$3,511	\$4,158
Investing activities	(538 )	(1,085 )
Financing activities	(2,957 )	(2,725 )
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 (90 days to 120 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 \$647 million change in cash flow from operating activities compared to 2017 was primarily attributable to:

- Higher R&D licensing and collaboration payments of approximately \$700 million primarily due to the Nektar transaction in 2018;
- Lower litigation settlement proceeds of approximately \$500 million related to Merck's PD-1 antibody Keytruda\* in 2017; and
- Lower out-license proceeds of approximately \$400 million primarily related to the Biogen and Roche transactions in 2017.

Partially offset by:

- Timing of cash collections and payments in the ordinary course of business of approximately \$1.0 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 original maturities greater than 90 days at the time of purchase reduced by proceeds from business divestitures (including royalties) and the sale and maturity of marketable

securities.

The \$547 million change in cash flow from investing activities compared to 2017 was primarily attributable to:

• Higher net sales and maturities of marketable securities with maturities greater than 90 days of approximately \$500 million primarily due to higher yields on cash and cash equivalents and to fund business development activities; and  
• Higher business divestiture proceeds of approximately \$400 million primarily due to the sale of the small molecule active pharmaceutical ingredient manufacturing operations in Swords, Ireland to SK Biotek and the divestiture of certain mature brands in 2018.

Partially offset by:

• Higher net acquisition and other payments of approximately \$500 million primarily due to the purchase of 8.3 million shares of Nektar common stock in 2018.

38

---

## 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 \$232 million change in cash flow from financing activities compared to 2017 was primarily attributable to:

- Lower net borrowings of \$2.1 billion resulting primarily from the issuance of long-term debt used to repurchase common stock in 2017.

Partially offset by:

- Lower repurchases of common stock of \$1.9 billion primarily due to the accelerated share repurchase agreements in 2017.

## 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 developments in our marketed products and our late-stage pipeline:

### Product Indication Date Developments

	August 2018	Approval in Japan for adjuvant treatment of melanoma.
	July 2018	EC approval for the adjuvant treatment of adult patients with involvement of lymph nodes or metastatic disease who have undergone complete resection.
Melanoma	June 2018	Announced results from the Phase III CheckMate-238 trial evaluating Opdivo versus Yervoy in patients with stage IIIB/C or stage IV melanoma who are at high risk of recurrence following complete surgical resection demonstrated statistically longer recurrence-free survival for Opdivo, the primary endpoint of the study, versus Yervoy at a minimum follow-up of 24 months across key subgroups, including disease stages and BRAF mutation status.
Multiple Myeloma	June/August 2018	Announced in June 2018 that the FDA lifted a partial clinical hold placed on CheckMate-602, a randomized, open-label Phase III study evaluating the addition of Opdivo to pomalidomide and dexamethasone in patients with relapsed or refractory multiple myeloma. The decision follows consultation with the FDA and agreement on amendments to the study protocol. In August 2018, the Company discontinued further enrollment of this study following a futility analysis.
NSCLC	June 2018	Approval in China for the treatment of locally advanced or metastatic NSCLC after prior platinum-based chemotherapy in adult patients without EGFR or ALK genomic tumor aberrations.
	April 2018	Announced that the pivotal, randomized Phase III CheckMate-078 trial evaluating Opdivo versus docetaxel in a predominantly Chinese population with previously treated advanced NSCLC demonstrated superior overall survival benefit in the primary endpoint regardless of PD-L1 expression or tumor histology.
SCCHN	April 2018	Announced two-year overall survival data from CheckMate-141, a Phase III study, evaluating Opdivo compared with investigator's choice chemotherapy (cetuximab, docetaxel or methotrexate) in patients with recurrent or metastatic SCCHN after failure on platinum-based therapy.

Opdivo  
SCLC

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

October 2018	Announced topline results from the Phase III Checkmate-331 study did not meet its primary endpoint of overall survival with Opdivo versus chemotherapy in patients with previously treated relapsed SCLC.
August 2018	FDA approval as the first and only IO treatment option for patients with metastatic SCLC whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy.
August 2018	Approval in Japan for patients with malignant pleural mesothelioma which has progressed after chemotherapy.
August 2018	Approval in Japan of an every 2 week/30 minute infusion dose and administration schedule for Opdivo in six indications.
June 2018	Announced the CHMP of the EMA has recommended expanded approval of the current indications for Opdivo to include the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. This is the first time the CHMP has recommended a PD-1 inhibitor as an adjuvant treatment for any type of cancer. The CHMP recommendation will be reviewed by the EC which has the authority to approve medicines for the EU.
Various	Announced preliminary data from the ongoing PIVOT Phase I/II Study, which is evaluating the combination of Opdivo with Nektar's investigational medicine, NKTR-214. The preliminary results presented at the 2018 American Society of Clinical Oncology reported safety, efficacy and biomarker data for patients enrolled in the Phase I dose-escalation stage of the study and for the first patients consecutively enrolled in select dose expansion cohorts in Phase II.
June 2018	EC approval of an every four-week (Q4W) Opdivo dosing schedule of 480 mg infused over 60 minutes as an option for patients with advanced melanoma and previously treated RCC as well as the approval of a two-week Opdivo dosing option of 240 mg infused over 30 minutes to replace weight-based dosing for all six approved monotherapy indications in the EU.
April 2018	FDA approval of the Company's sBLA to update Opdivo dosing to include 480 mg infused every four weeks for a majority of approved indications as well as a shorter 30 minute infusion across all approved indications.
March 2018	

## Product Indication Date Developments

Product Indication	Date	Developments
CRC	October 2018	Announced new data from a cohort of the CheckMate-142 study in which Opdivo plus low-dose Yervoy demonstrated durable clinical benefit as a first-line treatment in patients with MSI-H or dMMR mCRC.
	July 2018	FDA approval of Opdivo plus low-dose Yervoy for the treatment of adult and pediatric patients 12 years and older with MSI-H or dMMR mCRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan.
Melanoma	October 2018	Announced four-year data from the Phase III CheckMate-067 clinical trial which continues to demonstrate durable, long-term survival benefits with the first-line combination of Opdivo+Yervoy, versus Yervoy alone, in patients with advanced melanoma.
	May 2018	Approval in Japan of Opdivo+Yervoy combination for chemotherapy-naive patients with unresectable melanoma.
mUC	October 2018	Announced follow-up data evaluating Opdivo monotherapy and Opdivo in combination with Yervoy in patients with platinum-pretreated mUC. Results from the Phase I/II CheckMate-032 trial showed that patients who received the combination of Opdivo 1 mg/kg plus Yervoy 3 mg/kg experienced a higher objective response rate compared to those who received Opdivo 3 mg/kg plus Yervoy 1 mg/kg or Opdivo alone.
Opdivo+Yervoy	October 2018	Announced updates regarding regulatory actions by health authorities in the U.S. and EU for the ongoing review of its applications for an indication in metastatic first-line NSCLC with Opdivo plus low-dose Yervoy in patients with TMB greater than or equal to 10 mutations per megabase. The CHMP requested additional information from CheckMate-227, including an overall survival analysis of Opdivo+Yervoy in patients who have TMB less than 10 mutations per megabase. The FDA determined that the submission of this new information constituted a major amendment to the sBLA and notified the Company that the review period was extended by three months with a new PDUFA goal date of May 20, 2019.
	NSCLC	June 2018
	June 2018	Announced results from a part of the Phase III CheckMate-227 trial that evaluated Opdivo plus low-dose Yervoy and Opdivo plus chemotherapy versus chemotherapy in patients with first-line NSCLC with PD-L1 expression <1%, across squamous and non-squamous tumor histologies extended progression-free survival.
	May 2018	Announced the EMA validated a type II variation application for treatment in adult patients with first-line metastatic NSCLC who have TMB greater than or equal to 10 mutations per megabase.
	October 2018	Announced the results of a new analysis from the Phase III CheckMate-214 study, demonstrating that therapy with Opdivo+Yervoy in patients with previously untreated advanced or metastatic RCC was associated with significantly longer treatment-free survival.
RCC	August 2018	Approval in Japan of Opdivo plus low-dose Yervoy for the treatment of unresectable or metastatic RCC.

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

	July 2018	Announced the Company will be receiving a negative opinion from the CHMP for Opdivo+Yervoy combination for previously untreated patients with intermediate and poor-risk advanced RCC. We disagree with this opinion and, in the interest of patients, we plan to pursue a re-examination under the EU regulatory process.
	June 2018	Announced patient-reported outcomes data from the Phase III CheckMate-214 trial in intermediate- and poor-risk patients with advanced RCC treated with Opdivo plus low-dose Yervoy versus sunitinib over a two-year follow-up period reported significant and sustained health-related quality of life improvements.
	April 2018	FDA approval of Opdivo+Yervoy combination for previously untreated patients with intermediate and poor-risk advanced RCC.
EliquisNVAF	March 2018	Announced findings from the largest real-world data analysis of NVAF patients receiving direct oral anticoagulants showing that Eliquis is associated with lower rates of stroke or systemic embolism and major bleeding than rivaroxaban or dabigatran.
	September 2018	Announced the EMA has validated the Company's type II variation application for Empliciti in combination with pomalidomide and low-dose dexamethasone (EPd) for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI), and have demonstrated disease progression on the last therapy.
EmplicitiRRMM	August 2018	FDA acceptance for priority review of the Company's sBLA for EPd for the treatment of patients with RRMM who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor. The FDA action date is December 27, 2018.
	June 2018	Announced the ELOQUENT-3 trial, an international Phase II study evaluating the addition of EPd in patients with RRMM, achieved its primary endpoint, showing a statistically significant and clinically meaningful improvement in PFS for patients treated with EPd compared with pomalidomide and dexamethasone (Pd) alone.

## Product Indication Date Developments

Sprycel	ALL	August 2018	Announced FDA accepted the Company's sBLA for Sprycel in combination with chemotherapy for the treatment of pediatric patients with Philadelphia chromosome-positive ALL. The FDA action date is December 29, 2018.
	CML	July 2018	EC expanded the indication for Sprycel to include the treatment of children and adolescents aged 1 year to 18 years with chronic phase Philadelphia chromosome positive CML and to include a powder for oral suspension.
Yervoy	Melanoma	January 2018	EC approval of advanced (unresectable or metastatic) melanoma in pediatric patients 12 years of age and older.
TYK2 Inhibitor	Psoriasis	September 2018	Announced results from a Phase II study of BMS-986165, an oral, selective TYK2 inhibitor which delivered significant skin clearance in patients with moderate to severe plaque psoriasis.

## 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 2017 Annual Report on Form 10-K. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2018. For information regarding the impact of recently adopted accounting standards, refer to “—Note.1 Basis of Presentation and Recently Issued Accounting Standards”.

## 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 2017 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 2017 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.

41

---



There were no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2018 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 2017 Annual Report on Form 10-K.

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

The following table summarizes the surrenders of our equity securities during the three months ended September 30, 2018:

Period	Total Number of Shares Purchased <sup>(a)</sup>	Average Price Paid per Share <sup>(a)</sup>	Total Number of Shares Purchased as Part of Publicly Announced Programs <sup>(b)</sup>	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs <sup>(b)</sup>
Dollars in Millions, Except Per Share Data				
July 1 to 31, 2018	8,072	\$ 54.80	—	\$ 1,348
August 1 to 31, 2018	8,339	\$ 59.61	—	\$ 1,348
September 1 to 30, 2018	7,339	\$ 61.08	—	\$ 1,348
Three months ended September 30, 2018	23,750		—	

Includes shares repurchased as part of publicly announced programs and shares of common stock surrendered to (a) 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. In October 2016, (b) 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. Refer to "Item 1. Financial Statements—Note 16. Equity" for information on the accelerated share repurchase agreements.

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, 2018, 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 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; Keytruda is a trademark of Merck Sharp & Dohme Corp.; Onglyza is a trademark of AstraZeneca AB; Plavix is a trademark of Sanofi; Prostavac is a trademark of Bavarian Nordic A/S; and Tybost is a trademark of Gilead Sciences Ireland UC and/or one of its affiliates. Brand names of products that are in all italicized letters, without an asterisk, are registered trademarks of BMS and/or one of its subsidiaries.

## SUMMARY OF ABBREVIATED TERMS

Bristol-Myers Squibb Company may be referred to as Bristol-Myers Squibb, BMS, the Company, we, our or us in this Quarterly Report on Form 10-Q. Throughout this Quarterly Report on Form 10-Q we have used terms which are defined below:

2017 Form 10-K	Annual Report on Form 10-K for the fiscal year ended December 31, 2017	MDL	multi-district litigation
ALK	anaplastic lymphoma kinase	Merck	Merck & Co., Inc.
ALL	acute lymphoblastic leukemia	MSI-H	microsatellite instability-high
ASC	accounting standards codification	mUC	metastatic urothelial carcinoma
AstraZeneca	AstraZeneca PLC	Nektar	Nektar Therapeutics
Bavarian Nordic	Bavarian Nordic A/S	NKT	natural killer T cells
Biogen	Biogen, Inc.	NSCLC	non-small cell lung cancer
Cardioxyl	Cardioxyl Pharmaceuticals, Inc.	NVAF	non-valvular atrial fibrillation
Cheplapharm	Cheplapharm Arzneimittel GmbH	Ono	Ono Pharmaceutical Co., Ltd.
CHMP	Committee for Medicinal Products for Human Use	OTC	over-the-counter
CML	chronic myeloid leukemia	PD-1	programmed cell death protein 1
Cormorant	Cormorant Pharmaceuticals	PD-L1	programmed death-ligand 1
CRC	colorectal cancer	PDUFA	Prescription Drug User Fee Act
CytomX	CytomX Therapeutics, Inc.	PFS	progression-free survival
dMMR	DNA mismatch repair deficient	Promedior	Promedior, Inc.
EC	European Commission	PsA	psoriatic arthritis
EGFR	epidermal growth factor receptor	PsiOxus	PsiOxus Therapeutics, Ltd.
EMA	European Medicines Agency	Quarterly Report on Form 10-Q	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018
EPO	European Patent Office	R&D	research and development
EPS	earnings per share	RA	rheumatoid arthritis
EU	European Union	RCC	renal cell carcinoma
FASB	Financial Accounting Standards Board	Rigel	Rigel Pharmaceuticals, Inc.
FDA	U.S. Food and Drug Administration	Roche	Roche Holding AG
Flexus	Flexus Biosciences, Inc.	RRMM	relapsed/refractory multiple myeloma
GAAP	U.S. generally accepted accounting principles	sBLA	supplemental Biologics License Application
Gilead	Gilead Sciences, Inc.	SCCHN	squamous cell carcinoma of the head and neck
GTN	gross-to-net	SCLC	small cell lung cancer
HCV	hepatitis C virus	SEC	Securities and Exchange Commission
HIV	human immunodeficiency virus	SK Biotek	SK Biotek Co., Ltd.
IFM	IFM Inflammation, Inc.	TMB	tumor mutational burden
IO	immuno-oncology	TYK2	tyrosine kinase 2
IPRD	in-process research and development	U.S.	United States
JIA	juvenile idiopathic arthritis	UK	United Kingdom
LOE	loss of exclusivity	VAT	value added tax
mCRC	metastatic colorectal cancer		

**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 25, 2018 By: /s/ Giovanni Caforio  
Giovanni Caforio  
Chairman of the Board and Chief Executive Officer

Date: October 25, 2018 By: /s/ Charles Bancroft  
Charles Bancroft  
Chief Financial Officer