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

FORM 10-Q TABLE OF CONTENTS

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.

18

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.

CELGENE CORPORATION AND SUBSIDIARIES
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.

22

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

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.

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

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
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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

33

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
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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

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

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.

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

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):