CELGENE CORP /DE/
Form 10-Q
October 26, 2017

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

[x] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2017

OR

[ ] 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 001-34912
CELGENE CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	22-2711928
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
86 Morris Avenue, Summit, NJ	07901
(Address of principal executive offices)	(Zip Code)

(908) 673-9000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes X No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes X No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	X Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicated 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 7(a)(2)(B) of the Securities Act.

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

As of October 23, 2017, 787,316,931 shares of Common Stock, par value $.01 per share, were outstanding.

CELGENE CORPORATION

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)
(Dollars in millions, except per share amounts)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Net product sales	$3,283	$2,969	$9,494	$8,208
Other revenue	4	14	26	41
Total revenue	3,287	2,983	9,520	8,249
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	118	108	342	325
Research and development	1,347	1,653	3,177	3,335
Selling, general and administrative	608	698	2,167	1,973
Amortization of acquired intangible assets	80	87	250	354
Acquisition related charges and restructuring, net	49	25	75	25
Total costs and expenses	2,202	2,571	6,011	6,012
Operating income	1,085	412	3,509	2,237
Other income and (expense):				
Interest and investment income, net	33	7	72	21
Interest (expense)	(127)	(128)	(380)	(373)
Other (expense), net	—	(35)	(18)	(12)
Income before income taxes	991	256	3,183	1,873
Income tax provision	3	85	162	303
Net income	$988	$171	$3,021	$1,570
Net income per common share:				
Basic	$1.26	$0.22	$3.87	$2.02
Diluted	$1.21	$0.21	$3.72	$1.95
Weighted average shares:				
Basic	784.1	775.8	781.2	777.3
Diluted	815.2	801.5	812.6	803.7

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
(Dollars in millions)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Net income	$988	$171	$3,021	$1,570
Other comprehensive income (loss):				
Foreign currency translation adjustments	23	4	64	7
Net unrealized gains (losses) related to cash flow hedges (See Notes 1 and 2):				
Unrealized holding (losses)	(131)	(53)	(397)	(244)
Tax (expense) benefit	—	(1)	7	18
Unrealized holding (losses), net of tax	(131)	(54)	(390)	(226)
Reclassification adjustment for (gains) included in net income	(6)	(69)	(169)	(216)
Tax (benefit)	—	(1)	(2)	(2)
Reclassification adjustment for (gains) included in net income, net of tax	(6)	(70)	(171)	(218)
Excluded component related to cash flow hedges (See Notes 1 and 2):				
Amortization of excluded component (loss) gain	(5)	—	(10)	—
	(5)	—	(10)	—
Net unrealized gains (losses) on marketable securities available-for-sale:				
Unrealized holding gains (losses)	444	(8)	673	(361)
Tax (expense) benefit	(157)	2	(238)	129
Unrealized holding gains (losses), net of tax	287	(6)	435	(232)
Reclassification adjustment for (gains) losses included in net income	(2)	31	32	71
Tax expense (benefit)	1	(11)	(12)	(25)
Reclassification adjustment for (gains) losses included in net income, net of tax	(1)	20	20	46
Total other comprehensive income (loss)	167	(106)	(52)	(623)
Comprehensive income	$1,155	$65	$2,969	$947

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(Dollars in millions, except per share amounts)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 5,511	$ 6,170
Marketable securities available-for-sale	6,248	1,800
Accounts receivable, net of allowances of $34 and $31 at September 30, 2017 and December 31, 2016, respectively	1,816	1,621
Inventory	537	498
Other current assets	671	779
Total current assets	14,783	10,868
Property, plant and equipment, net	1,002	930
Intangible assets, net	10,137	10,392
Goodwill	4,866	4,866
Other non-current assets	948	1,030
Total assets	$ 31,736	$ 28,086
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	1,400	501
Accounts payable	263	247
Accrued expenses and other current liabilities	2,265	2,115
Income taxes payable	55	41
Current portion of deferred revenue	66	55
Total current liabilities	4,049	2,959
Deferred revenue, net of current portion	46	28
Income taxes payable	469	420
Other non-current tax liabilities	2,519	2,519
Other non-current liabilities	1,929	1,771
Long-term debt, net of discount	12,874	13,789
Total liabilities	21,886	21,486
Commitments and Contingencies (See Note 15)		
Stockholders' Equity:		
Preferred stock, $.01 par value per share, 5.0 million shares authorized; none outstanding at September 30, 2017 and December 31, 2016, respectively	—	—
Common stock, $.01 par value per share, 1,150.0 million shares authorized; issued 970.4 million and 954.1 million shares at September 30, 2017 and December 31, 2016, respectively	10	10
Common stock in treasury, at cost; 183.3 million and 175.5 million shares at September 30, 2017 and December 31, 2016, respectively	(17,243)	(16,281)
Additional paid-in capital	13,604	12,378
Retained earnings	13,142	10,074
Accumulated other comprehensive income	337	419
Total stockholders' equity	9,850	6,600
Total liabilities and stockholders' equity	$ 31,736	$ 28,086

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(Dollars in millions)

	Nine-Month Periods Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net income	$3,021	$1,570
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	100	90
Amortization	255	277
Impairment charges	51	187
Deferred income taxes	(195)	(257)
Change in value of contingent consideration	75	12
(Gain) on sale of business	—	(38)
Net (gain) on sale of investments	(18)	(7)
Share-based compensation expense	482	452
Share-based employee benefit plan expense	35	29
Derivative instruments	14	193
Other, net	(18)	(9)
Change in current assets and liabilities, excluding the effect of acquisitions and disposals:		
Accounts receivable	(139)	(144)
Inventory	(37)	(62)
Other operating assets	(285)	137
Accounts payable and other operating liabilities	28	164
Income tax payable	165	158
Deferred revenue	23	11
Net cash provided by operating activities	3,557	2,763
Cash flows from investing activities:		
Proceeds from sales of marketable securities available-for-sale	3,307	542
Purchases of marketable securities available-for-sale	(7,019)	(560)
Capital expenditures	(176)	(170)
Proceeds from sales of investment securities	14	13
Purchases of investment securities	(88)	(122)
Other	(27)	(1)
Net cash (used in) investing activities	(3,989)	(298)
Cash flows from financing activities:		
Payment for treasury shares	(925)	(2,026)
Principal repayments on current portion of long-term debt	(500)	—
Proceeds from issuance of long-term debt	496	—
Net proceeds from common equity put options	—	8
Net proceeds from share-based compensation arrangements	637	191
Net cash (used in) financing activities	(292)	(1,827)
Effect of currency rate changes on cash and cash equivalents	65	5
Net (decrease) increase in cash and cash equivalents	(659)	643
Cash and cash equivalents at beginning of period	6,170	4,880
Cash and cash equivalents at end of period	$5,511	$5,523

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS - (Continued)
(Unaudited)
(Dollars in millions)

	Nine-Month Periods Ended September 30,	
	2017	2016
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized (gain) loss on marketable securities available-for-sale	$ (673)	$ 361
Investment in Human Longevity, Inc. common stock	—	40
Investment in Celularity, Inc. common stock	22	—
Supplemental disclosure of cash flow information:		
Interest paid	461	463
Income taxes paid	450	345

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
(In all accompanying tables, amounts of dollars expressed in millions,
except per share amounts, unless otherwise indicated)

1. Nature of Business, Basis of Presentation and Significant Accounting Policies

Celgene Corporation, together with its subsidiaries (collectively “we,” “our,” “us,” “Celgene” or the “Company”), is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. Celgene Corporation was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®), THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.) and IDHIFA®. IDHIFA® was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) or (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved diagnostic test. We began recognizing revenue related to IDHIFA® during the third quarter of 2017. In addition, we earn revenue from other product sales and licensing arrangements.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Investments in limited partnerships and interests where we have an equity interest of 50% or less and do not otherwise have a controlling financial interest are accounted for by either the equity or cost method.

We operate in a single segment engaged in the discovery, development, manufacturing, marketing, distribution and sale of innovative therapies for the treatment of cancer and inflammatory diseases. Consistent with our operational structure, our Chief Executive Officer (CEO), as the chief operating decision maker, manages and allocates resources at the global corporate level. Our global research and development organization is responsible for discovery of new drug candidates and supports development and registration efforts for potential future products. Our global supply chain organization is responsible for the manufacturing and supply of products. Regional/therapeutic area commercial organizations market, distribute and sell our products. The business is also supported by global corporate staff functions. Managing and allocating resources at the global corporate level enables our CEO to assess both the overall level of resources available and how to best deploy these resources across functions, therapeutic areas, regional commercial organizations and research and development projects in line with our overarching long-term corporate-wide strategic goals, rather than on a product or franchise basis. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, allocating resources, setting incentive compensation targets, as well as forecasting future period financial results.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. We are subject to certain risks and uncertainties related to, among other things, product development, regulatory approval, market acceptance, scope of patent and proprietary rights, competition, outcome of legal and governmental proceedings, credit risk, technological change and product liability.

Interim results may not be indicative of the results that may be expected for the full year. In the opinion of management, these unaudited consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited consolidated financial statements. Certain prior year amounts have been reclassified to conform to the current year's presentation.

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 (2016 Annual Report on Form 10-K). During the third quarter of 2017, we adopted Accounting Standards Update No. 2017-12, "Targeted Improvements to Accounting for Hedging Activities" (ASU 2017-12). As a result of the adoption of ASU 2017-12, we have updated our Derivative Instruments and Hedges accounting policies. There were no other changes to our significant accounting policies from those disclosed in our 2016 Annual Report on Form 10-K. See Notes 2 and 7 for additional details related to the adoption of ASU 2017-12.

Derivative Instruments and Hedges: All derivative instruments are recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships

between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether derivative instruments are highly effective in offsetting the changes in the fair value or cash flows of hedged items. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in Other (expense), net in our Consolidated Statements of Income. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements in foreign exchange, our stock price and interest rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce our risk or cost.

Prior to the adoption of ASU 2017-12, we were required to separately measure and reflect the amount by which the hedging instrument did not offset the changes in the fair value or cash flows of hedged items, which was referred to as the ineffective amount. We assessed hedge effectiveness on a quarterly basis and recorded the gain or loss related to the ineffective portion of derivative instruments, if any, in Other (expense), net in the Consolidated Statements of Income. Pursuant to the provisions of ASU 2017-12, we are no longer required to separately measure and recognize hedge ineffectiveness. Upon adoption of ASU 2017-12, we no longer recognize hedge ineffectiveness in our Consolidated Statements of Income, but we instead recognize the entire change in the fair value of:

- cash flow hedges included in the assessment of hedge effectiveness in Other comprehensive income (loss). The amounts recorded in Other comprehensive income (loss) will subsequently be reclassified to earnings in the same line item in the Consolidated Statements of Income as impacted by the hedged item when the hedged item affects earnings; and

- fair value hedges included in the assessment of hedge effectiveness in the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

Prior to the adoption of ASU 2017-12, we excluded option premiums and forward points (excluded components) from our assessment of hedge effectiveness for our foreign exchange cash flow hedges. We recognized all changes in fair value of the excluded components in Other (expense), net in the Consolidated Statements of Income. The amendments in ASU 2017-12 continue to allow those components to be excluded from the assessment of hedge effectiveness, which we have elected to continue to apply. Pursuant to the provisions of ASU 2017-12, we no longer recognize changes in the fair value of the excluded components in Other (expense), net, but we instead recognize the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

2. New Accounting Standards

New accounting standards which have been adopted

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory" (ASU 2015-11). ASU 2015-11 applies only to inventory for which cost is determined by methods other than last in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 was effective for us beginning in the first quarter of 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-07, "Investments-Equity Method and Joint Ventures" (ASU 2016-07). ASU 2016-07 eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively as if the equity method had been in effect during all previous periods that the investment had been held. Under the new guidance, available-for-sale equity securities that become qualified for the equity method of accounting will result in the recognition through earnings of the unrealized holding gain or loss in accumulated other comprehensive income at the date the investment becomes qualified for use of the equity method. ASU 2016-07 was effective for us beginning in the first quarter of 2017. The adoption of this updated standard did not have a material impact on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation" (ASU 2016-09). The new standard was effective for us on January 1, 2017. Among other provisions, the new standard requires that excess tax benefits and tax deficiencies that arise upon vesting or exercise of share-based payments be recognized as income tax benefits

and expenses in the income statement. Previously, such amounts were recorded to additional paid-in-capital. This aspect of the new guidance was required to be adopted prospectively, and accordingly, the income tax provisions for the three- and nine-month periods ended September 30, 2017 includes $103 million and $273 million, respectively, of excess tax benefits arising from share-based compensation awards that vested or were exercised during the periods. In addition, at January 1, 2017, the Company recorded a cumulative-effect adjustment to Retained earnings, with a corresponding increase to net deferred tax assets, in the amount of $18 million related to previously unrecognized excess tax benefits outstanding in the Consolidated Balance Sheet. In addition, the adoption of the new standard increased the diluted share count for the three- and nine-month periods ended September 30, 2017 by approximately 7.0 million and 7.3 million shares, respectively. The new standard also amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring that excess income tax benefits and tax deficiencies be classified in Cash flows from operating activities (such amounts were previously included in Cash flows from financing activities). The Company elected to adopt this aspect of the new guidance retrospectively, and accordingly, to conform to the current year presentation, $130 million of excess tax benefits were reclassified from Net Cash Used in Financing Activities to Net Cash Provided by Operating Activities and included within the change in Income taxes payable in the Consolidated Statement of Cash Flows for the nine-month period ended September 30, 2016. As a result, Net Cash Used in Financing Activities increased by $130 million with a corresponding increase in Net Cash Provided by Operating Activities in the Consolidated Statement of Cash Flows for the nine-month period ended September 30, 2016.

In August 2017, the FASB issued ASU 2017-12 which we adopted on August 31, 2017 (Adoption Date). The guidance was issued to improve and more closely align a company’s financial reporting of its hedging relationships with the objective of a company’s risk management activities. Among other provisions, the new standard (1) eliminates the separate measurement and reporting of hedge ineffectiveness and (2) permits an entity to recognize in earnings the initial value of an excluded component under a systematic and rational method over the life of the derivative instrument. In accordance with ASU 2017-12, certain provisions were required to be applied on a modified retrospective basis, which requires a cumulative effect adjustment to accumulated other comprehensive income with a corresponding adjustment to retained earnings as of the beginning of the fiscal year of adoption, or January 1, 2017 (Application Date). In addition, certain provisions in the guidance require modifications to existing presentation and disclosure requirements on a prospective basis. See Note 7 for disclosures relating to the Company’s derivative instruments and hedging activities.

Pursuant to the provisions of ASU 2017-12, we are no longer required to separately measure and report hedge ineffectiveness, which was previously recorded in Other (expense), net in our Consolidated Statements of Income. For fair value hedges, the entire change in the fair value of the hedging instrument included in the assessment of hedge effectiveness is recorded in the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item. The timing of recognition of the change in fair value of a hedging instrument included in the assessment of hedge effectiveness is the same as prior to the adoption of ASU 2017-12. For cash flow hedges the entire change in the fair value of the hedging instrument included in the assessment of hedge effectiveness is recorded in Other comprehensive income (loss). Those amounts are subsequently reclassified to earnings in the same line item in the Consolidated Statements of Income as impacted by the hedged item when the hedged item affects earnings.

In accordance with the transition provisions of ASU 2017-12, the Company is required to eliminate the separate measurement of ineffectiveness for its cash flow hedging instruments existing as of the Adoption Date through a cumulative effect adjustment to retained earnings as of the Application Date. We did not record a cumulative effect adjustment to eliminate ineffectiveness amounts as all such amounts were not material to the Company’s previously issued Consolidated Financial Statements. In addition, we did not have any ineffectiveness during fiscal year 2017.

The Company may continue to elect to exclude certain portions of its derivative instruments' change in fair value from the assessment of hedge effectiveness (excluded component). In accordance with the new guidance, the Company may recognize in earnings the initial value of the excluded component on a systematic and rational method over the life of the derivative instrument. Alternatively, the Company may elect to continue to recognize all fair value changes in an excluded component currently in earnings, which is consistent with the guidance prior to the issuance of ASU 2017-12. We will recognize in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument. Previously, we recognized all changes in fair value of the excluded components in Other (expense), net in the Consolidated Statements of Income. We believe the revised guidance in ASU 2017-12 better portrays the economic results of our risk management activities and hedging relationships in our Consolidated Financial Statements. In accordance with the transition provisions of ASU 2017-12, we modified the recognition model for the excluded component from a mark-to-market approach to an amortization approach for all hedges existing as of the Adoption Date with a cumulative-effect adjustment of $30 million that reduced Accumulated other comprehensive income with a corresponding adjustment that increased Retained earnings as of the Application Date. The effect of the change in recognition model to an amortization approach, increased both income before income taxes and net income by approximately $57 million and $49 million,

respectively, for the three-month period ended September 30, 2017 and $94 million and $80 million, respectively, for the nine-month period ended September 30, 2017. In addition, the effect of the change in recognition model to an amortization approach also increased both the Company's basic and diluted income per share by $0.06 for the three-month period ended September 30, 2017 and by $0.10 for the nine-month period ended September 30, 2017.

In addition, the Company assessed the impact of applying the guidance to its Consolidated Financial Statements on previously issued interim reports for the three-month period ended March 31, 2017, and the three- and six-month periods ended June 30, 2017. The Company concluded that the impacts to the previously issued interim reports were not material and therefore no recast of such reports have been made at this time. During the nine-month period ended September 30, 2017, the Company recorded pre-tax expense of $11 million for the three-month period ended March 31, 2017 and pre-tax income of $48 million for the three-month period ended June 30, 2017 as a result of applying the new guidance, which is included in the effects disclosed above. Upon filing of the interim reports on Form 10-Q for the quarterly periods ended March 31, 2018 and June 30, 2018, we intend to recast the financial statements for the quarterly periods ended March 31, 2017 and June 30, 2017, respectively, to reflect the adoption of ASU 2017-12. In addition, we intend to recast the quarterly periods ended March 31, 2017 and June 30, 2017 within our quarterly results of operations footnote included within our annual financial statements to be filed on Form 10-K for the fiscal year ending December 31, 2017.

New accounting standards which have not yet been adopted

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within a five step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard will be effective for us beginning January 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. We will adopt the standard using the modified retrospective method.

We have completed an analysis of existing contracts with our customers and assessed the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards. Based on our review of current customer contracts, we do not expect the implementation of ASU 2014-09 to have a material quantitative impact on our consolidated financial statements as the timing of revenue recognition for product sales is not expected to significantly change. In limited instances, we may recognize revenue earlier than under the current standard. Currently, we defer certain revenue where the price pursuant to the underlying customer arrangement is not fixed and determinable. Under the new standard, such customer arrangements will be accounted for as variable consideration, which may result in revenue being recognized earlier provided we can reliably estimate the ultimate price expected to be realized from the customer. We will continue to assess new customer contracts throughout 2017. The new standard will result in additional revenue-related disclosures in the footnotes to our consolidated financial statements. Adoption

of this standard will require changes to our business processes, systems and controls to support the additional required disclosures. We are in the process of identifying and designing such changes to ensure our readiness.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, "Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU 2016-01). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. Changes in measurement under either alternative will be recognized in net income. Companies that elect the fair value option for financial liabilities must recognize changes in fair value related to instrument-specific credit risk in other

comprehensive income (OCI). Companies must assess valuation allowances for deferred tax assets related to available-for-sale debt securities in combination with their other deferred tax assets. ASU 2016-01 will be effective for us beginning in the first quarter of 2018 and early adoption is available to publicly traded companies to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in OCI. We expect the implementation of this standard to have an impact on our consolidated financial statements and related disclosures, as we held publicly traded equity investments as of September 30, 2017 with a fair value of approximately $1.9 billion in a net unrealized gain position of $925 million, and having an associated deferred tax liability of $328 million, as of September 30, 2017. We will record a cumulative-effect adjustment to retained earnings for the amount of unrealized gains or losses, net of tax at the beginning of the fiscal year of adoption. The guidance related to equity investments without readily determinable fair values should be applied prospectively to equity investments that exist as of the date of adoption. The implementation of ASU 2016-01 is expected to increase volatility in our net income as the volatility currently recorded in OCI related to changes in the fair market value of available-for-sale equity investments will be reflected in net income after adoption.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" (ASU 2016-02). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either an operating or finance lease. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures. We expect the implementation of this standard to have an impact on our consolidated financial statements and related disclosures as we had aggregate future minimum lease payments of approximately $213 million as of December 31, 2016 under our portfolio of non-cancelable leased office and research facilities at that time which had various expirations dates between 2017 and 2025 as included in our 2016 Annual Report on Form 10-K. We anticipate recognition of additional assets and corresponding liabilities related to these leases on our consolidated balance sheet.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, "Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments" (ASU 2016-13). ASU 2016-13 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective for us on January 1, 2020. Early adoption will be available on January 1, 2019. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments" (ASU 2016-15). ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 is effective for us in our first quarter of fiscal 2018 and earlier adoption is permitted. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued Accounting Standards Update No. 2016-16, "Intra-Entity Transfers of Assets Other Than Inventory” (ASU 2016-16). ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets

other than inventory to be recognized as current period income tax expense or benefit and removes the requirement to defer and amortize the consolidated tax consequences of intra-entity transfers. The new standard will be effective for us on January 1, 2018 and will be adopted using a modified retrospective approach which requires a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, “Business Combinations” (ASU 2017-01). ASU 2017-01 provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities (a “set”) does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The new standard will be effective for us on January 1, 2018 and will be adopted on a prospective basis.

Early adoption is permitted. We anticipate that the adoption of this standard will result in more acquisitions being accounted for as asset acquisitions.

3. Acquisitions and Divestitures

Acquisitions in Fiscal 2017:

Delinia, Inc. (Delinia): On February 3, 2017, we acquired all of the outstanding shares of Delinia, a privately held biotechnology company focused on developing novel therapeutics for the treatment of autoimmune diseases. The transaction expands our Inflammation and Immunology pipeline primarily through the acquisition of Delinia's lead program, DEL-106, as well as related second generation programs. DEL-106 is a novel IL-2 mutein Fc fusion protein designed to preferentially upregulate regulatory T cells (Tregs), immune cells that are critical to maintaining natural self-tolerance and immune system homeostasis.

The consideration included an initial payment of $302 million. In addition, the sellers of Delinia are eligible to receive up to $475 million in contingent development, regulatory and commercial milestones. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment was allocated primarily to the DEL-106 program, resulting in a $300 million research and development asset acquisition expense and approximately $2 million of net assets acquired.

Other acquisitions: In addition, during the first quarter of 2017, we acquired all of the outstanding shares of a privately held biotechnology company for total initial consideration of $26 million. The sellers are also eligible to receive up to $210 million in contingent development and regulatory approval milestones. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The consideration transferred resulted in a $25 million research and development asset acquisition expense and $1 million of net assets acquired.

Acquisitions in Fiscal 2016:

EngMab AG (EngMab): On September 27, 2016, we acquired all of the outstanding shares of EngMab, a privately held biotechnology company focused on T-cell bi-specific antibodies. EngMab's lead molecule, EM901 is a preclinical T-cell bi-specific antibody targeting B-cell maturation antigen (BCMA). The acquisition also included another early stage program.

The consideration included an initial payment of 607 million Swiss Francs (CHF) (approximately $625 million), contingent development and regulatory milestones of up to CHF 150 million (approximately $155 million) and contingent commercial milestones of up to approximately CHF 2.3 billion (approximately $2.3 billion) based on cumulative sales levels of between $1.0 billion and $40.0 billion. The acquisition of EngMab did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment was allocated primarily to the EM901 molecule and another early stage program, resulting in a $623 million research and development asset acquisition expense and $2 million of net working capital acquired.

Divestitures in Fiscal 2017:

Celgene Pharmaceutical (Shanghai) Co. Ltd. (Celgene China): On August 31, 2017, we completed the sale of our Celgene commercial operations in China to BeiGene, Ltd. (BeiGene). The transaction resulted in an immaterial loss

on disposal that was recorded on our Consolidated Statement of Income in Other (expense), net during the three-month period ended September 30, 2017. In conjunction with the sale, we contemporaneously entered into both a product supply agreement and strategic collaboration arrangement with BeiGene. See Note 14 for additional details related to the collaboration arrangement with BeiGene.

Divestitures in Fiscal 2016:

LifebankUSA: In February 2016, we completed the sale of certain assets of Celgene Cellular Therapeutics (CCT) comprising CCT's biobanking business known as LifebankUSA, CCT’s biomaterials portfolio of assets, including Biovance®, and CCT's rights to PSC-100, a placental stem cell program, to Human Longevity, Inc. (HLI), a genomics and cell therapy-based diagnostic and therapeutic company based in San Diego, California. We received 3.4 million shares of HLI Class A common stock with a fair value of $40 million as consideration in the transaction. The fair value of the shares of common stock we received was determined based on the most recent preferred share offering and reduced for the estimated value of the liquidation preference not offered to common shareholders. The transaction generated a $38 million gain that was recorded on our Consolidated Statement of Income in Other (expense), net during the nine-month period ended September 30, 2016. As of September 30, 2017, our total investment in HLI represents approximately 14% of HLI's outstanding capital stock.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

4. Earnings Per Share

(Amounts in millions, except per share)	Three-Month Periods Ended September 30, 2017	2016	Nine-Month Periods Ended September 30, 2017	2016
Net income	$988	$171	$3,021	$1,570
Weighted-average shares:				
Basic	784.1	775.8	781.2	777.3
Effect of dilutive securities:				
Options, restricted stock units, performance-based restricted stock units and other	31.1	25.7	31.4	26.4
Diluted	815.2	801.5	812.6	803.7
Net income per share:				
Basic	$1.26	$0.22	$3.87	$2.02
Diluted	$1.21	$0.21	$3.72	$1.95

The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 11.4 million and 20.7 million shares for the three-month periods ended September 30, 2017 and 2016, respectively, and 21.5 million and 21.7 million shares for the nine-month periods ended September 30, 2017 and 2016, respectively.

Share Repurchase Program: During the period of April 2009 through September 30, 2017, our Board of Directors approved repurchases of up to an aggregate of $20.5 billion of our common stock.

As part of the management of our share repurchase program, we may, from time to time, sell put options on our common stock with strike prices that we believe represent an attractive price to purchase our shares. If the trading price of our shares exceeds the strike price of the put option at the time the option expires, we will have economically reduced the cost of our share repurchase program by the amount of the premium we received from the sale of the put option. If the trading price of our stock is below the strike price of the put option at the time the option expires, we would purchase the shares covered by the option at the strike price of the put option. During the three-month and nine-month periods ended September 30, 2017 and 2016, we recorded put option activity on our Consolidated Statements of Income in Other (expense), net as follows:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Gain from sale of put options	$ —	$ —	$ —	$ 8

As of September 30, 2017 and December 31, 2016, we had no outstanding put options.

We have purchased 0.9 million and 7.7 million shares of common stock under the share repurchase program from all sources at a total cost of $114 million and $925 million during the three- and nine-month periods ended September 30,

2017, respectively. As of September 30, 2017, we had a remaining share repurchase authorization of $3.8 billion.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

5. Accumulated Other Comprehensive Income (Loss)

The components of other comprehensive income (loss) consist of changes in pension liability, changes in net unrealized gains (losses) on marketable securities classified as available-for-sale, net unrealized gains (losses) related to cash flow hedges, the amortization of the excluded component related to cash flow hedges and changes in foreign currency translation adjustments.

The accumulated balances related to each component of other comprehensive income (loss), net of tax, are summarized as follows:

	Pension Liability Adjustment	Net Unrealized Gains (Losses) On Available-for-Sale Marketable Securities	Net Unrealized Gains (Losses) Related to Cash Flow Hedges	Amortization of Excluded Component Related to Cash Flow Hedges (See Notes 1 & 2)	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Income (Loss)
Balance as of December 31, 2016	$ (38)	$ 144	$ 415	$ —	$ (102)	$ 419
Cumulative effect adjustment for the adoption of ASU 2017-12 (See Note 2)	—	—	(12)	(18)	—	(30)
Other comprehensive income (loss) before reclassifications, net of tax	—	435	(390)	(10)	64	99
Reclassified losses (gains) from accumulated other comprehensive income (loss), net of tax	—	20	(171)	—	—	(151)
Net current-period other comprehensive income (loss), net of tax	—	455	(561)	(10)	64	(52)
Balance as of September 30, 2017	$ (38)	$ 599	$ (158)	$ (28)	$ (38)	$ 337
Balance as of December 31, 2015	$ (14)	$ 272	$ 586	$ —	$ (76)	$ 768
Other comprehensive (loss) income before reclassifications, net of tax	—	(232)	(226)	—	7	(451)
Reclassified losses (gains) from accumulated other comprehensive income (loss), net of tax	—	46	(218)	—	—	(172)
Net current-period other comprehensive (loss) income, net of tax	—	(186)	(444)	—	7	(623)
Balance as of September 30, 2016	$ (14)	$ 86	$ 142	$ —	$ (69)	$ 145

Accumulated Other Comprehensive Income (Loss) Components	Classification in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income (Loss)	
		Three-Month Periods	Nine-Month Periods

		Ended September 30, 2017	2016	Ended September 30, 2017	2016
Gains (losses) related to cash-flow hedges:					
Foreign exchange contracts	Net product sales	$7	$71	$174	$221
Treasury rate lock agreements	Interest (expense)	(1)	(2)	(4)	(4)
Interest rate swap agreements	Interest (expense)	—	—	(1)	(1)
	Income tax provision (expense) benefit	—	1	2	2
Gains (losses) on available-for-sale marketable securities:					
Realized gain (loss) on sales of marketable securities	Interest and investment income, net	2	(31)	(32)	(71)
	Income tax provision (expense) benefit	(1)	11	12	25
Total reclassification, net of tax		$7	$50	$151	$172

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

6. Financial Instruments and Fair Value Measurement

The tables below present information about assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016 and the valuation techniques we utilized to determine such fair value.

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our level 1 assets consist of marketable equity securities. Our level 1 liability relates to our publicly traded Contingent Value Rights (CVRs). See Note 18 of Notes to Consolidated Financial Statements included in our 2016 Annual Report on Form 10-K for a description of the CVRs.
- Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Our level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities (MBS), global corporate debt securities, asset backed securities, ultra short income fund investments, time deposits and repurchase agreements with original maturities of greater than three months, foreign currency forward contracts, purchased foreign currency options and interest rate swap contracts. Our level 2 liabilities relate to written foreign currency options, foreign currency forward contracts and interest rate swap contracts.
- Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. We do not have any level 3 assets. Our level 3 liabilities consist of contingent consideration related to undeveloped product rights and technology platforms resulting from the acquisitions of Gloucester Pharmaceuticals, Inc. (Gloucester), Nogra Pharma Limited (Nogra), Avila Therapeutics, Inc. (Avila) and Quanticel Pharmaceuticals, Inc. (Quanticel).

Our contingent consideration obligations are recorded at their estimated fair values and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements are estimated using probability-weighted discounted cash flow approaches that are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly. These inputs include, as applicable, estimated probabilities and timing of achieving specified development and regulatory milestones, estimated annual sales and the discount rate used to calculate the present value of estimated future payments. Significant changes which increase or decrease the probabilities of achieving the related development and regulatory events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations. Changes in the fair value of contingent consideration obligations are recognized in Acquisition related charges and restructuring, net in the Consolidated Statements of Income. The fair value of our contingent consideration as of September 30, 2017 and December 31, 2016 was calculated using the following significant unobservable inputs:

Inputs	Ranges (weighted average) utilized as of:	
	September 30, 2017	December 31, 2016
Discount rate	1.5 to 12.0% (9.1%)	1.5% to 12.0% (8.6%)
Probability of payment	0% to 95% (41.8%)	0% to 95% (42%)
Projected year of payment for development and regulatory milestones	2017 to 2029 (2020)	2017 to 2029 (2019)
Projected year of payment for sales-based milestones and other amounts calculated as a percentage of annual sales	2020 to 2032 (2025)	2019 to 2033 (2024)

The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester, Avila and Quanticel are estimated to be approximately $120 million, $475 million and $314 million, respectively and $1.9 billion plus other amounts calculated as a percentage of annual sales pursuant to the license agreement with Nogra. See Note 17 for additional details related to the GED-0301 (mongersen) trials impacting the Nogra contingent consideration liability.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Balance as of September 30, 2017	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	$ 6,248	$ 1,887	$ 4,361	$ —
Purchased currency options	60	—	60	—
Interest rate swaps	22	—	22	—
Total assets	$ 6,330	$ 1,887	$ 4,443	$ —
Liabilities:				
Contingent value rights	$ (66)	$ (66)	$ —	$ —
Forward currency contracts	(10)	—	(10)	—
Written currency options	(161)	—	(161)	—
Other acquisition related contingent consideration	(1,481)	—	—	(1,481)
Total liabilities	$ (1,718)	$ (66)	$ (171)	$ (1,481)

	Balance as of December 31, 2016	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	$ 1,800	$ 891	$ 909	$ —
Forward currency contracts	379	—	379	—
Purchased currency options	140	—	140	—
Interest rate swaps	31	—	31	—
Total assets	$ 2,350	$ 891	$ 1,459	$ —
Liabilities:				
Contingent value rights	$ (44)	$ (44)	$ —	$ —
Written currency options	(54)	—	(54)	—
Other acquisition related contingent consideration	(1,490)	—	—	(1,490)
Total liabilities	$ (1,588)	$ (44)	$ (54)	$ (1,490)

There were no security transfers between levels 1, 2 and 3 during the three-month periods ended September 30, 2017 and 2016. The following tables represent a roll-forward of the fair value of level 3 instruments:

	Three-Month Period Ended September 30, 2017				
Liabilities:	Gloucester	Nogra	Avila	Quanticel	Total

Balance as of June 30, 2017	$(22)	$(1,372)	$(3)	$ (91)	$(1,488)
Amounts acquired or issued, including measurement period adjustments	—	—	—	—	—
Net change in fair value	—	(31)	—	(5)	(36)
Settlements, including transfers to Accrued expenses and other current liabilities	—	—	—	43	43
Balance as of September 30, 2017	$(22)	$(1,403)	$(3)	$ (53)	$(1,481)

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Three-Month Period Ended September 30, 2016				
Liabilities:	Gloucester	Nogra	Avila	Quanticel	Total
Balance as of June 30, 2016	$(20)	$(1,295)	$(15)	$ (140)	$(1,470)
Amounts acquired or issued, including measurement period adjustments	—	—	—	11	11
Net change in fair value	2	(30)	—	(13)	(41)
Settlements, including transfers to Accrued expenses and other current liabilities	—	—	—	20	20
Balance as of September 30, 2016	$(18)	$(1,325)	$(15)	$ (122)	$(1,480)

There were no security transfers between levels 1, 2 and 3 during the nine-month periods ended September 30, 2017 and 2016. The following tables represent a roll-forward of the fair value of level 3 instruments:

	Nine-Month Period Ended September 30, 2017				
Liabilities:	Gloucester	Nogra	Avila	Quanticel	Total
Balance as of December 31, 2016	$(21)	$(1,346)	$ (8)	$ (115)	$(1,490)
Amounts acquired or issued, including measurement period adjustments	—	—	—	—	—
Net change in fair value	(1)	(57)	5	—	(53)
Settlements, including transfers to Accrued expenses and other current liabilities	—	—	—	62	62
Balance as of September 30, 2017	$(22)	$(1,403)	$ (3)	$ (53)	$(1,481)

	Nine-Month Period Ended September 30, 2016				
Liabilities:	Gloucester	Nogra	Avila	Quanticel	Total
Balance as of December 31, 2015	$(19)	$(1,239)	$(97)	$ (167)	$(1,522)
Amounts acquired or issued, including measurement period adjustments	—	—	—	11	11
Net change in fair value	1	(86)	82	(16)	(19)
Settlements, including transfers to Accrued expenses and other current liabilities	—	—	—	50	50
Balance as of September 30, 2016	$(18)	$(1,325)	$(15)	$ (122)	$(1,480)

7. Derivative Instruments and Hedging Activities

During the third quarter of 2017, we adopted ASU 2017-12. Among other provisions, the new standard required modifications to existing presentation and disclosure requirements on a prospective basis. As such, certain disclosures for the three- and nine-month periods ended September 30, 2016 below conform to the disclosure requirements prior to the adoption of ASU 2017-12. See Note 2 for additional information related to the adoption of ASU 2017-12.

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We actively manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts. In instances where these financial instruments are accounted for as cash flow hedges or fair value hedges we may from time to time terminate the hedging relationship. If a hedging relationship is terminated, we generally either settle the instrument or enter into an offsetting instrument.

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CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Foreign Currency Risk Management

We maintain a foreign exchange exposure management program to mitigate the impact of volatility in foreign exchange rates on future foreign currency cash flows, translation of foreign earnings and changes in the fair value of assets and liabilities denominated in foreign currencies.

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. Dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically within the next three years, with a maximum of five years. We manage our anticipated transaction exposure principally with foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased foreign currency put options.

Foreign Currency Forward Contracts: We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, manage exchange rate volatility in the translation of foreign earnings, and reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding as of September 30, 2017 and December 31, 2016 had settlement dates within 22 months and 31 months, respectively. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and any unrealized gains or losses are reported in OCI and reclassified to the Consolidated Statement of Income in the same periods during which the underlying hedged transactions affect earnings. If a hedging relationship is terminated with respect to a foreign currency forward contract, accumulated gains or losses associated with the contract remain in OCI until the hedged forecasted transaction occurs and are reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. Prior to the adoption of ASU 2017-12, the forward point components of these foreign currency forward contracts were excluded from assessing effectiveness of the hedging relationship and all fair value adjustments of forward point amounts were recorded on the Consolidated Statements of Income in Other (expense), net. Upon adoption of ASU 2017-12, we recognize in earnings the initial value of the forward point components on a straight-line basis over the life of the derivative instrument within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item. See Note 2 for additional information related to the adoption of ASU 2017-12.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of September 30, 2017 and December 31, 2016:

	Notional Amount	
Foreign Currency	September 30, 2017	December 31, 2016
Australian Dollar	$71	$ 49
British Pound	128	199
Canadian Dollar	278	193
Euro	1,211	1,812
Japanese Yen	469	597

Total	$2,157	$ 2,850

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2017, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also manage a portfolio of foreign currency contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies and, from time to time, we enter into foreign currency contracts to manage exposure related to translation of foreign earnings. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in Other (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding as of September 30, 2017 and December 31, 2016 were $882 million and $934 million, respectively.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Foreign Currency Option Contracts: From time to time, we may hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in that local currency. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and local currency notional amounts but with different strike prices. This combination of transactions is generally referred to as a "collar." The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency option contracts outstanding as of September 30, 2017 and December 31, 2016 had settlement dates within 39 months and 48 months, respectively. If the U.S. Dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. Dollar equivalent value of our anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the sale of the call option is equal to the premium paid for the purchased put option, resulting in a net zero cost for each collar. Outstanding foreign currency option contracts entered into to hedge forecasted revenue were as follows as of September 30, 2017 and December 31, 2016:

	Notional Amount[(1)]	
	September 30, 2017	December 31, 2016
Foreign currency option contracts designated as hedging activity:		
Purchased Put	$3,319	$ 1,790
Written Call	3,739	2,009

(1) U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied by the strike value of the foreign currency option. The local currency notional amounts of our purchased put and written call that are designated as hedging activities are equal to each other.

We also have entered into foreign currency put option contracts to hedge forecasted revenue which were not part of a collar strategy. Such put option contracts had a notional value of $387 million as of September 30, 2017 and December 31, 2016, and settlement dates within 15 months and 24 months, respectively.

Interest Rate Risk Management

Forward Starting Interest Rate Swaps and Treasury Rate Locks: In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) or treasury rate lock agreements (treasury rate locks) that are designated as cash flow hedges to hedge against changes in interest rates that could impact expected future issuances of debt. To the extent these hedges of cash flows related to anticipated debt are effective, any realized or unrealized gains or losses on the forward starting swaps or treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

As of September 30, 2017 and December 31, 2016, we had outstanding forward starting swaps with effective dates in 2017 and 2018 and maturing in ten years that were designated as cash flow hedges with notional amounts as shown in the table below:

	Notional Amount	
	September 30, 2017	December 31, 2016
Forward starting interest rate swap contracts:		
Forward starting swaps with effective dates in 2017	$500	$ 500
Forward starting swaps with effective dates in 2018	500	500

Interest Rate Swap Contracts: From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in benchmark interest rates. Gains or losses resulting from changes in fair value of the underlying debt attributable to the hedged benchmark interest rate risk are recorded on the Consolidated Statement of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheet. 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 on the Consolidated Statement of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheet. Consequently, there is no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense on the Consolidated Statements of Income. If a hedging relationship is terminated for an interest rate swap contract, accumulated gains or losses associated with the contract are measured and recorded as a reduction or increase of current and future interest expense associated with the previously hedged debt obligations.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The following table summarizes the notional amounts of our outstanding interest rate swap contracts as of September 30, 2017 and December 31, 2016:

	Notional Amount	
	September 30, 2017	December 31, 2016
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
3.875% senior notes due 2025	$200	$ 200

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2017 and 2016 and also terminated the hedging relationship by settling certain of those swap contracts during 2017 and 2016. In 2017, we terminated the hedging relationship on certain outstanding swap contracts amounting to $200 million notional amount by settling such swap contracts. In July 2016, we terminated the hedging relationship on all of our then outstanding swap contracts, amounting to $3.6 billion notional amount, by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of $3 million and $196 million during the nine-month periods ended September 30, 2017 and 2016, respectively, which is accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 for additional details related to reductions of current and future interest expense.

The following tables summarize the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of September 30, 2017 and December 31, 2016:

		September 30, 2017	
	Consolidated Balance Sheet Classification	Fair Value	
Instrument		Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	$30	$ 20
	Accrued expenses and other current liabilities	20	51
	Other non-current liabilities	62	164
Interest rate swap agreements	Other current assets	27	—
	Other non-current liabilities	—	7
Derivatives not designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	20	5
	Accrued expenses and other current liabilities	2	5
Interest rate swap agreements	Other current assets	1	—
	Other non-current assets	2	1
Total		$164	$ 253

[1] Derivative instruments in this category are subject to master netting arrangements and are presented on a net basis in the Consolidated Balance Sheet in accordance with ASC 210-20.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Instrument	Consolidated Balance Sheet Classification	December 31, 2016 Fair Value Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	$317	$ 10
	Other non-current assets	178	71
Interest rate swap agreements	Other current assets	1	—
	Other non-current assets	38	7
	Other non-current liabilities	—	2
Derivatives not designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	57	4
	Accrued expenses and other current liabilities	—	2
Interest rate swap agreements	Other current assets	2	2
	Other non-current assets	3	2
Total		$596	$ 100

[1] Derivative instruments in this category are subject to master netting arrangements and are presented on a net basis in the Consolidated Balance Sheet in accordance with ASC 210-20.

As of September 30, 2017 and December 31, 2016, the following amounts were recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges:

Consolidated Balance Sheet Classification in Which the Hedged Item Is Included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
	September 30, 2017[1]	December 31, 2016[1]	September 30, 2017[2]	December 31, 2016[2]
Current portion of long-term debt, net of discount	$401	$ 501	$2	$ 1
Long-term debt, net of discount	$6,287	$ 6,703	$141	$ 163

[1] The current portion of long-term debt, net of discount includes $401 million and $501 million of carrying value with discontinued hedging relationships at September 30, 2017 and December 31, 2016, respectively. The long-term debt, net of discount includes approximately $3.8 billion and $4.2 billion of carrying value with discontinued hedging relationships at September 30, 2017 and December 31, 2016, respectively.

[2] The current portion of long-term debt, net of discount includes $2 million and $1 million of hedging adjustments on discontinued hedging relationships at September 30, 2017 and December 31, 2016, respectively. The long-term debt, net of discount includes $147 million and $172 million of hedging adjustment on discontinued hedging relationships on long-term debt at September 30, 2017 and December 31, 2016, respectively.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The following tables summarize the effect of derivative instruments designated as cash flow hedging instruments in Accumulated OCI for the three-month periods ended September 30, 2017 and 2016:

	Three-Month Period Ended September 30, 2017				
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Classification of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Classification of Gain/(Loss) Recognized in Income Related to Amount Excluded from Effectiveness Testing	Amount of Gain/(Loss) Recognized in Income Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts	$(130)	Net product sales	$ 7	Net product sales	$ 5
				Other (expense), net	(8)
Treasury rate lock agreements	—	Interest (expense)	(1)	N/A	—
Interest rate swap agreements	(1)	Interest (expense)	—	N/A	—

(1) Net losses of $55 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) For the three-month period ended September 30, 2017, the straight-line amortization of the initial value of the amount excluded from the assessment of hedge effectiveness for our foreign exchange contracts recognized in OCI was a loss of $5 million. There were no excluded components for our treasury rate lock and interest rate swap agreements.

	Three-Month Period Ended September 30, 2016				
	(Effective Portion)			(Ineffective Portion and Amount Excluded from Effectiveness Testing)	
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Classification of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Classification of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
Foreign exchange contracts	$(55)	Net product sales	$ 71	Other (expense), net	$ —
Treasury rate lock agreements	—	Interest (expense)	(2)	Other (expense), net	—
Interest rate swap agreements	2	Interest (expense)	—	Other (expense), net	—

The following tables summarize the effect of derivative instruments designated as cash flow hedging instruments on the Consolidated Statements of Income for the nine-month periods ended September 30, 2017 and 2016:

	Nine-Month Period Ended September 30, 2017				

Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative[1],[2]	Classification of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Classification of Gain/(Loss) Recognized in Income Related to Amount Excluded from Effectiveness Testing	Amount of Gain/(Loss) Recognized in Income Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts	$(379)	Net product sales	$ 174	Net product sales	$ 10
				Other (expense), net	—
Treasury rate lock agreements	—	Interest (expense)	(4)	N/A	—
Interest rate swap agreements	(18)	Interest (expense)	(1)	N/A	—

[1] Net losses of $55 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

[2] For the nine-month period ended September 30, 2017, the straight-line amortization of the initial value of the amount excluded from the assessment of hedge effectiveness for our foreign exchange contracts recognized in OCI was a loss of $28 million of which $18 million related

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

to the cumulative effect adjustment related to the adoption of ASU 2017-12. There were no excluded components for our treasury rate lock and interest rate swap agreements.

	Nine-Month Period Ended September 30, 2016					
	(Effective Portion)			(Ineffective Portion and Amount Excluded from Effectiveness Testing)		
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Classification of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Classification of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative	
Foreign exchange contracts	$(197)	Net product sales	$ 221	Other (expense), net	$ 23	(1)
Treasury rate lock agreements	—	Interest (expense)	(4)	Other (expense), net	—	
Interest rate swap agreements	(47)	Interest (expense)	(1)	Other (expense), net	—	

(1) The amount of net gains recognized in income represents $21 million of gains related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and $2 million of gains related to the ineffective portion of the hedging relationships.

The following table summarizes the effect of derivative instruments which were designated as fair value hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2017 and 2016:

		Amount of Gain Recognized in Income on Derivative			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Instrument	Classification of Gain Recognized in Income on Derivative	2017 (1)	2016 (1)	2017 (2)	2016 (2)
Interest rate swap agreements	Interest (expense)	$9	$ 10	$ 30	$ 36

(1) The amounts include a benefit of $9 million and $8 million relating to the amortization of the cumulative amount of fair value hedging adjustments included in the carrying amount of the hedged liability for discontinued hedging relationships for the three-month periods ending September 30, 2017 and September 30, 2016.

(2) The amounts include a benefit of $27 million and $11 million relating to the amortization of the cumulative amount of fair value hedging adjustments included in the carrying amount of the hedged liability for discontinued hedging relationships for the nine-month periods ending September 30, 2017 and September 30, 2016.

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2017 and 2016:

		Amount of (Loss) Gain Recognized in Income on Derivative			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Instrument	Classification of (Loss) Gain Recognized in Income on Derivative	2017	2016	2017	2016
Foreign exchange contracts	Other (expense), net	$(5)	$(12)	$(47)	$(39)
Put options on our common stock	Other (expense), net	—	—	—	8

The impact of gains and losses on foreign exchange contracts not designated as hedging instruments related to changes in the fair value of assets and liabilities denominated in foreign currencies are generally offset by net foreign exchange gains and losses, which are also included on the Consolidated Statements of Income in Other (expense), net for all periods presented. When we enter into foreign exchange contracts not designated as hedging instruments to mitigate the impact of exchange rate volatility in the translation of foreign earnings, gains and losses will generally be offset by fluctuations in the U.S. Dollar translated amounts of each Income Statement account in current and/or future periods.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Classification and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships					
	Three-Month Period Ended September 30, 2017			Nine-Month Period Ended September 30, 2017		
	Net product sales	Interest (expense)	Other (expense), net	Net product sales	Interest (expense)	Other (expense), net
Total amounts of income and expense line items presented in the Consolidated Statements of Income in which the effects of fair value or cash flow hedges are recorded	$3,283	$ (127)	$ —	$9,494	$ (380)	$ (18)
The effects of fair value and cash flow hedging:						
Gain (loss) on fair value hedging relationships						
Interest rate swap agreements:						
Hedged items	—	—	—	—	(2)	—
Derivatives designated as hedging instruments [1]	—	9	—	—	30	—
Gain (loss) on cash flow hedging relationships						
Foreign exchange contracts:						
Amount of gain or (loss) reclassified from AOCI into income	7	—	—	174	—	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	5	—	(8)	10	—	—
Treasury rate lock agreements:						
Amount of gain or (loss) reclassified from AOCI into income	—	(1)	—	—	(4)	—
Amount excluded from effectiveness testing recognized in earnings based on changes in fair value	—	—	—	—	—	—
Interest rate swap agreements:						
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	—	(1)	—
Amount excluded from effectiveness testing recognized in earnings based on changes in fair value	—	—	—	—	—	—

[1] The amounts include a benefit of $9 million and $27 million relating to the amortization of the cumulative amount of fair value hedging adjustments included in the carrying amount of the hedged liability for discontinued hedging relationships for the three- and nine-month periods ending September 30, 2017.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

8. Cash, Cash Equivalents and Marketable Securities Available-for-Sale

Time deposits, repurchase agreements, and commercial paper instruments with original maturities less than three months and money market funds are included in Cash and cash equivalents. As of September 30, 2017, the carrying value of our time deposits and repurchase agreements was $1.4 billion, commercial paper instruments was $142 million, and money market funds was $2.2 billion, all of which are included in Cash and cash equivalents. As of December 31, 2016, the carrying value of our time deposits and repurchase agreements was $2.8 billion, commercial paper instruments was $65 million, and money market funds was $1.6 billion, all of which were included in Cash and cash equivalents. The carrying values approximated fair value as of September 30, 2017 and December 31, 2016.

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security as of September 30, 2017 and December 31, 2016 were as follows:

September 30, 2017	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	$ 474	$ —	$ (1)	$ 473
U.S. government-sponsored agency securities	42	—	—	42
U.S. government-sponsored agency MBS	19	—	—	19
Corporate debt - global	2,317	1	(1)	2,317
Asset backed securities	201	—	—	201
Ultra short income fund	350	—	—	350
Time deposits[1] and Repurchase agreements[1]	959	—	—	959
Marketable equity securities	962	930	(5)	1,887
Total available-for-sale marketable securities	$ 5,324	$ 931	$ (7)	$ 6,248

December 31, 2016	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	$ 121	$ —	$ (1)	$ 120
U.S. government-sponsored agency MBS	31	—	—	31
Corporate debt - global	378	—	(1)	377
Asset backed securities	17	—	—	17
Time deposits[1]	364	—	—	364
Marketable equity securities	672	238	(19)	891
Total available-for-sale marketable securities	$ 1,583	$ 238	$ (21)	$ 1,800

[1] Have original maturities of greater than three months.

U.S. Treasury securities include government debt instruments issued by the U.S. Department of the Treasury. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. government sponsored enterprises. U.S. government-sponsored agency MBS include mortgage-backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Corporate debt-global includes obligations issued by investment-grade corporations, including some issues that have been guaranteed by governments and government agencies. Asset backed securities consist of triple-A rated securities with cash flows collateralized by credit card receivables and auto loans. Ultra short income fund includes investments in certificates of deposit, repurchase agreements, commercial paper and corporate notes. Time deposits and repurchase agreements in the tables above have

original maturities greater than three months. Our repurchase agreements are collateralized by U.S. government securities, cash, bonds, commercial paper and bank certificates of deposit. As of September 30, 2017, all of our time deposits and repurchase agreements had original maturities less than one year. Marketable equity securities consist of investments in publicly traded equity securities.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Duration periods of available-for-sale debt securities as of September 30, 2017 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	$ 1,988	$1,988
Duration of one through three years	1,382	1,381
Duration of three through five years	33	33
Total	$ 3,403	$3,402

9. Inventory

Inventories as of September 30, 2017 and December 31, 2016 are summarized by major category as follows:

	September 30, 2017	December 31, 2016
Raw materials	$ 266	$ 274
Work in process	113	87
Finished goods	158	137
Total	$ 537	$ 498

10. Intangible Assets and Goodwill

Intangible Assets: Our finite-lived intangible assets primarily consist of developed product rights and technology obtained from the Pharmion Corp. (Pharmion), Gloucester, Abraxis BioScience, Inc. (Abraxis), Avila and Quanticel acquisitions. Our indefinite lived intangible assets consist of acquired in-process research and development (IPR&D) product rights from the Receptos Inc. (Receptos), Nogra and Gloucester acquisitions. See Note 17 for additional details related to the GED-0301 (mongersen) trials impacting the Nogra IPR&D asset.

The gross carrying amount and accumulated amortization of intangible assets as of September 30, 2017 and December 31, 2016 are summarized as follows:

September 30, 2017	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	$3,406	$ (1,878)	$1,528
Technology	483	(391)	92
Licenses	66	(29)	37
Other	43	(34)	9
	3,998	(2,332)	1,666
Non-amortizable intangible assets:			
Acquired IPR&D product rights	8,471	—	8,471
Total intangible assets	$12,469	$ (2,332)	$10,137

December 31, 2016	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	$3,406	$ (1,694)	$1,712

Technology	483	(326)	157
Licenses	66	(26)	40
Other	43	(31)	12
	3,998	(2,077)	1,921
Non-amortizable intangible assets:			
Acquired IPR&D product rights	8,471	—	8,471
Total intangible assets	$ 12,469	$ (2,077)	$ 10,392

CELGENE CORPORATION AND SUBSIDIARIES
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Amortization expense related to intangible assets was $81 million and $89 million for the three-month periods ended September 30, 2017 and 2016, respectively, and $255 million and $359 million for the nine-month periods ended September 30, 2017 and 2016, respectively. The amortization expense decreases for the three-month and nine-month periods primarily related to the technology platform asset that was written-off in its entirety prior to the third quarter of 2017, which was obtained in the acquisition of Avila. Assuming no changes in the gross carrying amount of finite lived intangible assets, the future annual amortization expense related to intangible assets is expected to be approximately $336 million in 2017, $252 million in 2018, $156 million in 2019, $154 million in 2020 and $152 million in 2021.

Goodwill: As of September 30, 2017 and December 31, 2016, our goodwill related to the 2015 acquisitions of Receptos and Quanticel, 2014 acquisition of Nogra, 2012 acquisition of Avila, 2010 acquisitions of Abraxis and Gloucester, 2008 acquisition of Pharmion and 2004 acquisition of Penn T Limited.

11. Debt

Short-Term Borrowings and Current Portion of Long-Term Debt: We had no outstanding short-term borrowings as of September 30, 2017 or December 31, 2016. The carrying value of the current portion of long-term debt outstanding as of September 30, 2017 and December 31, 2016 includes:

	September 30, 2017	December 31, 2016
1.900% senior notes due 2017	$ —	$ 501
2.125% senior notes due 2018	999	—
2.300% senior notes due 2018	401	—
Total short-term debt	$ 1,400	$ 501

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after September 30, 2017 have an aggregate principal amount of $12.850 billion with varying maturity dates and interest rates. The carrying values of the long-term portion of these senior notes as of September 30, 2017 and December 31, 2016 includes:

	September 30, 2017	December 31, 2016
2.125% senior notes due 2018	$ —	$ 998
2.300% senior notes due 2018	—	402
2.250% senior notes due 2019	506	509
2.875% senior notes due 2020	1,494	1,493
3.950% senior notes due 2020	515	518
2.250% senior notes due 2021	497	—
3.250% senior notes due 2022	1,046	1,054
3.550% senior notes due 2022	994	994
4.000% senior notes due 2023	739	744
3.625% senior notes due 2024	1,001	1,001
3.875% senior notes due 2025	2,480	2,475
5.700% senior notes due 2040	247	247
5.250% senior notes due 2043	393	393
4.625% senior notes due 2044	987	987
5.000% senior notes due 2045	1,975	1,974
Total long-term debt	$ 12,874	$ 13,789

As of September 30, 2017 and December 31, 2016, the fair value of our outstanding Senior Notes was approximately $15.1 billion and $14.6 billion, respectively, and represented a Level 2 measurement within the fair value measurement hierarchy.

Debt Issuance: In August 2017, we issued an additional $500 million principal amount of 2.250% senior notes due 2021 (2021 Notes). The 2021 Notes were issued at 99.706% of par, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately $2 million have been recorded as a direct deduction from

the carrying amount of the 2021 Notes on our Consolidated Balance Sheets. The offering costs are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the 2021 Notes is payable semi-annually in arrears on February 15 and August 15 of each year, beginning on February 15, 2018 and the principal on the 2021 Notes is due in full at the maturity date. The 2021 Notes may be redeemed at our option, in whole or in part, at any time at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the 2021 Notes to be redeemed or the sum of the present values of the remaining schedule payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 15% basis points. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the 2021 Notes at a purchase price equal to 101% of the principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

Debt Repayments: In August 2017, we repaid the 1.900% senior notes with a principal amount of $500 million upon maturity.

From time to time, we have used treasury rate locks and forward starting interest rate swap contracts to hedge against changes in interest rates in anticipation of issuing fixed-rate notes. As of September 30, 2017, and December 31, 2016 a balance of $56 million and $61 million, respectively, in net losses remained in accumulated other comprehensive income related to the settlement of these derivative instruments and will be recognized as interest expense over the life of the notes.

As of September 30, 2017, we were party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes as described in Note 7. Our swap contracts outstanding as of September 30, 2017 effectively converted the hedged portion of our fixed-rate notes to floating rates. From time to time, we terminate the hedging relationship on certain of our swap contracts by settling the contracts or by entering into offsetting contracts. Any net proceeds received or paid in these settlements are accounted for as a reduction or increase of current and future interest expense associated with the previously hedged notes. As of September 30, 2017 and December 31, 2016, we had balances of $149 million and $173 million, respectively, of net unamortized gains recorded as a component of our debt as a result of past swap contract settlements. See Note 7 for additional details related to interest rate swap contract activity.

Commercial Paper: In April 2016, our Board of Directors authorized an increase in the maximum amount of commercial paper issuable to $2.0 billion. As of September 30, 2017 and December 31, 2016, we had available capacity to issue up to $2.0 billion of commercial paper, and there were no borrowings under the program.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of $2.0 billion. During the second quarter of 2017, we amended our Credit Facility to extend the expiration date to April 17, 2022. Amounts may be borrowed in U.S. Dollars for general corporate purposes. The Credit Facility currently serves as backup liquidity for our commercial paper borrowings. As of September 30, 2017 and December 31, 2016, there was no outstanding borrowings against the Credit Facility. The Credit Facility contains affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2017.

12. Share-Based Compensation

We have a stockholder-approved stock incentive plan, the Celgene Corporation 2017 Stock Incentive Plan (formerly the 2008 Stock Incentive Plan) (Plan) that provides for the granting of options, restricted stock units (RSUs), performance stock units (PSUs) and other share-based awards to our employees, officers and non-employee directors. The Management Compensation and Development Committee of the Board of Directors (Compensation Committee) may determine the type, amount and terms, including vesting, of any awards made under the Plan.

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The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2017 and 2016:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Cost of goods sold (excluding amortization of acquired intangible assets)	$ 7	$ 8	$ 22	$ 25
Research and development	65	63	200	189
Selling, general and administrative	87	77	260	238
Total share-based compensation expense	159	148	482	452
Tax benefit related to share-based compensation expense	49	41	136	125
Reduction in income	$ 110	$ 107	$ 346	$ 327

The tax benefit related to share-based compensation expense above excludes excess tax benefits of $103 million and $273 million from share-based compensation awards that vested or were exercised during the three- and nine-month periods ended September 30, 2017, respectively. See Note 2 for additional information related to the adoption of ASU 2016-09.

The following table summarizes the activity for stock options, RSUs and PSUs for the nine-month period ended September 30, 2017 (in millions unless otherwise noted):

	Stock Options	RSUs	PSUs (in thousands)
Outstanding as of December 31, 2016	73.8	7.1	463
Changes during the Year:			
Granted	8.7	1.6	169
Exercised / Released	(14.6)	(1.6)	(35)
Forfeited	(1.4)	(0.4)	(34)
Outstanding as of September 30, 2017	66.5	6.7	563

Total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized as of September 30, 2017 were as follows (dollars in millions):

	Stock Options	RSUs	PSUs
Unrecognized compensation cost	$ 564	$ 341	$ 30
Expected weighted-average period in years of compensation cost to be recognized	2.1	1.5	1.5

13. Income Taxes

We adopted ASU 2016-09, effective January 1, 2017. See Note 2 for additional information related to the adoption of this accounting standard update.

We regularly evaluate the likelihood of the realization of our deferred tax assets and reduce the carrying amount of those deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of our deferred tax assets, including recent cumulative

earnings experience by taxing jurisdiction, expectations of future taxable income, the carryforward periods available to us for tax reporting purposes and other relevant factors. Significant judgment is required in making this assessment.

Our tax returns are under routine examination in many taxing jurisdictions. The scope of these examinations includes, but is not limited to, the review of our taxable presence in a jurisdiction, our deduction of certain items, our claims for research and development credits, our compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from our tax returns as filed. Our U.S. federal income tax returns have been audited by the Internal Revenue Service (IRS) through the year ended December 31, 2008. Tax returns for the years ended December 31, 2009, 2010 and 2011 are currently under examination by the IRS. We are also subject to audits by various state and foreign taxing authorities, including most U.S. states and countries where we have operations.

CELGENE CORPORATION AND SUBSIDIARIES
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We regularly reevaluate our tax positions and the associated interest and penalties, if applicable, resulting from audits of federal, state and foreign income tax filings, as well as changes in tax law (including regulations, administrative pronouncements, judicial precedents, etc.) that would reduce the technical merits of the position to below more likely than not. We believe that our accruals for tax liabilities are adequate for all open years. Many factors are considered in making these evaluations, including past history, recent interpretations of tax law and the specifics of each matter. Because tax regulations are subject to interpretation and tax litigation is inherently uncertain, these evaluations can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. We apply a variety of methodologies in making these estimates and assumptions, which include studies performed by independent economists, advice from industry and subject matter experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as our industry experience. These evaluations are based on estimates and assumptions that have been deemed reasonable by management. However, if management's estimates are not representative of actual outcomes, our results of operations could be materially impacted.

Unrecognized tax benefits, generally represented by liabilities on the Consolidated Balance Sheets and all subject to tax examinations, arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. These unrecognized tax benefits relate primarily to issues common among multinational corporations. Virtually all of these unrecognized tax benefits, if recognized, would impact the effective income tax rate. We account for interest and potential penalties related to uncertain tax positions as part of our provision for income taxes. For the nine-month period ended September 30, 2017 gross unrecognized tax benefits increased by $149 million, primarily from an increase in unrecognized tax benefits related to current year operations of $62 million, an increase in unrecognized tax benefits related to prior year tax positions of $69 million and accrued interest of $18 million. The liability for unrecognized tax benefits is expected to increase in the next 12 months relating to operations occurring in that period. Any settlements of examinations with taxing authorities or statute of limitations expirations would likely result in a decrease in our liability for unrecognized tax benefits and a corresponding increase in taxes paid or payable and/or a decrease in income tax expense. It is reasonably possible that the amount of the liability for unrecognized tax benefits could change by a significant amount during the next twelve-month period as a result of settlements or statute of limitations expirations. Finalizing examinations with the relevant taxing authorities can include formal administrative and legal proceedings and, as a result, it is difficult to estimate the timing and range of possible change related to the Company's unrecognized tax benefits. An estimate of the range of possible change cannot be made until issues are further developed or examinations close. Our estimates of tax benefits and potential tax benefits may not be representative of actual outcomes and variation from such estimates could materially affect our consolidated financial statements in the period of settlement or when the statutes of limitations expire.

During the third quarter of 2017, we completed an updated analysis of our current and prior year estimates of our U.S. research and development and orphan drug tax credits. The analysis resulted in additional net income tax benefits of approximately $65 million including $55 million related to prior year estimated tax credits, which were recorded on our Consolidated Statements of Income within Income tax provision during the three- and nine-month periods ended September 30, 2017. The change in estimate related to prior years was recognized as a discrete tax benefit in the third quarter of 2017 and the change in estimate related to the current year was recognized as a component of our estimated annual effective tax rate. The effect of the change in estimate increased net income by approximately $65 million for both the three- and nine-month periods ended September 30, 2017. On a per share basis, this increased the Company's basic and diluted income per share by $0.08 for both the three- and nine-month periods ended September 30, 2017.

14. Collaboration Arrangements

We enter into collaborative arrangements for the research and development, license, manufacture and/or commercialization of products and/or product candidates. In addition, we also acquire products, product candidates and research and development technology rights and establish research and development collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our research and development capabilities, product pipeline and marketed product base. These arrangements may include non-refundable, upfront payments, payments by us for options to acquire rights to products and product candidates and other rights, as well as contingent obligations by us for potential development, regulatory and commercial performance milestone payments, cost sharing arrangements, royalty payments, profit sharing and equity investments (including equity investments in the event of an initial public offering of equity by our partners). The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success. Although we do not consider any individual alliance to be material, certain of the more notable alliances are described in Note 17 of Notes to Consolidated Financial Statements included in our 2016 Annual Report on Form 10-K. The following is a brief description of significant developments in the relationships between Celgene and our collaboration partners during the nine months ended September 30, 2017:

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

BeiGene: On July 5, 2017, we entered into a strategic collaboration to develop and commercialize BeiGene's investigational anti-programmed cell death protein-1 (PD-1) inhibitor, BGB-A317, for patients with solid tumor cancers in the United States, Europe, Japan and the rest of the world outside of Asia. BeiGene will retain exclusive rights for the development and commercialization of BGB-A317 for hematological malignancies globally and for solid tumors in Asia (with the exception of Japan). BeiGene acquired our commercial operations in China and gained an exclusive license to commercialize our approved therapies in China - ABRAXANE®, REVLIMID® and VIDAZA®. See Note 3 for additional details related to the divestiture of Celgene China. In addition, BeiGene was granted licensing rights in China to CC-122, under the same terms and conditions as our approved commercial products. CC-122 is a next generation CelMOD® agent currently in development by us for relapsed / refractory multiple myeloma, lymphoma and hepatocellular carcinoma. This transaction closed on August 31, 2017.

BeiGene will receive upfront licensing fees totaling $263 million of which we paid $92 million as of September 30, 2017 with the remaining amount due in the fourth quarter of 2017. In addition, we acquired 32.7 million of BeiGene's ordinary shares for $150 million. As of September 30, 2017, our total investment in BeiGene represents approximately 5.5% of BeiGene's outstanding ordinary shares. We recorded a $268 million upfront research and development expense in our Consolidated Statement of Income during the three-month period ended September 30, 2017 for the license consideration transferred and the unfavorable supply arrangement entered into in conjunction with the sale of Celgene China. In addition, the sale of Celgene China resulted in an immaterial loss on disposal, which was recorded on our Consolidated Statement of Income in Other (expense), net during the three-month period ended September 30, 2017. BeiGene is eligible to receive up to $980 million in development, regulatory and sales milestone payments as well as royalties on future sales of BGB-A317.

The license arrangement will expire in its entirety on the later of (a) expiration of the last valid claim that covers the composition of matter or method of use of the last licensed product, (b) expiration of regulatory exclusivity for the last licensed product or (c) twelve years after the first commercial sale of the last licensed product. The license agreement may be terminated by us, at our sole discretion, or by either party, among other things upon material breach by the other party. The supply arrangement has an initial term of ten years, which can be extended upon the mutual agreement of both parties.

FORMA Therapeutics Holdings LLC (FORMA): On March 21, 2014, we entered into a second collaboration arrangement with FORMA (March 2014 Collaboration), pursuant to which FORMA granted us an option to license the rights to select current and future FORMA drug candidates during a term of three and one-half years. In addition, with respect to each licensed drug candidate, we have the obligation to pay designated amounts when certain development, regulatory and sales milestone events occur, with such amounts being variable and contingent on various factors. With respect to each licensed drug candidate, we will assume responsibility for all global development activities and costs after completion of Phase 1 clinical trials. FORMA will retain U.S. rights to all such licensed assets, including responsibility for manufacturing and commercialization. Under this collaboration arrangement, we also have an option to enter into up to two additional collaborations.

During July 2017, we agreed to pay an upfront payment of $195 million for the first of the two additional collaborations, which was paid during the three-month period ended September 30, 2017. FORMA granted us an option to license the worldwide rights (except the U.S.) to select current and future drug candidates for the next two years and three months (or through October 1, 2019). In addition, with respect to each licensed drug candidate, we have the same rights and obligations as under the March 2014 Collaboration.

If we exercise our option to enter into an additional collaboration pursuant to the March 2014 Collaboration, we will receive an exclusive option to acquire FORMA, including the U.S. rights to all licensed drug candidates, and

worldwide rights to other wholly-owned assets within FORMA at that time.

Potential Future Milestone Payments: For the nine-month period ended September 30, 2017, we entered into arrangements that include the potential for future milestone payments of $408 million related to the attainment of specified development and regulatory milestones over a period of several years. Our obligation to fund these efforts is contingent upon our continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs.

CELGENE CORPORATION AND SUBSIDIARIES
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A financial summary of certain period activity and the period-end balances related to our collaboration arrangements is presented below[1],[2],[3]:

		Three-Month Periods Ended September 30, Research and Development Expense				
		Upfront Fees	Milestones	Extension/Termination of Arrangements	Amortization of Prepaid Research and Development	Equity Investments Made During Period
BeiGene	2017	$268	$ —	$ —	$ —	$ 174
	2016	—	—	—	—	—
Forma	2017	195	—	—	—	—
	2016	42	—	—	—	—
Jounce	2017	—	—	—	—	—
	2016	238	—	—	—	24
Juno	2017	—	—	—	—	31
	2016	—	—	—	—	—
Other Collaboration Arrangements	2017	121	10	13	4	28
	2016	44	—	9	12	15

		Nine-Month Periods Ended September 30, Research and Development Expense				
		Upfront Fees	Milestones	Extension/Termination of Arrangements	Amortization of Prepaid Research and Development	Equity Investments Made During Period
Agios	2017	$8	$ —	$ —	$ —	$ 31
	2016	200	25	—	1	—
BeiGene	2017	268	—	—	—	174
	2016	—	—	—	—	—
Forma	2017	224	—	—	—	—
	2016	71	—	—	—	—
Jounce	2017	—	—	—	—	10
	2016	238	—	—	—	24
Juno[3]	2017	—	—	—	—	33
	2016	50	—	—	—	41
Other Collaboration Arrangements	2017	169	10	20	11	64

2016	12950	9	21	52

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CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Balances as of:	Intangible Asset Balance	Equity Investment Balance	Percentage of Outstanding Equity	
Agios	September 30, 2017	$ —	$ 392	12.1	%
	December 31, 2016	—	219	12.4	%
BeiGene	September 30, 2017	—	261	5.5	%
	December 31, 2016	—	—	N/A	
Jounce	September 30, 2017	—	54	10.7	%
	December 31, 2016	—	24	11.4	%
Juno	September 30, 2017	—	498	9.7	%
	December 31, 2016	—	194	9.7	%
Other Collaboration Arrangements	September 30, 2017	14	615	N/A	
	December 31, 2016	22	416	N/A	

(1) Activity and balances are presented specifically for notable new collaborations and for those collaborations which we have described in detail in our 2016 Annual Report on Form 10-K if there has been significant activity during the periods presented. Amounts related to collaborations that are not specifically presented are included in the aggregate as Other Collaboration Arrangements.

(2) In addition to the expenses noted in the tables above, we may also incur expenses for collaboration agreement related activities that are managed or funded by us.

(3) Our equity investment in Juno made in the first quarter of 2016 was transacted at a price per share that exceeded the market value of Juno's publicly traded common stock on the transaction closing date, resulting in an expense for the premium of $6 million that was recorded in the Consolidated Statement of Income as Other (expense), net in the first quarter of 2016.

15. Commitments and Contingencies

Collaboration Arrangements and Acquired Research and Development Assets: We have entered into certain research and development collaboration arrangements with third parties that include our funding of certain development, manufacturing and commercialization efforts and the potential for making future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. In addition, we have also made certain acquisitions that included potential future development, regulatory and commercial milestones. Our obligation to fund these efforts and make milestone payments is contingent upon our continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded for the potential future achievement of these targets in our accompanying Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016. See Note 3 for additional details related to our acquisitions, Note 14 for additional details related to collaboration arrangements, and Note 17 for additional details related to the GED-0301 (mongersen) trials.

Contingencies: We believe we maintain insurance coverage adequate for our current needs. Our operations are subject to environmental laws and regulations which, among other things, impose limitations on the discharge of pollutants into the air and water and establish standards for the treatment, storage and disposal of solid and hazardous wastes.

We review the effects of such laws and regulations on our operations and modify our operations as appropriate. We believe we are in substantial compliance with all applicable environmental laws and regulations.

We have ongoing customs, duties and value-added-tax examinations in various countries that have yet to be settled. Based on our knowledge of the claims and facts and circumstances to date, none of these matters, individually or in the aggregate, are deemed to be material to our financial condition.

CELGENE CORPORATION AND SUBSIDIARIES
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16. Legal Proceedings

Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and others and we have been subject to claims and other actions related to our business activities. While the ultimate outcome of investigations, inquiries, information requests and legal proceedings is difficult to predict, adverse resolutions or settlements of those matters may result in, among other things, modification of our business practices, product recalls, costs and significant payments, which may have a material adverse effect on our results of operations, cash flows or financial condition.

Pending patent proceedings include challenges to the scope, validity and/or enforceability of our patents relating to certain of our products, uses of products or processes. Further, as certain of our products mature or they near the end of their regulatory exclusivity periods, it is more likely that we will receive challenges to our patents, and in some jurisdictions we have received such challenges. We are also subject, from time to time, to claims of third parties that we infringe their patents covering products or processes. Although we believe we have substantial defenses to these challenges and claims, there can be no assurance as to the outcome of these matters and an adverse decision in these proceedings could result in one or more of the following: (i) a loss of patent protection, which could lead to a significant reduction of sales that could materially affect our future results of operations, cash flows or financial condition (ii) our inability to continue to engage in certain activities, and (iii) significant liabilities, including payment of damages, royalties and/or license fees to any such third party.

Among the principal matters pending are the following:

Patent-Related Proceedings:

REVLIMID®: In 2012, our European patent EP 1 667 682 (the ’682 patent) relating to certain polymorphic forms of lenalidomide expiring in 2024 was opposed in a proceeding before the European Patent Office (EPO) by Generics (UK) Ltd. and Teva Pharmaceutical Industries Ltd. On July 21, 2015, the EPO determined that the ’682 patent was not valid. Celgene appealed the EPO ruling to the EPO Board of Appeal, thereby staying any revocation of the patent until the appeal is finally adjudicated. No appeal hearing date has been set. We do not anticipate a decision from the EPO Board of Appeal for several years and intend to vigorously defend our intellectual property rights.

In 2010, Celgene’s European patent EP 1 505 973 (the ’973 patent) relating to certain uses of lenalidomide expiring in 2023 was opposed in a proceeding before the EPO by Synthon B.V. and an anonymous party. On February 25, 2013, the EPO determined that the ’973 patent was not valid. Celgene appealed the EPO ruling to the EPO Board of Appeal, thereby staying any revocation of the patent until the appeal is finally adjudicated. A hearing date has been set for January 2018.

We believe that our patent portfolio for lenalidomide in Europe, including the composition of matter patent which expires in 2022, is strong and defensible. Although we believe that we will prevail in the EPO proceedings, in the event these patents are found not to be valid, we still expect that we will have protection in the EU for lenalidomide under other patents through at least 2022.

We received a letter dated June 26, 2017 from Accord Healthcare Ltd. (Accord) notifying us of Accord’s filing of three individual lawsuits against us in the United Kingdom seeking to commence patent revocation proceedings originally for three British patents (which was amended later to include a recently-granted, related divisional patent for a total of four challenged British patents). The patents named in the lawsuit, which was filed in the High Court of Justice in London, are EP (UK) 0925294 (the ‘294 patent), EP (UK) 1505973 (the '973 patent); EP (UK) 2915533 (the '533

patent) and EP (UK) 1667682 (the '682 patent), all claiming aspects of REVLIMID®. The Court has set separate trial dates for each patent. The’294 patent trial will begin between October 1-5, 2018; the ‘973 and ‘533 (combined) patents trial will begin on October 29, 2018; and the ‘682 patent trial will begin on November 26, 2018. These proceedings are limited to the patents granted in Great Britain. We intend to vigorously defend our intellectual property rights in these matters.

We received a Notice of Allegation dated June 13, 2017 from Dr. Reddy’s Laboratories Ltd. (DRL) notifying us of the filing of DRL’s Abbreviated New Drug Submission (ANDS) with Canada’s Minister of Health, with respect to Canadian Letters Patent Nos. 2,261,762; 2,476,983; 2,477,301; 2,537,092; 2,687,924; 2,687,927; 2,688,694; 2,688,695; 2,688,708; 2,688,709; 2,741,412; and 2,741,575. DRL is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25mg REVLIMID® (lenalidomide) capsules in Canada.

We commenced a court proceeding in the Federal Court of Canada (T-1143-17) on July 27, 2017, seeking an Order prohibiting the Minister of Health from granting marketing approval to DRL until expiry of these patents. A hearing has been scheduled for

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May 6-10, 2019. We received a further Notice of Allegation dated September 20, 2017 from DRL relating to the same submission, but also referencing 2.5 mg capsules. DRL's Notice of Allegation contains invalidity allegations relating to Canadian Letters Patent Nos. 2,537,092; 2,687,924; 2,687,927; 2,688,694; 2,688,695; 2,688,708; 2,688,709; 2,741,412; and 2,741,575. We will be commencing a court proceeding by November 3, 2017, seeking an order prohibiting the Minister of Health from granting marketing approval to DRL until expiry of these patents.

We received a Notice Letter dated September 9, 2016 from DRL notifying us of DRL's Abbreviated New Drug Application (ANDA) which contains Paragraph IV certifications against U.S. Patent Nos. 7,456,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; and 9,101,622 that are listed in the FDA list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book (Orange Book) for REVLIMID®. DRL is seeking to manufacture and market a generic version of 2.5mg, 5mg, 10mg, 15mg, 20mg, and 25mg REVLIMID® (lenalidomide) capsules in the United States.

In response to the Notice Letter, we timely filed an infringement action against DRL in the United States District Court for the District of New Jersey on October 20, 2016. As a result of the filing of our action, the FDA cannot grant final approval of DRL's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) March 9, 2019. On November 18, 2016, DRL filed an answer and counterclaims asserting that the patents-in-suit are invalid and/or not infringed. On December 27, 2016, we filed a reply to DRL's counterclaims. Fact discovery is set to close on May 31, 2018. The Court has not yet entered a schedule for expert discovery or trial. We subsequently received an additional Notice Letter from DRL dated June 8, 2017 notifying us of additional Paragraph IV certifications against U.S. Patent Nos. 7,189,740; 8,404,717; and 9,056,120 that are listed in the Orange Book for REVLIMID®. In response to the Notice Letter, we timely filed an infringement action against DRL in the United States District Court for the District of New Jersey on July 20, 2017. As a result of the filing of our action, the FDA cannot grant final approval of DRL's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) December 8, 2019. On October 3, 2017, DRL filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed. Our reply to DRL's counterclaims are due on November 7, 2017. The Court has yet to enter a schedule for fact discovery, expert discovery or trial.

We received a Notice Letter dated February 27, 2017 from Zydus Pharmaceuticals (USA) Inc. (Zydus) notifying us of Zydus' ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 7,456,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; and 9,101,622 that are listed in the Orange Book for REVLIMID®. Zydus is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25mg REVLIMID® (lenalidomide) capsules in the United States.

In response to the Notice Letter, we timely filed an infringement action against Zydus in the United States District Court for the District of New Jersey on April 12, 2017. As a result of the filing of our action, the FDA cannot grant final approval of Zydus' ANDA at least until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) August 27, 2019. On August 7, 2017, Zydus filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed. On September 11, 2017, we filed a reply to Zydus's counterclaims. Fact discovery is set to close on February 1, 2019. The Court has yet to enter a schedule for expert discovery and trial.

We received a Notice Letter dated June 30, 2017 from Cipla LTD, India (Cipla) notifying us of Cipla's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 7,456,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; and 9,101,622 that are listed in the Orange Book for REVLIMID®. Cipla is seeking to manufacture and market a generic version of 5 mg, 10 mg, 15 mg, 20 mg, and 25mg REVLIMID® (lenalidomide) capsules in the

United States.

In response to the Notice Letter, on August 15, 2017, we timely filed an infringement action against Cipla in the United States District Court for the District of New Jersey. As a result of the filing of our action, the FDA cannot grant final approval of Cipla's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) January 3, 2020. On October 13, 2017, DRL filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed. Our reply to Cipla's counterclaims is due on November 17, 2017. A scheduling conference is currently set for November 28, 2017. The Court has yet to enter a schedule for fact discovery, expert discovery and trial.

We received a Notice Letter dated July 24, 2017 from Lotus Pharmaceutical Co., Inc. (Lotus) notifying us of Lotus's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 5,635,517; 6,315,720; 6,561,977; 6,755,784; 7,189,740; 7,456,800; 7,855,217; 7,968,569; 8,315,886; 8,404,717; 8,530,498; 8,626,531; 8,648,095; 9,056,120; 9,101,621; and 9,101,622 that are listed in the Orange Book for REVLIMID®. Lotus is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25mg REVLIMID® (lenalidomide) capsules in the United States.

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In response to the Notice Letter, we timely filed an infringement action against Lotus in the United States District Court for the District of New Jersey on September 6, 2017. As a result of the filing of our action, the FDA cannot grant final approval of Lotus's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) January 25, 2020. On October 5, 2017, Lotus filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed. Our reply to Lotus's counterclaims is due on November 9, 2017. A scheduling conference is currently set for November 16, 2017. The Court has yet to enter a schedule for fact discovery, expert discovery and trial.

POMALYST®: In 2015, our European patent EP 2 105 135 (the '135 patent) relating to certain pharmaceutical compositions for treating cancer expiring in 2023 was opposed in a proceeding before the EPO by Generics (UK) Ltd., Accord Healthcare Ltd., Hexal AG, IPS Intellectual Property Services, Synthon B.V., and Actavis Group PTC EHF. On December 19, 2016, the EPO determined that the '135 patent was not valid. Regulatory exclusivity for POMALYST® will expire in Europe in 2023.

We received a Notice Letter dated March 30, 2017 from Teva Pharmaceuticals USA, Inc. (Teva) notifying us of Teva's ANDA submitted to the FDA that contains Paragraph IV certifications against U.S. Patent Nos. 6,316,471; 8,198,262; 8,673,939; 8,735,428; and 8,828,427 that are listed in the Orange Book. Teva is seeking to manufacture and market a generic version of 1 mg, 2 mg, 3 mg, and 4 mg POMALYST® (pomalidomide) capsules in the United States. We later received similar Notice Letters (the Pomalidomide Notice Letters) from six other generic drug manufacturers - Par Pharmaceutical, Inc. (Par); Apotex, Inc. (Apotex); Hetero USA, Inc. (Hetero); Aurobindo Pharma Ltd. (Aurobindo); Mylan Pharmaceuticals Inc. (Mylan); and Breckenridge Pharmaceutical, Inc. (Breckenridge) - relating to these and other POMALYST® patents listed in the Orange Book.

In response to the Pomalidomide Notice Letters, we timely filed an infringement actions in the United States District Court for the District of New Jersey against Teva and Par on May 4, 2017 and against Apotex, Hetero, Aurobindo, Mylan, and Breckenridge on May 11, 2017. As a result of the filing of our actions, the FDA cannot grant final approval of these ANDAs at least until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) August 8, 2020. On July 13, 2017, Apotex and Hetero each filed answers and counterclaims asserting that the patents-in-suit are invalid and/or not infringed, and further seeking declaratory judgments of noninfringement and invalidity for additional Celgene patents listed in the Orange Book, namely U.S. Patent Nos. 6,315,720, 6,561,977, 6,755,784, 8,315,886, and 8,626,531.

On July 24, 2017, Par filed an answer, but did not file any counterclaims. On October 17, 2017, we jointly filed a Stipulation with Par requesting dismissal and stating that Par had converted its Paragraph IV certifications to Paragraph III certifications. On July 31, 2017, Breckenridge filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed. On August 7, 2017, Teva filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed.

On August 17, 2017, we filed replies to Apotex's and Hetero's counterclaims, as well as counter-counterclaims against Hetero and Apotex asserting infringement of U.S. Patent Nos. 6,315,720, 6,561,977, 6,755,784, 8,315,886, and 8,626,531. On September 5, 2017, we filed a reply to Breckenridge's counterclaims. On September 6, 2017, Apotex filed a reply to our counter-counterclaims. On September 8, Hetero filed a reply to our counter-counterclaims. On September 11, 2017, we filed a reply to Teva's counterclaims. On September 15, 2017, Aurobindo filed an answer and counterclaims asserting that each of the patents are invalid and/or not infringed, and further seeking declaratory judgments of noninfringement and invalidity for additional Celgene patents listed in the Orange Book, namely U.S. Patent Nos. 6,315,720, 6,561,977, 6,755,784, 8,315,886, and 8,626,531. We filed our reply to Aurobindo's counterclaims on October 20, 2017. The Court has not yet entered schedules in any of these cases.

On August 9, 2017, Mylan filed a motion to dismiss the complaint. Celgene opposed Mylan's motion on September 29, 2017. Mylan filed its reply in support of its motion on October 24, 2017. The Court has not yet set a hearing date for this motion.

OTEZLA® (Apremilast): In February 2015, Polypharma S.A., Teva Pharmaceuticals, Ltd., Zentiva k.s. and LEK Pharmaceutical d.d. opposed Celgene's European patent EP 2 276 483 (the '483 patent), which is directed to certain crystalline forms of apremilast. An oral hearing was held on March 21, 2017 at the EPO, whereby the Opposition Division determined that the '483 patent was not valid. Celgene plans to appeal the EPO ruling to the EPO Board of Appeal, which will have the effect of staying any revocation of the patent until the appeal is finally adjudicated. Upon the filing of an appeal, we would not anticipate a decision from the EPO Board of Appeal for several years. This patent will expire on March 27, 2028 and has been granted an SPC which extends the patent term to January 16, 2030. The regulatory exclusivity will expire on January 15, 2025.

THALOMID® (thalidomide): We received a Notice Letter dated December 18, 2014 from Lannett Holdings, Inc. (Lannett) notifying us of Lannett's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 5,629,327; 6,045,501; 6,315,720; 6,561,976; 6,561,977; 6,755,784; 6,869,399; 6,908,432; 7,141,018; 7,230,012; 7,435,745; 7,874,984; 7,959,566; 8,204,763;

8,315,886; 8,589,188; and 8,626,531 that are listed in the Orange Book for THALOMID® (thalidomide). Lannett is seeking to market a generic version of 50mg, 100mg, 150mg, and 200mg of THALOMID® capsules.

On January 30, 2015, we filed an infringement action against Lannett in the United States District Court for the District of New Jersey. On October 24, 2017, we entered into an agreement with Lannett to settle all outstanding claims in the litigation. We have agreed to provide Lannett with a license to our patents required to manufacture and sell an unlimited quantity of generic thalidomide in the United States beginning on August 1, 2019. Lannett's ability to market thalidomide in the U.S. will be contingent on obtaining approval of its ANDA.

ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin bound): We received a Notice Letter dated February 23, 2016 from Actavis LLC (Actavis) notifying us of Actavis's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 7,820,788; 7,923,536; 8,138,229; and 8,853,260 that are listed in the Orange Book for ABRAXANE®. We then received a Notice Letter dated October 25, 2016 from Cipla notifying us of Cipla's ANDA, which contains Paragraph IV certifications against the same four patents for ABRAXANE®. Actavis and Cipla are seeking to manufacture and market a generic version of ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) 100 mg/vial.

On April 6, 2016, we filed an infringement action against Actavis in the United States District Court for the District of New Jersey. As a result of the filing of our action, the FDA cannot grant final approval of Actavis's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) August 24, 2018. On May 3, 2016, Actavis filed an answer and counterclaims asserting that the patents-in-suit are invalid and/or not infringed and we filed a reply to Actavis's counterclaims on June 10, 2016. Fact discovery is set to close on November 13, 2017, and expert discovery is set to close April 10, 2018. The Court has not yet set a date for a trial.

On December 8, 2016, we filed an infringement action against Cipla in the United States District Court for the District of New Jersey. As a result of the filing of our action, the FDA cannot grant final approval of Cipla's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) April 25, 2019. On January 20, 2017, Cipla filed an answer and counterclaims asserting that the patents-in-suit are invalid and/or not infringed. Our reply was filed on February 24, 2017. Fact discovery is currently set to close on April 26, 2018 and expert discovery is currently set to close on November 1, 2018. The Court has not yet set a date for trial.

On January 13, 2017, the UK High Court of Justice handed down a ruling after a hearing held on December 20, 2016 in which Celgene argued that the UK Intellectual Property Office improperly rejected our request for an SPC to the ABRAXANE® patent UK No. 0 961 612 (the '612 patent). In that ruling, the High Court referred the matter to the Court of Justice for the EU (CJEU). No hearing date has been set at the CJEU. If the CJEU were to find in Celgene's favor, the SPC would not only be granted in the UK, but in other jurisdictions that have previously rejected our initial request including Germany, Sweden and Ireland. The '612 patent expired in Europe in September 2017. However, if the SPC is granted, the patent will be reinstated and then set to expire in 2022. Data exclusivity in Europe will expire in January 2019.

Proceedings involving the United States Patent and Trademark Office (USPTO):

Under the America Invents Act (AIA), any person may seek to challenge an issued patent by petitioning the USPTO to institute a post grant review. On April 23, 2015, we were informed that the Coalition for Affordable Drugs VI LLC filed petitions for Inter Partes Review (IPRs) challenging the validity of Celgene's patents U.S. 6,045,501 (the '501 patent) and U.S. 6,315,720 (the '720 patent) covering certain aspects of our REMS program. On October 27, 2015, the USPTO Patent Trial and Appeal Board (PTAB) instituted IPR proceedings relating to these patents. An oral hearing

was held on July 21, 2016; the decisions, rendered on October 26, 2016, held that the ’501 and ’720 patents are invalid, primarily due to obviousness in view of certain publications. On November 25, 2016, we requested a rehearing with respect to these patents. On September 8, 2017, the PTAB denied our rehearing request for the ’501 patent, but granted our rehearing request pertaining to a certain claim of the ’720 patent.

An appeal of the final written decisions of the PTAB can be made to the United States Court of Appeals for the Federal Circuit until November 13, 2017. The ’501 and ’720 patents remain valid and enforceable pending appeal. We retain other patents covering certain aspects of our REMS program, as well as other patents that cover our products that use our REMS system.

On April 4, 2017, Actavis LLC filed petitions for IPRs challenging the validity of our patents U.S. 8,138,229 (the '229 patent); 7,923,536 (the '536 patent); 7,820,788 (the '788 patent); and 8,853,260 (the '260 patent) covering certain aspects of our ABRAXANE® product. We filed our preliminary response on July 12, 2017.

On October 10, 2017, the PTAB instituted IPR proceedings on the ’788, ’536, and ’229 patents, and the trial on those patents is scheduled for July 11, 2018. The ’788, ’536, and ’229 patents remain valid and enforceable pending the conclusion of the IPR, including any rehearing requests or appeals. On October 11, 2017, the PTAB denied institution of an IPR on the ’260 patent, which remains valid and enforceable.

Other Proceedings:

In 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission (FTC) seeking documents and other information relating to requests by manufacturers of generic drugs to purchase our patented REVLIMID® and THALOMID® brand drugs in order for the FTC to evaluate whether there may be reason to believe that we have engaged in unfair methods of competition. In 2010, the State of Connecticut issued a subpoena referring to the same issues raised by the 2009 CID. Also in 2010, we received a second CID from the FTC relating to this matter. We continue to cooperate with the FTC and State of Connecticut investigations.

On April 3, 2014, Mylan filed a lawsuit against us in the United States District Court for the District of New Jersey alleging that we violated various federal and state antitrust and unfair competition laws by allegedly refusing to sell samples of our THALOMID® and REVLIMID® brand drugs so that Mylan can conduct the bioequivalence testing necessary for ANDAs to be submitted to the FDA for approval to market generic versions of these products. Mylan is seeking injunctive relief, damages and declaratory judgment. We filed a motion to dismiss Mylan’s complaint on May 25, 2014. Mylan filed its opposition to our motion to dismiss on June 16, 2014. The Federal Trade Commission filed an amicus curiae brief in opposition to our motion to dismiss on June 17, 2014. On December 22, 2014, the court granted Celgene’s motion to dismiss (i) Mylan’s claims based on Section 1 of the Sherman Act (without prejudice), and (ii) Mylan's related claims arising under the New Jersey Antitrust Act. The court denied our motion to dismiss the remaining claims which primarily relate to Section 2 of the Sherman Act. On January 6, 2015, we filed a motion to certify for interlocutory appeal the order denying our motion to dismiss with respect to the claims relating to Section 2 of the Sherman Act, which appeal was denied by the United State Court of Appeals for the Third Circuit on March 5, 2015. On January 20, 2015, we filed an answer to Mylan’s complaint. Fact discovery closed in June 2016 and expert discovery closed in November 2016. On December 16, 2016, we moved for summary judgment, seeking a ruling that judgment be granted in our favor on all claims. The motion for summary judgment has been fully briefed by the parties and will be argued on November 30, 2017. No trial date has been set. We intend to vigorously defend against Mylan’s claims.

In 2011, the United States Attorney’s Office for the Central District of California informed us that they were investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In 2012, we learned that two other United States Attorneys’ offices (the Northern District of Alabama and the Eastern District of Texas) and various state Attorneys General were conducting related investigations. In February 2014, three civil qui tam actions related to those investigations brought by three former Celgene employees on behalf of the federal and various state governments under the federal false claims act and similar state laws were unsealed after the United States Department of Justice (DOJ) declined to intervene in any of these actions. However, the DOJ retained the right to intervene in these actions at any time.

Additionally, while several states similarly declined to intervene in some of these actions, they also retained the right to intervene in the future. The plaintiffs in the Northern District of Alabama and Eastern District of Texas actions voluntarily dismissed their cases. On April 25, 2014, we filed a motion to dismiss the complaint in the remaining (Central District of California) action, United States of America ex. rel. Beverly Brown v. Celgene Corp., unsealed February 5, 2014 (the Brown Action), which was denied except with respect to certain state claims. We filed our answer to the complaint on August 28, 2014. Fact discovery closed on September 25, 2015. Expert discovery closed

on June 30, 2016.

The Relator (the person who brought the lawsuit on behalf of the government) submitted an expert report that, based on certain theories, purported to calculate damages and penalties. On July 25, 2016, we filed a motion to strike the Relator’s expert report. The Magistrate Judge granted our motion, striking substantial portions of the report on August 23, 2016, significantly reducing the expert’s calculation of damages and penalties. Relator appealed this decision to the District Court Judge.

On August 29, 2016, the parties filed a Joint Stipulation on Defendant Celgene's Motion for Summary Judgment or, In the Alternative, Partial Summary Judgment. On December 28, 2016, the court entered an order granting in part and denying in part Celgene’s motion for summary judgment. Specifically, the court dismissed Relator’s anti-kickback claims and all claims related to prescriptions submitted to TRICARE, the Veterans Administration and the Tennessee, Texas and Wisconsin Medicaid programs. The court denied Celgene’s motion as to all other issues and upheld the District Court’s decision to strike substantial portions of Relator’s expert report. On January 30, 2017, we filed a Motion for Reconsideration of The Order Partially Denying Summary

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Judgment Or For Certification For Immediate Appeal And Stay. This motion sought to dispose of the remainder of the Relator's claims. Relator filed her Opposition to our motion on February 6, 2017.

A confidential mediation under Federal Rule of Civil Procedure Rule 408 was held on February 25, 2017. Relator and Celgene participated in the mediation and discussions continued after that date. On March 6, 2017, the Judge ordered that the trial begin on April 25, 2017. Relator and Celgene jointly sought, and obtained, a 90-day continuance of the trial date until July 25, 2017. On June 26, 2017, the court held a status conference, in which it directed the parties to submit any proposed settlement agreement to which Relator, Celgene, and the DOJ had agreed to the court by July 13, 2017 with a motion to approve the settlement. The court stated that it would rule on any motion to approve the settlement on July 25, 2017. As a result, we accrued $315 million related to this matter as a probable and reasonably estimable loss contingency during the second quarter of 2017.

On July 13, 2017, the parties submitted a proposed settlement and motion to approve the settlement to the court. On July 25, 2017, the court accepted the settlement. Under the terms of the settlement, we paid a total of $315 million (including fees and expenses) to resolve the matter with the United States, 28 States, the District of Columbia, the City of Chicago and the Relator. The settlement includes no admission of any wrongdoing by us, and we are not required to enter into a Corporate Integrity Agreement as part of the settlement.

On June 7, 2013, Children's Medical Center Corporation (CMCC) filed a lawsuit against us in the Superior Court of the Commonwealth of Massachusetts alleging that our obligation to pay a 1% royalty on REVLIMID® net sales revenue and a 2.5% royalty on POMALYST®/IMNOVID® net sales under a license agreement entered into in December 2002 extended beyond February 28, 2013 and that our failure to make royalty payments to CMCC subsequent to February 28, 2013 breached the license agreement.

On July 8, 2014, CR Rev Holdings, LLC (CR Rev) filed a complaint against Celgene in the same action. CR Rev alleged that CMCC sold and assigned to CR Rev a substantial portion of the royalty payments owed by Celgene on the sale of REVLIMID®. CR Rev has alleged causes of action with respect to REVLIMID® identical to those alleged by CMCC, and sought unspecified damages and a declaration that the license agreement is still in effect.

On February 2, 2017, we entered into a Settlement Agreement with CMCC and CR Rev resolving the litigation, providing CMCC with a payment of approximately $199 million (see Notes 9 and 18 to Notes to Consolidated Financial Statements included in our 2016 Annual Report on Form 10-K) and providing us with an exclusive, worldwide, royalty free license to certain patent rights. The Settlement Agreement also provides for potential contingent royalty and other payments, which have not been accrued for as we do not believe such payments are probable.

On November 7, 2014, the International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund (IUB) filed a putative class action lawsuit against us in the United States District Court for the District of New Jersey alleging that we violated various antitrust, consumer protection, and unfair competition laws by (a) allegedly securing an exclusive supply contract with Seratec S.A.R.L. so that Barr Laboratories allegedly could not secure its own supply of thalidomide active pharmaceutical ingredient; (b) allegedly refusing to sell samples of our THALOMID® and REVLIMID® brand drugs to various generic manufacturers for the alleged purpose of bioequivalence testing necessary for ANDAs to be submitted to the FDA for approval to market generic versions of these products; and (c) allegedly bringing unjustified patent infringement lawsuits in order to allegedly delay approval for proposed generic versions of THALOMID® and REVLIMID®. IUB, on behalf of itself and a putative class of third party payers, is seeking injunctive relief and damages.

In February 2015, we filed a motion to dismiss IUB's complaint, and upon the filing of a similar putative class action making similar allegations by the City of Providence (Providence), the parties agreed that the decision in the motion to dismiss IUB's complaint would apply to the identical claims in Providence's complaint. In October 2015, the court denied our motion to dismiss on all grounds.

We filed our answers to the IUB and Providence complaints in January 2016. On June 14, 2017, a new complaint was filed by the same counsel representing the plaintiffs in the IUB case, making similar allegations and adding three new plaintiffs - International Union of Operating Engineers Stationary Engineers Local 39 Health and Welfare Trust Fund (Local 39), The Detectives' Endowment Association, Inc. (DEA) and David Mitchell. Counsel identified the new complaint as related to the IUB and Providence cases and, on August 1, 2017, filed a Consolidated Amended complaint on behalf of IUB, Providence, Local 39, DEA, and Mitchell. On September 28, 2017, the same counsel filed another complaint, which it identified as related to the consolidated case, and which made similar allegations on behalf of an additional asserted class representative: New England Carpenters Health Benefits

Fund. The completion of fact discovery and expert discovery in these cases is scheduled for April 2, 2018 and September 13, 2018, respectively. No trial date has been set. We intend to vigorously defend against these claims.

In December 2015, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts, and in November 2016, we received a second subpoena related to the same inquiry. The materials requested primarily relate to patient assistance programs, including our support of 501(c)(3) organizations that provide financial assistance to eligible patients. We are cooperating with these requests.

In August 2017, we received an order issued by the Federal Court in Ottawa, Ontario, Canada at the request of the Canadian Competition Bureau, requiring that we provide certain materials and information relating to our risk management program and requests by generic manufacturers to purchase our products in Canada. We are cooperating with this request.

17. Subsequent Events

In October 2017, we announced that the GED-0301 (mongersen) phase III REVOLVE (CD-002) trial in Crohn's disease (CD) and the SUSTAIN (CD-004) extension trial (Trials) will discontinue. Celgene decided to stop the Trials following an October recommendation of the Data Monitoring Committee, which assessed overall benefit/risk during a recent interim futility analysis. There were no meaningful safety imbalances identified in the interim futility analysis. In addition, at this time, the phase III DEFINE (CD-003) trial in CD will not be initiated. We are waiting to review the full dataset from the phase II trial with GED-0301 in ulcerative colitis (UC) to determine next steps.

As a result of the decision to discontinue the Trials, we will recognize a fourth-quarter 2017 charge to earnings related to the significant impairment of the GED-0301 IPR&D asset of approximately $1.6 billion, as well as wind-down costs associated with discontinuing the Trials and certain development activities, partially offset by a benefit related to the significant reduction in the GED-0301 contingent consideration liabilities of approximately $1.4 billion.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words "expects," "anticipates," "believes," "intends," "estimates," "aims," "plans," "
"could," "will," "will continue," "seeks," "should," "predicts," "potential," "outlook," "guidance," "target," "forecast," "probab
the negative of such terms and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions and projections, which are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws. We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements and therefore you should not place too much reliance on them. These factors include, among others, those described in the sections "Forward-Looking Statements" and "Risk Factors" contained in our 2016 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in this report and our other public reports filed with the SEC. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

Executive Summary

Celgene Corporation, together with its subsidiaries (collectively "we," "our," "us," "Celgene" or the "Company"), is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. Celgene Corporation was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®), THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.) and IDHIFA®. IDHIFA® was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) or (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved diagnostic test. We began recognizing revenue related to IDHIFA® during the third quarter of 2017. In addition, we earn revenue from other product sales and licensing arrangements.

We continue to invest substantially in research and development in support of multiple ongoing proprietary clinical development programs which support our existing products and pipeline of new drug candidates. Our clinical trial activity includes trials across the disease areas of hematology, solid tumors, and inflammation and immunology. REVLIMID® is in several phase III trials covering a range of hematological malignancies that include multiple myeloma, lymphomas and myelodysplastic syndromes (MDS). In solid tumors, ABRAXANE® is currently in various stages of investigation for pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA® is being evaluated in a phase III trial for Behçet's disease, and is continuing to be studied in ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. We also have a growing number of potential products in phase III trials across multiple diseases. In the inflammation and immunology therapeutic area, we have phase III trials underway for

ozanimod in relapsing multiple sclerosis (RMS) and ulcerative colitis (UC). In hematology, phase III trials are underway for CC-486 and luspatercept in MDS, for CC-486 in AML and for luspatercept in beta-thalassemia.

Beyond our phase III programs, we have access to a growing early-to-mid-stage pipeline of novel potential therapies to address significant unmet medical needs that consists of new drug candidates and cell therapies developed in-house, licensed from other companies or able to be optioned from collaboration partners. We believe that continued use of our primary commercial stage products, participation in research and development collaboration arrangements, depth of our product pipeline, potential regulatory approvals of new products and new indications for existing products will provide the catalysts for future growth.

Recent Developments

A comprehensive list of the diseases that our primary commercial stage products are approved to treat for the major markets of the United States, the European Union and Japan is provided in Part I, Item 1. Business in our 2016 Annual Report on Form 10-K filed with the SEC. The following tables present significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended September 30, 2017, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

Regulatory agency actions:

Product	Disease Indication	Major Market	Regulatory Agency	Action
IDHIFA® (Enasidenib)	AML	U.S.	FDA	Approval

Phase III Trials:

Product Candidate	Trial	Disease Indication	Action
GED-0301[(1)]	REVOLVE (CD-002)	Crohn's disease	Discontinued
GED-0301[(1)]	SUSTAIN (CD-004)	Crohn's disease	Discontinued

[(1)] In October 2017, we announced that the GED-0301 (mongersen) phase III REVOLVE (CD-002) trial in Crohn's disease (CD) and the SUSTAIN (CD-004) extension trial (Trials) will discontinue. We decided to stop the Trials following an October recommendation of the Data Monitoring Committee, which assessed overall benefit/risk during a recent interim futility analysis. There were no meaningful safety imbalances identified in the interim futility analysis. In addition, at this time, the phase III DEFINE (CD-003) trial in CD will not be initiated. We are waiting to review the full dataset from the phase II trial with GED-0301 in UC to determine next steps.

As a result of the decision to discontinue the Trials, we concluded on October 18, 2017 that we will recognize a fourth-quarter 2017 charge to earnings related to the significant impairment of the approximately $1.6 billion GED-0301 In-Process Research and Development (IPR&D) asset, as well as wind-down costs associated with discontinuing the Trials and certain development activities, partially offset by a benefit related to the significant reduction in the approximately $1.4 billion of GED-0301 contingent consideration liabilities. The exact amount of the net pre-tax charge to earnings has not yet been determined, but is estimated to be in the range of $300 million to $500 million, or $0.27 to $0.45 per diluted share, after tax.

Recent Transactions

BeiGene, Ltd. (BeiGene): On July 5, 2017, we entered into a strategic collaboration to develop and commercialize BeiGene's investigational anti-programmed cell death protein-1 (PD-1) inhibitor, BGB-A317, for patients with solid tumor cancers in the United States, Europe, Japan and the rest of the world outside of Asia. BeiGene will retain exclusive rights for the development and commercialization of BGB-A317 for hematological malignancies globally and for solid tumors in Asia (with the exception of Japan). BeiGene acquired our commercial operations in China (Celgene China) and gained an exclusive license to commercialize our approved therapies in China - ABRAXANE®, REVLIMID® and VIDAZA®. See Note 3 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to the divestiture of Celgene China. In addition, BeiGene was granted licensing rights in China to CC-122, under the same terms and conditions as our approved commercial products. CC-122 is a next generation CelMOD® agent currently in development by us for RRMM, lymphoma and hepatocellular carcinoma. This transaction closed on August 31, 2017.

BeiGene will receive upfront licensing fees totaling $263 million of which we paid $92 million as of September 30, 2017 with the remaining amount due in the fourth quarter of 2017. In addition, we acquired 32.7 million of BeiGene's ordinary shares for $150 million. As of September 30, 2017, our total investment in BeiGene represents approximately

5.5% of BeiGene's outstanding ordinary shares. We recorded a $268 million upfront research and development expense in our Consolidated Statement of Income during the three-month period ended September 30, 2017 for the license consideration transferred and the unfavorable supply arrangement entered into in conjunction with the sale of Celgene China. In addition, the sale of Celgene China resulted in an immaterial loss on disposal, which was recorded on our Consolidated Statement of Income in Other (expense), net during the three-month period ended September 30, 2017. BeiGene is eligible to receive up to $980 million in development, regulatory and sales milestone payments as well as royalties on future sales of BGB-A317.

FORMA Therapeutics Holdings LLC (FORMA): On March 21, 2014, we entered into a second collaboration arrangement with FORMA (March 2014 Collaboration), pursuant to which FORMA granted us an option to license the rights to select current and future FORMA drug candidates during a term of three and one-half years. In addition, with respect to each licensed drug candidate, we have the obligation to pay designated amounts when certain development, regulatory and sales milestone events occur, with such amounts being variable and contingent on various factors. With respect to each licensed drug candidate, we will assume responsibility for all global development activities and costs after completion of Phase 1 clinical trials. FORMA will retain U.S. rights to all such licensed assets, including responsibility for manufacturing and commercialization. Under this collaboration arrangement, we also have an option to enter into up to 2 additional collaborations.

During July 2017, we agreed to pay an upfront payment of $195 million for the first of the 2 additional collaborations, which was paid during the three-month period ended September 30, 2017. FORMA granted us an option to license the worldwide rights (except the U.S.) to select current and future drug candidates for the next two years and three months (or through October 1, 2019). In addition, with respect to each licensed drug candidate, we have the same rights and obligations as under the March 2014 Collaboration.

If we exercise our option to enter into an additional collaboration pursuant to the March 2014 Collaboration, we will receive an exclusive option to acquire FORMA, including the U.S. rights to all licensed drug candidates, and worldwide rights to other wholly-owned assets within FORMA at that time.

Financial Update

The following table summarizes net product sales, total revenue and earnings for the three-month periods ended September 30, 2017 and 2016 (dollar amounts in millions, except per share amounts):

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Net product sales	$3,283	$2,969	$ 314	10.6 %
Total revenue	3,287	2,983	304	10.2 %
Net income	988	171	817	477.8 %
Diluted earnings per share	$1.21	$0.21	$ 1.00	476.2 %

Total net product sales for the three-month period ended September 30, 2017 increased by $314 million, or 10.6%, to approximately $3.3 billion compared to the three-month period ended September 30, 2016. The increase was comprised of net volume increases of $325 million, or 11.0%, and net price increases of $18 million, or 0.6%. The increase in volume was primarily driven by increased unit sales of REVLIMID®, POMALYST®/IMNOVID®, ABRAXANE® and OTEZLA®. The price impact was primarily attributable to price increases in the U.S., which were partially offset by price decreases in Europe. Changes in foreign currency exchange rates including the impact of foreign exchange hedging activity unfavorably impacted net product sales by $29 million, or 1.0%.

Total revenue increased by $304 million, or 10.2%, to approximately $3.3 billion for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, reflecting increases of $273 million, or 15.0%, in the United States and $31 million, or 2.7%, in international markets.

In addition to the increase in total revenue discussed above, notable items impacting net income and diluted earnings per share for the three-month periods ended September 30, 2017 and 2016 are as follows (dollar amounts in millions):

	Income Statement Classification	Three-Month Periods	Increase (Decrease)

		Ended September 30,		
		2017	2016	
Collaboration arrangements (see Note 14*)	Research and development	$611	$345	$ 266
Research and development asset acquisition expense (see Note 3*)	Research and development	—	623	(623)
Research & development and orphan drug tax credit study (See Note 13*)	Income tax provision (benefit)	(65)	—	(65)

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

The following table summarizes net product sales, total revenue and earnings for the nine-month periods ended September 30, 2017 and 2016 (dollar amounts in millions, except per share amounts):

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Net product sales	$9,494	$8,208	$ 1,286	15.7 %
Total revenue	9,520	8,249	1,271	15.4 %
Net income	3,021	1,570	1,451	92.4 %
Diluted earnings per share	$3.72	$1.95	$ 1.77	90.8 %

Total net product sales for the nine-month period ended September 30, 2017 increased by $1.3 billion, or 15.7%, to approximately $9.5 billion compared to the nine-month period ended September 30, 2016. The increase was comprised of net volume increases of $1.1 billion, or 13.7%, and net price increases of $219 million, or 2.7%. The increase in volume was primarily driven by increased unit sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA®. The price impact was primarily attributable to price increases in the U.S., which were partially offset by price decreases in Europe. Changes in foreign currency exchange rates including the impact of foreign exchange hedging activity unfavorably impacted net product sales by $57 million, or 0.7%.

Total revenue increased by $1.3 billion, or 15.4%, to approximately $9.5 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, reflecting increases of $947 million, or 18.5%, in the United States and $324 million, or 10.3%, in international markets.

In addition to the increase in total revenue discussed above, notable items impacting net income and diluted earnings per share for the nine-month periods ended September 30, 2017 and 2016 are as follows (dollar amounts in millions):

	Income Statement Classification	Nine-Month Periods Ended September 30,		Increase (Decrease)
		2017	2016	
Collaboration arrangements (see Note 14*)	Research and development	$710	$794	$ (84)
Research and development asset acquisition expenses (see Note 3*)	Research and development	325	623	(298)
Litigation-related loss contingency accrual expense (see Note 16*)	Selling, general and administrative	315	130	185
Amortization of acquired intangible assets (see Note 10*)	Amortization of acquired intangible assets	250	354	(104)
Research & development and orphan drug tax credit study (See Note 13*)	Income tax provision (benefit)	(65)	—	(65)
Gain on sale of LifebankUSA business (See Note 3*)	Other (expense), net	—	38	(38)

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

Three-Month Periods Ended September 30, 2017 and 2016

Net Product Sales and Other Revenues

Net product sales and other revenue for the three-month periods ended September 30, 2017 and 2016 were as follows (dollar amounts in millions):

REVLIMID®

	Three-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2017	2016		
U.S.	$1,361	$1,154	$ 207	17.9 %
International	720	738	(18)	(2.4)%
Worldwide	$2,081	$1,892	$ 189	10.0 %

REVLIMID® net sales increased by $189 million, or 10.0%, to $2.1 billion for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, primarily due to increased sales in the U.S. market. In the U.S., sales growth increased primarily due to price increases, and to a lesser extent an increase in unit sales primarily from treatment duration of patients using REVLIMID® in multiple myeloma. In addition, unit sales increased across all international regions, primarily in Europe and Japan, driven by increased duration of use and market share gains. International volume growth was more than offset by net price decreases and the unfavorable impact of a smaller Russian tender received in the third quarter of 2017 as compared to the third quarter of 2016.

POMALYST®/IMNOVID®

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
U.S.	$ 268	$ 203	$ 65	32.0 %
International	149	138	11	8.0 %
Worldwide	$ 417	$ 341	$ 76	22.3 %

POMALYST®/IMNOVID® net sales increased by $76 million, or 22.3%, to $417 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, primarily due to increased unit sales in the U.S. and international markets, as well as price increases in the U.S. Unit sales increased across all international regions, primarily in Europe. Increases in market share and treatment duration contributed to the increase in U.S. and international net sales. International volume growth was partially offset by net price decreases.

OTEZLA®

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
U.S.	$ 250	$ 244	$ 6	2.5 %
International	58	31	27	87.1 %
Worldwide	$ 308	$ 275	$ 33	12.0 %

OTEZLA® net sales increased by $33 million, or 12.0%, to $308 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. The increase was primarily due to increased unit sales across all regions, most notably in Europe, and the launch of OTEZLA® in Japan. We anticipate a slowing in market growth, offset by continued market share expansion in the U.S. due to new managed care contracts, as well as increasing contributions from early launch countries in Europe, the launch in Japan, and launches subsequent to additional international approvals. Net price in the U.S. was unfavorably impacted by the higher gross-to-net impact from managed care contracts effective in 2017 and we expect this trend to continue.

ABRAXANE®

	Three-Month Periods Ended	Increase	Percent Change

	September 30, 2017	2016			
U.S.	$ 149	$ 144	$ 5	3.5	%
International	102	89	13	14.6	%
Worldwide	$ 251	$ 233	$ 18	7.7	%

ABRAXANE® net sales increased by $18 million, or 7.7%, to $251 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. The sales growth was primarily driven by international markets, which included increases in unit sales that were partially offset by decreases in price.

OTHER PRODUCT SALES

	Three-Month Periods Ended September 30,		(Decrease)	Percent Change
	2017	2016		
U.S.	$60	$61	$ (1)	(1.6)%
International	166	167	(1)	(0.6)%
Worldwide	$226	$228	$ (2)	(0.9)%

All other product sales, which include IDHIFA®, VIDAZA®, azacitidine for injection, which is an authorized generic version of VIDAZA® (generic azacitidine for injection), THALOMID®, and ISTODAX®, decreased by $2 million primarily due to decreases in generic azacitidine for injection, THALOMID® and VIDAZA®, which were partially offset by net sales from the launch of IDHIFA®.

Other Revenue: Other revenue decreased by $10 million to $4 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. This decrease is primarily due to a reduction in royalty revenue from Novartis AG (Novartis) based upon its sales of both RITALIN® and FOCALIN XR®, both of which have been negatively impacted by generic competition in certain markets. We expect this trend to continue through the remainder of 2017.

Gross to Net Sales Accruals: We record gross to net sales accruals for government rebates, chargebacks and distributor service fees, sales discounts, and sales returns and allowances. For a discussion of our gross to net sales accruals, see Critical Accounting Estimates and Significant Accounting Policies in our 2016 Annual Report on Form 10-K.

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2017 and 2016 were as follows (in millions):

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total
Balance as of June 30, 2017	$ 493	$ 213	$ 18	$ 13	$737
Allowances for sales during prior periods	(3)	(3)	—	—	(6)
Allowances for sales during 2017	201	268	49	4	522
Credits/deductions issued for sales during prior periods	(132)	(2)	—	(2)	(136)
Credits/deductions issued for sales during 2017	(110)	(254)	(48)	(1)	(413)
Balance as of September 30, 2017	$ 449	$ 222	$ 19	$ 14	$704
Balance as of June 30, 2016	$ 327	$ 166	$ 15	$ 14	$522
Allowances for sales during prior periods	3	(7)	—	(1)	(5)
Allowances for sales during 2016	164	191	40	3	398
Credits/deductions issued for sales during prior periods	(67)	—	—	(2)	(69)
Credits/deductions issued for sales during 2016	(84)	(184)	(40)	(1)	(309)
Balance as of September 30, 2016	$ 343	$ 166	$ 15	$ 13	$537

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2017 and 2016 are as follows:

Government rebate provisions increased by $31 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, which was primarily due to a $36 million increase in international government rebates, partially offset by a $5 million decrease in the U.S. market. The increase in international government rebates was primarily driven by higher sales volumes and increased rebate rates. The decrease in the U.S. market was primarily due to a $22 million decrease in expense related to Medicare Part D Coverage Gap, primarily due to prior period claims received in the third quarter of 2016. Additionally, lower than expected claims received in the third quarter of 2017. This decrease was partially offset by a $17 million increase in Medicaid rebates (primarily in the managed care channel) due to higher sales volumes and increased rebate rates.

Chargebacks and distributor service fees provisions increased by $81 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. Chargebacks increased by approximately $30 million and distributor service fees increased by approximately $51 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates. The distributor service fee increase was primarily attributable to increased sales volumes and new managed care contracts effective January 1, 2017 for OTEZLA®, which accounted for $39 million of the increase, and a $5 million increase in commercial copayment program expense which also was attributable to higher sales volumes.

Discount provisions increased by $9 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, primarily due to higher sales volumes. The increase primarily related to an increase of $5 million related to REVLIMID® and increases related to OTEZLA® and POMALYST®.

Provisions for sales returns and allowances increased by $2 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016.

Operating Costs and Expenses

Operating costs, expenses and related percentages for the three-month periods ended September 30, 2017 and 2016 were as follows (dollar amounts in millions):

Cost of Goods Sold (excluding amortization of acquired intangible assets)

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Cost of goods sold (excluding amortization of acquired intangible assets)	$118	$108	$ 10	9.3 %
Percent of Net product sales	3.6 %	3.6 %		

Cost of goods sold (excluding amortization of acquired intangible assets) increased by $10 million to $118 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) was flat for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016.

Research and Development

	Three-Month Periods Ended September 30,		(Decrease)	Percent Change
	2017	2016		
Research and development	$1,347	$1,653	$ (306)	(18.5)%
Percent of Total revenue	41.0 %	55.4 %		

Research and development expenses decreased by $306 million to $1.3 billion for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. The decrease was due to $623 million of research and development asset acquisition expense incurred in the prior year, partially offset by an increase of $266 million in expenses related to collaboration arrangements. See Note 3 and Note 14 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our asset acquisitions and our collaboration arrangements, respectively. Our research and development expenses may fluctuate from period-to-period based on the volume and timing of closing asset acquisitions and collaboration arrangements and associated obligations pursuant to such arrangements.

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The following table provides a breakdown of research and development expenses (in millions):

	Three-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2017	2016		
Human pharmaceutical clinical programs	$323	$289	$ 34	11.8 %
Other pharmaceutical programs	194	201	(7)	(3.5)%
Drug discovery and development	219	195	24	12.3 %
Collaboration arrangements	611	345	266	77.1 %
Research and development asset acquisition expenses (See Note 3*)	—	623	(623)	(100.0)%
Total	$1,347	$1,653	$ (306)	(18.5)%

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

Selling, General and Administrative

	Three-Month Periods Ended September 30,		(Decrease)	Percent Change
	2017	2016		
Selling, general and administrative	$608	$698	$ (90)	(12.9)%
Percent of Total revenue	18.5 %	23.4 %		

Selling, general and administrative expenses decreased by $90 million to $608 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016. The decrease was primarily due to a $77 million decrease in expenses for donations to independent non-profit patient assistance organizations in the U.S. and a $30 million decrease in litigation-related loss contingency accrual expense.

Amortization of Acquired Intangible Assets

	Three-Month Periods Ended September 30,		(Decrease)	Percent Change
	2017	2016		
Amortization of acquired intangible assets	$ 80	$ 87	$ (7)	(8.0)%

Amortization of intangible assets acquired as a result of business combinations is summarized below for the three-month periods ended September 30, 2017 and 2016 (in millions):

	Three-Month Periods Ended September 30,		(Decrease)
Acquisitions	2017	2016	
Abraxis	$ 37	$ 38	$ (1)
Avila	—	7	(7)
Gloucester	23	23	—
Pharmion	1	1	—
Quanticel	19	18	1
Total amortization	$ 80	$ 87	$ (7)

The decrease in amortization expense was primarily related to the complete write down of the technology platform asset that was obtained in the acquisition of Avila. The write down was completed prior to the third quarter of 2017.

Acquisition Related Charges and Restructuring, net

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Acquisition related charges and restructuring, net	$ 49	$ 25	$ 24	96.0 %

Acquisition related charges and restructuring, net for the three-month period ended September 30, 2017 increased by $24 million to $49 million compared to the three-month period ended September 30, 2016. Acquisition related charges primarily relate to the fair value adjustments of our contingent consideration obligations. The increase was due to a $31 million increase in expense related to increases in the fair value of our liability related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis. This increase was partially offset by a decrease in expense related to changes in the fair value of our contingent liabilities associated with the acquisition of Quanticel. See Note 6 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our contingent consideration liabilities.

Other Income and Expenses

Interest and Investment Income, net: Interest and investment income, net increased by $26 million to $33 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016 primarily due to higher investment balances and higher yields compared to the prior year.

Interest (Expense): Interest (expense) decreased by $1 million to $127 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016.

Other (Expense), net: Other (expense), net and fluctuations in the components of Other (expense), net is summarized below for the three-month periods ended September 30, 2017 and 2016 (in millions):

	Three-Month Periods Ended September 30,		Increase (Decrease)
	2017	2016	
Foreign exchange gains (loss), including foreign exchange derivative instruments not designated as hedging instruments (See Note 7*)	$13	$(1)	$14
Fair value adjustments of forward point amounts (See Notes 1, 2 & 7*)	(8)	—	(8)
Investment impairment charges	(1)	(46)	45
Other	(4)	12	(16)
Total Other (expense), net	$—	$(35)	$35

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

Income Tax Provision: The income tax provision decreased by $82 million to $3 million for the three-month period ended September 30, 2017 compared to the three-month period ended September 30, 2016, primarily as a result of a decrease in the effective tax rate, partially offset by an increase in income before taxes. The effective tax rate for the three-month period ended September 30, 2017 was 0.3%, a reduction of 32.9 percentage points from our effective tax rate of 33.2% for the three-month period ended September 30, 2016. The reduction in our effective tax rate was primarily due to excess tax benefits from employee stock compensation deductions, for which our third quarter 2017 effective tax rate was reduced by 10.4 percentage points (see Note 2 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report), U.S. research and development and orphan drug tax credits, for which our third quarter effective tax rate was reduced by 5.7 percentage points, and the absence from our estimated annual effective tax rate in 2017 of nondeductible research and development expenses recorded in 2016 from our acquisition of EngMab, partially offset by non-deductible research and development expenses recorded in 2017 for the Delinia asset acquisition and certain expenses recorded in 2017 for the Brown Action for which no tax benefit is available (See Notes 3 and 16, respectively, of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report). The tax benefits recognized in the quarter for U.S. research and development and orphan drug tax

credits were the result of a change in estimate upon completion of a comprehensive analysis (See Note 13 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report).

Our effective tax rate is a function of the distribution of our pre-tax income among the many jurisdictions in which we operate. Our pre-tax income is earned and taxed in either the U.S. at a statutory tax rate of 35%, or outside the U.S. at significantly lower statutory tax rates. Our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the timing and amount of tax benefits from employee stock compensation, payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements, and many other factors which are difficult to forecast.

Nine-Month Periods Ended September 30, 2017 and 2016

Net Product Sales and Other Revenues

Net product sales and other revenues for the nine-month periods ended September 30, 2017 and 2016 were as follows (dollar amounts in millions):

REVLIMID®

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
U.S.	$3,953	$3,230	$ 723	22.4 %
International	2,046	1,936	110	5.7 %
Worldwide	$5,999	$5,166	$ 833	16.1 %

REVLIMID® net sales increased by $833 million, or 16.1%, to approximately $6.0 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily due to increased sales in the U.S. market. In the U.S., sales growth increased due to both price increases and an increase in unit sales from market penetration and treatment duration of patients using REVLIMID® in multiple myeloma. In addition, unit sales increased across all international regions, primarily in Europe and Japan, driven by increased duration of use and market share gains. International volume growth was partially offset by net price decreases.

POMALYST®/IMNOVID®

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
U.S.	$725	$559	$ 166	29.7 %
International	447	374	73	19.5 %
Worldwide	$1,172	$933	$ 239	25.6 %

POMALYST®/IMNOVID® net sales increased by $239 million, or 25.6%, to $1.2 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily due to increased sales in the U.S. and to a lesser extent international markets. In the U.S., sales growth increased primarily due to an increase in unit sales, and to a lesser extent price increases. In addition, unit sales increased across all international regions, primarily in Europe. Increases in market share and treatment duration contributed to the increases in U.S. and international net sales. International volume growth was partially offset by net price decreases.

OTEZLA®

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
U.S.	$755	$636	$ 119	18.7 %

International	153	76	77	101.3 %
Worldwide	$908	$712	$ 196	27.5 %

OTEZLA® net sales increased by $196 million, or 27.5%, to $908 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily due to increased worldwide unit sales. Net sales in the United States were volume driven reflecting increased market share and expanding patient access as fiscal year 2016 was the second full year on the market in the U.S. We anticipate a slowing in market growth, offset by continued market share expansion in the U.S. due to new managed care contracts, as well as increasing contributions from early launch countries in Europe, the launch in Japan, and launches subsequent to additional international approvals. Net price in the U.S. was unfavorably impacted by the higher gross-to-net impact from managed care contracts effective in 2017 and we expect this trend to continue.

ABRAXANE®

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2017	2016		
U.S.	$452	$462	$ (10)	(2.2)%
International	289	245	44	18.0 %
Worldwide	$741	$707	$ 34	4.8 %

ABRAXANE® net sales increased by $34 million, or 4.8%, to $741 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily due to increases in unit sales in international markets. The increase was partially offset by net price decreases in international markets as well as decreased unit sales in the U.S.

OTHER PRODUCT SALES

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2017	2016		
U.S.	$159	$195	$ (36)	(18.5)%
International	515	495	20	4.0 %
Worldwide	$674	$690	$ (16)	(2.3)%

All other product sales, which include IDHIFA®, VIDAZA®, generic azacitidine for injection, THALOMID®, and ISTODAX®, decreased by $16 million primarily due to decreases in generic azacitidine for injection and THALOMID® net sales, which were partially offset by increases in VIDAZA® net sales and net sales from the launch of IDHIFA®.

Other Revenue: Other revenue decreased by $15 million to $26 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. This decrease is primarily due to a reduction in royalty revenue from Novartis based upon its sales of both RITALIN® and FOCALIN XR®, both of which have been negatively impacted by generic competition in certain markets. We expect this trend to continue through the remainder of 2017.

Gross to Net Sales Accruals: We record gross to net sales accruals for government rebates, chargebacks and distributor service fees, sales discounts, and sales returns and allowances. For a discussion of our gross to net sales accruals, see Critical Accounting Estimates and Significant Accounting Policies in our 2016 Annual Report on Form 10-K.

Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2017 and 2016 were as follows (in millions):

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total

Balance as of December 31, 2016	$ 371	$ 190	$ 16	$ 18	$595
Allowances for sales during prior periods	7	(26)	—	(5)	(24)
Allowances for sales during 2017	625	799	139	9	1,572
Credits/deductions issued for sales during prior periods	(296)	(97)	(16)	(6)	(415)
Credits/deductions issued for sales during 2017	(258)	(644)	(120)	(2)	(1,024)
Balance as of September 30, 2017	$ 449	$ 222	$ 19	$ 14	$704
Balance as of December 31, 2015	$ 225	$ 142	$ 12	$ 17	$396
Allowances for sales during prior periods	17	(13)	—	(5)	(1)
Allowances for sales during 2016	483	548	112	9	1,152
Credits/deductions issued for sales during prior periods	(157)	(56)	(10)	(5)	(228)
Credits/deductions issued for sales during 2016	(225)	(455)	(99)	(3)	(782)
Balance as of September 30, 2016	$ 343	$ 166	$ 15	$ 13	$537

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2017 and 2016 are as follows:

Government rebate provisions increased by $132 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, which was primarily due to an $81 million increase in the U.S. market and a $51 million increase in international government rebates. The increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with $79 million due to an increase in Medicaid rebates (primarily in the managed care channel) and $2 million due to an increase in expense related to Medicare Part D Coverage Gap. The increase in international government rebates was primarily driven by higher sales volumes and increased rebate rates.

Chargebacks and distributor service fees provisions increased by $238 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. Chargebacks increased by approximately $100 million and distributor service fees increased by approximately $138 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates, including a $10 million increase related to the TRICARE program driven by higher sales volumes. The distributor service fee increase was primarily attributable to increased sales volumes and new managed care contracts effective January 1, 2017 for OTEZLA®, which accounted for $97 million of the increase, as well as a $21 million increase in commercial copayment program expense and a $10 million increase in the distributor service fee expense, both of which also were attributable to higher sales volumes.

Discount provisions increased by $27 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily due to higher sales volumes. The increase was primarily comprised of an increase of $16 million related to REVLIMID® as well as increases related to OTEZLA® and POMALYST®.

Provisions for sales returns and allowances remained unchanged for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016.

Operating Costs and Expenses

Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2017 and 2016 were as follows (dollar amounts in millions):

Cost of Goods Sold (excluding amortization of acquired intangible assets)

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Cost of goods sold (excluding amortization of acquired intangible assets)	$342	$325	$ 17	5.2 %
Percent of Net product sales	3.6 %	4.0 %		

Cost of goods sold (excluding amortization of acquired intangible assets) increased by $17 million to $342 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 3.6% for the nine-month period ended September 30, 2017 compared to 4.0% for the nine-month period ended September 30, 2016, primarily due to POMALYST®, OTEZLA® and REVLIMID® which have a lower cost, comprising a higher percentage of net product sales, while sales of ABRAXANE®, VIDAZA® and azacitidine for injection, which have a higher cost, made up a lower percentage of net product sales.

Research and Development

	Nine-Month Periods Ended September 30,		Decrease	Percent Change
	2017	2016		
Research and development	$3,177	$3,335	$ (158)	(4.7)%
Percent of Total revenue	33.4%	40.4%		

Research and development expenses decreased by $158 million to $3.2 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. The decrease was primarily due to a decrease of $298 million of research and development asset acquisition expenses as well as a $84 million decrease in expenses related to collaboration arrangements. These decreases were partially offset by an increase of $217 million in clinical trial and drug discovery and development activity. See Note 3 and Note 14 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisitions and our collaboration arrangements, respectively. Our research and development expenses may fluctuate from period-to-period based on the volume and timing of closing asset acquisitions and collaboration arrangements and associated obligations pursuant to such arrangements.

The following table provides a breakdown of research and development expenses (in millions):

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2017	2016		
Human pharmaceutical clinical programs	$989	$856	$ 133	15.5 %
Other pharmaceutical programs	583	576	7	1.2 %
Drug discovery and development	570	486	84	17.3 %
Collaboration arrangements	710	794	(84)	(10.6)%
Research and development asset acquisition expenses (See Note 3*)	325	623	(298)	(47.8)%
Total	$3,177	$3,335	$ (158)	(4.7)%

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

Selling, General and Administrative

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Selling, general and administrative	$2,167	$1,973	$ 194	9.8 %
Percent of Total revenue	22.8 %	23.9 %		

Selling, general and administrative expenses increased by $194 million to $2.2 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. The increase was primarily due to higher litigation-related loss contingency accrual expenses incurred in 2017. During 2017, we recorded a litigation-related loss contingency accrual expense of $315 million related to the Brown Action, which represented our probable and reasonably estimable risk of loss. During the nine-month period ended September 30, 2016, we recorded a $130 million litigation-related loss contingency accrual expense with respect to the lawsuit filed against us by the CMCC, which represented our probable and reasonably estimable risk of loss at that time. Subsequently, we reached a settlement agreement with CMCC during the first quarter of 2017. See Note 16 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional information related to these legal matters. The increase in selling, general and administrative expenses was partially offset by a $50 million decrease in donations to independent non-profit patient assistance organizations in the U.S.

Amortization of Acquired Intangible Assets

	Nine-Month Periods Ended September	(Decrease)	Percent Change

	30, 2017	2016		
Amortization of acquired intangible assets	$250	$354	$ (104)	(29.4)%

Amortization of intangible assets acquired as a result of business combinations is summarized below for the nine-month periods ended September 30, 2017 and 2016 (in millions):

	Nine-Month Periods Ended September 30,		(Decrease)
Acquisitions	2017	2016	
Abraxis	$113	$114	$ (1)
Avila	10	114	(104)
Gloucester	69	69	—
Pharmion	3	3	—
Quanticel	55	54	1
Total amortization	$250	$354	$ (104)

The decrease in amortization expense was primarily related to the complete write down of the technology platform asset that was obtained in the acquisition of Avila.

Acquisition Related Charges and Restructuring, net

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2017	2016		
Acquisition related charges and restructuring, net	$ 75	$ 25	$ 50	200.0%

Acquisition related charges and restructuring, net was a charge of $75 million for the nine-month period ended September 30, 2017, increasing by $50 million compared to the nine-month period ended September 30, 2016. Acquisition related charges primarily relate to the fair value adjustments of our contingent consideration obligations. The increase was due to a $77 million decrease in the benefit related to reductions in the fair value of our contingent liabilities associated with our acquisition of Avila. In addition, there was a $29 million increase in expense related to increases in the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis. These increases in expense were partially offset by a $45 million decrease in the net expense related to changes in the fair value of our contingent liabilities associated with Nogra and Quanticel. In addition, there was a decrease of $13 million in restructuring costs which were incurred in the prior period. See Note 6 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our contingent consideration liabilities.

Other Income and Expenses

Interest and Investment Income, net: Interest and investment income, net increased by $51 million to $72 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016 primarily due to higher investment balances and higher yields compared to the prior year. In addition, investment income increased as a result of a realized gain of approximately $9 million from the sale of available for sale marketable securities.

Interest (Expense): Interest (expense) increased by $7 million to $380 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016.

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Other (Expense), net: Other (expense), net and fluctuations in the components of Other (expense), net is summarized below for the nine-month periods ended September 30, 2017 and 2016 (in millions):

	Nine-Month Periods Ended September 30,		Increase (Decrease)
	2017	2016	
Foreign exchange gains, including foreign exchange derivative instruments not designated as hedging instruments (See Note 7*)	$20	$4	$ 16
Premium paid on equity investment (See Note 14*)	—	(6)	6
Fair value adjustments of forward point amounts (See Notes 1, 2 & 7*)	—	21	(21)
Gain from sale of put options (See Note 4*)	—	8	(8)
Investment impairment charges	(49)	(93)	44
Gain on sale of LifebankUSA business (See Note 3*)	—	38	(38)
Gain on sale of equity investment in Flexus Biosciences, Inc.	9	7	2
Other	2	9	(7)
Total Other (expense), net	$(18)	$(12)	$ (6)

* References to Notes in this table are to the Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report.

Income Tax Provision: The income tax provision decreased by $141 million to $162 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016, primarily as a result of a decrease in the effective tax rate, partially offset by an increase in income before taxes. The effective tax rate for the nine-month period ended September 30, 2017 was 5.1%, a reduction of 11.1 percentage points from our effective tax rate of 16.2% for the nine-month period ended September 30, 2016. The reduction in our effective tax rate was primarily due to excess tax benefits from employee stock compensation deductions, for which our year-to-date 2017 effective tax rate was reduced by 8.6 percentage points (see Note 2 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report), U.S. research and development and orphan drug tax credits, for which our year-to-date 2017 effective tax rate was reduced by 1.8 percentage points, and the absence in 2017 of nondeductible research and development expenses recorded in 2016 from our acquisition of EngMab, partially offset by non-deductible research and development expenses recorded in 2017 for the Delinia asset acquisition and certain expenses recorded in 2017 for the Brown Action for which no tax benefit is available (See Notes 3 and 16, respectively, of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report). The tax benefits recognized in the nine-month period ended September 30, 2017 for U.S. research and development and orphan drug tax credits were the result of a change in estimate upon completion of a comprehensive analysis. (See Note 13 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report).

Our effective tax rate is a function of the distribution of our pre-tax income among the many jurisdictions in which we operate. Our pre-tax income is earned and taxed in either the U.S. at a statutory tax rate of 35%, or outside the U.S. at significantly lower statutory tax rates. Our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the timing and amount of tax benefits from employee stock compensation, payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements, and many other factors which are difficult to forecast.

Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of (in millions):

	September 30, 2017	December 31, 2016	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$ 5,511	$ 6,170	$ (659)
Marketable securities available-for-sale	6,248	1,800	4,448
Total financial assets	$ 11,759	$ 7,970	$ 3,789
Debt:			
Short-term borrowings and current portion of long-term debt	$ 1,400	$ 501	$ 899
Long-term debt, net of discount	12,874	13,789	(915)
Total debt	$ 14,274	$ 14,290	$ (16)
Working capital[(1)]	$ 10,800	$ 7,964	$ 2,836

(1) Includes Cash and cash equivalents, Marketable securities available-for-sale, Accounts receivable, net of allowances, Inventory and Other current assets, less Short-term borrowings and current portion of long-term debt, Accounts payable, Accrued expenses and other current liabilities, and the current portion of Income taxes payable.

We rely primarily on positive cash flows from operating activities, proceeds from sales of available-for-sale marketable securities and borrowings in the form of long-term notes payable and short-term commercial paper to provide for our liquidity requirements. We expect continued growth in our expenditures, particularly those related to research and development, clinical trials, commercialization of new products, international expansion and capital investments. However, we anticipate that existing cash and cash equivalent balances, marketable securities available-for-sale, cash generated from operations and existing sources of and access to financing are adequate to fund our operating needs, capital expenditures, debt service requirements and our plans to purchase our stock and pursue strategic business initiatives for the foreseeable future.

Many of our operations are conducted outside the United States and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of September 30, 2017, we held approximately $9.0 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business, including intercompany transactions, as well as for other reasons, such as repurchases of our common stock, internal reorganizations, business-development activities and debt issuances. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the United States, no accrual for U.S. taxes is provided. Approximately $900 million of our foreign earnings, included in the $9.0 billion of short-term funds in foreign tax jurisdictions, may not be required for use in offshore operations and may be available for use in the United States. These earnings are not treated as permanently reinvested and accordingly, our deferred tax liabilities as of September 30, 2017 and December 31, 2016 included approximately $317 million for the estimated U.S. federal and state income taxes that may be incurred should these earnings be repatriated. The remaining foreign earnings are unremitted and expected to be permanently reinvested outside the United States. We do not rely on these earnings as a source of funds for our domestic business as we expect to have sufficient current cash resources combined with future cash flows in the United States to fund our U.S. operational and strategic needs.

Share Repurchase Program: Our Board of Directors approved an aggregate $20.5 billion common stock repurchase program of which we have approximately $3.8 billion remaining for future share repurchases as of September 30,

2017. During the three- and nine-month periods ended September 30, 2017, we used $114 million and $925 million of cash for purchases of our common stock measured on a settlement date basis, respectively.

Components of Working Capital

Cash, Cash Equivalents and Marketable Securities Available-for-Sale: We invest our excess cash primarily in money market funds, repurchase agreements, time deposits, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities (MBS), global corporate debt securities, asset backed securities and ultra-short income fund investments. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are

classified as marketable securities available-for-sale. See Note 8 to the Unaudited Consolidated Financial Statements included elsewhere in this report. The $3.8 billion increase in cash, cash equivalents and marketable securities available-for-sale as of September 30, 2017 compared to December 31, 2016 was primarily due to $3.6 billion of cash from operating activities and $673 million of net unrealized holding gains on marketable securities available-for-sale, which were partially offset by $292 million of net cash used in financing activities.

Accounts Receivable, Net: Accounts receivable, net increased by $195 million to approximately $1.8 billion as of September 30, 2017 compared to December 31, 2016. Sales made outside the United States typically have payment terms that are greater than 60 days, thereby extending collection periods beyond those in the United States. We expect our accounts receivable balance to grow as our international sales continue to expand.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt situation in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Many of our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.

Inventory: Inventory balances increased by $39 million to $537 million as of September 30, 2017 compared to December 31, 2016.

Other Current Assets: Other current assets decreased by $108 million to $671 million as of September 30, 2017 compared to December 31, 2016 primarily due to a $308 million decrease in the fair value of derivative instruments, which was partially offset by a $116 million increase in prepaid taxes, a $21 million increase in receivables due to employee stock option exercises and $63 million of net other increases.

Commercial Paper: We have a commercial paper program (Program) under which we issue unsecured commercial paper notes (Commercial Paper) on a private placement basis, the proceeds of which are used for general corporate purposes. In April 2016, our Board of Directors authorized an increase in the maximum amount of commercial paper issuable to $2.0 billion. As of September 30, 2017, we had available capacity to issue up to $2.0 billion of Commercial Paper and there were no borrowings under the Program. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis. Borrowings under the Program, if any, are accounted for as short-term borrowings.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of $2.0 billion, which was increased from $1.8 billion in April 2016. We extended the Credit Facility in April 2017 from April 17, 2021 to April 17, 2022. Amounts may be borrowed in U.S. Dollars for general corporate purposes. The Credit Facility currently serves as backup liquidity for our Commercial Paper borrowings. As of September 30, 2017, there was no outstanding borrowing against the Credit Facility.

The Credit Facility and the Revolving Credit Agreement contain affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2017.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by $166 million to approximately $2.5 billion as of September 30, 2017 compared to December 31, 2016. The increase was primarily due to increases of $248 million related to collaboration agreement accruals, $106 million for sales adjustment accruals, $72 million for clinical trials and research and development expense accruals, and $64 million for contingent consideration accruals, which includes the net change in fair value (see Note 6 to the Unaudited Consolidated Financial Statements contained elsewhere in this report) as well as transfers from long-term liabilities. These increases were partially offset by the payment of a December 31, 2016 litigation-related loss contingency accrual of $199 million (see Note 16 of Notes to the Unaudited Consolidated Financial Statements contained elsewhere in this report), a decrease of $67 million of accrued interest expense, a decrease of $53 million for compensation related accruals and $5 million of net other decreases.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by $63 million to $524 million as of September 30, 2017 compared to December 31, 2016, primarily from the current provision for income taxes of $357 million, an

increase in prepaid income taxes of $133 million and $23 million of net other increases, which were partially offset by income tax payments of $450 million.

Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2017 and 2016 were as follows (in millions):

	Nine-Month Periods Ended September 30,		
	2017	2016	Change
Net cash provided by operating activities	$3,557	$2,763	$ 794
Net cash (used in) investing activities	(3,989)	(298)	(3,691)
Net cash (used in) financing activities	(292)	(1,827)	1,535

Operating Activities: Net cash provided by operating activities increased by $794 million to $3.6 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. The increase in net cash provided by operating activities was primarily attributable to a $1.5 billion increase in net income, partially offset by payments of approximately $514 million for litigation-related loss contingency accruals. See Note 16 for more information regarding settlement of certain legal proceedings. The nine-month period ended September 30, 2016 included non-recurring cash inflows from derivative activities primarily related to cash receipts of $196 million to settle interest rate swap contracts that had been designated as fair value hedges of certain of our fixed rate notes. See Note 7 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to interest rate swap settlements.

Investing Activities: Net cash used in investing activities increased by approximately $3.7 billion to $4.0 billion for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. The increase in net cash used in investing activities was primarily due to the $3.7 billion of net purchases of marketable securities available-for-sale during 2017 compared to $18 million of net purchases of marketable securities available-for-sale during 2016.

Financing Activities: Net cash used in financing activities decreased by approximately $1.5 billion to $292 million for the nine-month period ended September 30, 2017 compared to the nine-month period ended September 30, 2016. The decrease in net cash used in financing activities was primarily attributable to the $925 million of payments under our share repurchase program during 2017 compared to $2.0 billion of payments under our share repurchase program during 2016. In addition, net cash used in financing activities decreased due to an increase of $446 million in net proceeds from share-based compensation arrangements. In August 2017, we issued an additional $500 million principal amount of 2.250% senior notes due 2021 and received net cash proceeds of approximately $496 million. In August 2017, we repaid the 1.900% senior notes with a principal amount of $500 million upon maturity. See Note 11 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details.

Contractual Obligations

For a discussion of our contractual obligations, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2016 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2016 aside from those disclosed in Note 3 and Note 14 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report. See also, Note 17 of Notes to Unaudited Consolidated Financial Statements and Management's Discussion & Analysis of Financial Condition and Results of Operations - Executive Summary contained elsewhere in this report

for additional details related to the GED-0301 (mongersen) trials.

Critical Accounting Estimates and Significant Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management’s 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. Our critical accounting estimates are disclosed in the Management’s Discussion and Analysis of Financial Condition and Results of Operations section of our 2016 Annual Report on Form 10-K. During the third quarter of 2017, we adopted Accounting Standards Update No. 2017-12, "Targeted Improvements to Accounting for Hedging Activities" (ASU 2017-12). As a result of the adoption of ASU 2017-12, we have updated our Derivative Instruments and Hedges accounting policies. See Note 1 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report for

additional details. There were no other changes to our significant accounting policies from those disclosed in our 2016 Annual Report on Form 10-K. In addition, See Note 2 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report for additional details related to new accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings.

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. As of September 30, 2017, our market risk sensitive instruments consisted of marketable securities available-for-sale, our long-term debt and certain derivative contracts.

Marketable Securities Available-for-Sale: As of September 30, 2017, our marketable securities available-for-sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed (MBS) securities, global corporate debt securities, asset backed securities, ultra short income-fund securities, time deposits and repurchase agreements with original maturities of greater than three months and marketable equity securities. U.S. Treasury securities include government debt instruments issued by the U.S. Department of the Treasury. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. government sponsored enterprises. U.S. government-sponsored agency MBS include mortgage-backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Corporate debt-global includes obligations issued by investment-grade corporations, including some issues that have been guaranteed by governments and government agencies. Asset backed securities consist of triple-A rated securities with cash flows collateralized by credit card receivables and auto loans. Ultra short income fund includes investments in certificates of deposit, repurchase agreements, commercial paper and corporate notes. Our time deposits and repurchase agreements have original maturities greater than three months. Our repurchase agreements are collateralized by U.S. government securities, cash, bonds, commercial paper and bank certificates of deposit.

Our marketable securities available-for-sale are primarily equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration arrangements. In addition, we invest in debt securities that are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges related to debt securities, is included in Interest and investment income, net on the Consolidated Statements of Income. Realized gains and losses and other than temporary impairment charges related to equity securities are included in Other income, net on the Consolidated Statements of Income.

As of September 30, 2017, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as marketable securities available-for-sale were as follows (dollar amounts in millions):

	Duration		Total	

	Less Than 1 Year	1 to 3 Years	3 to 5 Years	
Principal amount	$1,985	$1,378	$32	$3,395
Fair value	1,988	1,381	33	3,402
Weighted average interest rate	1.3 %	1.8 %	2.4 %	1.5 %

Short-Term Borrowings and Current Portion of Long-Term Debt: We had no outstanding short-term borrowings as of September 30, 2017 or December 31, 2016. The carrying value of the current portion of long-term debt outstanding as of September 30, 2017 and December 31, 2016 includes:

	September 30, 2017	December 31, 2016
1.900% senior notes due 2017	$ —	$ 501
2.125% senior notes due 2018	999	—
2.300% senior notes due 2018	401	—
Total short-term debt	$ 1,400	$ 501

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after September 30, 2017 have an aggregate principal amount of $12.850 billion with varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of September 30, 2017 are summarized below (in millions):

	Principal Amount	Carrying Value
2.250% senior notes due 2019	$500	$506
2.875% senior notes due 2020	1,500	1,494
3.950% senior notes due 2020	500	515
2.250% senior notes due 2021	500	497
3.250% senior notes due 2022	1,000	1,046
3.550% senior notes due 2022	1,000	994
4.000% senior notes due 2023	700	739
3.625% senior notes due 2024	1,000	1,001
3.875% senior notes due 2025	2,500	2,480
5.700% senior notes due 2040	250	247
5.250% senior notes due 2043	400	393
4.625% senior notes due 2044	1,000	987
5.000% senior notes due 2045	2,000	1,975
Total long-term debt	$12,850	$12,874

As of September 30, 2017, the fair value of our senior notes outstanding was $15.1 billion.

MARKET RISK MANAGEMENT

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We actively manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts. In instances where these financial instruments are accounted for as cash flow hedges or fair value hedges we may from time to time terminate the hedging relationship. If a hedging relationship is terminated, we generally either settle the instrument or enter into an offsetting instrument.

Foreign Currency Risk Management

We maintain a foreign exchange exposure management program to mitigate the impact of volatility in foreign exchange rates on future foreign currency cash flows, translation of foreign earnings and changes in the fair value of assets and liabilities denominated in foreign currencies.

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. Dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically within the next three years, with a maximum of five years. We manage our anticipated transaction exposure principally with foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased foreign currency put options.

Foreign Currency Forward Contracts: We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, manage exchange rate volatility in the translation of foreign earnings, and reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding as of September 30, 2017 and December 31, 2016 had settlement dates within 22 months and 31 months, respectively. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and any unrealized gains or losses are reported in OCI and reclassified to the Consolidated Statement of Income in the same periods during which the underlying hedged transactions affect earnings. If a hedging relationship is terminated with respect to a foreign currency forward contract, accumulated gains or losses associated with the contract remain in OCI until the hedged forecasted transaction occurs and are reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. Prior to the adoption of ASU 2017-12, the forward point components of these foreign currency forward contracts were excluded from assessing effectiveness of the hedging relationship and all fair value adjustments of forward point amounts were recorded on the Consolidated Statements of Income in Other (expense), net. Upon adoption of ASU 2017-12, we recognize in earnings the initial value of the forward point components on a straight-line basis over the life of the derivative instrument within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item. See Note 2 for additional information related to the adoption of ASU 2017-12.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of September 30, 2017 and December 31, 2016:

	Notional Amount	
Foreign Currency	September 30, 2017	December 31, 2016
Australian Dollar	$71	$ 49
British Pound	128	199
Canadian Dollar	278	193
Euro	1,211	1,812
Japanese Yen	469	597
Total	$2,157	$ 2,850

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2017, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also manage a portfolio of foreign currency contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies and, from time to time, we enter into foreign currency contracts to manage exposure related to translation of foreign earnings. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in Other (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding as of September 30, 2017 and December 31, 2016 were $882 million and $934 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2017 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately $299 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in OCI and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.

Foreign Currency Option Contracts: From time to time, we may hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in that local currency. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and local currency notional amounts but with different strike prices. This combination of transactions is generally referred to as a “collar.” The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency option contracts outstanding

as of September 30, 2017 and December 31, 2016 had settlement dates within 39 months and 48 months, respectively. If the U.S. Dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. Dollar equivalent value of our anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the sale of the call option is equal to the premium paid for the purchased put option, resulting in a net zero cost for each collar. Outstanding foreign currency option contracts entered into to hedge forecasted revenue were as follows as of September 30, 2017 and December 31, 2016:

	Notional Amount[(1)]	
	September 30, 2017	December 31, 2016
Foreign currency option contracts designated as hedging activity:		
Purchased Put	$3,319	$ 1,790
Written Call	3,739	2,009

[(1)] U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied by the strike value of the foreign currency option. The local currency notional amounts of our purchased put and written call that are designated as hedging activities are equal to each other.

We also have entered into foreign currency put option contracts to hedge forecasted revenue which were not part of a collar strategy. Such put option contracts had a notional value of $387 million as of September 30, 2017 and December 31, 2016, and settlement dates within 15 months and 24 months, respectively.

Assuming that the September 30, 2017 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately $241 million if the U.S. Dollar were to strengthen and decrease by approximately $263 million if the U.S. Dollar were to weaken. However, since the contracts hedge specific forecasted intercompany transactions denominated in foreign currencies, any change in the fair value of the contract would be reported in OCI and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings.

Interest Rate Risk Management

Forward Starting Interest Rate Swaps and Treasury Rate Locks: In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) or treasury rate lock agreements (treasury rate locks) that are designated as cash flow hedges to hedge against changes in interest rates that could impact expected future issuances of debt. To the extent these hedges of cash flows related to anticipated debt are effective, any realized or unrealized gains or losses on the forward starting swaps or treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

As of September 30, 2017 and December 31, 2016, we had outstanding forward starting swaps with effective dates in 2017 and 2018 and maturing in ten years that were designated as cash flow hedges with notional amounts as shown in the table below:

	Notional Amount	
	September 30, 2017	December 31, 2016
Forward starting interest rate swap contracts:		
Forward starting swaps with effective dates in 2017	$500	$ 500
Forward starting swaps with effective dates in 2018	500	500

A sensitivity analysis to measure potential changes in the market value of our forward starting interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates as of September 30, 2017 would have increased the fair value of our contracts by approximately $83 million. A one percentage point decrease as of September 30, 2017 would have decreased the aggregate fair value of our contracts by approximately $92 million.

Interest Rate Swap Contracts: From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in benchmark interest rates. Gains or losses resulting from changes in fair value of the underlying debt attributable to the hedged benchmark interest rate risk are recorded on the Consolidated Statement of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheet. 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

on the Consolidated Statement of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheet. Consequently, there is no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense on the Consolidated Statements of Income. If a hedging relationship is terminated for an interest rate swap contract, accumulated gains or losses associated with the contract are measured and recorded as a reduction or increase of current and future interest expense associated with the previously hedged debt obligations.

The following table summarizes the notional amounts of our outstanding interest rate swap contracts as of September 30, 2017 and December 31, 2016:

	Notional Amount	
	September 30, 2017	December 31, 2016
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
3.875% senior notes due 2025	$200	$ 200

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2017 and 2016 and also terminated the hedging relationship by settling certain of those swap contracts during 2017 and 2016. In 2017, we terminated the hedging relationship on certain outstanding swap contracts amounting to $200 million notional amount by settling such swap contracts. In July 2016, we terminated the hedging relationship on all of our then outstanding swap contracts, amounting to $3.6 billion notional amount, by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of $3 million and $196 million during the nine-month periods ended September 30, 2017 and 2016, respectively, which is accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 for additional details related to reductions of current and future interest expense.

A sensitivity analysis to measure potential changes in the market value of our debt and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates as of September 30, 2017 would have reduced the aggregate fair value of our net payable by approximately $1.0 billion. A one percentage point decrease as of September 30, 2017 would have increased the aggregate fair value of our net payable by approximately $1.2 billion.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this quarterly report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e), or the Exchange Act). Based upon the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to our management (including our Chief Executive Officer and Chief Financial Officer) to allow timely decisions regarding required disclosures.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The information called for by this item is incorporated herein by reference to Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

Item 1A. Risk Factors

The following describes major risks to our business and should be considered carefully. Any of these factors could significantly and negatively affect our business, prospects, financial condition, operating results or credit ratings, which could cause the trading prices of our equity securities to decline. The risks described below are not the only risks we may face. Additional risks and uncertainties not presently known to us, or risks that we currently consider immaterial, could also negatively affect us.

Our operating results may be subject to significant fluctuations.

Our operating results may fluctuate from quarter to quarter and year to year for a number of reasons, including the risks discussed elsewhere in this “Risk Factors” section. Events such as a delay in product development or a revenue shortfall may cause financial results for a particular period to be below our expectations. In addition, we have experienced and may continue to experience fluctuations in our quarterly operating results due to the timing of charges that we may take. We have recorded, or may be required to record, charges that include development milestone and license payments under collaboration and license agreements, amortization of acquired intangibles and other acquisition related charges, and impairment charges. Several other factors, including government rebates, distributor buying patterns and government tender timing, impact the dollar value of product sales recorded in any particular quarter.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. We recognize foreign currency gains or losses arising from our operation in the period in which we incur those gains or losses. Although we utilize foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased put options to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful. As a result, currency fluctuation among our reporting currency, the U.S. Dollar, and the currencies in which we do business will affect our operating results. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency and other hedge transactions. In particular, we may incur higher than expected charges from hedge ineffectiveness or from the termination of a hedge arrangement. For more information, see Item 3. "Quantitative and Qualitative Disclosures About Market Risk."

We are dependent on the continued commercial success of our primary products, REVLIMID®, POMALYST®/IMNOVID®, ABRAXANE®, OTEZLA®, VIDAZA® and THALOMID®.

Our business is largely dependent on the commercial success of REVLIMID®, POMALYST®/IMNOVID®, ABRAXANE®, OTEZLA®, VIDAZA® and THALOMID®. REVLIMID® currently accounts for over half of our total revenue. As new products, such as POMALYST®/IMNOVID® and OTEZLA®, have obtained regulatory approval and gained market acceptance, our dependence on REVLIMID® has decreased, a trend that we expect to continue. A significant decline in REVLIMID® net revenue, in the absence of offsetting increases in revenue from our other marketed products, would have a material adverse effect on our results of operations, cash flows and financial condition. The success of these products depends on acceptance by regulators, key opinion leaders, physicians, and patients as effective drugs with certain advantages over other therapies. A number of factors, as discussed in greater detail below, may adversely impact the degree of acceptance of these products, including their efficacy, safety, price

and benefits over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans.

If unexpected adverse events are reported in connection with the use of any of these products, physician and patient acceptance of the product could deteriorate and the commercial success of such product could be adversely affected. We are required to report to the FDA or similar bodies in other countries events associated with our products relating to death or serious injury. Adverse events could result in additional regulatory controls, such as the imposition of costly post-approval clinical studies or revisions to our approved labeling which could limit the indications or patient population for a product or could even lead to the withdrawal of a product from the market. THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities. REVLIMID® and POMALYST®/IMNOVID® are also considered toxic to the human fetus and their respective labels contain warnings against use which could result in embryo-fetal exposure. While we have restricted

distribution systems for THALOMID®, REVLIMID®, and POMALYST®/IMNOVID®, and endeavor to educate patients regarding the potential known adverse events, including pregnancy risks, we cannot ensure that all such warnings and recommendations will be complied with or that adverse events resulting from non-compliance will not occur.

Our future commercial success depends on gaining regulatory approval for products in development, and obtaining approvals for our current products for additional indications.

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from the FDA and similar bodies in other countries. Our future growth would be negatively impacted if we fail to obtain timely, or at all, requisite regulatory approvals in the United States and internationally for products in development and approvals for our existing products for additional indications.

The principal risks to obtaining and maintaining regulatory approvals are as follows:

- In general, preclinical tests and clinical trials can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials may not lead to regulatory approval;
- Delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality;
- Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or legislation;
- Even if a product is approved, the scope of the approval may significantly limit the indicated uses or the patient population for which the product may be marketed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the product;
- After a product is approved, the FDA or similar bodies in other countries may withdraw or modify an approval in a significant manner or request that we perform additional clinical trials or change the labeling of the product due to a number of reasons, including safety concerns, adverse events and side effects;
- Products, such as REVLIMID® and POMALYST®/IMNOVID®, that receive accelerated approval can be subject to an expedited withdrawal if post-marketing restrictions are not adhered to or are shown to be inadequate to assure safe use, or if the drug is shown to be unsafe or ineffective under its conditions of use;
- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our approved products;
- Approved products, as well as their manufacturers, are subject to continuing and ongoing review by regulatory agencies, and the discovery of previously unknown problems with these products or the failure to comply with manufacturing or quality control requirements may result in restrictions on the manufacture, sale or use of a product or its withdrawal from the market; and
- Changes in regulatory agency policy or the adoption of new regulations or legislation could impose restrictions on the sale or marketing of our approved products.

If we fail to comply with laws or government regulations or policies our business could be adversely affected.

The discovery, preclinical development, clinical trials, manufacturing, risk evaluation and mitigation strategies (such as our REMS program), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and government regulations and policies. In addition, individual states, acting through their attorneys general, are increasingly seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. If we fail to comply with the laws and regulations regarding the promotion and sale of our products, appropriate distribution of our products under our restricted distribution systems, off-label promotion and the promotion of unapproved products, government agencies may bring enforcement actions against us or private litigants may assert claims on behalf of the government against us that could inhibit our commercial capabilities and/or result in significant damage awards and penalties.

Other matters that may be the subject of governmental or regulatory action which could adversely affect our business include laws, regulations and policies governing:

- protection of the environment, privacy, healthcare reimbursement programs, and competition;
- parallel importation of prescription drugs from outside the United States at prices that are regulated by the governments of various foreign countries; and
- mandated disclosures of clinical trial or other data, such as the EMA's policy on publication of clinical data.

Sales of our products will be significantly reduced if access to and reimbursement for our products by governmental and other third-party payers are reduced or terminated.

Sales of our current and future products depend, in large part, on the conditions under which our products are paid for by health maintenance, managed care, pharmacy benefit and similar health care management organizations (HCMOs), or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers.

The influence of HCMOs has increased in recent years due to the growing number of patients receiving coverage through a few large HCMOs as a result of industry consolidation. One objective of HCMOs is to contain and, where possible, reduce healthcare expenditures. HCMOs typically use formularies (lists of approved medicines available to members of a particular HCMO), clinical protocols, volume purchasing, long-term contracts and other methods to negotiate prices with pharmaceutical providers. Due to their lower cost generally, generic medicines are typically placed in preferred tiers of HCMO formularies. Additionally, many formularies include alternative and competitive products for treatment of particular medical problems. Exclusion of our products from a formulary or HCMO-implemented restrictions on the use of our products can significantly impact drug usage in the HCMO patient population, and consequently our revenues.

Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of patients' healthcare costs. These health care management organizations and third-party payers are increasingly challenging the prices charged for medical products and services, seeking to implement cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Our products continue to be subject to increasing price and reimbursement pressure due to price controls imposed by governments in many countries; increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and the tendency of governments and private health care providers to favor generic pharmaceuticals. In addition, governmental and private third-party payers and purchasers of our products may restrict access to formularies or otherwise discourage use of our products. Limitations on patient access to our drugs, adoption of price controls and cost-containment measures could adversely affect our business. In addition, our operating results may also be affected by distributors seeking to take advantage of price differences among various markets by buying our products in low cost markets for resale in higher cost markets.

The Affordable Care Act and other federal and state legislation may affect our pricing policies and government reimbursement of our products which may adversely impact our revenues and profitability.

In the U.S. there have been and are likely to continue to be a number of legislative and regulatory proposals and enactments related to drug pricing and reimbursement at both the federal and state level that could impact our profitability. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law in March 2010, and are referred to collectively as the Healthcare Reform Acts. These reforms have significantly impacted the pharmaceutical industry and, in the coming years, it is likely that additional changes, including the possible repeal of all or certain aspects of these reforms, will be made. Moreover, changes could be made to governmental healthcare and insurance reimbursement programs that could significantly impact the profitability of our products. Additionally, the pricing and reimbursement of pharmaceutical products, in general and specialty drugs in particular, have received the attention of U.S. policymakers, state legislators and others. At this time, we cannot predict the impact of this increased scrutiny on the pricing or reimbursement of our products or pharmaceutical products generally.

The Healthcare Reform Acts, among other things, made significant changes to the Medicaid rebate program by increasing the minimum rebates that manufacturers like us are required to pay. These changes also expanded the government's 340B drug discount program by expanding the category of entities qualified to participate in the program and benefit from its deeply discounted drug pricing. The Healthcare Reform Acts also obligate the Health Resources and Services Administration (HRSA), which administers the 340B program, to update the agreement that each manufacturer must sign to participate in the 340B program to require each manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug product available to any other purchaser at any price, and to report the ceiling prices for its drugs to the government. HRSA issued this update in late 2016, and we signed an amendment to our agreement on December 29, 2016.

HRSA also issued proposed regulations to implement an administrative dispute resolution (ADR) process for certain disputes arising under the 340B program, including (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit, that a covered entity has violated the prohibition on diversion of covered outpatient drugs to ineligible patients or duplicate discounts. The exact timing and content of final action on these matters is uncertain at this time. Depending on their final form, these actions could affect our obligations under the 340B program in ways that may have an adverse impact on our business. Additionally, earlier this year, HRSA finalized a regulation regarding the 340B pricing methodology and providing guidelines for when civil monetary penalties may be issued for "knowing and intentional" manufacturer overcharges of 340B covered entities. HRSA has delayed the effective date of this regulation to July 1, 2018.

We have received an inquiry from HRSA regarding our limited distribution networks for REVLIMID®, POMALYST®, and THALOMID® and our compliance with the 340B program. We have cooperated fully in responding to this inquiry and believe that we have complied with applicable legal requirements. If, however, we are ultimately required to change our sales or pricing practices with regard to the distribution of these drugs, there would be an adverse effect on our revenues and profitability.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations.

Many existing and potential customers for our products become members of group purchasing organizations (GPOs). GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of that contractual arrangement. Our failure to enter into or renew contracts with GPOs may cause us to lose market share and could adversely affect our sales.

Our long-term success depends, in part, on intellectual property protection.

Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that if claims of any of our owned or licensed patents are challenged by one or more third parties (through, for example, litigation or post grant review in the United States Patent and Trademark Office (USPTO) or European Patent Office (EPO)), a court or patent authority ruling on such challenge will ultimately determine, after all opportunities for appeal have been exhausted, that our patent claims are valid and enforceable. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using such products or processes, be subject to significant liabilities to such third party and/or be required to obtain license rights from such third party. Lawsuits involving patent claims are costly and could affect our results of operations, result in significant expense and divert the attention of managerial and scientific personnel. For more information on challenges to certain of our patents and settlement of certain of these challenges, see Note 16 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

In addition, we do not know whether any of our owned or licensed pending patent applications will result in the issuance of patents or, if patents are issued, whether they will be dominated by third-party patent rights, provide significant proprietary protection or commercial advantage or be circumvented, opposed, invalidated, rendered unenforceable or infringed by others.

Our intellectual property rights may be affected in ways that are difficult to anticipate at this time under the provisions of the America Invents Act enacted in 2011. This law represents a significant change to the US patent system. Uncertainty exists in the application and interpretation of various aspects of the America Invents Act. For example, post grant review procedures have been implemented that potentially represent a significant threat to a company's patent portfolio. Members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant review. Once instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. For more information with respect to IPRs, see Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report. A procedure similar to the IPR has existed in Europe for many years and we have defended our European patents in certain of those proceedings. We cannot predict whether any other Celgene patents will ever become the subject of a post grant review. If a significant product patent is successfully challenged in a post grant review proceeding it may be revoked, which would have a serious negative impact on our ability to maintain exclusivity in the market-place for our commercial products affected by such revocation and could adversely affect our future revenues and profitability.

On October 2, 2014, the EMA adopted its clinical transparency policy, "Policy on Publication of Clinical Data for Medicinal Products for Human Use" (Clinical Data Policy), which became effective on January 1, 2015. In general, under the Clinical Data Policy, clinical data is not deemed to be commercially confidential data. Therefore, there is a risk that unpublished proprietary information, including trade secrets that are incorporated into a marketing application before the EMA may be made publicly available. It is difficult to predict how any public disclosure of our trade secrets or other confidential and proprietary information made available under the Clinical Data Policy may adversely impact our patent rights and our competitive advantage in the marketplace.

Also, procedures for obtaining patents and the degree of protection against the use of a patented invention by others vary from country to country. There can be no assurance that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention or that any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country will be similar to or recognized by the judicial interpretation given to a corresponding patent issued in another country.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We also rely upon unpatented, proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. Despite precautions taken by us, there can be no assurance that these agreements provide meaningful protection, that they will not be breached, that we would have adequate remedies for any such breach or that our proprietary and trade secret technologies will not otherwise become known to others or found to be non-proprietary.

We receive confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees’ former employers. Litigation may be necessary to defend against these claims, which can result in significant costs if we are found to have improperly used the confidential or proprietary information of others. Even if we are successful in defending against these claims, litigation could result in substantial costs and diversion of personnel and resources.

Our products may face competition from lower cost generic or follow-on products.

Manufacturers of generic drugs are seeking to compete with our drugs and present a significant challenge to us. Those manufacturers may challenge the scope, validity or enforceability of our patents in court, requiring us to engage in complex, lengthy and costly litigation. If any of our owned or licensed patents are infringed or challenged, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on our sales of that product. In addition, manufacturers of innovative drugs as well as generic drug manufacturers may be able to design their products around our owned or licensed patents and compete with us using the resulting alternative technology. For more information concerning certain pending proceedings relating to our intellectual property rights and settlements of certain challenges, see Note 16 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Upon the expiration or loss of patent protection for a product, or upon the “at-risk” launch (despite pending patent infringement litigation against the generic product) by a manufacturer of a generic version of one of our products, we can quickly lose a significant portion of our sales of that product. In addition, if generic versions of our competitors’ branded products lose their market exclusivity, our patented products may face increased competition or pricing pressure.

Our business operates in an extremely competitive environment.

The pharmaceutical and biotechnology industries in which we operate are highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms, including, but not limited to:

- Hematology and Oncology: AbbVie, Amgen, AstraZeneca, Bristol-Myers-Squibb, Eisai, Gilead, Johnson & Johnson, Merck, Novartis, Roche/Genentech, Sanofi and Takeda; and
- Inflammation and Immunology: AbbVie, Amgen, Biogen, Eisai, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer and UCB S.A.

Some of these companies have considerably greater financial, technical and marketing resources than we have, enabling them, among other things, to make greater research and development investments. We also experience competition in drug development from universities and other research institutions, and we compete with others in acquiring technology from these sources. The pharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances are made and become more widely known. The development of products or processes by our competitors with significant advantages over those that we are developing could adversely affect our future revenues and profitability.

A decline in general economic conditions would adversely affect our results of operations.

Sales of our products are dependent, in large part, on third-party payers. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. For information about receivable balances relating to government-owned or -controlled hospitals in European countries, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

In addition, due to tightened global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including portions of our product manufacturing, clinical development of future collaboration products, conduct of clinical trials and supply of raw materials. If such third parties are unable to satisfy their commitments to us, our business could be adversely affected.

We may be required to modify our business practices, pay fines and significant expenses or experience other losses due to governmental investigations or other enforcement activities.

We may become subject to litigation or governmental investigations in the United States and foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and we have been subject to claims and other actions related to our business activities.

While the ultimate outcomes of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters could result in, among other things:

- significant damage awards, fines, penalties or other payments, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that preclude us from operating our business in a certain manner;
- changes and additional costs to our business operations to avoid risks associated with such litigation or investigations;
- product recalls;
- reputational damage and decreased demand for our products; and
- expenditure of significant time and resources that would otherwise be available for operating our business.

For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Note 16 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

The development of new biopharmaceutical products involves a lengthy and complex process and we may be unable to commercialize any of the products we are currently developing.

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process takes many years of effort without any assurance of ultimate success. Our product development efforts with respect to a product candidate may fail for many reasons, including:

- the failure of the product candidate in preclinical or clinical studies;
- adverse patient reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the product candidate;
- our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;
- our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate;
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

If a product were to fail to be approved or if sales fail to materialize for a newly approved product, we may incur losses related to the write-down of inventory, impairment of property, plant and equipment dedicated to the product or expenses related to restructuring.

Disruptions of our manufacturing and distribution operations could significantly interrupt our production and distribution capabilities.

We have our own manufacturing facilities for many of our products and we have contracted with third parties to provide other manufacturing, finishing, and packaging services. Any of those manufacturing processes could be partially or completely disrupted by fire, contamination, natural disaster, terrorist attack or governmental action. A disruption could lead to substantial production delays and the need to establish alternative manufacturing sources for the affected products requiring additional regulatory approvals. In the interim, our finished goods inventories may be insufficient to satisfy customer orders on a timely basis. Further, our business interruption insurance may not adequately compensate us for any losses that may occur.

In all the countries where we sell our products, governmental regulations define standards for manufacturing, packaging, labeling, distributing and storing pharmaceutical products. Our failure to comply, or the failure of our contract manufacturers and distributors to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions.

We have contracted with various distributors to distribute most of our branded products. If our distributors fail to perform and we cannot secure a replacement distributor within a reasonable period of time, our revenue could be adversely affected.

The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures.

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of our distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result,

a smaller number of large wholesale distributors and pharmacy chains control a significant share of the market. We expect that consolidation of drug wholesalers and pharmacy chains will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements and their purchases may exceed customer demand, resulting in increased returns or reduced wholesaler purchases in later periods.

Risks from the improper conduct of employees, agents, contractors or collaborators could adversely affect our business or reputation.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that violate the laws or regulations of the jurisdictions in which we operate,

including employment, anti-corruption, environmental, competition and privacy laws. Such improper actions, particularly with respect to foreign healthcare professionals and government officials, could subject us to civil or criminal investigations, monetary and injunctive penalties, adversely impact our ability to conduct business in certain markets, negatively affect our results of operations and damage our reputation.

We are subject to a variety of risks related to the conduct and expansion of our business internationally, particularly in emerging markets.

As our operations expand globally, we are subject to risks associated with conducting business in foreign markets, particularly in emerging markets. Those risks include:

- increased management, travel, infrastructure and legal compliance costs;
- longer payment and reimbursement cycles;
- difficulties in enforcing contracts and collecting accounts receivable;
- local marketing and promotional challenges;
- lack of consistency, and unexpected changes, in foreign regulatory requirements and practices;
- increased risk of governmental and regulatory scrutiny and investigations;
- increased exposure to fluctuations in currency exchange rates;
- the burdens of complying with a wide variety of foreign laws and legal standards;
- operating in locations with a higher incidence of corruption and fraudulent business practices;
- difficulties in staffing and managing foreign sales and development operations;
- import and export requirements, tariffs, taxes and other trade barriers;
- weak or no protection of intellectual property rights;
- possible enactment of laws regarding the management of and access to data and public networks and websites;
- possible future limitations on foreign-owned businesses;
- increased financial accounting and reporting burdens and complexities; and
- other factors beyond our control, including political, social and economic instability, popular uprisings, war, terrorist attacks and security concerns in general.

As we continue to expand our business into multiple international markets, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. Any of these risks could harm our international operations and reduce our sales, adversely affecting our business, results of operations, financial condition and growth prospects.

We may not realize the anticipated benefits of acquisitions and strategic initiatives.

We may face significant challenges in effectively integrating entities and businesses that we acquire and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquired businesses will depend in part upon whether we can integrate our businesses in an efficient and effective manner. Our integration of acquired businesses involves a number of risks, including:

- demands on management related to the increase in our size after an acquisition;
- the diversion of management’s attention from daily operations to the integration of acquired businesses and personnel;

- higher than anticipated integration costs;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;
- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records and procedures, as well as in maintaining uniform standards and controls, including internal control over financial reporting, and related procedures and policies.

In addition, we may not be able to realize the projected benefits of corporate strategic initiatives we may pursue in the future.

We may not be able to continue to attract and retain highly qualified managerial, scientific, manufacturing and commercial talent.

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified managerial, scientific, medical, manufacturing, commercial and other professional personnel, and competition for these types of personnel is intense. We cannot be sure that we will be able to attract or retain skilled personnel or that the costs of doing so will not materially increase.

Risks associated with using hazardous materials in our business could subject us to significant liability.

We use certain hazardous materials in our research, development, manufacturing and other business activities. If an accident or environmental discharge occurs, or if we discover contamination caused by prior owners and operators of properties we acquire, we could be liable for remediation obligations, damages and fines that could exceed our insurance coverage and financial resources. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, requiring us to expend more financial resources either in compliance or in purchasing supplemental insurance coverage.

We are subject to various legal proceedings, claims and investigative demands in the ordinary course of our business, the ultimate outcome of which may result in significant expense, payments and penalties.

We and certain of our subsidiaries are involved in various legal proceedings that include patent, product liability, consumer, commercial, antitrust and other claims that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable. Although we believe we have substantial defenses in these matters, we could in the future be subject to adverse judgments, enter into settlements of claims or revise our expectations regarding the outcomes of certain matters, and such developments could have a material adverse effect on our results of operations in the period in which such judgments are received or settlements occur. For more information regarding settlement of certain legal proceedings, see Note 16 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation under the U.S. Federal Food, Drug, and Cosmetic Act, the Medicaid Drug Rebate Program, the False Claims Act, the Foreign Corrupt Practices Act and other federal and state statutes, including those discussed elsewhere in this report, as well as anti-kickback and false claims laws, and similar laws in international jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information demands from government authorities, and been subject to claims and other actions related to our business activities brought by governmental authorities, as well as by consumers, third-party payers, stockholders and others. There can be no assurance that existing or future proceedings will not result in significant expense, civil payments, fines or other

adverse consequences. For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Note 16 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Product liability claims could adversely affect our business, results of operations and financial condition.

Product liability claims could result in significant damage awards or settlements. Such claims can also be accompanied by consumer fraud claims or claims by third-party payers seeking reimbursement of the cost of our products. In addition, adverse determinations or settlements of product liability claims may result in suspension or withdrawal of a product marketing authorization or changes

to our product labeling, including restrictions on therapeutic indications, inclusion of new contraindications, warnings or precautions, which would have a material adverse effect on sales of such product. We have historically purchased product liability coverage from third-party carriers for a portion of our potential liability. Such insurance has become increasingly difficult and costly to obtain. In this context and in light of the strength of our balance sheet we now self-insure these risks beginning in 2016. Product liability claims, regardless of their merits or ultimate outcome, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. There can be no assurance that we will be able to recover under any existing third-party insurance policy or that such coverage will be adequate to fully cover all risks or damage awards or settlements. Additionally, if we are unable to meet our self-insurance obligations for claims that are more than we estimated or reserved for that require substantial expenditures, there could be a material adverse effect on our financial statements and results of operations.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in both the United States and various foreign jurisdictions and our domestic and international tax liabilities are largely dependent upon the distribution of income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include interpretations of existing tax laws, the accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings.

Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and cause our profitability to decline.

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results. We utilize foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased put options, all of which are derivative instruments, to manage foreign currency risk. We use these derivative instruments to hedge certain forecasted transactions, manage exchange rate volatility in the translation of foreign earnings and reduce exposures to foreign currency fluctuations of certain balance sheet items denominated in foreign currencies. The use of these derivative instruments is intended to mitigate a portion of the exposure of these risks with the intent to reduce our risk or cost, but generally would not fully offset any change in operating results as a consequence of fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations. See Note 7 of Notes to Unaudited Consolidated Financial Statements and Item 3. “Quantitative and Qualitative Disclosures About Market Risk” contained elsewhere in this report.

We may experience an adverse market reaction if we are unable to meet our financial reporting obligations.

As we continue to expand at a rapid pace, the development of new and/or improved automated systems will remain an ongoing priority. During this expansion period, our internal control over financial reporting may not prevent or detect misstatements in our financial reporting. Such misstatements may result in litigation and/or negative publicity and possibly cause an adverse market reaction that may negatively impact our growth plans and the value of our common stock.

Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on our results of operations and financial condition.

The value allocated to certain of our assets could be substantially impaired due to a number of factors beyond our control. Also, if any of our strategic equity investments decline in value, we may be required to write down such investments. In addition, new or revised accounting standards, rules and interpretations could result in changes to the recognition of income and expense that may materially and adversely affect our financial results.

The price of our common stock may fluctuate significantly.

The market for our shares of common stock may fluctuate significantly. The following key factors may have an adverse impact on the market price of our common stock:

- results of our clinical trials or adverse events associated with our marketed products;
- fluctuations in our commercial and operating results;

- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- changes or anticipated changes in laws and governmental regulations, including changes in tax, healthcare, environmental, competition and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- patent or proprietary rights developments;
- changes in pricing and third-party reimbursement policies for our products;
- the outcome of litigation involving our products, processes or intellectual property;
- the existence and outcome of governmental investigations and proceedings;
- regulatory actions that may impact our products or potential products;
- disruptions in our manufacturing processes or supply chain;
- failure of our collaboration partners to successfully develop potential drug candidates;
- competition; and
- investor reaction to announcements regarding business or product acquisitions.

In addition, a market downturn in general and/or in the biopharmaceutical sector in particular, may adversely affect the market price of our securities, which may not necessarily reflect the actual or perceived value of our Company.

Our business would be adversely affected if we are unable to service our debt obligations.

We have incurred various forms of indebtedness, including senior notes, commercial paper and a senior unsecured credit facility. Our ability to pay interest and principal amounts when due, comply with debt covenants or repurchase the senior notes if a change of control occurs, will depend upon, among other things, continued commercial success of our products and other factors that affect our future financial and operating performance, including prevailing economic conditions and financial, business and regulatory factors, many of which are beyond our control.

If we are unable to generate sufficient cash flow to service the debt service requirements under our debt instruments, we may be forced to take remedial actions such as:

- restructuring or refinancing our debt;
- seeking additional debt or equity capital;
- reducing or delaying our business activities, acquisitions, investments or capital expenditures, including research and development expenditures; or
- selling assets, businesses, products or other potential revenue streams.

Such measures might not be successful and might not enable us to service our debt obligations. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms, if at all.

A breakdown or breach of our information technology systems and cyber security efforts could subject us to liability, reputational damage or interrupt the operation of our business.

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown and unauthorized intrusion. We could also experience a business

interruption, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Similarly, data privacy breaches by those who access our systems may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, employees, customers or other business partners, may be exposed to unauthorized persons or to the public. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue. We continuously monitor our data, information technology systems (and those of our third-party providers where appropriate) and our personnel's usage of these systems to reduce these risks and potential threats. However, cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers) that could adversely affect our business and result in financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties.

The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

We have certain charter and by-law provisions that may deter a third-party from acquiring us and may impede the stockholders’ ability to remove and replace our management or board of directors.

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5.0 million shares of preferred stock and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third-party from acquiring a majority of our outstanding voting stock. Additionally, our by-laws contain provisions intended to strengthen the board’s position in the event of a hostile takeover attempt. These provisions could impede the stockholders’ ability to remove and replace our management and/or board of directors. Furthermore, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

In addition to the risks relating to our common stock, holders of our CVRs are subject to additional risks.

On October 15, 2010, we acquired all of the outstanding common stock of Abraxis BioScience, Inc. (Abraxis) and in connection with our acquisition, contingent value rights (CVRs) were issued entitling each holder of a CVR to a pro rata portion of certain net sales payments if certain specified conditions are satisfied. In addition to the risks relating to our common stock, CVR holders are subject to additional risks, including:

- an active public market for the CVRs may not continue to exist or the CVRs may trade at low volumes, both of which could have an adverse effect on the market price of the CVRs;
- if the net sales targets specified in the CVR Agreement are not achieved within the time periods specified, no payment will be made and the CVRs will expire valueless;
- since the U.S. federal income tax treatment of the CVRs is unclear, any part of a CVR payment could be treated as ordinary income and the tax thereon may be required to be paid prior to the receipt of the CVR payment;

- any payments in respect of the CVRs are subordinated to the right of payment of certain of our other indebtedness;
- we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations under the CVR Agreement to continue to commercialize ABRAXANE® or any of the other Abraxis pipeline products, we may discontinue such efforts, which would have an adverse effect on the value of the CVRs.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(c) Issuer Purchases of Equity Securities

From April 2009 through September 2017, our Board of Directors approved purchases of up to $20.5 billion of our common stock. Approved amounts exclude share purchase transaction fees.

The following table presents the number of shares purchased during the three-month period ended September 30, 2017, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs
July 1 - July 31	—	$—	—	$3,920,120,056
August 1 - August 31	871,070	$128.91	871,070	$3,807,831,454
September 1 - September 30	—	$—	—	$3,807,831,454
Total	871,070	$128.91	871,070	

During the three-month period ended September 30, 2017, we purchased approximately 0.9 million shares of common stock under the share repurchase program from all sources at a cost of approximately $112 million, excluding commissions. As of September 30, 2017, we had a remaining purchase authorization of approximately $3.8 billion.

During the period covered by this report, we did not sell any of our equity shares that were not registered under the Securities Act of 1933, as amended.

Item 6. Exhibits

31.1*	Certification by the Company's Chief Executive Officer.
31.2*	Certification by the Company's Chief Financial Officer.
32.1*	Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2*	Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101*	The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) Notes to Unaudited Consolidated Financial Statements.

* Filed herewith.

SIGNATURE

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.

CELGENE
CORPORATION

Date: October 26, 2017 By: /s/Peter N. Kellogg
Peter N. Kellogg
Executive Vice
President and Chief
Financial Officer
(principal financial
and accounting
officer)