

CELGENE CORP /DE/
Form 10-Q
October 25, 2018

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

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any,

every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Accelerated filer

Non-accelerated filer

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 13(a) of the Exchange Act.

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

As of October 22, 2018, 699,251,840 shares of Common Stock, par value \$.01 per share, were outstanding.

CELGENE CORPORATION

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(Dollars in millions, except per share amounts)

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30, 2018	2017	September 30, 2018	2017
Revenue:				
Net product sales	\$3,890	\$3,283	\$11,229	\$9,494
Other revenue	2	4	15	26
Total revenue	3,892	3,287	11,244	9,520
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	157	118	418	342
Research and development	1,081	1,347	4,535	3,177
Selling, general and administrative	746	608	2,400	2,167
Amortization of acquired intangible assets	127	80	341	250
Acquisition related charges and restructuring, net	101	49	166	75
Total costs and expenses	2,212	2,202	7,860	6,011
Operating income	1,680	1,085	3,384	3,509
Other income and (expense):				
Interest and investment income, net	8	33	30	72
Interest (expense)	(193)	(127)	(551)	(380)
Other (expense) income, net	(117)	—	852	(18)
Income before income taxes	1,378	991	3,715	3,183
Income tax provision	296	3	742	162
Net income	\$1,082	\$988	\$2,973	\$3,021
Net income per common share:				
Basic	\$1.54	\$1.26	\$4.12	\$3.87
Diluted	\$1.50	\$1.21	\$4.02	\$3.72
Weighted average shares:				
Basic	702.0	784.1	722.0	781.2
Diluted	719.7	815.2	740.4	812.6

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, 2018		2017		Nine-Month Periods Ended September 30, 2018		2017	
Net income	\$1,082	\$988	\$2,973	\$3,021				
Other comprehensive income (loss):								
Foreign currency translation adjustments	(2) 23	(14) 64				
Net unrealized gains (losses) related to cash flow hedges:								
Unrealized holding gains (losses)	54	(131) 181	(397)			
Tax benefit	—	—	1	7				
Unrealized holding gains (losses), net of tax	54	(131) 182	(390)			
Reclassification adjustment for (gains) losses included in net income	(13) (6) 27	(169)			
Tax (benefit)	—	—	(1) (2)			
Reclassification adjustment for (gains) losses included in net income, net of tax	(13) (6) 26	(171)			
Excluded component related to cash flow hedges:								
Amortization of excluded component (gains)	(3) (5) (18) (10)			
Reclassification of realized excluded component losses to net income	6	—	23	—				
Net reclassification adjustment included in net income	3	(5) 5	(10)			
Net unrealized gains (losses) on available-for-sale debt / marketable securities (see Note 1):								
Unrealized holding gains (losses)	—	444	(9) 673				
Tax (expense) benefit	—	(157) 2	(238)			
Unrealized holding gains (losses), net of tax	—	287	(7) 435				
Reclassification adjustment for (gains) losses included in net income	—	(2) 18	32				
Tax expense (benefit)	—	1	(4) (12)			
Reclassification adjustment for (gains) losses included in net income, net of tax	—	(1) 14	20				
Total other comprehensive income (loss)	42	167	206	(52)			
Comprehensive income	\$1,124	\$1,155	\$3,179	\$2,969				

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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,480	\$ 7,013
Debt securities available-for-sale	66	3,219
Equity investments with readily determinable fair values	1,832	1,810
Accounts receivable, net of allowances of \$39 and \$36 as of September 30, 2018 and December 31, 2017, respectively	2,120	1,921
Inventory	510	541
Other current assets	819	388
Total current assets	7,827	14,892
Property, plant and equipment, net	1,313	1,070
Intangible assets, net	16,342	8,436
Goodwill	8,004	4,866
Other non-current assets	729	877
Total assets	\$ 34,215	\$ 30,141
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	\$ 502	\$ —
Accounts payable	292	305
Accrued expenses and other current liabilities	2,705	2,523
Income taxes payable	105	84
Current portion of deferred revenue	79	75
Total current liabilities	3,683	2,987
Deferred revenue, net of current portion	74	34
Income taxes payable	2,451	2,490
Deferred income tax liabilities	2,811	1,327
Other non-current liabilities	594	544
Long-term debt, net of discount	19,742	15,838
Total liabilities	29,355	23,220
Commitments and Contingencies (See Note 15)		
Stockholders' Equity		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$.01 par value per share, 1,150.0 million shares authorized; issued 979.9 million and 971.7 million shares as of September 30, 2018 and December 31, 2017, respectively	10	10
Common stock in treasury, at cost; 281.0 million and 212.4 million shares as of September 30, 2018 and December 31, 2017, respectively	(26,315)	(20,243)
Additional paid-in capital	14,756	13,806
Retained earnings	16,486	13,061
Accumulated other comprehensive (loss) income	(77)	287
Total stockholders' equity	4,860	6,921

Total liabilities and stockholders' equity	\$ 34,215	\$ 30,141
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See accompanying Notes to Unaudited Consolidated Financial Statements

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CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in millions)

	Nine-Month Periods Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net income	\$2,973	\$3,021
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	119	100
Amortization	346	255
Impairment charges	30	51
Deferred income taxes	(10)	(195)
Change in value of contingent consideration and success payments	74	75
Net loss on sales of debt securities available-for-sale	18	—
Fair value adjustments on equity investments	(830)	(18)
Share-based compensation expense	731	482
Share-based employee benefit plan expense	33	35
Derivative instruments	(11)	14
Other, net	(14)	(18)
Change in current assets and liabilities, excluding the effect of acquisitions and disposals:		
Accounts receivable	(225)	(139)
Inventory	31	(37)
Other operating assets	(374)	(285)
Accounts payable and other operating liabilities	(66)	28
Income tax payable	(22)	165
Payment of contingent consideration	(22)	—
Deferred revenue	47	23
Net cash provided by operating activities	2,828	3,557
Cash flows from investing activities:		
Proceeds from sales of debt securities available-for-sale	3,383	3,290
Purchases of debt securities available-for-sale	(240)	(6,716)
Capital expenditures	(232)	(176)
Proceeds from sales of equity investment securities	96	32
Purchases of equity investment securities	(176)	(392)
Payments for acquisition of business, net of cash acquired	(8,648)	—
Other	—	(27)
Net cash (used in) investing activities	(5,817)	(3,989)
Cash flows from financing activities:		
Payment for treasury shares	(6,096)	(925)
Proceeds from short-term borrowing	5,709	—
Principal repayments on short-term borrowing	(5,710)	—
Proceeds from issuance of long-term debt	4,452	496
Principal repayments on current portion of long-term debt	—	(500)
Payment of contingent consideration	(40)	—
Net proceeds from share-based compensation arrangements	129	637
Net cash (used in) financing activities	(1,556)	(292)

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Effect of currency rate changes on cash and cash equivalents	12	65
Net (decrease) in cash and cash equivalents	(4,533)	(659)
Cash and cash equivalents at beginning of period	7,013	6,170
Cash and cash equivalents at end of period	\$2,480	\$5,511

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	Nine-Month Periods Ended September 30, 2017
Supplemental schedule of non-cash investing and financing activity:	
Change in net unrealized loss (gain) on debt securities available-for-sale/marketable securities available-for-sale	\$ 9 \$(673)
Investment in Celularity, Inc. common stock	— 22
Supplemental disclosure of cash flow information:	
Interest paid	581 461
Income taxes paid	974 450

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 New Accounting Standards

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 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[®]. 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 one of three methods: the equity method, as an investment without a readily determinable fair value or as an investment with a readily determinable fair value.

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.

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

Certain prior year amounts have been reclassified to conform to the current year's presentation. During the first quarter of 2018, we adopted Accounting Standards Update No. 2016-01, "Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU 2016-01). As such, we have recast our previously reported marketable securities available-for-sale of \$5,029 million on our Consolidated Balance Sheet as of December 31, 2017 to conform to the current year presentation as shown in the table below. There were no changes to total current assets or total assets as a result of this reclassification.

	December 31, 2017	
	As Reported	As Revised
Marketable securities available-for-sale	\$5,029	N/A
Debt securities available-for-sale	N/A	\$ 3,219
Equity investments with readily determinable fair values	N/A	1,810

In addition, as a result of adopting ASU 2016-01, we have also recast certain activity within our previously reported Consolidated Statement of Cash Flows for the nine-month period ended September 30, 2017 to conform to the current year presentation as shown in the table below. There were no changes to Net cash provided by operating activities, Net cash (used in) investing activities and Net cash (used in) financing activities as a result of this reclassification.

	Nine-Month Period Ended September 30, 2017	
	As Reported	As Revised
Purchases of marketable securities available-for-sale	\$(7,019)	N/A
Purchases of investment securities	(88)	N/A
Purchases of debt securities available-for-sale	N/A	\$(6,716)
Purchases of equity investment securities	N/A	(392)
Proceeds from sales of marketable securities available-for-sale	3,307	N/A
Proceeds from sales of investment securities	14	N/A
Proceeds from sales of debt securities available-for-sale	N/A	3,290
Proceeds from sales of equity investment securities	N/A	32

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our 2017 Annual Report on Form 10-K. Such significant accounting policies are applicable for periods prior to the adoption of the following new accounting standards.

New accounting standards which have been adopted

In May 2014, the Financial Accounting Standards Board (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 previous 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. See Note 2 for revenue recognition disclosures.

The new standard was effective for us on January 1, 2018 and we elected to adopt it using a modified retrospective transition method, which required a cumulative effect adjustment to opening retained earnings as of January 1, 2018. The implementation of ASU 2014-09 using the modified retrospective transition method did not have a material quantitative impact on our consolidated financial statements as the timing of revenue recognition did not significantly change. We also elected the following practical expedients, which were available to us as a result of utilizing the modified retrospective transition method:

• We applied the provisions of the standard only to contracts that were not completed as of January 1, 2018; and

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

We did not retrospectively restate contracts for contract modifications executed before the beginning of the earliest period presented.

In accordance with the transition provisions of ASU 2014-09, we recorded a cumulative effect adjustment of \$4 million to increase Retained earnings (net of a \$1 million tax effect). In limited instances, the new standard permits us to recognize revenue earlier than under the previous revenue recognition guidance. Historically, we deferred certain revenue where the transaction price pursuant to the underlying customer arrangement was not fixed or determinable. Under the new standard, such customer arrangements are accounted for as variable consideration, which results in revenue being recognized earlier provided we can reliably estimate the ultimate price expected to be realized from the customer. In addition, ASU 2014-09 requires companies who elect to adopt the standard using the modified retrospective transition method to disclose within the footnotes the effects of applying the provisions of the previous standards to current year financial statements. Revenue and Net income for the three- and nine-month periods ended September 30, 2018, do not differ materially from amounts that would have resulted from application of the previous standards.

In January 2016 and February 2018, the FASB issued ASU 2016-01 and Accounting Standards Update No. 2018-03, "Technical Corrections and Improvements to Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU-2018-03), respectively. 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. We have elected to measure all of our equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment or at net asset value (NAV), as a practical expedient, if available. Changes in measurement of equity investments without readily determinable fair values will be recognized in Net income. The guidance related to equity investments without readily determinable fair values, in which the practical expedient has not been elected, will be applied prospectively to equity investments that exist as of the date of adoption. For equity investments without a readily determinable fair value in which the NAV per share practical expedient is elected, ASU 2018-03 clarified that the transition should not be performed prospectively, but rather as a cumulative effect adjustment to opening Retained earnings as of the beginning of the fiscal year of adoption. Equity investments without readily determinable fair values are recorded within Other non-current assets on the Consolidated Balance Sheets. We have not elected the fair value option for financial liabilities with instrument-specific credit risk. 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 was effective for us on January 1, 2018 which required a cumulative effect adjustment to opening Retained earnings to be recorded for equity investments with readily determinable fair values and equity investments without readily determinable fair values in which the NAV per share practical expedient was elected. As of the adoption date, we held publicly traded equity investments with a fair value of approximately \$1.8 billion in a net unrealized gain position of \$875 million, and having an associated deferred tax liability of \$188 million. We recorded a cumulative effect adjustment of \$687 million to decrease Accumulated other comprehensive (loss) income (AOCI) with a corresponding increase to Retained earnings for the amount of unrealized gains or losses, net of tax as of the beginning of fiscal year 2018. In addition, we held an equity investment without a readily determinable fair value in which we elected the NAV per share practical expedient. As such, on January 1, 2018, we recorded an additional cumulative effect adjustment of \$59 million to increase Equity investments without readily determinable fair values as the NAV was in excess of our cost basis as of the adoption date with a corresponding increase to Retained earnings of \$44 million, net of the tax effect of \$15 million. As a result of the implementation of ASU 2016-01, effective on January 1, 2018 unrealized gains and

losses in equity investments with readily determinable fair values and equity investments without readily determinable fair values for which observable price changes for identical or similar (e.g. dividend rights, voting rights, etc.) investments occur are recorded on the Consolidated Statements of Income within Other (expense) income, net. We recorded a net loss of \$123 million and net gain of \$830 million in Other (expense) income, net for the three- and nine-month periods ended September 30, 2018, respectively, as a result of adopting this standard. The implementation of ASU 2016-01 is expected to increase volatility in our net income as the volatility previously recorded in Other comprehensive income (OCI) related to changes in the fair market value of available-for-sale equity investments will now be reflected in Net income effective with the adoption date.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, "Income Statement-Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income" (ASU 2018-02). The new standard is effective on January 1, 2019 with early adoption permitted. The guidance permits a reclassification from AOCI to Retained earnings for stranded tax effects resulting from U.S. tax reform legislation enacted in December 2017 (2017 Tax Act). We elected to early adopt ASU 2018-02 on January 1, 2018. We use a specific identification approach to release the income tax effects in AOCI. We have recast our previously reported Marketable securities available-for-sale on our Consolidated Balance

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

Sheet as of December 31, 2017 to conform to the current year presentation as outlined earlier in this Note 1. As a result of adopting this standard, we recorded a cumulative effect adjustment to increase AOCI by \$117 million with a corresponding decrease to Retained earnings. We recorded the impacts of adopting ASU 2018-02 prior to recording the impacts of adopting ASU 2016-01 and included state income tax related effects in the amounts reclassified to Retained earnings.

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 was effective for us in our first quarter of fiscal 2018 and did not result in any changes to the presentation of our Consolidated Statement of Cash Flows upon adoption.

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 was effective for us on January 1, 2018. As of the adoption date, we had net prepaid tax assets of \$166 million related to intra-entity transfers of assets other than inventory which was recorded in Other non-current assets. Using the modified retrospective approach, we recorded a cumulative effect adjustment of \$166 million to decrease Retained earnings with a corresponding decrease in prepaid tax assets as of the beginning of fiscal year 2018.

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 was effective for us on January 1, 2018 and was adopted on a prospective basis. In the first quarter of 2018, we acquired Impact Biomedicines Inc. (Impact) and Juno Therapeutics Inc. (Juno) which were accounted for as an asset acquisition and a business combination, respectively. See Note 3 for further information on the acquisitions of Impact and Juno. We anticipate that the adoption of this standard will result in more acquisitions being accounted for as asset acquisitions.

The following table presents a summary of cumulative effect adjustments to Retained earnings due to the adoption of new accounting standards on January 1, 2018 as noted above:

Cumulative
 Effect
 Adjustments
 to Retained
 Earnings on
 January 1,
 2018
 Increase /
 (Decrease)

Cumulative effect adjustment to Retained earnings due to the adoption of the following new accounting standards:

ASU 2014-09	\$ 4	
ASU 2016-01	687	
ASU 2018-03	44	
ASU 2018-02	(117)
ASU 2016-16	(166)
Net cumulative effect adjustments to Retained earnings on January 1, 2018 due to the adoption of new accounting standards	\$ 452	

New accounting standards which have not yet been adopted

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

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019. In July 2018, the FASB issued Accounting Standards Update No. 2018-11, "Leases" (ASU 2018-11), which offers a transition option to entities adopting the new lease standard. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. We will adopt the standard using the modified retrospective method. We are currently evaluating the effect that the updated standards will have on our consolidated financial statements and related disclosures. We are in the process of completing an analysis of our existing lease arrangements including our assessment of any embedded leases. We will continue to assess new lease arrangements throughout 2018. The new standard will have an impact on our consolidated financial statements and result in additional lease-related disclosures in the footnotes to our consolidated financial statements. We had aggregate future minimum lease payments of approximately \$235 million as of December 31, 2017 under our portfolio of non-cancelable leased office and research facilities. In addition, Juno had \$106 million of aggregate future minimum lease payments as of December 31, 2017. We anticipate recognition of additional assets and corresponding liabilities related to these leases on our consolidated balance sheet. 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 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.

2. Revenue

Subsequent to January 1, 2018 we account for revenue in accordance with ASU 2014-09, which we adopted using the modified retrospective method. See Note 1 for further discussion of the adoption, including the impact on our consolidated financial statements. The majority of our revenue is derived from product sales. Our commercial stage products include REVLIMID[®], POMALYST[®]/IMNOVID[®], OTEZLA[®], ABRAXANE[®], IDHIFA[®], VIDAZA[®], azacitidine for injection (generic version of VIDAZA[®]) and THALOMID[®] (sold as THALOMID[®] or Thalidomide Celgene[®] outside of the U.S.). In addition, we recognize revenue from other product sales and royalties based on licensees' sales of our products or products using our technologies. We do not consider royalty revenue to be a material source of our consolidated revenue. As such, the following disclosure only relates to revenue associated with net product sales.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the current revenue standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied.

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying our performance obligations, we consider all goods promised in the contract regardless of whether explicitly stated in the customer

contract or implied by customary business practices. Generally, our contracts with customers require us to transfer an individual distinct product, which would represent a single performance obligation. In limited situations, our contracts with customers will require us to transfer two or more distinct products, which would represent multiple performance obligations for each distinct product. For contracts with multiple performance obligations, we allocate the contract's transaction price to each performance obligation on a relative standalone selling price basis. In determining our standalone selling prices for our products, we utilize observable prices for our goods sold separately in similar circumstances and to customers in the same geographical region or market. Our performance obligations with respect to our product sales are satisfied at a point in time, which transfer control upon delivery of product to our customers. We consider control to have transferred upon delivery because the customer has legal title to the asset, we have transferred physical possession of the asset, the customer has significant risks and rewards of ownership of the asset, and in most instances we have a present right to payment at that time. The aggregate dollar value of unfulfilled orders as of September 30, 2018 was not material.

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

Distribution

REVLIMID[®], POMALYST[®] and THALOMID[®] are distributed in the United States primarily through contracted pharmacies under the REVLIMID Risk Evaluation and Mitigation Strategy (REMS), POMALYST REMS[®] and THALOMID REMS[®] programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID[®], POMALYST[®] and THALOMID[®]. Internationally, REVLIMID[®], THALOMID[®]/Thalidomide Celgene[®] and IMNOVID[®] are distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the product's safe and appropriate distribution and use. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. OTEZLA[®], ABRAXANE[®], ISTODAX[®], IDHIFA[®] and VIDAZA[®] are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID[®], POMALYST[®]/IMNOVID[®] and THALOMID[®]/Thalidomide Celgene[®].

Significant Payment Terms

Our contracts with our customers state the terms of the sale including the description, quantity, and price for each product purchased as well as the payment and shipping terms. Our contractual payment terms vary by jurisdiction. In the United States, our contractual payment terms are typically due in no more than 30 days. Sales made outside the United States typically have payment terms that are greater than 60 days, thereby extending collection periods beyond those in the United States. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less. Any exceptions to this are either not material or we collect interest from the customer for the time period between the invoice due date and the payment date. As such, we do not adjust the invoice amount for the effects of a significant financing component as the impact is not material to our consolidated financial statements.

Contract Balances

When the timing of our delivery of product is different from the timing of payments made by the customers, we recognize either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). There were no significant changes in our contract asset or liability balances during the three- and nine-month periods ended September 30, 2018 other than from transactions in the ordinary course of operating activities as described above.

Contract Assets

In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some or all of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. We reflect these contract assets as Other current assets on the Consolidated Balance Sheet. For example, certain of our contractual arrangements do not permit us to bill until the product is sold through to the end-customer. As of September 30, 2018, such contract assets were \$31 million. For the three- and nine-month periods ended September 30, 2018, we recognized revenue included in such contract assets of \$15 million and \$43 million, respectively.

Contract Liabilities

In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. We reflect these contract liabilities as Deferred revenue on our Consolidated Balance Sheet. For example, certain of our contractual arrangements provide the customer with free product after the customer has purchased a contractual minimum amount of product. We concluded the free product represents a future performance obligation in the form of a contractual material right. As such, we defer a portion of the transaction price as a contract liability upon each sale of product until the contractual minimum volume is achieved. As we satisfy our remaining performance obligations we release a portion of the deferred revenue balance. Revenue recognized for the three- and nine-month periods ended September 30, 2018 that was reflected in the deferred revenue balance at the beginning of the year was \$7 million and \$105 million, respectively. As of September 30, 2018, such contract liabilities were \$153 million.

Gross-to-Net Sales Adjustments

We record gross-to-net sales accruals for government rebates, chargebacks, distributor service fees, other rebates and administrative fees, sales returns and allowances, and sales discounts. Provisions for discounts, early payments, rebates, sales returns, distributor service fees and chargebacks under terms customary in the industry are provided for in the same period the related sales are recorded. We record estimated reductions to revenue for volume-based discounts and rebates at the time of the initial sale based

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

upon the sales terms, historical experience and trend analysis. We estimate these accruals using an expected value approach based primarily upon our historical rebate and discount payments made and the provisions included in current customer contracts and government regulations.

Government Rebates, including Medicaid and Medicare Rebates

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. In the U.S., we participate in state government Medicaid programs and other Federal and state government programs, which require rebates to participating government entities. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We also analyze actual billings received from the states to further support the accrual rates. Manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as costs are incurred. In certain international markets government-sponsored programs require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Chargebacks, Distributor Service Fees, Other Rebates and Administrative Fees

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are included in chargeback accruals and are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and administrative fees may generally occur from one to 15 months from the date of sale. We record a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

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

Returns, Refunds and Warranties

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. We do not provide warranties on our products to our customers unless the product is defective as manufactured or damaged in transit within a reasonable period of time after receipt of the product by the customer.

Sales Discounts

Sales discounts are based on payment terms extended to customers, which are generally offered as an incentive for prompt payment. We record our best estimate of sales discounts to which customers are likely to be entitled based on both historical information and current trends.

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

	Three-Month		Nine-Month	
	Periods Ended		Periods Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Gross Product Sales	\$4,654	\$3,799	\$13,431	\$11,042
Gross-to-Net Adjustments:				
Government Rebates	(249)	(198)	(809)	(632)
Chargebacks and Distributor Services Fees	(449)	(265)	(1,206)	(773)
Sales Discounts	(62)	(49)	(177)	(139)
Sales Returns and Allowances	(4)	(4)	(10)	(4)
Total Gross-to-Net Adjustments	(764)	(516)	(2,202)	(1,548)
Net Product Sales	\$3,890	\$3,283	\$11,229	\$9,494

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Total revenues from external customers by our franchises (Hematology / Oncology and Inflammation & Immunology), product and geography for the three- and nine-month periods ended September 30, 2018 and 2017 were as follows:

		Three-Month Periods Ended September 30, 2018		Nine-Month Periods Ended September 30, 2017	
Hematology / Oncology:					
REVLIMID®					
	U.S.	\$1,667	\$1,361	\$4,740	\$3,953
	International	782	720	2,396	2,046
	Worldwide	2,449	2,081	7,136	5,999
POMALYST®/IMNOVID®					
	U.S.	357	268	998	725
	International	156	149	475	447
	Worldwide	513	417	1,473	1,172
ABRAXANE®					
	U.S.	174	149	485	452
	International	114	102	308	289
	Worldwide	288	251	793	741
VIDAZA®					
	U.S.	2	1	7	5
	International	137	150	451	460
	Worldwide	139	151	458	465
All Other					
	U.S.	52	59	159	154
	International	17	16	50	55
	Worldwide	69	75	209	209
Total Hematology / Oncology:					
	U.S.	2,252	1,838	6,389	5,289
	International	1,206	1,137	3,680	3,297
	Worldwide	3,458	2,975	10,069	8,586
Inflammation & Immunology:					
OTEZLA®					
	U.S.	348	250	915	755
	International	84	58	245	153
	Worldwide	432	308	1,160	908
Total net product sales					
	U.S.	2,600	2,088	7,304	6,044
	International	1,290	1,195	3,925	3,450
	Worldwide	3,890	3,283	11,229	9,494
Other revenue					
		2	4	15	26

Total revenue	\$3,892	\$3,287	\$11,244	\$9,520
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CELGENE CORPORATION AND SUBSIDIARIES
 NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

3. Acquisitions and Divestitures

Acquisitions in Fiscal 2018:

Impact Biomedicines, Inc. (Impact): On February 12, 2018, we acquired all of the outstanding shares of Impact, a privately held biotechnology company which was developing fedratinib, a highly selective JAK2 kinase inhibitor, for myelofibrosis.

The consideration included an initial payment of approximately \$1.1 billion. In addition, the sellers of Impact are eligible to receive contingent consideration based upon regulatory approvals of up to \$1.4 billion and contingent consideration of up to \$4.5 billion based upon the achievement of sales in any four consecutive calendar quarters between \$1.0 billion and \$5.0 billion. The acquisition of Impact was concentrated in one single identifiable asset and thus, for accounting purposes, we have concluded that the acquired assets do not meet the accounting definition of a business. The initial payment was allocated primarily to fedratinib, resulting in a \$1.1 billion research and development asset acquisition expense and the balance of approximately \$7 million was allocated to the remaining net assets acquired.

Juno Therapeutics, Inc. (Juno): On March 6, 2018 (Acquisition Date), we acquired all of the outstanding shares of Juno, resulting in Juno becoming our wholly-owned subsidiary. Juno is developing CAR (chimeric antigen receptor) T and TCR (T cell receptor) therapeutics with a broad, novel portfolio evaluating multiple targets and cancer indications. The acquisition added a novel scientific platform and scalable manufacturing capabilities including JCAR017 and JCARH125, both directed CAR T therapeutics currently in programs for relapsed and/or refractory diffuse large B-cell lymphoma and relapsed/refractory multiple myeloma, respectively.

Total consideration for the acquisition was approximately \$10.4 billion, consisting of \$9.1 billion for common stock outstanding, \$966 million for the fair value of our investment in Juno and \$367 million for the portion of equity compensation attributable to the pre-combination service period. In addition, the fair value of the awards attributed to post-combination service period was \$666 million, which will be recognized as compensation expense over the requisite service period in our post-combination financial statements. We recognized \$87 million and \$487 million of post combination share-based compensation for the three- and nine-month periods ended September 30, 2018, respectively.

The acquisition has been accounted for as a business combination using the acquisition method of accounting which requires that assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and requires the fair value of acquired in-process research and development (IPR&D) to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. A preliminary purchase price allocation has been performed and the recorded amounts for intangible assets, net, goodwill and current and deferred tax assets and liabilities are subject to change pending finalization of valuation efforts and review of tax matters. Subsequent to the Acquisition Date, the Company has recorded certain measurement period adjustments that were not material. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the acquisition date.

The total consideration for the acquisition of Juno was \$10.4 billion, which consisted of the following:

	Total Consideration
Cash paid for outstanding common stock at \$87.00 per share	\$ 9,101
Celgene investment in Juno at \$87.00 per share ⁽¹⁾	966

Cash for equity compensation attributable to pre-combination service ⁽²⁾	367
Total consideration	\$ 10,434

⁽¹⁾ The Company recognized a gain of \$458 million during the first quarter of 2018, as a result of remeasuring to fair value the equity interest in Juno held by us before the business combination, which was recorded in Other (expense) income, net within the Consolidated Statement of Income. See Note 1 for further information on the adoption of ASU 2016-01.

⁽²⁾ All equity compensation attributable to pre-combination service was paid during the first quarter of 2018.

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The preliminary purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the Acquisition Date based upon their respective preliminary fair values summarized below:

	Amounts Recognized as of the Acquisition Date (Provisional)	
Working capital ⁽¹⁾	\$	437
In-process research and development (IPR&D)	6,980	
Technology platform intangible asset	1,260	
Property, plant and equipment, net	144	
Other non-current assets	46	
Deferred tax liabilities, net	(1,530)
Other non-current liabilities	(41)
Total identifiable net assets	7,296	
Goodwill	3,138	
Total net assets acquired	\$	10,434

⁽¹⁾ Includes cash and cash equivalents, debt securities available-for-sale, accounts receivable, net of allowances, other current assets, accounts payable, accrued expenses and other current liabilities (including accrued litigation). See Note 16 for litigation matters related to Juno.

The fair value assigned to acquired IPR&D was based on the present value of expected after-tax cash flows attributable to JCAR017, which is in a pivotal phase II trial and JCARH125. The present value of expected after-tax cash flows attributable to JCAR017 and JCARH125 assigned to IPR&D was determined by estimating the after-tax costs to complete development of JCAR017 and JCARH125 into commercially viable products, estimating future revenue and ongoing expenses to produce, support and sell JCAR017 and JCARH125, on an after-tax basis, and discounting the resulting net cash flows to present value. The revenue and costs projections used were reduced based on the probability that products at similar stages of development will become commercially viable products. The rate utilized to discount the net cash flows to their present value reflects the risk associated with the intangible asset and is benchmarked to the cost of equity. Acquired IPR&D will be accounted for as indefinite-lived intangible assets until regulatory approvals for JCAR017 and JCARH125 in a major market or discontinuation of development.

The excess of purchase price over the fair value amounts assigned to identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is primarily attributable to the broadening of our product portfolio and research capabilities in the hematology and oncology therapeutic area, the assembled workforce and the deferred tax consequences of the IPR&D asset recorded for financial statement purposes. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

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

Juno actual results for the three-month period ended September 30, 2018 and from the Acquisition Date through September 30, 2018, which are included in the Consolidated Statements of Income are as follows:

Classification in the Consolidated Statements of Income	Three-Month Acquisition	
	Period Ended	Date Through
	September 30, 2018	September 30, 2018
Other revenue	\$ 1	\$ 2
Research and development ⁽¹⁾	170	555
Selling, general and administrative ⁽¹⁾	46	256
Amortization of acquired intangible assets	21	49
Acquisition related charges and restructuring, net ⁽²⁾	49	98
Interest and investment income, net	2	5
Other (expense) income, net	4	15
Income tax provision (benefit), net	(63)	(146)
Total	\$ (216)	\$ (790)

⁽¹⁾ Includes share-based compensation expense related to the post-combination service period of \$58 million and \$29 million, which was recorded in Research and development and Selling, general and administrative expenses, respectively, for the three-month period ended September 30, 2018. Also includes share-based compensation expense related to the post-combination service period of \$291 million and \$196 million, which was recorded in Research and development and Selling, general and administrative expenses, respectively, for the period from the Acquisition Date through September 30, 2018.

⁽²⁾ Consists of acquisition related compensation expense, transaction costs and the change in fair value of contingent consideration and success payment liabilities. In addition, we incurred incremental acquisition costs related to Juno of nil and \$41 million for the three- and nine-month periods ended September 30, 2018 respectively.

Pro Forma Financial Information:

The following table provides unaudited pro forma financial information for the nine-month period ended September 30, 2018 and the three- and nine-month periods ended September 30, 2017 as if the acquisition of Juno had occurred on January 1, 2017.

	Nine-Month		Three-Month
	Periods Ended		Period
	September 30,		Ended
	2018	2017	September 30, 2017
Total revenue	\$ 11,254	\$ 9,545	\$ 3,311
Net income	2,947	2,361	868
Net income per common share: basic	\$ 4.08	\$ 3.02	\$ 1.11
Net income per common share: diluted	\$ 3.98	\$ 2.91	\$ 1.06

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of Celgene and Juno. The supplemental pro forma financial information reflects primarily the following pro forma adjustments:

Elimination of research related cost sharing transactions between Celgene and Juno;

The pro forma financial information assumes that the acquisition related transaction fees and costs, including post combination share-based compensation related to the acquisition, were removed from the three- and nine-month periods ended September 30, 2018 and were assumed to have been incurred during the first quarter of 2017;

The pro forma financial information assumes that the gain recognized as a result of remeasuring to fair value the equity interest we held in Juno prior to the business combination was removed from the nine-month period ended September 30, 2018 and was assumed to have been recognized during the first quarter of 2017;

Additional interest expense and amortization of debt issuance costs for a portion of the \$4.5 billion of debt that was issued in February 2018 to partially finance the acquisition;

Additional amortization expense on the acquired technology platform asset; and

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Statutory tax rates were applied, as appropriate, to each pro forma adjustment based on the jurisdiction in which the adjustment occurred.

The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings that may result from the combined operations of Celgene and Juno. Accordingly, these unaudited pro forma results are presented for illustrative purposes and are not intended to represent or be indicative of the actual results of operations of the combined company that would have been achieved had the acquisition occurred at the beginning of the periods presented, nor are they intended to represent or be indicative of future results of operations.

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.

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 Statements of Income in Other (expense) income, 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.

4. Earnings Per Share

	Three-Month		Nine-Month	
	Periods		Periods	Ended
	Ended		Ended	September 30,
	September		September	30,
	30,		30,	2018
	2018	2017	2018	2017
(Amounts in millions, except per share)				

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Net income		\$1,082	\$988	\$2,973	\$3,021
Weighted-average shares:					
Basic		702.0	784.1	722.0	781.2
Effect of dilutive securities:					
Options, restricted stock units, performance-based restricted stock units and other		17.7	31.1	18.4	31.4
Diluted		719.7	815.2	740.4	812.6
Net income per share:					
Basic		\$1.54	\$1.26	\$4.12	\$3.87
Diluted		\$1.50	\$1.21	\$4.02	\$3.72

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 41.0 million and 11.4 million shares for the three-month periods ended September

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

30, 2018 and 2017, respectively, and 43.2 million and 21.5 million shares for the nine-month periods ended September 30, 2018 and 2017, respectively.

Share Repurchase Program: In February and May 2018, our Board of Directors approved increases of \$5.0 billion and \$3.0 billion, respectively to our authorized share repurchase program, bringing the total amount authorized since April 2009 to \$28.5 billion of our common stock. As part of the existing Board authorized share repurchase program, in May 2018, we entered into an Accelerated Share Repurchase (ASR) agreement with a bank to repurchase an aggregate of \$2.0 billion of our common stock. As part of the ASR agreement, we received an initial delivery of approximately 18.0 million shares in May 2018 and a final delivery of approximately 6.0 million shares in August 2018. The total number of shares repurchased under the ASR agreement was 24.0 million shares at a weighted average price of \$83.53 per share.

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- and nine-month periods ended September 30, 2018 and 2017, there were no gains or losses from the sale of put options. As of September 30, 2018 and December 31, 2017, we had no outstanding put options.

Although there were no share repurchases during the three-month period ended September 30, 2018, we received approximately 6.0 million of our shares upon final settlement of the ASR agreement. We have purchased 67.8 million shares of common stock under the share repurchase program from all sources at a total cost of \$6.0 billion during the nine-month period ended September 30, 2018. As of September 30, 2018, we had a remaining share repurchase authorization of \$2.8 billion.

5. Accumulated Other Comprehensive (Loss) Income

During the third quarter of 2017, we adopted ASU 2017-12 on a modified retrospective basis. As a result of applying the new guidance during the nine-month period ended September 30, 2017, we recorded a cumulative effect adjustment of \$30 million to decrease AOCI as of the beginning of fiscal year 2017.

The components of other comprehensive (loss) income consist of changes in pension liability, changes in net unrealized gains (losses) on debt securities available-for-sale and equity investments with readily determinable fair values in 2017 and debt securities available-for-sale in 2018, 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.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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 Debt Securities / Marketable Securities ⁽¹⁾	Net Unrealized Gains (Losses) Related to Cash Flow Hedges	Amortization of Excluded Component Related to Cash Flow Hedges	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance as of December 31, 2017	\$ (22)	\$ 562	\$ (206)	\$ (15)	\$ (32)	\$ 287
Cumulative effect adjustment for the adoption of ASU 2016-01 and ASU 2018-02 (See Note 1)	—	(566)	(4)	—	—	(570)
Other comprehensive (loss) income before reclassifications, net of tax	—	(7)	182	(18)	(14)	143
Reclassified losses from accumulated other comprehensive income (loss), net of tax	—	14	26	23	—	63
Net current-period other comprehensive income (loss), net of tax	—	7	208	5	(14)	206
Balance as of September 30, 2018	\$ (22)	\$ 3	\$ (2)	\$ (10)	\$ (46)	\$ (77)
Balance as of December 31, 2016	\$ (38)	\$ 144	\$ 415	\$ —	\$ (102)	\$ 419
Cumulative effect adjustment for the adoption of ASU 2017-12	—	—	(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

⁽¹⁾ Balances as of December 31, 2017 are prior to the adoption of ASU 2016-01 and, as such, include equity securities with readily determinable fair values. Upon adoption of ASU 2016-01, we recorded a cumulative effect adjustment for our net unrealized gains related to our equity securities with readily determinable fair values as of January 1, 2018. Therefore, the unrealized gains (losses) position as of September 30, 2018 solely relate to debt securities available-for-sale. See Note 1 for further information related to the adoption of ASU 2016-01.

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Accumulated Other Comprehensive (Loss) Income Components	Classification in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive (Loss) Income			
		Three-Month Periods Ended September 30, 2018	Three-Month Periods Ended September 30, 2017	Nine-Month Periods Ended September 30, 2018	Nine-Month Periods Ended September 30, 2017
(Losses) gains related to cash-flow hedges:					
Foreign exchange contracts	Net product sales	\$14	\$7	\$(24)	\$174
Treasury rate lock agreements	Interest (expense)	(1)	(1)	(3)	(4)
Interest rate swap agreements	Interest (expense)	—	—	—	(1)
	Income tax provision - (expense) benefit	—	—	1	2
Excluded component related to cash-flow hedges:					
Foreign exchange contracts	Net product sales	(3)	5	(5)	10
(Losses) gains on available-for-sale debt securities / marketable securities ⁽¹⁾ :					
Realized gain (loss) on sales of debt securities / marketable securities	Interest and investment income, net	—	2	(18)	(32)
	Income tax provision - (expense) benefit	—	(1)	4	12
Total reclassification, net of tax		\$10	\$12	\$(45)	\$161

⁽¹⁾ (Losses) gains reclassified out of Accumulated other comprehensive (loss) income prior to December 31, 2017 are prior to the adoption of ASU 2016-01 and, as such, include equity securities with readily determinable fair values. Upon adoption of ASU 2016-01, we recorded a cumulative effect adjustment for our net unrealized gains related to our equity securities with readily determinable fair values as of January 1, 2018. Therefore, unrealized gains (losses) for the three- and nine-month periods ended September 30, 2018 solely relate to debt securities available-for-sale. See Note 1 for further information related to the adoption of ASU 2016-01.

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, 2018 and December 31, 2017 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 debt securities available-for-sale and equity investments with readily determinable fair values. 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 2017 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. From time to time, our level 2 assets consist 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). In addition, in connection with our acquisition of Juno in the first quarter of 2018, we assumed Juno's contingent consideration and success payment liabilities.

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

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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. The fair value of our contingent consideration as of September 30, 2018 and December 31, 2017 was calculated using the following significant unobservable inputs:

Inputs	Ranges (weighted average) utilized as of:	
	September 30, 2018	December 31, 2017
Discount rate	2.5% to 4.0% (3.2%)	2.7% to 12.0% (3.5%)
Probability of payment	0% to 68% (5%)	0% to 20% (4%)
Projected year of payment for development and regulatory milestones	2020 to 2029 (2024)	2020 to 2029 (2024)
Projected year of payment for sales-based milestones and other amounts calculated as a percentage of annual sales	N/A	2024 to 2030 (2028)

The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester, Avila, Quantice and those assumed in our acquisition of Juno are estimated to be approximately \$120 million, \$475 million, \$214 million and \$296 million, respectively, and \$1.8 billion plus other amounts calculated as a percentage of annual sales pursuant to the license agreement with Nogra.

Success payment obligations assumed through our acquisition of Juno are also recorded at their estimated fair values and are revalued quarterly. Changes in the fair value of contingent consideration and success payment obligations are recognized in Acquisition related charges and restructuring, net in the Consolidated Statements of Income.

Effective January 1, 2018, we adopted ASU 2016-01. Among other provisions, the new standard required modifications to existing presentation and disclosure requirements on a prospective basis. Certain disclosures as of December 31, 2017 below conform to the disclosure requirements of ASU 2016-01. See Note 1 for additional information related to the adoption of ASU 2016-01.

The following tables present the Company's hierarchy for its assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017:

Balance as of September 30, 2018	Fair Value Measurements as of September 30, 2018		
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

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Assets:				
Debt securities available-for-sale	\$ 66	\$—	\$ 66	\$ —
Equity investments with readily determinable fair values	1,832	1,832	—	—
Forward currency contracts	61	—	61	—
Purchased currency options	28	—	28	—
Total assets	\$ 1,987	\$ 1,832	\$ 155	\$ —
Liabilities:				
Contingent value rights	\$ (69)	\$ (69)	\$ —	\$ —
Interest rate swaps	(37)	—	(37)	—
Written currency options	(47)	—	(47)	—
Other acquisition related contingent consideration and success payments	(169)	—	—	(169)
Total liabilities	\$ (322)	\$ (69)	\$ (84)	\$ (169)

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Balance as of December 31, 2017	Fair Value Measurements as of December 31, 2017		
		Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt securities available-for-sale	\$ 3,219	\$—	\$ 3,219	\$ —
Equity investments with readily determinable fair values	1,810	1,810	—	—
Purchased currency options	36	—	36	—
Total assets	\$ 5,065	\$1,810	\$ 3,255	\$ —
Liabilities:				
Contingent value rights	\$ (42)	\$(42)	\$ —	\$ —
Forward currency contracts	(42)	—	(42)	—
Interest rate swaps	(7)	—	(7)	—
Written currency options	(172)	—	(172)	—
Other acquisition related contingent consideration	(80)	—	—	(80)
Total liabilities	\$ (343)	\$(42)	\$ (221)	\$ (80)

As of result of the implementation of ASU 2016-01 and ASU 2018-03, effective on January 1, 2018, we measure equity investments without a readily determinable fair value at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer or at NAV, as a practical expedient, if available. We record upward adjustments, downward adjustments and impairments of equity investments without readily determinable fair values within Other (expense) income, net on the Consolidated Statements of Income. The following table represents a roll-forward of equity investments without readily determinable fair values:

	Nine-Month Period Ended September 30, 2018
Balance as of December 31, 2017	\$ 513
Cumulative effect adjustment for the adoption of ASU 2018-03 (See Note 1)	59
Purchases	55
Upward adjustments	41
Sales	(23)
Downward adjustments and impairments	(117)
Transfer to readily determinable fair value	(41)
Balance as of September 30, 2018	\$ 487

For equity investments with and without readily determinable fair values held as of September 30, 2018, we recorded a net unrealized loss of \$123 million and a net unrealized gain of \$312 million within Other (expense) income, net on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2018, respectively.

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

There were no security transfers between levels 1, 2 and 3 during the three-month periods ended September 30, 2018 and 2017. The following table represents a roll-forward of the fair value of level 3 instruments:

	Three-Month Period Ended September 30, 2018
Liabilities:	
Balance as of June 30, 2018	\$ (193)
Net change in fair value	(46)
Settlements, including transfers to Accrued expenses and other current liabilities	70
Balance as of September 30, 2018	\$ (169)
	Three-Month Period Ended September 30, 2017
Liabilities:	
Balance as of June 30, 2017	\$ (1,488)
Net change in fair value	(36)
Settlements, including transfers to Accrued expenses and other current liabilities	43
Balance as of September 30, 2017	\$ (1,481)

There were no security transfers between levels 1, 2 and 3 during the nine-month periods ended September 30, 2018 and 2017. The following table represents a roll-forward of the fair value of level 3 instruments:

	Nine-Month Period Ended September 30, 2018
Liabilities:	
Balance as of December 31, 2017	\$ (80)
Amounts acquired from Juno, including measurement period adjustments	(116)
Net change in fair value	(45)
Settlements, including transfers to Accrued expenses and other current liabilities	72
Balance as of September 30, 2018	\$ (169)
	Nine-Month Period Ended September 30, 2017
Liabilities:	
Balance as of December 31, 2016	\$ (1,490)
Net change in fair value	(53)

Settlements, including transfers to Accrued expenses and other current liabilities	62
Balance as of September 30, 2017	\$ (1,481)

As previously reported in our 2017 Annual Report on Form 10-K, we reduced our contingent consideration liabilities related to Nogra by \$1,397 million due to the discontinuance of the GED-0301 phase III REVOLVE (CD-002) trial in Crohn's disease and the SUSTAIN (CD-004) extension trial in the fourth quarter of 2017.

7. Derivative Instruments and Hedging Activities

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.

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, 2018 and December 31, 2017 had settlement dates within 33 months and 20 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 Statements 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. 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.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of September 30, 2018 and December 31, 2017:

	Notional Amount	
	September 30, 2018	December 31, 2017
Australian Dollar	\$55	\$ 61
British Pound	120	97
Canadian Dollar	198	227
Euro	1,749	954
Japanese Yen	454	356
Total	\$2,576	\$ 1,695

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, 2018, 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) income, net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding as of September 30, 2018 and December 31, 2017 were \$621 million and \$885 million, respectively.

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

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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, 2018 and December 31, 2017 had settlement dates within 27 months and 36 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, 2018 and December 31, 2017:

	Notional Amount (1)	
	September 30, 2018	December 31, 2017
Foreign currency option contracts designated as hedging activity:		
Purchased Put	\$ 1,964	\$ 3,319
Written Call	2,250	3,739

(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 amount of nil and \$258 million as of September 30, 2018 and December 31, 2017, respectively. We de-designated all of our put option contracts as of September 30, 2018.

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, 2018 and December 31, 2017, we did not have any outstanding forward starting swaps or treasury rate locks.

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 Statements of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheets. 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 Statements of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheets. 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, 2018 and December 31, 2017:

	Notional Amount	
	September 30, 2018	December 31, 2017
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
3.450% senior notes due 2027	550	250
3.900% senior notes due 2028	200	—
Total	\$950	\$ 450

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2018 and 2017, and also terminated the hedging relationship by settling certain of those swap contracts during 2018 and 2017. In 2018, we settled \$150 million notional amount of certain swap contracts. There were no material cash proceeds as a result of settling such swap contracts. During 2017, we terminated the hedging relationship on certain outstanding swap contracts amounting to \$200 million notional amount by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of \$3 million during the year ended December 31, 2017, which are 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, 2018 and December 31, 2017:

Instrument	Balance Sheet Location	September 30, 2018	
		Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts ⁽¹⁾	Other current assets	\$60	\$ 24
	Accrued expenses and other current liabilities	4	4
	Other non-current assets	41	25
	Other non-current liabilities	13	27
Interest rate swap agreements	Other current assets	8	—
	Other non-current liabilities	—	46
Derivatives not designated as hedging instruments:			
Foreign exchange contracts ⁽¹⁾	Other current assets	17	3
	Accrued expenses and other current liabilities	3	13
Interest rate swap agreements	Other current assets	1	—
	Other non-current assets	7	7
Total		\$154	\$ 149

⁽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	Balance Sheet Location	December 31, 2017	
		Fair Value Asset	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts ⁽¹⁾	Other current assets	\$ 5	\$ 1
	Accrued expenses and other current liabilities	30	79
	Other non-current assets	1	—
	Other non-current liabilities	36	159
Interest rate swap agreements	Other current assets	3	—
	Other non-current liabilities	—	11
Derivatives not designated as hedging instruments:			
Foreign exchange contracts ⁽¹⁾	Other current assets	8	1
	Accrued expenses and other current liabilities	4	22
Interest rate swap agreements	Other current assets	2	2
	Other non-current assets	4	3
Total		\$ 93	\$ 278

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

As of September 30, 2018 and December 31, 2017, the following amounts were recorded on the Consolidated Balance Sheets 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, 2018 ⁽¹⁾	December 31, 2017 ⁽¹⁾	September 30, 2018 ⁽²⁾	December 31, 2017 ⁽²⁾
Current portion of long-term debt, net of discount	\$ 502	\$ —	\$ 3	\$ —
Long-term debt, net of discount	8,202	7,270	67	128

⁽¹⁾ The current portion of long-term debt, net of discount, includes \$502 million of carrying value with discontinued hedging relationships at September 30, 2018. The Long-term debt, net of discount includes approximately \$3.3 billion and \$3.8 billion of carrying value with discontinued hedging relationships as of September 30, 2018 and December 31, 2017, respectively.

⁽²⁾ The current portion of long-term debt, net of discount, includes \$3 million of discontinued hedging relationships at September 30, 2018. The Long-term debt, net of discount includes \$113 million and \$139 million of hedging adjustment on discontinued hedging relationships on long-term debt as of September 30, 2018 and December 31,

2017, respectively.

The following tables summarize the effect of derivative instruments designated as cash flow hedging instruments in AOCI for the three-month periods ended September 30, 2018 and 2017:

Three-Month Period Ended September 30, 2018

Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative (1)	Classification of Gain/(Loss) Recognized in OCI on Derivative	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 on Derivative Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts	\$54	Net product sales	\$ 14	Net product sales	\$ (3)
Treasury rate lock agreements	—	Interest (expense)	(1)	N/A	—

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

(1) Net gains of \$14 million are expected to be reclassified from AOCI into income in the next 12 months.

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 Effectiveness Testing	Amount of Gain/(Loss) Recognized in Income on Derivative Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts	\$ (130)	Net product sales	\$ 7	Net product sales Other (expense) income, net	\$ 5 (8)
Treasury rate lock agreements	—	Interest (expense)	(1)	N/A	—
Interest rate swap agreements	(1)	Interest (expense)	—	N/A	—

The following tables summarize the effect of derivative instruments designated as cash flow hedging instruments in AOCI for the nine-month periods ended September 30, 2018 and 2017:

Nine-Month Period Ended September 30, 2018

Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative (1)	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 Effectiveness Testing	Amount of Gain/(Loss) Recognized in Income on Derivative Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts	\$ 185	Net product sales	\$ (24)	Net product sales	\$ (5)
Treasury rate lock agreements	(4)	Interest (expense)	(3)	N/A	—

(1) Net gains of \$14 million are expected to be reclassified from AOCI into income in the next 12 months.

Nine-Month Period Ended September 30, 2017

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

(1) 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 which \$18 million related to the cumulative effect adjustment related to the adoptions of ASU 2017-12. There were no excluded components for our treasury rate lock and interest rate swap agreements.

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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, 2018 and 2017:

Instrument	Classification of (Loss)/Gain Recognized in Income on Derivative	Amount of (Loss)/Gain Recognized in Income on Derivative			
		Three-Month Periods Ended September 30, 2018	Three-Month Periods Ended September 30, 2017 ⁽¹⁾	Nine-Month Periods Ended September 30, 2018 ⁽¹⁾	Nine-Month Periods Ended September 30, 2017 ⁽¹⁾
Interest rate swap agreements	Interest (expense)	\$(1)	\$ 9	\$(8)	\$ 30

⁽¹⁾ The amounts include a benefit of \$8 million and \$9 million for the three-month periods ending September 30, 2018 and 2017, respectively and a benefit of \$24 million and \$27 million for the nine-month periods ending September 30, 2018 and 2017, respectively, 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.

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, 2018 and 2017:

Instrument	Classification of Gain/(Loss) Recognized in Income on Derivative	Classification of Gain/(Loss) Recognized in Income on Derivative			
		Three-Month Periods Ended September 30, 2018	Three-Month Periods Ended September 30, 2017	Nine-Month Periods Ended September 30, 2018	Nine-Month Periods Ended September 30, 2017
Foreign exchange contracts	Other (expense) income, net	\$9	\$(5)	\$18	\$(47)

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) income, 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, 2018		
	Net product sales	Interest (expense)	Other (expense) income, 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	\$3,890	\$ (193)	\$ (117)
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships			
Interest rate swap agreements:			
Hedged items	—	10	—
Derivatives designated as hedging instruments ⁽¹⁾	—	(1)	—
Gain (loss) on cash flow hedging relationships			
Foreign exchange contracts:			
Amount of gain or (loss) reclassified from AOCI into income	14	—	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	3	—	—
Reclassification adjustment for excluded component (loss) gain	(6)	—	—
Treasury rate lock agreements:			
Amount of gain or (loss) reclassified from AOCI into income	—	(1)	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	—	—	—

⁽¹⁾ The amounts include a benefit of \$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 period ending September 30, 2018.

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
Net Interest Other
product (expense) (expense)
sales income,

			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)	\$ —
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships			
Interest rate swap agreements:			
Hedged items	—	—	—
Derivatives designated as hedging instruments ⁽¹⁾	—	9	—
Gain (loss) on cash flow hedging relationships			
Foreign exchange contracts:			
Amount of gain or (loss) reclassified from AOCI into income	7	—	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	5	—	(8)
Treasury rate lock agreements:			
Amount of gain or (loss) reclassified from AOCI into income	—	(1)	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	—	—	—

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

⁽¹⁾ The amounts include a benefit of \$9 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 period ending September 30, 2017.

	Classification and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Nine-Month Period Ended September 30, 2018		
	Net product sales	Interest (expense)	Other (expense) income, 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	\$ 11,229	\$ (551)	\$ 852
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships			
Interest rate swap agreements:			
Hedged items	—	35	—
Derivatives designated as hedging instruments ⁽¹⁾	—	(8)	—
Gain (loss) on cash flow hedging relationships			
Foreign exchange contracts:			
Amount of gain or (loss) reclassified from AOCI into income	(24)	—	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	18	—	—
Reclassification adjustment for excluded component (loss) gain	(23)	—	—
Treasury rate lock agreements:			
Amount of gain or (loss) reclassified from AOCI into income	—	(3)	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	—	—	—

⁽¹⁾ The amounts include a benefit of \$24 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 period ending September 30, 2018.

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 Nine-Month Period Ended September 30, 2017		
	Net product sales	Interest (expense)	Other (expense) income, 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	\$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⁾	—	30	—
Gain (loss) on cash flow hedging relationships			
Foreign exchange contracts:			
Amount of gain or (loss) reclassified from AOCI into income	174	—	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / changes in fair value	10	—	—
Treasury rate lock agreements:			
Amount of gain or (loss) reclassified from AOCI into income	—	(4)	—
Amount excluded from effectiveness testing recognized using a systematic and rational amortization approach / 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 using a systematic and rational amortization approach / changes in fair value	—	—	—

⁽¹⁾ The amounts include a benefit of \$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 nine-month period ending September 30, 2017.

8. Cash, Cash Equivalents, Debt Securities Available-for-Sale and Equity Investments with Readily Determinable Fair Values

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, 2018, the carrying value of our time deposits and repurchase agreements was \$38 million and money market funds was \$1.5 billion, all of which are included in Cash and cash equivalents. As of December 31, 2017, the carrying value of our time deposits and repurchase agreements was \$1.2 billion, commercial paper instruments was \$35 million, and money market funds

was \$4.5 billion, all of which were included in Cash and cash equivalents. The carrying values approximated fair value as of September 30, 2018 and December 31, 2017.

Effective January 1, 2018, we adopted ASU 2016-01. Among other provisions, the new standard required modifications to existing presentation and disclosure requirements on a prospective basis. As such, certain disclosures as of December 31, 2017 below conform to the disclosure requirements prior to the adoption of ASU 2016-01. See Note 1 for additional information related to the adoption of ASU 2016-01.

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

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of debt securities available-for-sale by major security type and class of security and equity investments with readily determinable fair values as of September 30, 2018 and December 31, 2017 were as follows:

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
September 30, 2018				
Ultra short income fund	\$ 25	\$ —	—\$	—\$ 25
Time deposits ⁽¹⁾ and Repurchase agreements ⁽¹⁾	41	—	—	41
Total debt securities available-for-sale	\$ 66	\$ —	—\$	—\$ 66
December 31, 2017				
U.S. Treasury securities	\$ 445	\$ —	\$ (3)	\$ 442
U.S. government-sponsored agency securities	42	—	—	42
U.S. government-sponsored agency MBS	17	—	—	17
Corporate debt - global	2,080	—	(5)	2,075
Asset backed securities	203	—	(1)	202
Ultra short income fund	352	—	—	352
Time deposits ⁽¹⁾ and Repurchase agreements ⁽¹⁾	89	—	—	89
Total debt securities available-for-sale	\$ 3,228	\$ —	\$ (9)	\$ 3,219
Equity securities with readily determinable fair values	\$ 935	\$ 881	\$ (6)	\$ 1,810

⁽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, 2018, all of our time deposits and repurchase agreements had original maturities less than one year.

Equity securities with readily determinable fair values, which consist of investments in publicly traded equity securities, were \$1,832 million as of September 30, 2018.

Duration periods of debt securities available-for-sale as of September 30, 2018 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	\$ 66	\$ 66

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

9. Inventory

Inventories as of September 30, 2018 and December 31, 2017 are summarized by major category as follows:

	September 30, 2018	December 31, 2017
Raw materials	\$ 298	\$ 289
Work in process	87	89
Finished goods	125	163
Total inventory	\$ 510	\$ 541

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, Quantice and Juno acquisitions. The remaining weighted-average amortization period for finite-lived intangible assets not fully amortized is approximately 8.9 years. Our indefinite lived intangible assets consist of acquired IPR&D product rights from the Receptos Inc. (Receptos), Gloucester and Juno acquisitions.

The gross carrying amount and accumulated amortization of intangible assets as of September 30, 2018 and December 31, 2017 are summarized as follows:

September 30, 2018	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$ 3,406	\$ (2,174)) \$ 1,232
Technology	1,743	(513)) 1,230
Licenses	66	(33)) 33
Other	54	(38)) 16
	5,269	(2,758)) 2,511
Non-amortizable intangible assets:			
Acquired IPR&D product rights	13,831	—) 13,831
Total intangible assets	\$ 19,100	\$ (2,758)) \$ 16,342
December 31, 2017	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$ 3,406	\$ (1,939)) \$ 1,467
Technology	483	(410)) 73
Licenses	66	(30)) 36
Other	43	(34)) 9
	3,998	(2,413)) 1,585
Non-amortizable intangible assets:			
Acquired IPR&D product rights	6,851	—) 6,851
Total intangible assets	\$ 10,849	\$ (2,413)) \$ 8,436

The increase in the gross carrying value of intangible assets during the nine-month period ended September 30, 2018 was primarily due to the addition of approximately \$7.0 billion of IPR&D and \$1.3 billion of a technology platform asset from the Juno acquisition. The economic useful life of the technology platform asset is 15 years (see Note 3).

Amortization expense related to intangible assets was \$129 million and \$81 million for the three-month periods ended September 30, 2018 and 2017, respectively and \$346 million and \$255 million for the nine-month periods ended September 30, 2018 and 2017. Effective for the second quarter of 2018, we reduced the remaining estimated useful life of our ABRAXANE® intangible assets, which will result in full amortization by 2022 in conjunction with the recent settlements of patent-related proceedings (see

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Note 16). 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 \$474 million in 2018, \$442 million in 2019, \$440 million in 2020, \$438 million in 2021 and \$179 million in 2022.

Goodwill: The carrying value of goodwill increased to approximately \$8.0 billion as of September 30, 2018 compared to December 31, 2017 due to the acquisition of Juno (see Note 3).

11. Debt

Short-Term Borrowings and Current Portion of Long-Term Debt: The carrying value of Short-term borrowings and current portion of long-term debt as of September 30, 2018 and December 31, 2017 includes:

	September 30, December 31,	
	2018	2017
2.250% senior notes due 2019	\$ 502	\$ —
Total short-term borrowings and current portion of long-term debt	\$ 502	\$ —

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after September 30, 2018 have an aggregate principal amount of \$19.850 billion with varying maturity dates and interest rates. The carrying values of the long-term portion of these senior notes as of September 30, 2018 and December 31, 2017 includes:

	September 30, 2018	December 31, 2017
2.250% senior notes due 2019	\$ —	\$ 505
2.875% senior notes due 2020	1,496	1,495
3.950% senior notes due 2020	510	514
2.250% senior notes due 2021	498	497
2.875% senior notes due 2021	498	—
3.250% senior notes due 2022	1,037	1,044
3.550% senior notes due 2022	995	994
2.750% senior notes due 2023	747	746
3.250% senior notes due 2023	993	—
4.000% senior notes due 2023	732	737
3.625% senior notes due 2024	1,001	1,001
3.875% senior notes due 2025	2,472	2,478
3.450% senior notes due 2027	968	991
3.900% senior notes due 2028	1,483	—
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	1,975
4.350% senior notes due 2047	1,234	1,234
4.550% senior notes due 2048	1,476	—
Total long-term debt	\$ 19,742	\$ 15,838

As of September 30, 2018 and December 31, 2017, the fair value of our outstanding Senior Notes was approximately \$19.8 billion and \$16.6 billion, respectively, and represented a level 2 measurement within the fair value measurement hierarchy.

Debt Issuance: In February 2018, we issued \$500 million principal amount of 2.875% senior notes due 2021 (2021 Notes), \$1.000 billion principal amount of 3.250% senior notes due 2023 (2023 Notes), \$1.500 billion principal amount of 3.900% senior notes due 2028 (2028 Notes) and \$1.500 billion principal amount of 4.550% senior notes due 2048 (2048 Notes). The 2021 Notes, 2023 Notes, 2028 Notes and 2048 Notes were issued at 99.954%, 99.758%, 99.656% and 99.400% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

\$32 million were recorded as a direct deduction from the carrying amount of the 2021 Notes, 2023 Notes, 2028 Notes and 2048 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 19 and August 19 of each year, beginning August 19, 2018 and the principal is due in full at the maturity date. Interest on the 2023 Notes, 2028 Notes and 2048 Notes is payable semi-annually in arrears on February 20 and August 20 of each year, beginning August 20, 2018 and the principal is due in full at the maturity date. The 2021 Notes, 2023 Notes, 2028 Notes and 2048 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 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 10 basis points for the 2021 Notes, 15 basis points for the 2023 Notes, 20 basis points for the 2028 Notes and 25 basis points for the 2048 Notes. 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, 2023 Notes, 2028 Notes and 2048 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.

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, 2018, and December 31, 2017 a balance of \$32 million and \$31 million, respectively, in net losses remained in Accumulated OCI 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, 2018, 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, 2018 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, 2018 and December 31, 2017, we had balances of \$116 million and \$139 million, respectively, of 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: As of September 30, 2018 and December 31, 2017, we had available capacity to issue up to \$2.0 billion of Commercial Paper. As of September 30, 2018 and December 31, 2017, 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 2018, we amended our Credit Facility to extend the expiration date to April 25, 2023. 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, 2018 and December 31, 2017, 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, 2018.

12. Share-Based Compensation

We have stockholder-approved stock incentive plans, the Celgene Corporation 2017 Stock Incentive Plan and the 2014 Equity Incentive Plan (formerly known as the Juno Therapeutics, Inc. 2014 Equity Incentive Plan) (collectively, the Plans) that provide for the granting of options, restricted stock units (RSUs), performance stock units (PSUs) and other share-based and performance-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 Plans.

Shares of common stock available for future share-based grants under the 2014 Equity Incentive Plan were 13.9 million at the Acquisition Date.

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, 2018 and 2017:

	Three-Month Periods Ended September 30, 2018		Nine-Month Periods Ended September 30, 2017	
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 9	\$ 7	\$ 27	\$ 22
Research and development ⁽¹⁾	125	65	481	200
Selling, general and administrative ⁽²⁾	104	87	415	260
Total share-based compensation expense	238	159	923	482
Tax benefit related to share-based compensation expense	53	49	127	136
Reduction in net income	\$ 185	\$ 110	\$ 796	\$ 346

⁽¹⁾ The three- and nine-month periods ended September 30, 2018 include Juno related share-based compensation expense related to the post-combination service period of \$58 million and \$291 million, respectively.

⁽²⁾ The three- and nine-month periods ended September 30, 2018 include Juno related share-based compensation expense related to the post-combination service period of \$29 million and \$196 million, respectively.

The tax benefit related to share-based compensation expense above excludes excess tax benefits of \$6 million and \$103 million from share-based compensation awards that vested or were exercised during the three-month periods ended September 30, 2018 and 2017, respectively, and \$22 million and \$273 million for the nine-month periods ended September 30, 2018, and 2017, respectively.

The following table summarizes the activity for stock options, RSUs and PSUs for the nine-month period ended September 30, 2018 (in millions unless otherwise noted):

	Stock Options	RSUs	PSUs (in thousands)
Outstanding as of December 31, 2017	67.8	7.7	558
Changes during the Year:			
Conversion of Juno awards	3.7	2.5	336
Granted	9.9	3.7	180
Exercised / Released	(5.5)	(2.5)	(292)
Forfeited	(3.2)	(0.8)	(61)
Outstanding as of September 30, 2018	72.7	10.6	721

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, 2018 were as follows (dollars in millions):

	Stock Options	RSUs	PSUs
Unrecognized compensation cost	\$ 607	\$ 486	\$ 36
Expected weighted-average period in years of compensation cost to be recognized	2.2	1.7	1.3

13. Income Taxes

We adopted ASU 2016-01, ASU 2016-16 and ASU 2018-02, effective January 1, 2018. See Note 1 for additional information related to the adoption of these accounting standard updates.

The 2017 Tax Act was enacted on December 22, 2017 which reduced the U.S. statutory tax rate from 35% to 21% beginning in 2018. The 2017 Tax Act requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and introduces a new U.S. tax on certain off-shore earnings referred to as Global Intangible Low-Taxed Income (GILTI) beginning in 2018.

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

We are applying the guidance issued by the Securities and Exchange Commission (SEC) in Staff Accounting Bulletin 118 when accounting for the enactment-date effects of the 2017 Tax Act. The guidance provides for a measurement period up to one year in which provisional amounts may be adjusted as an income tax expense or benefit in the period the adjustment is determined.

As of September 30, 2018, we have not completed our accounting for the tax effects of the 2017 Tax Act. During the quarter ended September 30, 2018, guidance was released by U.S. tax authorities related to certain aspects of the 2017 Tax Act. As a result of our analysis of this guidance, we recorded income tax expense of \$36 million as an adjustment to the provisional amounts previously recorded for the one-time transition tax. We will continue to analyze the impact of the 2017 Tax Act during the accounting measurement period. Our actual results may materially differ from our current estimates due to, among other things, further guidance that may be issued by U.S. tax authorities or regulatory bodies to interpret the 2017 Tax Act.

The FASB allows companies to adopt an accounting policy to either recognize deferred taxes for GILTI or treat such as a tax cost in the year incurred. We have not yet determined our tax accounting policy and we have included in current income tax expense an amount related to our estimate of 2018 current year GILTI.

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.

We regularly re-evaluate 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, 2018 gross unrecognized tax benefits increased by \$311 million, including interest, primarily due to prior year tax positions. Of this amount, \$94 million was an increase to income tax expense during the nine-month period ended September 30, 2018 and the remainder were adjustments to non-current assets and non-current liabilities. 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

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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.

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 2017 Annual Report on Form 10-K. The following is a brief description for notable new collaborations and for those collaborations which we have described in detail in our 2017 Annual Report on Form 10-K if there has been significant activity during the nine-month period ended September 30, 2018. Amounts related to collaborations that are not specifically presented are included in the aggregate as Other Collaboration Arrangements.

Agios Pharmaceuticals, Inc. (Agios):

In September 2018, we terminated our joint worldwide development and profit share collaboration with Agios for AG-881 entered into during 2015. Our 2016 collaboration agreement with Agios remains in effect, which focuses on the research and development of immunotherapies against certain metabolic targets that exert their antitumor efficacy primarily via the immune system. We have retained our equity interest in Agios and exclusive license to IDHIFA[®] (enasidenib).

Lycera Corp. (Lycera):

In June 2018, our collaboration and option agreement with Lycera expired. As a result, we do not have an exclusive right to acquire Lycera. We have retained our equity interest in Lycera, an exclusive license for Lycera's portfolio of novel ex-vivo ROR agonist compounds and an exclusive license for Lycera's ROR antagonist compounds.

Prothena Corporation plc (Prothena):

On March 20, 2018, we entered into a collaboration agreement with Prothena to develop new therapies for a broad range of neurodegenerative diseases. The collaboration is focused on three proteins implicated in the pathogenesis of several neurodegenerative diseases, including tau, TDP-43 and an undisclosed target. In addition, we purchased approximately 1.2 million of Prothena's ordinary shares. We made a total payment of \$150 million, which was accounted for as a \$40 million equity investment with a readily determinable fair value and \$110 million as upfront collaboration consideration that was expensed immediately as research and development.

For each of the programs, we have an exclusive right to license clinical candidates in the U.S. at the investigational new drug (IND) filing and if exercised, would also have a right to expand the license to global rights at the completion of Phase 1. Following the exercise of global rights, we will be responsible for funding all further global clinical development and commercialization. Prothena may receive future potential exercise payments and regulatory and commercial milestones for each licensed program. Prothena will also receive additional royalties on net sales of any resulting marketed products.

The collaboration agreement has an initial term of six years, which may be extended up to two additional years. The collaboration agreement may be terminated at our discretion upon 60 days prior written notice to Prothena and by either party upon material breach of the other party, subject to cure periods.

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A financial summary of certain period activity and the period-end balances related to Prothena is presented below ⁽¹⁾:
 Nine-Month Period 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
2018	\$ 110	\$ —	\$ —	\$ 40
Balances as of:	Intangible Asset Balance	Equity Investment Balance	Percentage of Outstanding Equity	
September 30, 2018	\$ —	\$ 15	2.9 %	

⁽¹⁾ There was no collaboration activity related to Prothena during the three-month period ended September 30, 2018. In addition to the expenses noted in the table above, we may also incur expenses for collaboration agreement related activities that are managed or funded by us.

Vividion Therapeutics, Inc. (Vividion):

On March 1, 2018, we entered into a collaboration agreement with Vividion for the identification and development of small molecules against targets for a range of oncology, inflammatory and neurodegenerative indications. In addition, we purchased an immaterial amount of Vividion's Series A-3 preferred shares. We made a total upfront payment of \$101 million, which was accounted for as a \$4 million equity investment without a readily determinable fair value and \$97 million as upfront collaboration consideration that was expensed immediately as research and development.

Vividion will lead initial discovery efforts and identification of programs to be included in the collaboration, and we have the right to opt in on certain programs at a defined stage of development. For certain programs, including the first program, we will have the exclusive worldwide rights, with the potential for Vividion to receive up to double-digit royalties on sales and milestone payments. In accordance with the collaboration agreement, other programs will allow for us and Vividion to share equally either U.S. or worldwide development costs and profits and losses.

The collaboration agreement has an initial term of four years, which may be extended up to two additional years. The collaboration agreement may be terminated at our discretion upon 90 days prior written notice to Vividion and by either party upon material breach of the other party, subject to cure periods.

A financial summary of certain period activity and the period-end balances related to Vividion is presented below ⁽¹⁾:

Nine-Month Period 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
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2018\$97 \$ —\$ — \$ —\$ 4

Balances as of:	Intangible Asset Balance	Equity Investment Balance	Percentage of Outstanding Equity
September 30, 2018	\$ —	\$ 4	5.8 %

⁽¹⁾ There was no collaboration activity related to Vividion during the three-month period ended September 30, 2018. In addition to the expenses noted in the table above, we may also incur expenses for collaboration agreement related activities that are managed or funded by us.

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Other Collaboration Arrangements in 2018:

In addition to the collaboration arrangements described above, we entered into collaboration arrangements for the nine-month period ended September 30, 2018 that include the potential for future milestone payments of \$177 million related to the attainment of specified development, regulatory and sales 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.

A financial summary of certain period activity and the period-end balances related to our other collaboration arrangements is presented below ⁽¹⁾:

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
2018	\$ 8	\$ —	3	\$ 1	\$ 2
2017	\$ 58	10	13	4	233

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
2018	\$ 192	\$ 15	\$ 7	\$ 5	\$ 79
2017	\$ 669	10	20	11	312

Balances as of:	Intangible Equity		Percentage of Outstanding Equity
	Asset Balance	Investment Balance	
September 30, 2018	\$ 11	\$ 1,741	N/A
December 31, 2017	12	1,806	N/A

⁽¹⁾ In addition to the expenses noted in the table above, we may also incur expenses for collaboration agreement related activities that are managed or funded by us.

In addition to the collaboration arrangements described above, in conjunction with the acquisition of Juno we assumed Juno's legacy collaboration arrangements including Fred Hutchinson Cancer Research Center and Memorial Sloan Kettering Cancer Center.

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, 2018 and December 31, 2017. With our acquisition of Juno, we have assumed additional 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. See Note 3 for additional details related to our acquisitions and Note 14 for additional details related to collaboration arrangements.

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

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.

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.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

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. We 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 believe that our patent portfolio for lenalidomide in Europe, including the composition of matter patent, which expires in 2022, is strong. In the event that we do not prevail on the appeal relating to the '682 patent, we still expect

that we will have protection in the EU for lenalidomide until at least 2022.

In June 2017, Accord Healthcare Ltd. (Accord) commenced lawsuits against us in the United Kingdom (UK) seeking to revoke our UK patents protecting REVLIMID®. In June 2018, we entered into a settlement agreement with Accord resolving the lawsuits.

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 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID® (lenalidomide) capsules in Canada. We commenced a proceeding in the Federal Court of Canada on July 27, 2017, seeking an order prohibiting the Minister of Health from granting marketing approval to DRL until expiry of these patents.

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We received a further Notice of Allegation dated September 20, 2017 from DRL relating to the same submission, but also referencing 2.5 mg REVLIMID[®] (lenalidomide) 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 commenced a proceeding in the Federal Court of Canada on November 2, 2017, seeking an order prohibiting the Minister of Health from granting marketing approval to DRL until expiry of these patents. The hearings for these proceedings are scheduled for September 23-24, 2019 and September 30-October 3, 2019, respectively.

We received two Notices of Allegation on July 3, 2018 and July 6, 2018 from Natco Pharma (Canada) Inc. (Natco Canada) notifying us of the filing of Natco Canada's two separate ANDSs with Canada's Minister of Health, with respect to Canadian Letters Patent Nos. 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. Natco Canada is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID[®] (lenalidomide) capsules in Canada. We commenced infringement actions in the Federal Court of Canada on August 16, 2018, asserting all the patents, and seeking a declaration of infringement and a permanent injunction. The trial is anticipated to start on March 30, 2020.

We received a Notice Letter dated September 9, 2016 from DRL notifying us of its Abbreviated New Drug Application (ANDA) which contains Paragraph IV certifications against U.S. Patent Nos. 7,465,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621 and 9,101,622 that are listed in the U.S. Food and Drug Administration (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 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID[®] (lenalidomide) capsules in the United States. In response to the Notice Letter, we timely filed an infringement action against DRL in the U.S. 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 at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) March 12, 2019. On November 18, 2016, DRL filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. On December 27, 2016, we filed a reply to DRL's counterclaims. Fact discovery is closed. Expert discovery is scheduled to close on February 28, 2019. The court has not yet entered a schedule for trial.

We 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 that Notice Letter, we timely filed an infringement action against DRL in the U.S. 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 at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) December 9, 2019. On October 18, 2017, DRL filed an amended answer and counterclaims asserting that each of the patents is invalid and/or not infringed. We filed our reply to DRL's counterclaims on November 15, 2017. Fact discovery is set to close on May 31, 2019. The court has not yet entered a schedule for expert discovery or trial.

We received another Notice Letter from DRL dated February 26, 2018 notifying us of additional Paragraph IV certifications against U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886 and 8,626,531 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 U.S. District Court for the District of New Jersey on April 12, 2018. As a result of the filing of our action, the FDA cannot grant final approval of DRL's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) August 27, 2020. DRL filed an amended answer and counterclaims on May 31, 2018 asserting that each of the patents is invalid and/or not infringed. We filed our reply to

DRL's counterclaims on June 28, 2018. Fact discovery is set to close on May 31, 2019. The court has not yet entered a schedule for expert discovery or trial.

We received a Notice Letter dated February 27, 2017 from Zydus Pharmaceuticals (USA) Inc. (Zydus) notifying us of Zydus's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 7,465,800; 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 25 mg REVLIMID® (lenalidomide) capsules in the United States. In response to the Notice Letter, we timely filed an infringement action against Zydus in the U.S. 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's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) August 28, 2019. On August 7, 2017, Zydus filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. On September 11, 2017, we filed a reply to Zydus's counterclaims. Fact discovery is set to close on May 31, 2019. The court has yet to enter a schedule for expert discovery and trial.

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On April 27, 2018, we filed another infringement action against Zydus in the U.S. District Court for the District of New Jersey. The patents-in-suit are U.S. Patent Nos. 7,977,357; 8,193,219 and 8,431,598, which are patents not listed in the Orange Book. Zydus filed its answer on July 9, 2018 asserting that each of the patents is invalid and/or not infringed. Fact discovery is set to close on May 31, 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. 7,465,800; 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 25 mg 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 U.S. 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 at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) January 5, 2020. On October 13, 2017, Cipla filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. We filed our reply to Cipla's counterclaims on November 17, 2017. Fact discovery is set to close on May 31, 2019. The court has yet to enter a schedule for expert discovery and trial.

On May 8, 2018, we filed another infringement action against Cipla in the U.S. District Court for the District of New Jersey. The patents-in-suit are U.S. Patent Nos. 7,977,357; 8,193,219 and 8,431,598, which are patents that are not listed in the Orange Book. Cipla filed its answer and counterclaims on July 16, 2018 asserting that each of the patents is invalid and/or not infringed. We filed our reply to Cipla's counterclaims on August 20, 2018. Fact discovery is set to close on May 31, 2019. The court has yet to enter a schedule for 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; 7,465,800; 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 25 mg REVLIMID® (lenalidomide) capsules in the United States. In response to the Notice Letter, we timely filed an infringement action against Lotus in the U.S. 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 at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) January 25, 2020. On October 5, 2017, Lotus filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. We filed our reply to Lotus's counterclaims on November 9, 2017. Fact discovery is set to close on May 31, 2019. The court has yet to enter a schedule for expert discovery and trial.

On July 10, 2018, we filed another infringement action against Lotus in the U.S. District Court for the District of New Jersey. The patents-in-suit are U.S. Patent Nos. 7,977,357; 8,193,219 and 8,431,598, which are patents that are not listed in the Orange Book. Lotus filed its answer and counterclaims on July 18, 2018 asserting that each of the patents is invalid and/or not infringed. We filed our reply to Lotus's counterclaims on August 22, 2018. Fact discovery is set to close on May 31, 2019. The court has yet to enter a schedule for expert discovery and trial.

We received a Notice Letter dated November 28, 2017 from Apotex Inc. (Apotex) notifying us of Apotex's ANDA, which contains Paragraph IV certifications against U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 7,465,800; 7,468,363; 7,855,217; 8,315,886; 8,626,531 and 8,741,929 that are listed in the Orange Book for REVLIMID®. Apotex is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg

REVLIMID® (lenalidomide) capsules in the United States. In response to the Notice Letter, we timely filed an infringement action against Apotex in the U.S. District Court for the District of New Jersey on January 11, 2018. As a result of the filing of our action, the FDA cannot grant final approval of Apotex's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) May 29, 2020. On April 2, 2018, Apotex responded to the complaint by filing a motion to dismiss the case for failure to join a necessary party. We filed our response on May 21, 2018. Apotex filed its reply brief on June 11, 2018. On August 15, 2018, the parties submitted a proposed stipulation resolving the motion to dismiss. The court ordered the stipulation and the motion was terminated as moot. The court has yet to enter a schedule for fact discovery, expert discovery, or trial.

We received a Notice Letter dated May 30, 2018 from Sun Pharmaceutical Industries Limited (Sun) notifying us of Sun's ANDA, which contains Paragraph IV certifications against U.S. Patent Nos. 7,465,800; 7,855,217 and 7,968,569 that are listed in the Orange Book for REVLIMID®. Sun is seeking to manufacture and market a generic version of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID® (lenalidomide) capsules in the United States. In response to the Notice Letter, we timely filed an infringement action against Sun in the U.S. District Court for the District of New Jersey on July 13, 2018. As a result of the filing

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of our action, the FDA cannot grant final approval of Sun's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, or (ii) November 30, 2020. On August 14, 2018, Sun filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. We filed our reply to Sun's counterclaims on September 18, 2018. The court has not yet entered a schedule for fact discovery, expert discovery, or trial.

POMALYST®: We received a Notice Letter dated March 30, 2017 from Teva Pharmaceuticals USA, Inc. (Teva) (the Teva Notice Letter) notifying us of Teva's ANDA submitted to the FDA, which 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 for POMALYST®. 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 (together with the Teva Notice Letter, the Pomalidomide Notice Letters) from other generic drug manufacturers -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 May 2018, we received a similar Notice Letter from Synthon Pharmaceuticals Inc. (the Synthon Notice Letter).

In response to the Pomalidomide Notice Letters, we timely filed infringement actions in the U.S. District Court for the District of New Jersey against Teva 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 until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) August 8, 2020.

On July 13, 2017, Apotex and Hetero each filed answers and counterclaims asserting that each of the patents is invalid and/or not infringed, and further seeking declaratory judgments of noninfringement and invalidity for additional patents listed in the Orange Book for POMALYST®, namely U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886 and 8,626,531. On August 17, 2017, we filed replies to Apotex's and Hetero's counterclaims, as well as counter-counterclaims against Apotex and Hetero asserting infringement of U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886 and 8,626,531. Apotex and Hetero filed replies to our counter-counterclaims on September 6 and September 8, 2017.

On July 31, 2017, Breckenridge filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. We filed our reply to Breckenridge's counterclaims on September 5, 2017. On December 6, 2017, Breckenridge filed an amended pleading to include counterclaims seeking declaratory judgments of noninfringement and invalidity for additional patents listed in the Orange Book for POMALYST®, namely U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886 and 8,626,531. We replied to Breckenridge's amended counterclaims and asserted counter-counterclaims on January 3, 2018. Breckenridge filed its answer to our counter-counterclaims on January 24, 2018.

On August 7, 2017, Teva filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. On September 11, 2017, we filed a reply to Teva's counterclaims.

On August 9, 2017, Mylan filed a motion to dismiss the complaint, and on March 2, 2018, the court denied Mylan's motion to dismiss without prejudice and granted our request for venue-related discovery.

On September 15, 2017, Aurobindo filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed, and further seeking declaratory judgments of noninfringement and invalidity for additional patents listed in the Orange Book for POMALYST®, 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 and counter-counterclaims concerning U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886 and 8,626,531 on October 20, 2017. Aurobindo filed its answer to our counter-counterclaims on November 24, 2017.

In response to the Synthon Notice Letter, we timely filed an infringement action against Synthon in the U.S. District Court for the District of New Jersey on June 19, 2018. As a result of the filing of our actions, the FDA cannot grant final approval of Synthon's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) November 7, 2020. On July 16, 2018, Synthon filed an answer and counterclaims asserting that each of the patents asserted in the complaint is invalid and/or not infringed. On August 20, 2018, we filed our reply to Synthon's counterclaims. The court has not yet entered a schedule for fact discovery, expert discovery, or trial.

Fact discovery in the above-referenced Apotex, Aurobindo, Breckenridge, Hetero, Mylan, and Teva POMALYST® cases is scheduled to close on March 1, 2019 and expert discovery in these cases is scheduled to close on September 30, 2019. Trial has not been scheduled in any POMALYST® litigation.

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We received a Notice Letter dated August 7, 2018 from Hetero notifying us of an additional Paragraph IV certification against U.S. Patent No. 9,993,467 that is listed in the Orange Book for POMALYST®. In response to the Notice Letter, we timely filed an infringement action against Hetero in the U.S. District Court for the District of New Jersey on September 20, 2018. Hetero has not yet responded to the complaint.

We received a Notice Letter dated August 13, 2018 from Teva notifying us of an additional Paragraph IV certification against U.S. Patent No. 9,993,467 that is listed in the Orange Book for POMALYST®. In response to the Notice Letter, we timely filed an infringement action against Teva in the U.S. District Court for the District of New Jersey on September 27, 2018. Teva has not yet responded to the complaint.

We received a Notice Letter dated August 22, 2018 from Breckenridge notifying us of an additional Paragraph IV certification against U.S. Patent No. 9,993,467 that is listed in the Orange Book for POMALYST®. In response to the Notice Letter, we timely filed an infringement action against Breckenridge in the U.S. District Court for the District of New Jersey on October 5, 2018. Breckenridge has not yet responded to the complaint.

ABRAXANE®: 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 each seeking to manufacture and market a generic version of ABRAXANE® 100 mg/vial.

On April 6, 2016, we filed an infringement action against Actavis in the U.S. District Court for the District of New Jersey. We entered into a settlement with Actavis, effective January 23, 2018, to terminate that patent litigation and Inter Partes Review (IPR) challenges between the parties relating to certain patents for ABRAXANE®. As part of the settlement, the parties filed a Consent Judgment with the U.S. District Court for the District of New Jersey, which was entered on January 26, 2018, enjoining Actavis from marketing generic paclitaxel protein-bound particles for injectable suspension before expiration of the patents-in-suit, except as provided for in the settlement. In the settlement, we agreed to provide Actavis with a license to our patents required to manufacture and sell a generic paclitaxel protein-bound particles for injectable suspension product in the United States beginning on March 31, 2022.

On December 7, 2016, we filed an infringement action against Cipla in the U.S. 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 at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) April 25, 2019. On January 20, 2017, Cipla filed an answer and counterclaims asserting that each of the patents is invalid and/or not infringed. Our reply was filed on February 24, 2017. In September 2018, we entered into a settlement with Cipla to terminate this patent litigation. As part of the settlement, the parties filed a Consent Judgment with the U.S. District Court for the District of New Jersey, which was entered on October 9, 2018, enjoining Cipla from marketing generic paclitaxel protein-bound particles for injectable suspension before expiration of the patents-in-suit, except as provided for in the settlement. In the settlement, we agreed to provide Cipla with a license to our patents required to manufacture and sell a generic paclitaxel protein-bound particles for injectable suspension product in the United States beginning on September 27, 2022.

On January 13, 2017, the UK High Court of Justice handed down a ruling after a hearing held on December 20, 2016 in which we argued that the UK Intellectual Property Office improperly rejected our request for a Supplemental Protection Certificate (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). A hearing was held at the CJEU on June 21, 2018.

We expect a decision from the CJEU later this year. If the CJEU were to find in our favor, the ruling would need to be implemented in other jurisdictions in which the proceedings are pending, potentially resulting in the grant of SPCs not only in the UK, but also in other jurisdictions that have previously rejected our initial request including Germany and Ireland. The '612 patent expired in Europe in September 2017. However, if granted, the SPCs will expire in 2022. Data exclusivity in Europe will expire in January 2019.

We received a Notice of Allegation (NOA) dated March 22, 2018 from Panacea Biotec Ltd. (Panacea) notifying us of the filing of Panacea's ANDS with Canada's Minister of Health, with respect to Canadian Letters Patent No. 2,509,365 (the '365 patent). Panacea is seeking to manufacture and market a generic version of 100 mg/vial ABRAXANE® (paclitaxel powder for injectable suspension, nanoparticle, albumin-bound (nab®) paclitaxel) in Canada. On May 4, 2018, our subsidiaries, Abraxis BioScience, LLC and Celgene Inc. commenced an action for patent infringement in the Federal Court of Canada seeking, among other relief, a declaration of infringement in relation to the '365 patent.

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In June 2018, we settled certain patent disputes with Apotex involving ABRAXANE[®] that were triggered by Apotex filing an ANDA in the United States, IPR patent challenges before the U.S. Patent Office (see below), and the aforementioned NOA filed by Apotex's marketing partner, Panacea. In addition to dismissing the patent proceedings, in the settlement we agreed to provide Apotex with a license to our patents required to manufacture and sell a generic paclitaxel protein-bound particles for injectable suspension product in the United States beginning on September 27, 2022, and in certain countries outside of the United States, including Canada, beginning on a later date.

OTEZLA[®]: We received Notice Letters from each of the following company groups (individual or joint) between May 14, 2018 and June 1, 2018: Alkem Laboratories Ltd. (Alkem); Amneal Pharmaceuticals LLC (Amneal); Annora Pharma Private Ltd. (Annora) and Hetero USA Inc. (Hetero); Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A. Inc. (Aurobindo); Cipla Ltd. (Cipla); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (DRL); Emcure Pharmaceuticals Ltd. (Emcure) and Heritage Pharmaceuticals Inc. (Heritage); Glenmark Pharmaceuticals Ltd. (Glenmark); Macleods Pharmaceuticals Ltd. (Macleods); Mankind Pharma Ltd. (Mankind); MSN Laboratories Private Ltd. (MSN); Pharmascience Inc. (Pharmascience); Princeton Pharmaceutical Inc. (Princeton); Sandoz Inc. (Sandoz); Shilpa Medicare Ltd. (Shilpa); Teva Pharmaceuticals USA, Inc. (Teva) and Actavis LLC (Actavis); Torrent Pharmaceuticals Ltd. (Torrent); Unichem Laboratories, Ltd. (Unichem); and Zydus Pharmaceuticals (USA) Inc. (Zydus) notifying us of their ANDAs, which contain Paragraph IV certifications against one or more of the following patents: U.S. Patent Nos. 6,962,940; 7,208,516; 7,427,638; 7,659,302; 7,893,101; 8,455,536; 8,802,717; 9,018,243 and 9,872,854, which are listed in the Orange Book for OTEZLA[®]. Each of the companies is seeking to market a generic version of OTEZLA[®]. In response to the Notice Letters, we timely filed infringement actions in the U.S. District Court for the District of New Jersey. As a result of the filing of our actions, the FDA cannot grant final approval of any of these companies' ANDAs until at least the earlier of (i) a final decision that each of the asserted patents is invalid, unenforceable, and/or not infringed, and (ii) September 21, 2021.

Between August 8, 2018 and August 30, 2018, we filed amended complaints against Alkem, Amneal, Aurobindo, Cipla, DRL, Glenmark, Pharmascience, Sandoz, Teva and Actavis, Unichem, and Zydus additionally asserting U.S. Patent No. 9,724,330, which was recently listed in the Orange Book for OTEZLA[®].

Each defendant except for Glenmark has filed an Answer disputing infringement and/or validity of the patents asserted against it. Along with their answers, each of Alkem, Annora, Cipla, DRL, Emcure and Heritage, Macleods, Mankind, Pharmascience, Sandoz, Shilpa, Teva and Actavis, Torrent, and Unichem filed declaratory judgment counterclaims asserting that some or all of the patents are not infringed and/or are invalid.

THALOMID[®]: We received a Notice Letter dated July 19, 2018 from West-Ward Pharmaceuticals International Limited (West-Ward) notifying us of West-Ward's ANDA which contains Paragraph IV certifications against U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 6,869,399; 7,141,018; 7,230,012; 7,959,566; 8,315,886 and 8,626,531 that are listed in the Orange Book for THALOMID[®]. West-Ward is seeking to manufacture and market a generic version of 50 mg, 100 mg, 150 mg, and 200 mg THALOMID[®] (thalidomide) capsules in the United States. In response to the Notice letter, we timely filed an infringement action against West-Ward in the U.S. District Court for the District of New Jersey on August 31, 2018. As a result of the filing of our action, the FDA cannot grant final approval of West-Ward's ANDA until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) January 20, 2021. West-Ward has not yet responded to the complaint.

Juno patent-related proceedings:

KITE: On October 18, 2017, the day on which the FDA approved Kite Pharma, Inc.'s (Kite) Yescarta[™] KTE-C19 product, Juno filed a complaint against Kite in the U.S. District Court for the Central District of California. The

complaint alleged that Yescarta™ infringes claims 1-3, 5, 7-9, and 11 of U.S. Patent No. 7,446,190 (the '190 Patent). Kite answered the complaint on November 28, 2017, and filed counterclaims of non-infringement and invalidity against Juno. Juno filed a motion to dismiss Kite's counterclaims and to strike certain affirmative defenses on December 19, 2017.

On March 8, 2018, the court granted Juno's motion to dismiss and strike, and ordered Kite to file an amended answer and counterclaims. On the same day, the court denied Kite's motion to stay. On March 29, 2018, Kite filed an amended answer and counterclaims, asserting that the '190 Patent is invalid and/or not infringed. On April 9, 2018, we filed an answer to Kite's counterclaims. Fact and expert discovery are set to close on February 15, 2019 and April 29, 2019, respectively, and trial is scheduled to begin on October 15, 2019.

CITY OF HOPE: On August 22, 2017, City of Hope (COH) filed a lawsuit against Juno in the U.S. District Court for the Central District of California alleging that prior to our acquisition of Juno, Juno breached an exclusive license agreement (ELA) between

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Juno and COH by sublicensing COH intellectual property to us without COH's consent and by failing to pay COH related sublicensing revenues. COH sought damages in an amount no less than \$93.75 million in alleged sublicense revenues and a judicial declaration that the ELA has terminated. In July 2018, Juno and COH entered into a confidential settlement agreement dismissing the lawsuit and reinstating the ELA. The settlement amount was not materially different than the amount we had previously accrued for this matter.

Proceedings involving the U.S. Patent and Trademark Office (USPTO):

REMS IPR: 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 IPR challenging the validity of our U.S. Patent Nos. 6,045,501 (the '501 patent) and 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 PTAB's 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 certain claims of 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.

We timely appealed to the U.S. Court of Appeals for the Federal Circuit the PTAB's determinations regarding certain claims of the '720 patent and the '501 patent on November 6, 2017 and on November 9, 2017, respectively. On February 26, 2018, the USPTO intervened in our appeal. Our opening briefs were filed on May 31, 2018. The USPTO filed its briefs on August 30, 2018. Our reply briefs are due October 29, 2018. 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 patents that cover our products that use our REMS system.

ABRAXANE® IPR: On April 4, 2017, Actavis filed petitions for IPRs challenging the validity of our U.S. Patent Nos. 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. On October 10, 2017, the PTAB instituted IPR proceedings on the '229, '536, and '788 patents and on October 11, 2017 denied institution of the IPR on the '260 patent. On January 29, 2018, the parties submitted a joint motion to terminate all three IPRs in connection with the settlement entered into with Actavis mentioned above. On May 8, 2018, the PTAB granted the parties' joint motion to terminate.

On November 9, 2017, Apotex and Cipla each filed petitions for IPRs challenging the validity of the '229, '536, and '788 patents. On May 8, 2018, the PTAB denied institution of all IPRs.

REVLIMID® IPRs: On February 23, 2018, Apotex filed a petition for IPR challenging the validity of our U.S. Patent No. 8,741,929. On September 27, 2018, the PTAB denied institution of the IPR.

On August 3, 2018, DRL filed petitions for IPR challenging the validity of our U.S. Patent Nos. 9,056,120; 8,404,717 and 7,189,740. Our preliminary responses are due on November 14, 2018, November 30, 2018, and December 11, 2018, respectively.

On September 12, 2018, Lotus filed a petition for IPR challenging the validity of our U.S. Patent No. 7,968,569. Our preliminary response is due on December 18, 2018.

JUNO IPR: On August 13, 2015, Kite filed a petition for IPR challenging the validity of U.S. Patent No. 7,446,190 (the '190 Patent), exclusively licensed from Memorial Sloan Kettering Cancer Center. On February 11, 2016, the

PTAB instituted the IPR proceedings. A hearing was held before the PTAB on October 20, 2016. On December 16, 2016, the PTAB issued a final written decision upholding all claims of the '190 Patent. On February 16, 2017, Kite filed a notice of appeal of the PTAB's final written decision to the U.S. Court of Appeals for the Federal Circuit. On June 6, 2018, the Federal Circuit affirmed the decision of the Patent Trial and Appeal Board, upholding all claims of the '190 Patent.

Other Proceedings:

MYLAN: On April 3, 2014, Mylan filed a lawsuit against us in the U.S. 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 may conduct the bioequivalence testing necessary to submit ANDAs to the FDA for approval to market generic versions of these products. Mylan is seeking injunctive relief, damages and a 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.

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On December 22, 2014, the court granted our 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 U.S. 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 was argued on December 13, 2017. Thereafter, the court ordered the parties to mediate and administratively stayed the case pending the mediation. The mediation was held on January 25, 2018, but no settlement was reached. Supplemental briefing on the motion for summary judgment was filed on February 1, 2018. On October 3, 2018, the Court granted in part and denied in part our motion for summary judgment. No trial date has been set.

THALOMID® AND REVLIMID® ANTITRUST LITIGATION: 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 U.S. 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. Plaintiffs added allegations that our settlements of patent infringement lawsuits against certain generic manufacturers have had anticompetitive effects. 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 (NEC). The NEC action has been consolidated with the original action involving IUB, Providence, DEA, Local 39, and Mitchell into a master action for all purposes.

On October 2, 2017, the plaintiffs filed a motion for certification of two damages classes under the laws of thirteen states and the District of Columbia and a nationwide injunction class. On February 26, 2018, we filed our opposition to the plaintiffs' motion and a motion for judgment on the pleadings dismissing all state law claims where the plaintiffs no longer seek to represent a class. The plaintiffs filed their opposition to our motion for judgment on the pleadings on April 2, 2018, and we filed our reply on April 13, 2018. The plaintiffs filed their reply in support of their class

certification motion on May 18, 2018. Fact discovery in these cases closed on May 17, 2018. The plaintiffs filed opening expert reports on June 18, 2018; responsive and rebuttal reports were due on August 27, 2018 and October 15, 2018, respectively. Expert discovery in these cases is scheduled to close on November 30, 2018. No trial date has been set.

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.

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JUNO SECURITIES CLASS ACTION: In July 2016, two putative securities class action complaints (the Veljanoski Complaint and the Wan Complaint) were filed against Juno and its chief executive officer, Hans E. Bishop, in the U.S. District Court for the Western District of Washington. On September 7, 2016, an additional putative securities class action complaint (the Paradisco Complaint and, together with the Veljanoski Complaint and the Wan Complaint, the Complaints) was filed against Juno, Mr. Bishop, and its chief financial officer, Steve Harr, in the U.S. District Court for the Western District of Washington. The Complaints generally allege material misrepresentations and omissions in public statements regarding patient deaths in Juno’s Phase II clinical trial of JCAR015 as well as, violations by all named defendants of Sections 10(b) and 20(a) of the Securities Exchange Act. On October 7, 2016, the Complaints were consolidated into a single action. On December 12, 2016, the court-appointed lead plaintiff and a named plaintiff filed a Consolidated Amended Complaint (Consolidated Complaint), which includes claims against Juno, Mr. Bishop, Dr. Harr, and Juno’s chief medical officer, Dr. Mark J. Gilbert (the Defendants). The Consolidated Complaint includes allegations similar to those in the previous Complaints, as well as additional allegations regarding purported material misrepresentations and omissions in public statements after July 7, 2016 regarding the safety of JCAR015. The parties mediated on May 9, 2018, following which the parties agreed to a settlement in principle of the class action for which the parties will be seeking court approval. The settlement amount was not materially different than the amount we had previously accrued for this matter.

CELGENE SECURITIES CLASS ACTION: On March 29, 2018, the City of Warren General Employees’ Retirement System filed a putative class action against us and certain of our officers in the U.S. District Court for the District of New Jersey. The complaint alleges that the defendants violated federal securities laws by making misstatements and/or omissions concerning (1) trials of GED-0301, (2) 2020 outlook and projected sales of OTEZLA[®], and (3) the new drug application for Ozanimod. On May 3, 2018, a similar putative class action lawsuit against us and certain of our officers was filed by Charles H. Witchcoff in the U.S. District Court for the District of New Jersey. The complaint alleges that defendants violated federal securities laws by making material misstatements and/or omissions concerning (1) trials of GED-0301, (2) 2020 outlook and projected sales of OTEZLA[®], and (3) the new drug application for Ozanimod. On September 27, 2018, the court consolidated the two actions and appointed a lead plaintiff, lead counsel, and co-liaison counsel for the putative class. On October 9, 2018, the court entered a scheduling order which requires lead plaintiff to file an amended complaint by December 10, 2018; defendants to file their motion to dismiss the amended complaint by February 8, 2019; lead plaintiff to file its opposition to the motion to dismiss by April 9, 2019; and defendants to file their reply by May 9, 2019.

On July 12, 2018, Saratoga Advantage Trust Health and Biotechnology Portfolio filed a shareholder derivative complaint against certain members of our board of directors in the U.S. District Court for the District of New Jersey. The complaint alleges that (i) certain defendants made misrepresentations and omissions of material fact concerning, among other things, trials of GED-0301, sales of OTEZLA[®], 2017 and 2020 fiscal guidance, and the new drug application for Ozanimod and (ii) all defendants failed to adequately supervise Celgene with regard to trials of GED-0301, sales of OTEZLA[®], 2017 and 2020 fiscal guidance, the new drug application for Ozanimod, and the promotion and marketing of REVLIMID[®].

The plaintiff has agreed to stay the defendants’ obligation to answer or otherwise respond to the allegations in the complaint in deference to the Celgene Securities Class Actions and subject to thirty days’ notice by either plaintiff or defendants of an intent to proceed.

On October 11, 2018, Sam Baran Gerold filed a shareholder derivative complaint against certain members of our board of directors in the Superior Court of New Jersey. The complaint alleges that (i) defendants breached certain fiduciary duties related to, among other things, GED-0301, OTEZLA[®], and the new drug application for Ozanimod and (ii) because of that breach, the defendants caused Celgene to waste its corporate assets and the defendants were

unjustly enriched.

On October 19, 2018, Susan Fisher filed a stockholder derivative complaint against certain of our present and former directors or executives in the U.S. District Court of Delaware. The complaint alleges that defendants (i) violated Section 14(a) of the Securities Exchange Act by participating in the issuance of materially misleading proxies and (ii) failed to exercise proper oversight of Celgene, and that, because of that failure, the defendants caused Celgene to waste its corporate assets and the defendants were unjustly enriched.

HUMANA, INC (HUMANA): On May 16, 2018, Humana filed a lawsuit against us in the Pike County Circuit Court of the Commonwealth of Kentucky. Humana's complaint alleges we engage in unlawful off-label marketing in connection with sales of THALOMID® and REVLIMID® and asserts claims against us for fraud, breach of contract, negligent misrepresentation, unjust enrichment, and violations of New Jersey's Racketeer Influenced and Corrupt Organizations Act. The complaint seeks, among other things, treble and punitive damages, injunctive relief and attorneys' fees and costs. On June 13, 2018, we removed Humana's lawsuit to the U.S. District Court for the Eastern District of Kentucky and, on July 11, 2018, filed a motion to dismiss Humana's

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

complaint in full. On July 12, 2018, Humana moved to remand the case to state court. The court has not set a hearing date for the motions.

scalp psoriasis. In 2018, the phase III trial (RELIEF®) for OTEZLA® in patients with active Behçet's disease showed statistically significant reductions in oral ulcers when compared to placebo. Also in 2018, the phase III study (STYLE™) for OTEZLA® in patients with moderate to severe scalp psoriasis achieved a highly statistically significant improvement in its primary endpoint. 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 completed two phase III trials (RADIANCE™ and SUNBEAM™) for ozanimod in relapsing multiple sclerosis (RMS) and phase III trials are underway in ulcerative colitis and Crohn's disease. In hematology, the phase III trial (MEDALIST™) for luspatercept in patients with low-to-intermediate risk myelodysplastic syndromes (MDS) achieved primary and key secondary endpoints during 2018. In addition, the phase III trial (BELIEVE™) for luspatercept in patients with Transfusion-dependent Beta-thalassemia achieved primary and key secondary endpoints during 2018. Phase III trials are underway for CC-486 in MDS and in acute myeloid leukemia (AML). In the second quarter of 2018 we initiated the pivotal TRANSCEND WORLD trial evaluating JCAR017 (lisocabtagene maraleucel) in R/R diffuse large B-cell lymphoma (DLBCL). In July 2017, we entered into global strategic immuno-oncology collaboration with BeiGene, Ltd. (BeiGene) to advance a PD-1

Inhibitor (BGB-A317) program for solid tumor cancers. In 2018, our partner, BeiGene, initiated a phase III trial for BGB-A317 in hepatocellular carcinoma (HCC).

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 2017 Annual Report on Form 10-K filed with the SEC. The following tables present significant developments in our pivotal and phase III clinical trials and regulatory approval requests that occurred during the three-month period ended September 30, 2018, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

Pivotal and Phase III Trials:

Product Candidate Trial	Disease Indication	Action
Marizomib	EORTC-BTG-1709ndGBM	Initiated

Regulatory agency actions:

Product	Disease Indication	Major Market	Regulatory Agency	Action
OTEZLA®	Behçet's	US	FDA	Submitted
OTEZLA® QD	Once-daily formulation	US	FDA	Application Withdrawn ⁽¹⁾

⁽¹⁾ On August 17, 2018 we made the decision to withdraw the New Drug Application (NDA) for the OTEZLA® once-daily formulation. This decision was not a result of any safety concern with the once-daily formulation and we will continue to assess for potential re-submission.

Recent Transactions

Accelerated Share Repurchase: In May 2018, we entered into an accelerated share repurchase (ASR) agreement to repurchase an aggregate of \$2.0 billion of our common stock. The ASR utilized part of the existing Board authorized share repurchase program which was increased by \$5.0 billion and \$3.0 billion in February and May 2018, respectively. As part of the ASR agreement, we received an initial delivery of approximately 18.0 million shares in May 2018 and a final delivery of approximately 6.0 million shares in August 2018. The total number of shares repurchased under the ASR agreement was approximately 24.0 million shares at a weighted average price of \$83.53 per share.

Financial Update

The following table summarizes Net product sales, Total revenue and earnings for the three-month periods ended September 30, 2018 and 2017 (dollar amounts in millions, except per share amounts):

Three-Month Periods Ended	Increase	Percent Change
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	September 30,			
	2018	2017		
Net product sales	\$3,890	\$3,283	\$ 607	18.5 %
Total revenue	3,892	3,287	605	18.4 %
Net income	1,082	988	94	9.5 %
Diluted earnings per share	\$ 1.50	\$ 1.21	\$ 0.29	24.0 %

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Total Net product sales for the three-month period ended September 30, 2018 increased by \$607 million, or 18.5%, to approximately \$3.9 billion compared to the three-month period ended September 30, 2017. The increase was comprised of net volume increases of \$483 million, or 14.7%, and net price increases of \$142 million, or 4.3%. The increase in volume was primarily driven by increased unit sales of REVLIMID[®], POMALYST[®]/IMNOVID[®] and OTEZLA[®]. The price impact was primarily attributable to net price increases in the U.S., which were partially offset by net price decreases across international markets. Changes in foreign currency exchange rates including the impact of foreign exchange hedging activity unfavorably impacted Net product sales by \$18 million, or (0.5)%.

Total revenue increased by \$605 million, or 18.4%, to approximately \$3.9 billion for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017, reflecting increases of \$514 million, or 24.6%, in the United States and \$91 million, or 7.6%, in international markets.

In addition to the increase in total revenue discussed above, notable items impacting Net income and diluted earnings per share for the three-month periods ended September 30, 2018 and 2017 are as follows:

	Income Statement Classification	Three-Month Periods Ended		Change
		September 30, 2018	September 30, 2017	
Collaboration arrangements (see Note 14*)	Research and development	\$12	\$611	\$(599)
Litigation-related loss contingency accrual expense (see Note 16*)	Selling, general and administrative	57	—	57
Amortization of acquired intangible assets (see Note 10*)	Amortization of acquired intangible assets	127	80	47
Fair value adjustments on equity investments (see Note 1 and Note 6*)	Other (expense) income, net	(123)	—	(123)
Share-based compensation expense (see Notes 3 and 12*) ⁽¹⁾	Cost of goods sold, Research and development, and Selling, general and administrative	238	159	79
Excess tax benefits related to share-based compensation awards (see Note 12*)	Income tax provision (benefit)	(6)	(103)	97
Research and development and orphan drug tax credit study (see Note 13*)	Income tax provision (benefit)	—	(65)	65

⁽¹⁾ Includes share-based compensation expense related to the acquisition of Juno post-combination service period of \$58 million and \$29 million, which was recorded in Research and development and Selling, general and administrative expenses, respectively, for the three-month period ended September 30, 2018.

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

The following table summarizes Net product sales, Total revenue and earnings for nine-month periods ended September 30, 2018 and 2017 (dollar amounts in millions, except per share amounts):

Nine-Month Periods Ended	September 30, 2018	September 30, 2017	Increase (Decrease)	Percent Change

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Net product sales	\$11,229	\$9,494	\$ 1,735	18.3	%
Total revenue	11,244	9,520	1,724	18.1	%
Net income	2,973	3,021	(48)	(1.6)%
Diluted earnings per share	\$4.02	\$3.72	\$ 0.30	8.1	%

Total Net product sales for the nine-month period ended September 30, 2018 increased by approximately \$1.7 billion, or 18.3%, to approximately \$11.2 billion compared to the nine-month period ended September 30, 2017. The increase was comprised of net volume increases of approximately \$1.4 billion, or 15.1%, and net price increases of \$335 million, or 3.5%. The increase in volume was primarily driven by increased unit sales of REVLIMID®, OTEZLA® and POMALYST®/IMNOVID®. The price impact was primarily attributable to net price increases in the U.S., which were partially offset by price decreases across international markets. Changes in foreign currency exchange rates including the impact of foreign exchange hedging activity unfavorably impacted Net product sales by \$33 million, or (0.3)%.

Total revenue increased by approximately \$1.7 billion, or 18.1%, to approximately \$11.2 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, reflecting increases of approximately \$1.3 billion, or 20.7%, in the United States and \$470 million, or 13.6%, in international markets.

In addition to the increase in total revenue discussed above, notable items impacting Net income and diluted earnings per share for the nine-month periods ended September 30, 2018 and 2017 are as follows:

	Income Statement Classification	Nine-Month Periods Ended September 30,		Change
		2018	2017	
Collaboration arrangements (see Note 14*)	Research and development	\$426	\$710	\$(284)
Research and development asset acquisition expenses (see Note 3*)	Research and development	1,125	325	800
Adjustment of clinical trial and development activity wind-down costs	Selling, general and administrative	(60)	—	(60)
Litigation-related loss contingency accrual expense (see Note 16*)	Selling, general and administrative	57	315	(258)
Amortization of acquired intangible assets (see Note 10*)	Amortization of acquired intangible assets	341	250	91
Juno acquisition costs (see Note 3*)	Acquisition related charges and restructuring, net	92	—	92
Fair value adjustments on equity investments (see Note 1, Note 3 and Note 6*)	Other (expense) income, net	830	—	830
Share-based compensation expense (see Notes 3 and 12*) ⁽¹⁾	Cost of goods sold, Research and development, and Selling, general and administrative	923	482	441
Excess tax benefits related to share-based compensation awards (see Note 12*)	Income tax provision (benefit)	(22)	(273)	251
Research and development and orphan drug tax credit study (see Note 13*)	Income tax provision (benefit)	—	(65)	65

⁽¹⁾ Includes share-based compensation expense related to the post-combination service period of \$291 million and \$196 million, which was recorded in Research and development and Selling, general and administrative expenses, respectively, for the nine-month period ended September 30, 2018.

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

Three-Month Periods Ended September 30, 2018 and 2017

Net Product Sales and Other Revenues

Net product sales and Other revenues for the three-month periods ended September 30, 2018 and 2017 were as follows:

REVLIMID®

Increase

	Three-Month Periods Ended September 30, 2018 2017			Percent Change
U.S.	\$1,667	\$1,361	\$ 306	22.5 %
International	782	720	62	8.6 %
Worldwide	\$2,449	\$2,081	\$ 368	17.7 %

REVLIMID® net sales increased by \$368 million, or 17.7%, to approximately \$2.4 billion for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. Sales growth was primarily volume-driven due to global increases in treatment duration and market share. In the U.S., sales growth increased due to both price and unit sales increases. International volume growth was partially offset by net price decreases.

POMALYST®/IMNOVID®

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
U.S.	\$ 357	\$ 268	\$ 89	33.2 %
International	156	149	7	4.7 %
Worldwide	\$ 513	\$ 417	\$ 96	23.0 %

POMALYST®/IMNOVID® net sales increased by \$96 million, or 23.0%, to \$513 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017, primarily due to increased sales in the U.S. market. In the U.S., sales growth increased due to both unit sales and price increases. Increases in market share and treatment duration contributed to the increase in U.S. unit sales. In addition, international unit sales increased, primarily due to increased treatment duration in Europe and Japan. International volume growth was partially offset by net price decreases.

OTEZLA®

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
U.S.	\$ 348	\$ 250	\$ 98	39.2 %
International	84	58	26	44.8 %
Worldwide	\$ 432	\$ 308	\$ 124	40.3 %

OTEZLA® net sales increased by \$124 million, or 40.3%, to \$432 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. In the U.S., sales growth increased primarily due to unit sales increases as a result of managed care contracts executed in 2017 and 2018, which contributed to higher gross-to-net charges. Volume increased in all international markets, led by Japan, where it was launched in 2017.

ABRAXANE®

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
U.S.	\$ 174	\$ 149	\$ 25	16.8 %
International	114	102	12	11.8 %
Worldwide	\$ 288	\$ 251	\$ 37	14.7 %

ABRAXANE® net sales increased by \$37 million, or 14.7%, to \$288 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017 primarily due to increases in global unit sales. In the U.S., sales growth increased due to both unit sales and price increases. International volume

growth was partially offset by net price decreases.

OTHER PRODUCT SALES

	Three-Month Periods Ended		(Decrease)	Percent Change
	September 30, 2018	2017		
U.S.	\$ 54	\$ 60	\$ (6)	(10.0)%
International	154	166	(12)	(7.2)%
Worldwide	\$ 208	\$ 226	\$ (18)	(8.0)%

All other product sales, which include IDHIFA[®], VIDAZA[®], generic azacitidine for injection, THALOMID[®], and ISTODAX[®], decreased by \$18 million primarily due to decreases in VIDAZA[®] net sales, partially offset by increased IDHIFA[®] net sales, which launched in the third quarter of 2017.

Other Revenue: Other revenue decreased by \$2 million to \$2 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. Beginning in 2018, we are no longer entitled to receive royalties from Novartis on sales of RITALIN® and FOCALIN XR®, which primarily contributed to the decrease in Other revenue.

Gross-to-Net Sales Accruals: We record gross-to-net sales accruals for government rebates, chargebacks and distributor service fees, sales discounts, and sales returns and allowances. For a discussion of our gross-to-net sales accruals, see Critical Accounting Estimates and Significant Accounting Policies in our 2017 Annual Report on Form 10-K.

Gross-to-net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2018 and 2017 were as follows:

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total
Balance as of June 30, 2018	\$ 680	\$ 306	\$ 21	\$ 16	\$1,023
Allowances for sales during prior periods	(13)	6	—	—	(7)
Allowances for sales during 2018	262	443	62	4	771
Credits/deductions issued for sales during prior periods	(162)	(1)	—	(2)	(165)
Credits/deductions issued for sales during 2018	(136)	(367)	(61)	(1)	(565)
Balance as of September 30, 2018	\$ 631	\$ 387	\$ 22	\$ 17	\$1,057
Balance as of June 30, 2017	\$ 493	\$ 213	\$ 18	\$ 13	\$737
Allowances for sales during prior periods	(3)	(3)	—	—	(6)
Allowances for sales during 2017	201	268	49	4	522
Credits/deductions issued for sales during prior periods	(132)	(2)	—	(2)	(136)
Credits/deductions issued for sales during 2017	(110)	(254)	(48)	(1)	(413)
Balance as of September 30, 2017	\$ 449	\$ 222	\$ 19	\$ 14	\$704

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2018 and 2017 are as follows:

Government rebate provisions increased by \$51 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017, due to a \$28 million increase in international government rebates and a \$23 million increase in the U.S. market. The increase in the U.S. and international government rebates was primarily driven by higher sales volumes and increased rebate rates. The increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, primarily due to an increase in Medicaid rebates (mostly in the managed care channel). In 2019, we expect the rebate provision for the Medicare Part D Coverage Gap to increase as a result of a planned increase in the portion manufacturers of pharmaceutical products are responsible for.

Chargebacks and distributor service fees provisions increased by \$184 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. Chargebacks increased by \$81 million and distributor service fees increased by \$103 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates. The distributor service fees increase was primarily attributable to increased sales volumes and new managed care contracts for OTEZLA®, which accounted for \$91 million of the increase, as well as a \$4 million increase in the distributor service fees expense and a \$4 million increase in commercial copayment program expense, both of which also were attributable to higher sales

volumes.

Discount provisions increased by \$13 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017, primarily due to higher sales volumes. The increase was primarily comprised of an increase of \$7 million related to REVLIMID[®] as well as increases related to OTEZLA[®] and POMALYST[®].

The provision for Sales Returns and Allowances for the three-month period ended September 30, 2018 was unchanged compared to the three-month period ended September 30, 2017.

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Operating Costs and Expenses

Operating costs, expenses and related percentages for the three-month periods ended September 30, 2018 and 2017 were as follows:

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

	Three-Month Periods Ended		Increase	Percent Change
	September 30, 2018	2017		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 157	\$ 118	\$ 39	33.1 %
Percent of Net product sales	4.0 %	3.6 %		

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$39 million to \$157 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. As a percent of Net product sales, Cost of goods sold (excluding amortization of acquired intangible assets) increased for the three-month period ended September 30, 2018 as compared to the three-month period ended September 30, 2017 primarily due to a raw materials charge recorded in the current year.

Research and Development

	Three-Month Periods Ended		(Decrease)	Percent Change
	September 30, 2018	2017		
Research and development	\$ 1,081	\$ 1,347	\$ (266)	(19.7)%
Percent of Total revenue	27.8 %	41.0 %		

Research and development expenses decreased by \$266 million to approximately \$1.1 billion for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. The decrease was primarily related to a reduction in expenses related to collaboration agreements in 2018 of \$599 million. The decrease was partially offset by \$170 million of incremental research and development expense related to the acquisition of Juno, including \$58 million of share-based compensation expense. See Note 14 and Note 3 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our collaboration agreements and acquisitions, respectively. Our research and development expenses may fluctuate from period-to-period based on the volume and timing of closing collaboration arrangements and asset acquisitions and associated obligations pursuant to such arrangements.

The following table provides a breakdown of Research and development expenses:

	Three-Month Periods Ended		Increase/(Decrease)	Percent Change
	September 30, 2018	2017		
Human pharmaceutical clinical programs	\$ 547	\$ 323	\$ 224	69.3 %
Other pharmaceutical programs	316	194	122	62.9 %
Drug discovery and development	206	219	(13)	(5.9)%
Collaboration arrangements (See Note 14*)	12	611	(599)	(98.0)%
Total	\$ 1,081	\$ 1,347	\$ (266)	(19.7)%

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

Selling, General and Administrative

	Three-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
Selling, general and administrative	\$746	\$608	\$ 138	22.7 %
Percent of Total revenue	19.2 %	18.5 %		

Selling, general and administrative expenses increased by \$138 million to \$746 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. This increase was primarily due to incremental expense of \$46 million due to the acquisition of Juno, including share-based compensation expense of \$29 million, as well as an increase of approximately \$20 million of marketing related expenses. In addition, the Company recorded litigation-related loss contingency accrual expense of approximately \$57 million during the three-month period ended September 30, 2018. See Note 3 and Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisition of Juno and legal proceedings, respectively.

Amortization of Acquired Intangible Assets

	Three-Month Periods Ended September 30, 2018 2017		Increase	Percent Change
Amortization of acquired intangible assets	\$ 127	\$ 80	\$ 47	58.8 %

Amortization of intangible assets acquired as a result of business combinations is summarized below for the three-month periods ended September 30, 2018 and 2017:

	Three-Month Periods Ended September 30, 2018 2017		Increase/(Decrease)
Acquisitions			
Abraxis	\$ 87	\$ 37	\$ 50
Gloucester	—	23	(23)
Juno	22	—	22
Pharmion	—	1	(1)
Quantice	18	19	(1)
Total amortization	\$ 127	\$ 80	\$ 47

Effective for the second quarter of 2018, we reduced the remaining estimated useful life of our ABRAXANE[®] intangible assets as a result of recent settlements of patent-related proceedings, which resulted in approximately \$50 million of accelerated amortization. Amortization expense also increased as a result of the technology platform asset acquired through our acquisition of Juno. These increases were partially offset by a reduction in amortization expense as the Gloucester intangible asset was fully amortized in the first quarter of 2018. See Note 3 and Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional information regarding our acquisition of Juno and the recent settlements regarding patent litigation, respectively.

Acquisition Related Charges and Restructuring, Net

	Three-Month Periods Ended September 30, 2018 2017		Increase	Percent Change
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Acquisition related charges and restructuring, net \$ 101 \$ 49 \$ 52 106.1 %

Acquisition related charges and restructuring, net was a net charge of \$101 million for the three-month period ended September 30, 2018, compared to a net charge of \$49 million for the three-month period ended September 30, 2017. The net charge in 2018 primarily relates to a charge due to the increase in the fair value of our liability related to publicly traded Contingent Value Rights (CVRs) of \$51 million that were issued as part of the acquisition of Abraxis BioScience, Inc. In addition, the net charge in 2018 also includes a charge of \$46 million related to a current period net change in fair value of legacy Juno success payment liabilities. The net charge in 2017 primarily related to an increase in the fair value of our contingent liabilities associated with the acquisition of Nogra Pharma Limited with no corresponding charge in 2018 due to the discontinuance of the GED-0301 trials in the fourth quarter of 2017. See Note 6 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our contingent consideration liabilities.

Other Income and Expenses

Other income and expense for the three-month periods ended September 30, 2018 and 2017 were as follows:

Interest and Investment Income, Net:

	Three-Month Periods Ended		(Decrease)	Percent Change
	September 30, 2018	2017		
Interest and investment income, net	\$ 8	\$ 33	\$ (25)	(75.8)%

Interest and investment income, net decreased by \$25 million to \$8 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017 primarily due to lower investment balances as compared to the prior year period.

Interest (Expense):

	Three-Month Periods Ended		Increase	Percent Change
	September 30, 2018	2017		
Interest (expense)	\$(193)	\$(127)	\$ (66)	52.0 %

Interest (expense) increased by \$66 million to \$193 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017 primarily due to the interest expense associated with the issuance of \$3.5 billion of senior notes during the second half of 2017 as well as the issuance of \$4.5 billion of senior notes during February of 2018. See Note 11 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to debt issuances.

Other (Expense) Income, Net:

	Three-Month Periods Ended		Increase/(Decrease)
	September 30, 2018	2017	
Foreign exchange gains, including foreign exchange derivative instruments not designated as hedging instruments (See Note 7*)	\$1	\$13	\$ (12)
Fair value adjustments on equity investments (see Notes 1 and 6*)	(123)	—	(123)
Fair value adjustments of forward point amounts (See Note 7*)	—	(8)	8
Investment impairment charge	—	(1)	1
Other	5	(4)	9
Total Other (expense) income, net	\$(117)	\$—	\$ (117)

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

Income Tax Provision: The Income tax provision increased by \$293 million to \$296 million for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017, primarily as a result

of an increase in the effective tax rate. The effective tax rate for the three-month period ended September 30, 2018 was 21.5%, an increase of 21.2 percentage points from our effective tax rate of 0.3% for the three-month period ended September 30, 2017. The increase in our effective tax rate was primarily due to a decrease in excess tax benefits from employee stock compensation deductions, for which our effective tax rate was increased by 10.0 percentage points and a decrease in tax benefits from a non-recurring 2017 change in estimate related to our U.S. research and development and orphan drug tax credits, for which our effective tax rate was increased by 5.7 percentage points. Our effective tax rate was also increased by our estimate of U.S. tax on forecasted Global Intangible Low-Taxed Income (subject to taxation at an effective statutory tax rate of 10.5%), non-deductible research expenses incurred in our acquisition of Impact, and a decrease in tax benefits of lower statutory tax rates on pre-tax income earned outside the U.S., all of which were partially offset by a reduction in the U.S. statutory tax rate from 35% to 21%, which was enacted on December 22, 2017 as part of the U.S. tax reform legislation (2017 Tax Act).

Our effective tax rate in 2018 is a function of the distribution of our pre-tax income earned inside and outside of the U.S. Our pre-tax income earned in the U.S. is taxed at a U.S. statutory tax rate of 21%. Our pre-tax income earned outside the U.S. is taxed both in the U.S. at an effective federal statutory tax rate of 10.5% and in the foreign jurisdictions where we have operations at lower effective tax rates. Our global pre-tax income is also subject to taxation in most U.S. states. Our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the amount of research tax credits, the amount of foreign tax credits, the timing and amount of tax benefits from employee stock compensation, payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements and many other factors which are difficult to forecast.

Nine-Month Periods Ended September 30, 2018 and 2017

Net Product Sales and Other Revenues

Net product sales and Other revenues for the nine-month periods ended September 30, 2018 and 2017 were as follows:

REVLIMID®

	Nine-Month Periods Ended		Increase	Percent Change
	September 30, 2018	2017		
U.S.	\$4,740	\$3,953	\$ 787	19.9 %
International	2,396	2,046	350	17.1 %
Worldwide	\$7,136	\$5,999	\$ 1,137	19.0 %

REVLIMID® net sales increased by approximately \$1.1 billion, or 19.0%, to approximately \$7.1 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. Sales growth was primarily volume-driven due to global increases in treatment duration and market share. In the U.S., sales growth increased due to increases in both price and unit sales. Outside the U.S., customer buying patterns and sales of product for use in clinical trials favorably impacted the 2018 period. International volume growth was partially offset by net price decreases.

POMALYST®/IMNOVID®

	Nine-Month Periods Ended		Increase	Percent Change
	September 30, 2018	2017		
U.S.	\$998	\$725	\$ 273	37.7 %
International	475	447	28	6.3 %
Worldwide	\$1,473	\$1,172	\$ 301	25.7 %

POMALYST®/IMNOVID® net sales increased by \$301 million, or 25.7%, to approximately \$1.5 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, primarily due to increased sales in the U.S. market. In the U.S., sales growth increased due to both unit sales and price increases. Increases in market share and treatment duration contributed to the increase in U.S. unit sales. In addition, international unit sales increased, primarily due to sales growth in Europe as a result of increased treatment duration. International volume growth was partially offset by net price decreases.

OTEZLA®

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
U.S.	\$915	\$755	\$ 160	21.2 %
International	245	153	92	60.1 %
Worldwide	\$1,160	\$908	\$ 252	27.8 %

OTEZLA[®] net sales increased by \$252 million, or 27.8%, to approximately \$1.2 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, due to increased worldwide sales. In the U.S., sales growth increased primarily due to unit sales increases as a result of managed care contracts executed in 2017 and 2018, which contributed to higher gross-to-net charges. Volume increased in all international markets led by Japan, where it was launched in 2017.

ABRAXANE[®]

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
U.S.	\$485	\$452	\$ 33	7.3 %
International	308	289	19	6.6 %
Worldwide	\$793	\$741	\$ 52	7.0 %

ABRAXANE[®] net sales increased by \$52 million, or 7.0%, to \$793 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, primarily due to unit sales and price increases in the U.S. market. International volume growth was partially offset by net price decreases.

OTHER PRODUCT SALES

	Nine-Month Periods Ended September 30,		Increase/(Decrease)	Percent Change
	2018	2017		
U.S.	\$166	\$159	\$ 7	4.4 %
International	501	515	(14)	(2.7)%
Worldwide	\$667	\$674	\$ (7)	(1.0)%

All other product sales, which include IDHIFA[®], VIDAZA[®], generic azacitidine for injection, THALOMID[®], and ISTODAX[®] decreased by \$7 million primarily due to decreases in net sales from THALOMID[®], generic azacitidine for injection, ISTODAX[®] and VIDAZA[®], partially offset by increased net sales from IDHIFA[®], which launched in the third quarter of 2017.

Other Revenue: Other revenue decreased by \$11 million to \$15 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. Beginning in 2018, we are no longer entitled to receive royalties from Novartis on sales of RITALIN[®] and FOCALIN XR[®], which primarily contributed to the decrease in Other revenue.

Gross-to-Net Sales Accruals: We record gross-to-net sales accruals for government rebates, chargebacks and distributor service fees, sales discounts, and sales returns and allowances. For a discussion of our gross-to-net sales accruals, see Critical Accounting Estimates and Significant Accounting Policies in our 2017 Annual Report on Form 10-K.

Gross-to-net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2018 and 2017 were as follows:

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total
Balance as of December 31, 2017	\$ 544	\$ 270	\$ 20	\$ 15	\$849
Allowances for sales during prior periods	(31)	3	—	—	(28)
Allowances for sales during 2018	840	1,203	177	10	2,230
Credits/deductions issued for sales during prior periods	(350)	(164)	(19)	(5)	(538)
Credits/deductions issued for sales during 2018	(372)	(925)	(156)	(3)	(1,456)
Balance as of September 30, 2018	\$ 631	\$ 387	\$ 22	\$ 17	\$1,057
Balance as of December 31, 2016	\$ 371	\$ 190	\$ 16	\$ 18	\$595
Allowances for sales during prior periods	7	(26)	—	(5)	(24)
Allowances for sales during 2017	625	799	139	9	1,572
Credits/deductions issued for sales during prior periods	(296)	(97)	(16)	(6)	(415)
Credits/deductions issued for sales during 2017	(258)	(644)	(120)	(2)	(1,024)
Balance as of September 30, 2017	\$ 449	\$ 222	\$ 19	\$ 14	\$704

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2018 and 2017 are as follows:

Government rebate provisions increased by \$177 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, due to a \$108 million increase in international government rebates and a \$69 million increase in the U.S. market. The increase in international government rebates was primarily driven by higher sales volumes and increased rebate rates. The increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with \$64 million due to an increase in Medicaid rebates (primarily in the managed care channel) and \$5 million due to an increase in expense related to Medicare Part D Coverage Gap. In 2019, we expect the rebate provision for the Medicare Part D Coverage Gap to increase as a result of a planned increase in the portion manufacturers of pharmaceutical products are responsible for.

Chargebacks and distributor service fees provisions increased by \$433 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. Chargebacks increased by \$183 million and distributor service fees increased by \$250 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates, including a \$4 million increase related to the TRICARE program driven by higher sales volumes. The distributor service fee increase was primarily attributable to increased sales volumes and new managed care contracts for OTEZLA[®], which accounted for \$212 million of the increase, as well as a \$23 million increase in commercial copayment program expense and a \$10 million increase in the distributor service fee expense, both of which also were attributable to higher sales volumes.

Discount provisions increased by \$38 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, primarily due to higher sales volumes. The increase was primarily comprised of an increase of \$19 million related to REVLIMID[®] as well as increases related to OTEZLA[®] and POMALYST[®].

Provisions for sales returns and allowances increased by \$6 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017 as the prior year period included a \$5 million reduction in the ABRAXANE[®] returns reserve allowance related to inventory levels held by certain distributors at the

end of 2016 which were sold to end customers during the first quarter of 2017 and due to an increase in the OTEZLA® returns reserve in the second quarter of 2018.

Operating Costs and Expenses

Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2018 and 2017 were as follows:

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

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 418	\$ 342	\$ 76	22.2 %
Percent of Net product sales	3.7 %	3.6 %		

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$76 million to \$418 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. As a percent of Net product sales, Cost of goods sold (excluding amortization of acquired intangible assets) increased to 3.7% for the nine-month period ended September 30, 2018 compared to 3.6% for the nine-month period ended September 30, 2017 primarily due to a raw materials charge recorded in the current year.

Research and Development

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
Research and development	\$4,535	\$3,177	\$ 1,358	42.7 %
Percent of Total revenue	40.3 %	33.4 %		

Research and development expenses increased by approximately \$1.4 billion to approximately \$4.5 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. The increase was primarily due to higher research and development asset acquisition expense related to our purchase of Impact Biomedicines, Inc. (Impact) for approximately \$1.1 billion in 2018 as compared to \$325 million for two acquisitions in 2017. Also contributing to the increase was \$555 million of incremental research and development expense related to the acquisition of Juno, including \$291 million of share-based compensation expense. These increases were partially offset by a reduction of expenses related to collaboration agreements in 2018 of \$284 million. See Note 3 and Note 14 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisitions and our collaboration arrangements, respectively. Our research and development expenses may fluctuate from period-to-period based on the volume and timing of closing asset acquisitions and collaboration arrangements and associated obligations pursuant to such arrangements.

The following table provides a breakdown of Research and development expenses:

	Nine-Month Periods Ended September 30,		Increase/(Decrease)	Percent Change
	2018	2017		
Human pharmaceutical clinical programs	\$1,523	\$989	\$ 534	54.0 %
Other pharmaceutical programs	874	583	291	49.9 %
Drug discovery and development	587	570	17	3.0 %
Collaboration arrangements (See Note 14*)	426	710	(284)	(40.0)%
Research and development asset acquisition expenses (See Note 3*)	1,125	325	800	246.2 %

Total	\$4,535	\$3,177	\$ 1,358	42.7	%
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* References to Notes in this table are to the Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

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Selling, General and Administrative

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
Selling, general and administrative	\$2,400	\$2,167	\$ 233	10.8 %
Percent of Total revenue	21.3 %	22.8 %		

Selling, general and administrative expenses increased by \$233 million to approximately \$2.4 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. The increase is primarily due to incremental expense of \$256 million related to the acquisition of Juno, including \$196 million of share-based compensation expense. The increase was also due to an increase of approximately \$100 million of marketing related expenses and an increase of \$70 million in donations to independent non-profit patient assistance organizations in the U.S. These increases were partially offset by a decrease in litigation-related loss contingency accrual expense of \$258 million primarily related to the previously disclosed Brown Action, which was recorded in the second quarter of 2017. See Note 3 and Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisition of Juno and legal proceedings, respectively.

Amortization of Acquired Intangible Assets

	Nine-Month Periods Ended September 30,		Increase	Percent Change
	2018	2017		
Amortization of acquired intangible assets	\$341	\$250	\$ 91	36.4 %

Amortization of intangible assets acquired as a result of business combinations is summarized below for the nine-month periods ended September 30, 2018 and 2017:

	Nine-Month Periods Ended September 30,		Increase/(Decrease)
	2018	2017	
Acquisitions			
Abraxis	\$213	\$113	\$ 100
Avila	—	10	(10)
Gloucester	23	69	(46)
Juno	50	—	50
Pharmion	1	3	(2)
Quantice	54	55	(1)
Total amortization	\$341	\$250	\$ 91

Effective for the second quarter of 2018, we reduced the remaining estimated useful life of our ABRAXANE® intangible assets as a result of recent settlements of patent-related proceedings, which resulted in approximately \$100 million of accelerated amortization. Amortization expense also increased as a result of the technology platform asset acquired through our acquisition of Juno. These increases were partially offset by reductions in amortization expense as the Gloucester and Avila intangible assets were fully amortized in the first quarter of 2018 and the second quarter

of 2017, respectively. See Note 3 and Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional information regarding our acquisition of Juno and the recent settlements regarding patent litigation, respectively.

Acquisition Related Charges and Restructuring, net

	Nine-Month Periods Ended September 30, 2018 2017		Increase	Percent Change
Acquisition related charges and restructuring, net	\$ 166	\$ 75	\$ 91	121.3 %

Acquisition related charges and restructuring, net was a net charge of \$166 million for the nine-month period ended September 30, 2018, compared to a net charge of \$75 million for the nine-month period ended September 30, 2017. The net charge in 2018

primarily relates to \$92 million of acquisition and restructuring costs associated with the acquisition of Juno. In addition, the net charge in 2018 also includes a charge of \$48 million related to a current period net change in fair value of legacy Juno success payment liabilities. The net charge in 2017 primarily related to an increase in the fair value of our contingent liabilities associated with the acquisition of Nogra Pharma Limited with no corresponding charge in 2018 due to the discontinuance of the GED-0301 trials in the fourth quarter of 2017. See Note 3 and Note 6 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisition of Juno and contingent consideration liabilities, respectively

Other Income and Expenses

Other income and expense for the nine-month periods ended September 30, 2018 and 2017 were as follows:

Interest and Investment Income, Net:

	Nine-Month Periods Ended September 30, 2018		2017	(Decrease)	Percent Change
Interest and investment income, net	\$ 30	\$ 72	\$ (42)		(58.3)%

Interest and investment income, net decreased by \$42 million to \$30 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017 primarily due to lower investment balances as compared to the prior year period.

Interest (Expense):

	Nine-Month Periods Ended September 30, 2018		2017	Increase	Percent Change
Interest (expense)	\$(551)	\$(380)	\$(171)		45.0 %

Interest (expense) increased by \$171 million to \$551 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017 primarily due to the interest expense associated with the issuance of \$3.5 billion of senior notes during the second half of 2017 as well as the issuance of \$4.5 billion of senior notes during February of 2018. See Note 11 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to debt issuances.

Other (Expense) Income, Net:

	Nine-Month Periods Ended September 30, 2018		2017	Increase/(Decrease)
Foreign exchange gains, including foreign exchange derivative instruments not designated as hedging instruments (See Note 7*)	\$4	\$20	\$ (16)	
Fair value adjustments on equity investments (see Notes 1, 3 and 6*)	830	—	830	
Investment impairment charges	—	(49)	49	

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Gain on sale of equity investment in Flexus Biosciences, Inc.	—	9	(9)
Other	18	2	16	
Total Other (expense) income, net	\$852	\$(18)	\$	870

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

Income Tax Provision: The Income tax provision increased by \$580 million to \$742 million for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017, primarily as a result of an increase in the effective tax rate. The effective tax rate for the nine-month period ended September 30, 2018 was 20.0%, an increase of 14.9 percentage points from our effective tax rate of 5.1% for the nine-month period ended September 30, 2017. The increase in our effective tax rate was primarily due to a decrease in excess tax benefits from employee stock compensation deductions, for which our year-to-date effective tax rate was increased by 8.0 percentage points and a decrease in tax benefits from a non-recurring 2017

change in estimate related to our U.S. research and development and orphan drug tax credits, for which our year-to-date effective tax rate was increased by 1.8 percentage points. Our effective tax rate was also increased by our estimate of U.S. tax on forecasted Global Intangible Low-Taxed Income (subject to taxation at an effective statutory tax rate of 10.5%), non-deductible research expenses incurred in our acquisition of Impact, and a decrease in tax benefits of lower statutory tax rates on pre-tax income earned outside the U.S., all of which were partially offset by a reduction in the U.S. statutory tax rate from 35% to 21%, which was enacted on December 22, 2017 as part of the 2017 Tax Act.

Our effective tax rate in 2018 is a function of the distribution of our pre-tax income earned inside and outside of the U.S. Our pre-tax income earned in the U.S. is taxed at a U.S. statutory tax rate of 21%. Our pre-tax income earned outside the U.S. is taxed both in the U.S. at an effective federal statutory tax rate of 10.5% and in the foreign jurisdictions where we have operations at lower effective tax rates. Our global pre-tax income is also subject to taxation in most U.S. states. Our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the amount of research tax credits, the amount of foreign tax credits, the timing and amount of tax benefits from employee stock compensation, payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements and many other factors which are difficult to forecast.

Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of:

	September 30, 2018	December 31, 2017	Increase/(Decrease)	
Financial assets:				
Cash and cash equivalents	\$ 2,480	\$ 7,013	\$ (4,533)
Debt securities available-for-sale	66	3,219	(3,153)
Equity investments with readily determinable fair values	1,832	1,810	22	
Total financial assets	\$ 4,378	\$ 12,042	\$ (7,664)
Debt:				
Short-term borrowings and current portion of long-term debt	\$ 502	\$ —	\$ 502	
Long-term debt, net of discount	19,742	15,838	3,904	
Total debt	\$ 20,244	\$ 15,838	\$ 4,406	
Working capital ⁽¹⁾	\$ 4,223	\$ 11,980	\$ (7,757)

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

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

Many of our operations are conducted outside the United States and significant portions of our Cash, cash equivalents and short-term investments are held internationally. As of September 30, 2018, we held approximately \$2.6 billion of these short-term funds in foreign tax jurisdictions. As a result of the 2017 Tax Act, we expect to have access to this cash with minimal to no additional U.S. tax impact. Therefore, we no longer consider these funds permanently reinvested offshore. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business, including intercompany transactions, as well as for other reasons, such as repurchases of our common stock, internal reorganizations, business-development activities, restrictions on distributions out of foreign tax jurisdictions and debt issuances. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Under the 2017 Tax Act, a company's post-1986 previously untaxed foreign Earnings and Profits (E&P) was mandatorily deemed to be repatriated and taxed, which is also referred to as the toll charge. We have elected to pay the toll charge in annual installments over eight years through 2025.

Share Repurchase Program: In February and May 2018, our Board of Directors approved increases of \$5.0 billion and \$3.0 billion to our authorized share repurchase program, respectively, bringing the total amount authorized since April 2009 to an aggregate of up to \$28.5 billion for our common stock repurchase program of which we have approximately \$2.8 billion remaining for future share repurchases as of September 30, 2018, after deducting \$2.0 billion paid in May 2018 pursuant to an accelerated share repurchase (ASR) agreement. During the three- and nine-month periods ended September 30, 2018, we used nil and \$6.1 billion of cash for purchases of our common stock measured on a settlement date basis, respectively, including the \$2.0 billion paid for the ASR for which we have received full delivery of shares.

Components of Working Capital

Cash, Cash Equivalents, Debt Securities Available-for-Sale and Equity Investments with Readily Determinable Fair Values: From time to time, we invest our excess cash primarily in money market funds, repurchase agreements, time deposits, commercial paper, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities (MBS), global corporate debt securities, asset backed securities and ultra-short income fund investments. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as Debt securities available-for-sale. See Note 8 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report. The approximate \$7.7 billion decrease in Cash, cash equivalents, Debt securities available-for-sale and Equity investments with readily determinable fair values as of September 30, 2018 compared to December 31, 2017 was primarily due to approximately \$8.6 billion of payments for the acquisition of Juno, net of cash acquired, and approximately \$6.1 billion of payments under our share repurchase program, partially offset by approximately \$4.5 billion in proceeds from the February 2018 issuance of senior notes and approximately \$2.8 billion of cash from operating activities.

Accounts Receivable, Net: Accounts receivable, net increased by \$199 million to approximately \$2.1 billion as of September 30, 2018 compared to December 31, 2017. Sales made outside the United States typically have payment terms that are greater than 60 days, thereby extending collection periods beyond those in the United States. We expect our accounts receivable balance to grow as our international sales continue to expand.

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

Inventory: Inventory balances decreased by \$31 million to \$510 million as of September 30, 2018 compared to December 31, 2017.

Other Current Assets: Other current assets increased by \$431 million to \$819 million as of September 30, 2018 compared to December 31, 2017 primarily due to increases of \$242 million in prepaid taxes, \$149 million in tax receivable, \$44 million in the fair value of derivative instruments and \$31 million earned but unbilled revenue associated with contract assets (See Note 2 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report). These increases were partially offset by \$35 million of net other decreases.

Commercial Paper: We have a commercial paper program (Program) under which we issue unsecured commercial paper notes (Commercial Paper) on a private placement basis, the proceeds of which are used for general corporate purposes. As of September 30, 2018, we had available capacity to issue up to \$2.0 billion of Commercial Paper and there were no borrowings under the Program. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis. Borrowings under the Program, if any, are accounted for as short-term borrowings.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of \$2.0 billion. During the second quarter of 2018, we amended our Credit Facility to extend the expiration date to April 25, 2023. 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, 2018, there was no outstanding borrowing against the Credit Facility.

The Credit Facility and the Revolving Credit Agreement contain affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2018.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable and Accrued expenses and other current liabilities increased by \$169 million to approximately \$3.0 billion as of September 30, 2018 compared to December 31, 2017. The increase was primarily due to increases of \$206 million for sales adjustment accruals, \$130 million related to success payment obligations assumed through our acquisition of Juno and \$60 million for VAT tax payable. These increases were partially offset by a decrease of \$185 million associated with the adjustment of clinical trial and development activity wind-down costs associated with the discontinuance of GED-0301 clinical trials in Crohn's disease which was settled and a decrease of \$42 million for accounts payable and other accruals.

Income Taxes Payable (Current and Non-Current): Income taxes payable decreased by \$18 million to approximately \$2.6 billion as of September 30, 2018 compared to December 31, 2017, primarily due to income tax payments of \$974 million, which were partially offset by the current provision for income taxes of \$753 million and an increase in prepaid income taxes of \$200 million.

Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2018 and 2017 were as follows:

	Nine-Month Periods Ended September 30,		
	2018	2017	Change
Net cash provided by operating activities	\$2,828	\$3,557	\$(729)
Net cash (used in) investing activities	(5,817)	(3,989)	(1,828)
Net cash (used in) financing activities	(1,556)	(292)	(1,264)

Operating Activities: Net cash provided by operating activities decreased by \$729 million to approximately \$2.8 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. The decrease in net cash provided by operating activities was primarily driven by the approximate \$1.1 billion initial payment made in 2018 for the acquisition of Impact compared to \$325 million for two acquisitions in 2017 as well as an increase of \$524 million in cash paid for income taxes. These decreases were partially offset by 2017 payments totaling \$315 million for litigation-related loss contingency accruals related to the previously disclosed Brown Action and a decrease of \$270 million in upfront payments for collaboration arrangements in 2018 as compared to 2017. See Note 3, Note 14 and Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to the Impact acquisition, collaboration arrangements and legal proceedings, respectively.

Investing Activities: Net cash used in investing activities increased by approximately \$1.8 billion to approximately \$5.8 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. The increase in net cash used in investing activities was primarily due to approximately \$8.6 billion of payments for the acquisition of Juno, net of cash acquired, partially offset by approximately \$3.1 billion of net sales of debt securities available-for-sale in 2018 compared to approximately \$3.4 billion of net purchases of debt securities available-for-sale in 2017. See Note 3 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to the Juno acquisition.

Financing Activities: Net cash used in financing activities increased by approximately \$1.3 billion to approximately \$1.6 billion for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. Net cash used in financing activities increased due to approximately \$6.1 billion of payments under our share repurchase program during 2018 compared to \$925 million of payments under our share repurchase program during 2017. See Note 4 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details. This increase in net cash used in financing activities was partially offset by proceeds from the February 2018 debt issuance, which provided approximately \$4.5 billion compared to proceeds from the August 2017 debt issuance which provided \$496 million. See Note 11 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details.

Contractual Obligations

For a discussion of our contractual obligations, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2017 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2017 aside from those disclosed in Note 3 and Note 14 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report except as follows:

Collaboration Arrangements and Acquired Research and Development Assets: In addition to the research and development collaboration agreements with third parties and acquired research and development assets from third parties with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets disclosed in our 2017 Annual Report on Form 10-K, the acquisition of Juno added additional research and development collaboration agreements with third parties and acquired research and development assets from third parties with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these additional efforts is contingent upon 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 related to the attainment of specified development, regulatory approval and sales-based milestones over a period of several years are inherently uncertain, and accordingly, no amounts have been recorded for these future potential payments in our Consolidated Balance Sheets as of September 30, 2018 contained in this Quarterly Report on Form 10-Q. Potential milestone payments (not including potential royalty payments) under these acquired arrangements from Juno total approximately \$2.5 billion.

Critical Accounting Estimates and Significant Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting estimates are disclosed in the Management’s Discussion and Analysis of Financial Condition and Results of Operations section of our 2017 Annual Report on Form 10-K. See Note 1 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for new accounting standards adopted during the first quarter of 2018.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. As of September 30, 2018, our market risk sensitive instruments consisted of debt securities available-for-sale and equity investments with readily determinable fair values, our long-term debt and certain derivative contracts (See Notes 8, 11 and 7 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details, respectively).

Debt Securities Available-for-Sale: As of September 30, 2018, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as Debt securities available-for-sale were as follows:

	Duration			
	Less			
	Than	1 to 3	3 to 5	Total
	1	Years	Years	
	Year			
Principal amount	\$66	\$ —	\$ —	\$66
Fair value	66	—	—	66
Weighted average interest rate	2.6 %	—%	—%	2.6 %

Equity Investments with Readily Determinable Fair Values

Our Equity investments with readily determinable fair values are primarily equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration arrangements. Realized and unrealized gains and losses related to such securities are included in Other (expense) income, net on the Consolidated Statements of Income.

Debt Obligations

Short-Term Borrowings and Current Portion of Long-Term Debt: The carrying value of Short-term borrowings and current portion of long-term debt as of September 30, 2018 and December 31, 2017 includes:

	September 30, December 31,	
	2018	2017
2.250% senior notes due 2019	\$ 502	\$ —
Total short-term borrowings and current portion of long-term debt	\$ 502	\$ —

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after September 30, 2018 have an aggregate principal amount of \$19.850 billion with varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of September 30, 2018 are summarized below:

	Principal Amount	Carrying Value
2.875% senior notes due 2020	\$ 1,500	\$ 1,496
3.950% senior notes due 2020	500	510
2.250% senior notes due 2021	500	498
2.875% senior notes due 2021	500	498
3.250% senior notes due 2022	1,000	1,037
3.550% senior notes due 2022	1,000	995
2.750% senior notes due 2023	750	747
3.250% senior notes due 2023	1,000	993
4.000% senior notes due 2023	700	732
3.625% senior notes due 2024	1,000	1,001
3.875% senior notes due 2025	2,500	2,472
3.450% senior notes due 2027	1,000	968
3.900% senior notes due 2028	1,500	1,483
5.700% senior notes due 2040	250	247
5.250% senior notes due 2043	400	393
4.625% senior notes due 2044	1,000	987
5.000% senior notes due 2045	2,000	1,975
4.350% senior notes due 2047	1,250	1,234
4.550% senior notes due 2048	1,500	1,476
Total long-term debt	\$ 19,850	\$ 19,742

As of September 30, 2018, the fair value of our senior notes outstanding was \$19.8 billion.

MARKET RISK MANAGEMENT

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We actively manage the impact of foreign exchange rate and interest rate

movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts. In instances where these financial instruments are accounted for as cash flow hedges or fair value hedges we may from time to time terminate the

hedging relationship. If a hedging relationship is terminated, we generally either settle the instrument or enter into an offsetting instrument.

Foreign Currency Risk Management

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

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

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

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding as of September 30, 2018 and December 31, 2017 had settlement dates within 33 months and 20 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 Other comprehensive income (OCI) and reclassified to the Consolidated Statements 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. 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.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of September 30, 2018 and December 31, 2017:

Foreign Currency	Notional Amount	
	September 30, 2018	December 31, 2017
Australian Dollar	\$55	\$ 61
British Pound	120	97
Canadian Dollar	198	227
Euro	1,749	954
Japanese Yen	454	356
Total	\$2,576	\$ 1,695

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, 2018, 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) income, net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding as of September 30, 2018 and December 31, 2017 were \$621 million and \$885 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2018 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$304 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in OCI and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.

Foreign Currency Option Contracts: From time to time, we may hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in that local currency. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and local currency notional amounts but with different strike prices. This combination of transactions is generally referred to as a "collar." The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency option contracts outstanding as of September 30, 2018 and December 31, 2017 had settlement dates within 27 months and 36 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, 2018 and December 31, 2017:

	Notional Amount (1)	
	September 30, 2018	December 31, 2017
Foreign currency option contracts designated as hedging activity:		
Purchased Put	\$1,964	\$ 3,319
Written Call	2,250	3,739

(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 amount of nil and \$258 million as of September 30, 2018 and December 31, 2017, respectively. We de-designated all of our put option contracts as of September 30, 2018.

Assuming that the September 30, 2018 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately \$115 million if the U.S. Dollar were to strengthen and decrease by approximately \$131 million if the U.S. Dollar were to weaken. However, since the contracts hedge specific forecasted intercompany transactions denominated in foreign currencies, any change in the fair value of the contract would be reported in OCI and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings.

Interest Rate Risk Management

Forward Starting Interest Rate Swaps and Treasury Rate Locks: In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) or treasury rate lock agreements (treasury rate locks) that

are designated as cash flow hedges to hedge against changes in interest rates that could impact expected future issuances of debt. To the extent these hedges of cash flows related to anticipated debt are effective, any realized or unrealized gains or losses on the forward starting swaps or treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes. As of September 30, 2018 and December 31, 2017, we did not have any outstanding forward starting swaps or treasury rate locks.

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 Statements of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheets. 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 Statements of Income within Interest (expense) with an associated offset to the derivative asset or liability on

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

The following table summarizes the notional amounts of our outstanding interest rate swap contracts as of September 30, 2018 and December 31, 2017:

	Notional Amount	
	September 30, 2018	December 31, 2017
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
3.450% senior notes due 2027	550	250
3.900% senior notes due 2028	200	—
Total	\$950	\$ 450

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2018 and 2017, and also terminated the hedging relationship by settling certain of those swap contracts during 2018 and 2017. In 2018, we settled \$150 million notional amount of certain swap contracts. There were no material cash proceeds as a result of settling such swap contracts. During 2017, we terminated the hedging relationship on certain outstanding swap contracts amounting to \$200 million notional amount by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of \$3 million during the year ended December 31, 2017, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 to the Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to reductions of current and future interest expense.

A sensitivity analysis to measure potential changes in the market value of our debt and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates as of September 30, 2018 would have reduced the aggregate fair value of our net payable by approximately \$1.4 billion. A one percentage point decrease as of September 30, 2018 would have increased the aggregate fair value of our net payable by approximately \$1.6 billion.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Our operating results may be subject to significant fluctuations.

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

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

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

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

may adversely impact the degree of acceptance of these products, including their efficacy, safety, price and benefits over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans.

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

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

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

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

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

- In general, preclinical tests and clinical trials can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials may not lead to regulatory approval;

- Delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality;

- Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or legislation;

Even if a product is approved, the scope of the approval may significantly limit the indicated uses or the patient population for which the product may be marketed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the product;

After a product is approved, the FDA or similar bodies in other countries may withdraw or modify an approval in a significant manner or request that we perform additional clinical trials or change the labeling of the product due to a number of reasons, including safety concerns, adverse events and side effects;

Products, such as REVLIMID® and POMALYST®/IMNOVID®, that receive accelerated approval can be subject to an expedited withdrawal if post-marketing restrictions are not adhered to or are shown to be inadequate to assure safe use, or if the drug is shown to be unsafe or ineffective under its conditions of use;

- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our approved products;

Approved products, as well as their manufacturers, are subject to continuing and ongoing review by regulatory agencies, and the discovery of previously unknown problems with these products or the failure to comply with manufacturing or quality control requirements may result in restrictions on the manufacture, sale or use of a product or its withdrawal from the market; and

- Changes in regulatory agency policy or the adoption of new regulations or legislation could impose restrictions on the sale or marketing of our approved products.

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

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

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

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

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

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

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

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

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

In the U.S. there have been and are likely to continue to be a number of legislative and regulatory proposals and enactments (e.g., the President's American Patients First Blueprint) related to drug pricing and reimbursement at both the federal and state level that could impact our profitability. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law in March 2010, and are referred to collectively as the Healthcare Reform Acts. These reforms have significantly impacted the pharmaceutical industry and, in the coming years, it is likely that additional changes, including the possible repeal of all or certain aspects of these reforms, will be made. Moreover, changes could be made to governmental healthcare and insurance reimbursement programs that could significantly impact the profitability of our products. Additionally, the pricing and reimbursement of pharmaceutical products, in general and specialty drugs in particular, have received the attention of

U.S. policymakers, state legislators and others. At this time, we cannot predict the impact of this increased scrutiny on the pricing or reimbursement of our products or pharmaceutical products generally.

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

at any price, and to report the ceiling prices for its drugs to the government. HRSA issued this update in late 2016, and we signed an amendment to our agreement on December 29, 2016.

HRSA also issued proposed regulations to implement an administrative dispute resolution (ADR) process for certain disputes arising under the 340B program, including (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit, that a covered entity has violated the prohibition on diversion of covered outpatient drugs to ineligible patients or duplicate discounts. The exact timing and content of final action on these matters is uncertain at this time. Depending on their final form, these actions could affect our obligations under the 340B program in ways that may have an adverse impact on our business. Additionally, in early 2016, HRSA finalized a regulation regarding the 340B pricing methodology and providing guidelines for when civil monetary penalties may be issued for “knowing and intentional” manufacturer overcharges of 340B covered entities. HRSA has delayed the effective date of this regulation to July 1, 2019.

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

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

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

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

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

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

Our intellectual property rights may be affected by certain provisions of the America Invents Act (“AIA”) enacted in 2011. For example, under the AIA, members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant proceeding, such as a Post Grant Review (PGR) or Inter Partes Review (IPR). Once a post grant proceeding is instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. For more information with respect to IPRs, see Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report. A similar procedure (known as a patent opposition) has existed in Europe for many years and we have defended our European patents in certain of those proceedings. We cannot predict whether any other Celgene patents will ever become the subject of a post grant proceeding or patent opposition. If a significant product patent is successfully challenged in a post grant proceeding or patent opposition, it

may be revoked, which would have a serious negative impact on our ability to maintain exclusivity in the market-place for our commercial products affected by such revocation and could adversely affect our future revenues and profitability.

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

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

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

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

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

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

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

of certain challenges, see Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

Upon the expiration or loss of patent protection for a product, or upon the “at-risk” launch by a manufacturer of a generic version of one of our products, we can quickly lose a significant portion of our sales of that product. In addition, as additional competitors enter the market, our patented products may face increased competition or pricing pressure.

Orphan exclusivity and regulatory data protection for REVLIMID®’s multiple myeloma indication in Europe expired in June 2017. The regulatory marketing protection for REVLIMID® in Europe expired in June 2018. Notwithstanding that our intellectual property rights for REVLIMID® in Europe are due to remain in force through at least 2022, we expect that some generic drug companies may attempt to market a generic version of REVLIMID® in various countries in Europe before this time. We have recently been

made aware of a generic drug manufacturer receiving regulatory clearance for a generic version of REVLIMID® in some European countries. While we intend to enforce our intellectual property rights to the fullest extent possible, it may be possible for generic drug companies either to challenge successfully our rights in advance of launch or to otherwise gain entry into the market following the expiration of regulatory marketing protection for REVLIMID®.

Certain novel approaches to the treatment of diseases, such as chimeric antigen receptor (CAR) T cell therapy, may present significant challenges and risks for us.

The development of novel approaches for the treatment of diseases, such as our recent acquisition of Juno's CAR T cell immunotherapy and related technologies, presents many new challenges and risks due to the unique nature of genetic modification of patient cells ex vivo using certain viruses to reengineer these cells to ultimately treat diseases. The use of reengineered cells as a potential cancer treatment is a recent development and may not be broadly accepted by the regulatory, patient or medical communities. Further, we may not be able to satisfactorily establish the safety and efficacy or the reliability of these therapies. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, only a few products that involve the genetic modification of patient cells have been approved for commercial sale. Moreover, public perception of therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians and payors to subscribe to these novel treatment approaches. If we fail to overcome these and other challenges, or if significant adverse events are reported from similar therapies, our development of these novel treatment approaches may be hampered or delayed, which could adversely affect our future anticipated revenues and/or profitability related to this therapeutic program.

Our business operates in an extremely competitive environment.

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

Hematology and Oncology: AbbVie, Amgen, AstraZeneca, Bristol-Myers-Squibb, Eisai, Gilead, Johnson & Johnson, Merck, Novartis, Roche/Genentech, Sanofi and Takeda; and

Inflammation and Immunology: AbbVie, Amgen, Biogen, Eisai, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer and UCB S.A.

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

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

Sales of our products are dependent, in large part, on third-party payers. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. For information about receivable balances relating to government-owned or -controlled hospitals in European countries, see Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this report.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have limited experience manufacturing CAR T cell immunotherapies, and our processes may be more difficult or more expensive than the approaches taken by our current and future competitors. We cannot be sure that the manufacturing processes employed by us will result in CAR T cell immunotherapies that will be safe and effective. Logistical and shipment delays and other factors not in our control could prevent or delay the delivery of our product candidates to patients. Additionally, we are required to maintain a complex chain of identity and custody with respect to patient material as such material moves through the manufacturing process, and failure to maintain such chain of identity and custody could result in adverse patient outcomes, loss of product or regulatory remedial action, which could adversely affect our future anticipated revenues and/or profitability related to this therapeutic program.

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

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of our distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors and pharmacy chains control a significant share of the market. We expect that consolidation of drug wholesalers and pharmacy chains will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements and their purchases may exceed customer demand, resulting in increased returns or reduced wholesaler purchases in later periods.

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

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that violate the laws or regulations of the jurisdictions in which we operate, including employment, anti-corruption, environmental, competition and privacy laws. Such improper actions, particularly with respect to foreign healthcare professionals and government officials, could subject us to civil or criminal investigations, monetary and injunctive penalties, adversely impact our ability to

conduct business in certain markets, negatively affect our results of operations and damage our reputation.

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

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

- increased management, travel, infrastructure and legal compliance costs;
- longer payment and reimbursement cycles;

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

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

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

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

- demands on management related to the increase in our size after an acquisition;
- the diversion of management's attention from daily operations to the integration of acquired businesses and personnel;
- higher than anticipated integration costs;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;
- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records and procedures, as well as in maintaining uniform standards and controls, including internal control over financial reporting, and related procedures and policies.

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

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

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

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

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

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

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

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation under the U.S. Federal Food, Drug, and Cosmetic Act, the Medicaid Drug Rebate Program, the False Claims Act, the Foreign Corrupt Practices Act and other federal and state statutes, including those discussed elsewhere in this report, as well as anti-kickback and false claims laws, and similar laws in international jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information demands from government authorities, and been subject to claims and other actions related to our business activities brought by governmental authorities, as well as by consumers, third-party payers, stockholders and others. There can be no assurance that existing or future proceedings will not result in significant expense, civil payments, fines or other adverse consequences. For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

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

Product liability claims could result in significant damage awards or settlements. Such claims can also be accompanied by consumer fraud claims or claims by third-party payers seeking reimbursement of the cost of our products. In addition, adverse determinations or settlements of product liability claims may result in suspension or withdrawal of a product marketing authorization or changes to our product labeling, including restrictions on therapeutic indications, inclusion of new contra-indications, warnings or precautions, which would have a material adverse effect on sales of such product. We have historically purchased product liability coverage from third-party

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

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

We are subject to income taxes in both the United States and various foreign jurisdictions and our domestic and international tax liabilities are largely dependent upon the distribution of income among these different jurisdictions. Various factors may have

favorable or unfavorable effects on our effective income tax rate. These factors include interpretations of existing tax laws, the accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. See 'Liquidity and Capital Resources' within Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations as well as Note 13 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report. For additional details related to the 2017 Tax Act, see Note 16 of Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results. We utilize foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased put options, all of which are derivative instruments, to manage foreign currency risk. We use these derivative instruments to hedge certain forecasted transactions, manage exchange rate volatility in the translation of foreign earnings and reduce exposures to foreign currency fluctuations of certain balance sheet items denominated in foreign currencies. The use of these derivative instruments is intended to mitigate a portion of the exposure of these risks with the intent to reduce our risk or cost, but generally would not fully offset any change in operating results as a consequence of fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations. See Note 5 of Notes to Unaudited Consolidated Financial Statements and Item 3. Quantitative and Qualitative Disclosures About Market Risk contained elsewhere in this report.

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

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

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

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

The price of our common stock may fluctuate significantly.

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

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

- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- changes or anticipated changes in laws and governmental regulations, including changes in tax, healthcare, environmental, competition and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;

patent or proprietary rights developments;
changes in pricing and third-party reimbursement policies for our products;
the outcome of litigation involving our products, processes or intellectual property;
the existence and outcome of governmental investigations and proceedings;
regulatory actions that may impact our products or potential products;
disruptions in our manufacturing processes or supply chain;
failure of our collaboration partners to successfully develop potential drug candidates;
competition; and
investor reaction to announcements regarding business or product acquisitions.

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

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

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

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

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

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

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

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

could adversely affect our business and result in financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties.

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

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

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

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

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

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

- an active public market for the CVRs may not continue to exist or the CVRs may trade at low volumes, both of which could have an adverse effect on the market price of the CVRs;
 - if the net sales targets specified in the CVR Agreement are not achieved within the time periods specified, no payment will be made and the CVRs will expire valueless;
 - since the U.S. federal income tax treatment of the CVRs is unclear, any part of a CVR payment could be treated as ordinary income and the tax thereon may be required to be paid prior to the receipt of the CVR payment;
 - any payments in respect of the CVRs are subordinated to the right of payment of certain of our other indebtedness;
 - we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations under the CVR Agreement to continue to commercialize ABRAXANE® or any of the other Abraxis pipeline products, we may discontinue such efforts, which would have an adverse effect on the value of the CVRs.

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

(c) Issuer Purchases of Equity Securities

From April 2009 through September 2018, our Board of Directors approved purchases of up to \$28.5 billion of our common stock, including increases of \$5.0 billion and \$3.0 billion approved by our Board of Directors in February

and May 2018, respectively. Approved amounts exclude share purchase transaction fees.

As part of the existing Board authorized share repurchase program, in May 2018 we entered into an ASR agreement with an investment bank to repurchase an aggregate of \$2.0 billion of our common stock. As part of the ASR agreement we received an

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initial delivery of 17,987,922 shares in May 2018 and a final delivery of 5,956,747 shares in August 2018. The total number of shares repurchased under the ASR agreement was 23,944,669 at a weighted average price of \$83.53 per share.

The following table presents the number of shares purchased during the three-month period ended September 30, 2018, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs (1)
July 1 - July 31	—	\$	—	\$2,803,704,460
August 1 - August 31	5,956,747	\$	—5,956,747	\$2,803,704,460
September 1 - September 30	—	\$	—	\$2,803,704,460
Total	5,956,747	\$	—5,956,747	

(1) There were no share repurchases during the three-month period ended September 30, 2018. We received 5,956,747 of our shares upon final settlement of the ASR program which commenced during the second quarter of 2018. The delivery of these shares reduced our outstanding shares used to determine our weighted average shares outstanding for purposes of calculating basic and diluted earnings per share. The total number of shares that was repurchased under the ASR agreement was 23,944,669 at a cost of \$2.0 billion.

(2) The Average Price Paid per Share is based on the price paid per share in the open market and does not include ASR transactions.

As of September 30, 2018, we had a remaining purchase authorization of approximately \$2.8 billion.

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

Item 6. Exhibits

31.1* Certification by the Company's Chief Executive Officer.

31.2* Certification by the Company's Chief Financial Officer.

32.1* Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.

32.2* Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.

101* The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) Notes to Unaudited Consolidated

Financial Statements.

* Filed herewith.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CELGENE
CORPORATION

Date: October 25, 2018 By: /s/ David V. Elkins
David V. Elkins
Executive Vice
President and Chief
Financial Officer
(principal financial
and accounting
officer)