

CELGENE CORP /DE/  
Form 10-Q  
May 03, 2016

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 March 31, 2016

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)  Smaller reporting company

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

At April 26, 2016, 774,601,496 shares of Common Stock, par value \$.01 per share, were outstanding.

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CELGENE CORPORATION

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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited)

CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(In millions, except per share amounts)

	Three-Month Periods Ended March 31,	
	2016	2015
Revenue:		
Net product sales	\$2,494.7	\$2,055.2
Other revenue	16.9	25.6
Total revenue	2,511.6	2,080.8
Expenses:		
Cost of goods sold (excluding amortization of acquired intangible assets)	105.9	104.0
Research and development	733.2	506.0
Selling, general and administrative	543.0	529.2
Amortization of acquired intangible assets	91.8	63.6
Acquisition related charges and restructuring, net	36.2	19.0
Total costs and expenses	1,510.1	1,221.8
Operating income	1,001.5	859.0
Other income and (expense):		
Interest and investment income, net	6.8	9.0
Interest (expense)	(121.9)	(49.2)
Other income (expense), net	35.2	8.3
Income before income taxes	921.6	827.1
Income tax provision	120.9	108.2
Net income	\$800.7	\$718.9
Net income per common share:		
Basic	\$1.03	\$0.90
Diluted	\$0.99	\$0.86
Weighted average shares:		
Basic	780.6	798.9
Diluted	807.7	834.1

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 March 31,	
	2016	2015
Net income	\$800.7	\$718.9
Other comprehensive income (loss):		
Foreign currency translation adjustments	18.2	(23.2 )
Pension liability adjustment	—	(5.9 )
Net unrealized gains (losses) related to cash flow hedges:		
Unrealized holding gains (losses)	(221.0 )	406.9
Tax benefit	10.0	9.9
Unrealized holding gains (losses), net of tax	(211.0 )	416.8
Reclassification adjustment for (gains) included in net income	(86.7 )	(69.2 )
Tax (benefit)	(0.7 )	(0.5 )
Reclassification adjustment for (gains) included in net income, net of tax	(87.4 )	(69.7 )
Net unrealized gains (losses) on marketable securities available for sale:		
Unrealized holding (losses)	(381.8 )	(77.1 )
Tax benefit	139.0	26.5
Unrealized holding (losses), net of tax	(242.8 )	(50.6 )
Reclassification adjustment for (gains) losses included in net income	10.4	(0.6 )
Tax (benefit) expense	(3.6 )	0.2
Reclassification adjustment for (gains) losses included in net income, net of tax	6.8	(0.4 )
Total other comprehensive income (loss)	(516.2 )	267.0
Comprehensive income	\$284.5	\$985.9

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$4,445.5	\$ 4,880.3
Marketable securities available for sale	1,261.8	1,671.6
Accounts receivable, net of allowances of \$31.3 and \$30.3 at March 31, 2016 and December 31, 2015, respectively	1,420.3	1,420.9
Inventory	470.6	443.4
Other current assets	787.8	984.7
Total current assets	8,386.0	9,400.9
Property, plant and equipment, net	840.0	814.1
Intangible assets, net	10,763.5	10,858.1
Goodwill	4,876.5	4,879.0
Other assets	1,097.9	1,012.3
Total assets	\$25,963.9	\$ 26,964.4
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	219.7	240.8
Accrued expenses and other current liabilities	1,541.8	1,647.7
Income taxes payable	14.6	19.8
Current portion of deferred revenue	57.8	60.6
Total current liabilities	1,833.9	1,968.9
Deferred revenue, net of current portion	28.8	30.0
Income taxes payable	326.9	324.2
Other non-current tax liabilities	2,519.2	2,519.2
Other non-current liabilities	1,912.0	2,041.7
Long-term debt, net of discount	14,268.3	14,161.4
Total liabilities	20,889.1	21,045.4
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding at March 31, 2016 and December 31, 2015, respectively	—	—
Common stock, \$.01 par value per share, 1,150.0 million shares authorized; issued 941.9 million and 940.1 million shares at March 31, 2016 and December 31, 2015, respectively	9.4	9.4
Common stock in treasury, at cost; 167.2 million and 153.5 million shares at March 31, 2016 and December 31, 2015, respectively	(15,431.5 )	(14,051.8 )
Additional paid-in capital	11,370.3	11,119.3
Retained earnings	8,875.1	8,074.4
Accumulated other comprehensive income	251.5	767.7
Total stockholders' equity	5,074.8	5,919.0
Total liabilities and stockholders' equity	\$25,963.9	\$ 26,964.4

See accompanying Notes to Unaudited Consolidated Financial Statements



CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in millions)

	Three-Month Periods Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net income	\$ 800.7	\$ 718.9
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	29.2	28.1
Amortization	96.1	66.6
Deferred income taxes	(43.4 )	(106.6 )
Impairment charges	17.4	2.1
Change in value of contingent consideration	33.0	19.0
Gain on sale of business	(37.5 )	—
Share-based compensation expense	146.5	128.8
Share-based employee benefit plan expense	9.0	7.7
Derivative instruments	21.3	(7.0 )
Other, net	(2.3 )	0.6
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	23.1	(59.5 )
Inventory	(25.6 )	7.3
Other operating assets	38.6	(26.4 )
Accounts payable and other operating liabilities	(130.3 )	59.2
Income tax payable	(2.8 )	15.8
Deferred revenue	1.9	1.9
Net cash provided by operating activities	974.9	856.5
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	313.9	1,079.8
Purchases of marketable securities	(285.4 )	(678.8 )



available for sale			
Capital expenditures	(59.6	)	(42.3
Proceeds from sales of investment securities	0.3		6.8
Purchases of investment securities	(79.4	)	(27.5
Net cash (used in) provided by investing activities	(110.2	)	338.0
Cash flows from financing activities:			
Payment for treasury shares	(1,410.0	)	(1,012.6
Proceeds from short-term borrowing	—		90.0
Principal repayments on short-term borrowing	—		(189.6
Net proceeds from common equity put options	2.8		5.2
Net proceeds from share-based compensation arrangements	62.4		114.4
Excess tax benefit from share-based compensation arrangements	25.1		84.5
Net cash used in financing activities	(1,319.7	)	(908.1
Effect of currency rate changes on cash and cash equivalents	20.2		(40.3
Net (decrease) increase in cash and cash equivalents	(434.8	)	246.1
Cash and cash equivalents at beginning of period	4,880.3		4,121.6
Cash and cash equivalents at end of period	\$ 4,445.5		\$ 4,367.7

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	Three-Month Periods Ended March 31,	
	2016	2015
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized loss on marketable securities available for sale	\$381.8	\$77.1
Investment in Human Longevity, Inc. common stock	\$39.6	\$—
Supplemental disclosure of cash flow information:		
Interest paid	\$200.9	\$50.2
Income taxes paid	\$102.1	\$106.7

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 and Basis of Presentation

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

Our primary commercial stage products include REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, ABRAXANE<sup>®</sup>, OTEZLA<sup>®</sup>, VIDAZA<sup>®</sup>, azacitidine for injection (generic version of VIDAZA<sup>®</sup>), THALOMID<sup>®</sup> (sold as THALOMID<sup>®</sup> or Thalidomide Celgene<sup>™</sup> outside of the U.S.), and ISTODAX<sup>®</sup>. In addition we earn revenue through licensing arrangements.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Investments in limited partnerships and interests where we have an equity interest of 50% or less and do not otherwise have a controlling financial interest are accounted for by either the equity or cost method. Certain prior year amounts have been reclassified to conform to the current year's presentation.

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, European 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.

2. Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 (2015 Annual Report on Form 10-K).

New accounting standards which have been adopted

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs" (ASU 2015-03). ASU 2015-03 more closely aligns the presentation of debt issuance costs under U.S. GAAP with the presentation under comparable IFRS standards by requiring that debt issuance costs be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. We have adopted ASU 2015-03 during the three-month period ended March 31, 2016. Other assets and Long-term debt, net of discount have been restated as of December 31, 2015 to reflect the retroactive reclassification of \$89.0 million of debt issuance costs that have been reclassified from Other assets to Long-term debt, net of discount.

In April 2015, the FASB issued Accounting Standards Update No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement" (ASU 2015-05). ASU 2015-05 provides guidance to help companies evaluate the accounting for fees paid by a customer in a cloud computing arrangement. The new guidance clarifies that if a cloud computing arrangement includes a software license, the customer should account for the license consistent with its accounting for other software licenses. If the arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for us beginning in the first quarter of 2016. The adoption of this updated standard did not have a material impact on our consolidated financial statements and related disclosures.

In September 2015, the FASB issued Accounting Standards Update No. 2015-16, "Simplifying the Accounting for Measurement-Period Adjustments" (ASU 2015-16). ASU 2015-16 replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional

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

amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. ASU 2015-16 was effective for us beginning in the first quarter of 2016 and did not have a material impact on our consolidated financial statements and related disclosures.

New accounting standards which have not yet been adopted

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09). ASU 2014-09 supersedes nearly all existing revenue recognition guidance under U.S. GAAP and requires revenue to be recognized when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This accounting guidance is effective for us beginning in the first quarter of 2018 using one of two prescribed transition methods. We are currently evaluating the effect that the updated standard and transition method will have on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory" (ASU 2015-11). ASU 2015-11 applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new standard will be effective for us on January 1, 2017. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, "Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU 2016-01). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. Changes in measurement under either alternative will be recognized in net income. Companies that elect the fair value option for financial liabilities must recognize changes in fair value related to instrument-specific credit risk in other comprehensive income. Companies must assess valuation allowances for deferred tax assets related to available-for-sale debt securities in combination with their other deferred tax assets. ASU 2016-01 will be effective for us beginning in the first quarter of 2018 and early adoption is available to publicly traded companies for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. We expect the implementation of this standard to have an impact on our consolidated financial statements and related disclosures, as we held publicly traded equity investments at March 31, 2016 with a fair value of \$925.0 million, as well as equity investments accounted for under the cost method. A cumulative-effect adjustment to the balance sheet will be recorded as of the beginning of the fiscal year of adoption. The implementation of ASU 2016-01 is expected to increase volatility in our net income as the

volatility currently recorded in other comprehensive income related to changes in the fair market value of available for sale equity investments will be reflected in net income after adoption.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" (ASU 2016-02). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either operating or finance. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures, however, we anticipate recognition of additional assets and corresponding liabilities related to leases on our balance sheet.

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

In March 2016, the FASB issued Accounting Standards Update No. 2016-07, "Investments-Equity Method and Joint Ventures" (ASU 2016-07). ASU 2016-07 eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively as if the equity method had been in effect during all previous periods that the investment had been held. Under the new guidance, available-for-sale equity securities that become qualified for the equity method of accounting will result in the recognition through earnings of the unrealized holding gain or loss in accumulated other comprehensive income at the date the investment becomes qualified for use of the equity method. The new standard will be effective for us on January 1, 2017 and will be adopted on a prospective basis. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation" (ASU 2016-09). ASU 2016-09 changes several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, employee tax withholding, calculation of shares for use in diluted earnings per share, and classification on the statement of cash flows. The new standard will be effective for us on January 1, 2017. Early adoption is available. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

### 3. Acquisitions and Divestitures

Receptos, Inc. (Receptos): On August 27, 2015 (Acquisition Date), we acquired all of the outstanding common stock of Receptos, resulting in Receptos becoming our wholly-owned subsidiary. Receptos' lead drug candidate, ozanimod, is a small molecule that modulates sphingosine 1-phosphate 1 and 5 receptors and it is in development for immune-inflammatory indications, including inflammatory bowel disease and relapsing multiple sclerosis (RMS). In clinical trial results, ozanimod demonstrated several areas of potential advantage over existing oral therapies for the treatment of ulcerative colitis (UC) and RMS, including its cardiac, hepatotoxicity and lymphocyte recovery profile. The phase III TRUE NORTH trial in UC is currently underway with data expected in 2018. The phase III RADIANCE and SUNBEAM RMS trials are ongoing and data are expected in 2017. The acquisition of Receptos also included RPC4046, an anti-interleukin-13 (IL-13) antibody in development for eosinophilic esophagitis (EoE), an allergic/immune-mediated orphan disease. RPC4046 was licensed from AbbVie Bahamas Ltd. and AbbVie Inc. (collectively referred to as AbbVie). The phase II trial evaluating RPC4046 in EoE met the primary endpoint of reduction of mean eosinophil count. We are evaluating the data to determine next steps with the program. The results of operations and cash flows for Receptos are included in our consolidated financial statements from the Acquisition Date and the assets and liabilities of Receptos have been recorded at their respective fair values on the Acquisition Date and consolidated with our assets and liabilities.

We paid approximately \$7.626 billion, consisting of \$7.311 billion for common stock outstanding and \$0.315 billion for the portion of equity compensation attributable to the pre-combination period. In addition, we paid \$0.197 billion for the portion of equity compensation attributable to the post-combination service period, which has been recorded as expense over the required service period ending in the fourth quarter of 2015.

The acquisition has been accounted for 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 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, goodwill and associated deferred tax assets and liabilities are subject to change

pending finalization of valuation efforts.

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 Receptos is summarized as follows:

	Total Consideration
Cash paid for outstanding common stock	\$ 7,311.3
Cash for equity compensation attributable to pre-combination service	314.9
Total consideration	\$ 7,626.2



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. During the fourth quarter of 2015, adjustments were recorded to increase the amounts initially recorded for deferred tax assets, deferred tax liabilities and goodwill as of the Acquisition Date. The amounts recognized will be finalized as the information necessary to complete the analyses is obtained, but no later than one year from the Acquisition Date.

	Amounts Recognized as of the Acquisition Date (Provisional)
Working capital <sup>(1)</sup>	\$ 479.2
Property, plant and equipment	5.0
In-process research and development product rights	6,842.0
Current deferred tax assets	241.3
Other non-current assets	7.9
Non-current deferred tax liabilities <sup>(2)</sup>	(2,519.2 )
Total identifiable net assets	5,056.2
Goodwill	2,570.0
Total net assets acquired	\$ 7,626.2

<sup>(1)</sup> Includes cash and cash equivalents, available for sale marketable securities, other current assets, accounts payable, and accrued expenses and other current liabilities.

<sup>(2)</sup> Upon integration of the acquired intangible assets into our offshore research, manufacturing, and commercial operations, the deferred tax liability was reclassified to a non-current tax liability.

The fair values of current and other non-current assets, current liabilities and property, plant and equipment were determined to approximate their book values.

The fair value assigned to acquired IPR&D was based on the present value of expected after-tax cash flows attributable to ozanimod, which is in phase II and III testing. The present value of expected after-tax cash flows attributable to ozanimod and assigned to IPR&D was determined by estimating the after-tax costs to complete development of ozanimod into a commercially viable product, estimating future revenue and ongoing expenses to produce, support and sell ozanimod, 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 compounds 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 an indefinite-lived intangible asset until regulatory approval 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 inflammation and immunology 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. As a result of the exclusive development license from AbbVie for RPC4046 that Receptos held prior to our acquisition of Receptos, AbbVie holds an option to enter into a global collaboration for RPC4046 with us. If AbbVie does not exercise its option, we will have an exclusive worldwide license for the development and commercialization of RPC4046 for any and all indications. We do not consider this potential collaboration arrangement to be significant.

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

Pro Forma Financial Information:

The following table provides unaudited pro forma financial information for the three-month period ended March 31, 2015 as if the acquisition of Receptos had occurred on January 1, 2014.

	Three-Month Period Ended March 31, 2015
Total revenue	\$ 2,080.8
Net income	\$ 650.6
Net income per common share: basic	\$ 0.81
Net income per common share: diluted	\$ 0.78

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 Receptos. 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 Receptos. 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 period presented, nor are they intended to represent or be indicative of future results of operations.

QuanticeL Pharmaceuticals, Inc. (QuanticeL): On October 19, 2015, we completed our previously announced acquisition of QuanticeL, a privately held biotechnology company focused on cancer drug discovery, for consideration consisting of \$95.9 million in cash at closing plus contingent consideration consisting of future payments of up to \$385.0 million for achieving specified discovery and development targets. We have had a research collaboration arrangement with QuanticeL since 2011. Through this purchase, QuanticeL has become our wholly-owned subsidiary, and we will benefit from full access to QuanticeL's proprietary platform for the single-cell genomic analysis of human cancer, as well as QuanticeL's programs that target specific epigenetic modifiers, which we expect will advance our pipeline of innovative cancer therapies.

The acquisition was accounted for using the acquisition method of accounting for business combinations which requires the assets and liabilities of QuanticeL to be recorded at their respective fair values on the acquisition date and consolidated into our Consolidated Balance Sheets. The results of operations for QuanticeL have been included in our consolidated financial statements from the date of acquisition.

The fair value of consideration transferred in the acquisition of QuanticeL is shown in the table below:

	Fair Value at October 19, 2015
Cash	\$ 95.9
Fair value of pre-existing equity ownership	11.4
Contingent consideration	166.0
Total fair value of consideration	\$ 273.3

Prior to the acquisition of QuanticeL, we had an equity interest equal to approximately 5% of the company's total capital stock (on an "as converted" basis). Based on the fair market value of this interest derived from the purchase

price, we recognized a gain of \$10.3 million, which was reflected as a component of other income (expense), net within our Consolidated Statements of Income for the year ended December 31, 2015.

Our potential contingent consideration payments are classified as liabilities, which were measured at fair value as of the acquisition date, with \$82.3 million classified as current liabilities and \$83.7 million classified as non-current liabilities. We estimated the fair value of potential contingent consideration using a probability-weighted discounted cash flow approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant inputs that are not observable in the market and thus represents a level three liability within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a discount rate based on a market participant assumption. See Note 6 for post-acquisition changes in fair value. 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. The amounts recognized will be finalized as the information necessary to complete the analyses is obtained, but no later than one year from the acquisition date.

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

	Fair Value at October 19, 2015 (Provisional)
Working capital <sup>(1)</sup>	\$ 7.0
Property, plant and equipment	1.9
Other non-current assets	0.8
Technology platform intangible asset <sup>(2)</sup>	232.0
Debt obligations	(13.9 )
Non-current deferred tax liabilities	(72.3 )
Total identifiable net assets	155.5
Goodwill	117.8
Total net assets acquired	\$ 273.3

<sup>(1)</sup> Includes cash and cash equivalents, available-for-sale marketable securities, other current assets, accounts payable and accrued expenses and other current liabilities.

<sup>(2)</sup> Technology platform related to Quantice's proprietary technology platform for the single-cell genomic analysis of human cancer.

The fair values of current and other non-current assets, property, plant and equipment, current liabilities and debt were determined to approximate their book values.

The fair value of the technology platform intangible asset is equal to the present value of the after-tax cash flows attributable to the intangible asset, which was calculated based on the multi-period excess earnings method of the income approach. The multi-period excess earnings method of the income approach included estimating probability adjusted annual after-tax net cash flows through the cycle of development and commercialization of potential products generated by the technology platform then discounting the resulting probability adjusted net post-tax cash flows using a discount rate commensurate with the risk of our overall business operations to arrive at the net present value.

The excess of purchase price over the fair value amounts assigned to the identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is largely attributable to the deferred tax consequences of the finite-lived technology platform intangible asset recorded for financial statement purposes, as well as intangible assets that do not qualify for separate recognition at the time of the acquisition. We do not expect any portion of this goodwill to be deductible for tax purposes. 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.

The results of operations and cash flows from Quantice are included in our consolidated financial statements as of October 19, 2015.

**LifebankUSA:** In February 2016, we completed the sale of certain assets of Celgene Cellular Therapeutics (CCT) comprising CCT's biobanking business known as LifebankUSA, CCT's biomaterials portfolio of assets, including Biovance®, and CCT's rights to PSC-100, a placental stem cell program, to Human Longevity, Inc. (HLI), a genomics and cell therapy-based diagnostic and therapeutic company based in San Diego, California. We received 3.4 million shares of HLI Class A common stock with a fair value of \$39.6 million as consideration in the transaction. The fair value of the shares common stock we received was determined based on the most recent preferred share offering and reduced for the estimated value of the liquidation preference not offered to common share holders. The transaction generated a \$37.5 million gain that was recorded on our Consolidated Statements of Income in Other income

(expense). As of March 31, 2016 our total investment in HLI represents approximately 16% of HLI's outstanding capital stock.

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

## 4. Earnings Per Share

(Amounts in millions, except per share)	Three-Month Periods Ended March 31,	
	2016	2015
Net income	\$800.7	\$718.9
Weighted-average shares:		
Basic	780.6	798.9
Effect of dilutive securities:		
Options, restricted stock units, performance-based restricted stock units and other	27.1	35.2
Diluted	807.7	834.1
Net income per share:		
Basic	\$1.03	\$0.90
Diluted	\$0.99	\$0.86

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 18.5 million and 6.1 million shares for the three-month periods ended March 31, 2016 and 2015, respectively.

Share Repurchase Program: During the period of April 2009 through March 31, 2016, our Board of Directors approved repurchases of up to an aggregate of \$17.500 billion of our common stock.

As part of the management of our share repurchase program, we may, from time to time, sell put options on our common stock with strike prices that we believe represent an attractive price to purchase our shares. If the trading price of our shares exceeds the strike price of the put option at the time the option expires, we will have economically reduced the cost of our share repurchase program by the amount of the premium we received from the sale of the put option. If the trading price of our stock is below the strike price of the put option at the time the option expires, we would purchase the shares covered by the option at the strike price of the put option. During the three-month periods ended March 31, 2016 and 2015, we recorded gains from put option activity on our Consolidated Statements of Income in Other income (expense), net as follows:

	Three-Month Periods Ended March 31, 2016 2015	
Gain from sale of put options	\$ 4.4	\$ 3.9

At March 31, 2016, we had no outstanding put options.

We have purchased 14.1 million shares of common stock under the share repurchase program from all sources at a total cost of \$1.410 billion during the three-month period ended March 31, 2016. As of March 31, 2016, we had a remaining share repurchase authorization of \$2.481 billion.

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

5. Accumulated Other Comprehensive Income (Loss)

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

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

	Pension Liability	Net Unrealized Gains (Losses) From Marketable Securities	Net Unrealized Gains (Losses) From Hedges	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balance December 31, 2015	\$(13.9 )	\$ 271.5	\$ 586.4	\$ (76.3 )	\$ 767.7
Other comprehensive income (loss) before reclassifications	—	(242.8 )	(211.0 )	18.2	(435.6 )
Amounts reclassified from accumulated other comprehensive income	—	6.8	(87.4 )	—	(80.6 )
Net current-period other comprehensive income (loss)	—	(236.0 )	(298.4 )	18.2	(516.2 )
Balance March 31, 2016	\$(13.9 )	\$ 35.5	\$ 288.0	\$ (58.1 )	\$ 251.5
Balance December 31, 2014	\$(15.5 )	\$ 460.9	\$ 519.6	\$ (50.2 )	\$ 914.8
Other comprehensive income (loss) before reclassifications	(5.9 )	(50.6 )	416.8	(23.2 )	337.1
Amounts reclassified from accumulated other comprehensive income	—	(0.4 )	(69.7 )	—	(70.1 )
Net current-period other comprehensive income (loss)	(5.9 )	(51.0 )	347.1	(23.2 )	267.0
Balance March 31, 2015	\$(21.4 )	\$ 409.9	\$ 866.7	\$ (73.4 )	\$ 1,181.8

Accumulated Other Comprehensive Income Components	Affected Line Item in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income Three-Month Periods Ended March 31,	
		2016	2015
Gains (losses) from cash-flow hedges:			
Foreign exchange contracts	Net product sales	\$ 88.4	\$ 70.5
Treasury rate lock agreements	Interest (expense)	(1.3 )	(0.9 )
Interest rate swap agreements	Interest (expense)	(0.4 )	(0.4 )
	Income tax benefit	0.7	0.5



Gains (losses) from available-for-sale marketable securities:

Realized income (loss) on sales of marketable securities	Interest and investment income, net	(10.4 )	0.6
	Income tax benefit (expense)	3.6	(0.2 )
Total reclassification, net of tax		\$ 80.6	\$ 70.1

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

6. Financial Instruments and Fair Value Measurement

The tables below present information about assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015 and the valuation techniques we utilized to determine such fair value.

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of marketable equity securities. Our Level 1 liability relates to our publicly traded Contingent Value Rights (CVRs). See Note 18 of Notes to Consolidated Financial Statements included in our 2015 Annual Report on Form 10-K for a description of the CVRs.

Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Our Level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency MBS, non-U.S. government, agency and supranational securities, global corporate debt securities, asset backed securities, 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 Quantical.

Our contingent consideration obligations are recorded at their estimated fair values and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements are estimated using probability-weighted discounted cash flow approaches that are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly. These inputs include, as applicable, estimated probabilities and timing of achieving specified development and regulatory milestones, estimated annual sales and the discount rate used to calculate the present value of estimated future payments. Significant changes which increase or decrease the probabilities of achieving the related development and regulatory events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations. Changes in the fair value of contingent consideration obligations are recognized in Acquisition related charges and restructuring, net in the Consolidated Statements of Income. The fair value of our contingent consideration as of March 31, 2016 and December 31, 2015 was calculated using the following significant unobservable inputs:

Inputs	Ranges (weighted average) utilized as of:	
	March 31, 2016	December 31, 2015
Discount rate	0.8% to 12.0% (8.8%)	0.8% to 12.0% (8.8%)
Probability of payment	3% to 95% (54%)	0% to 95% (53%)
Projected year of payment for development and regulatory milestones	2016 to 2029 (2019)	2016 to 2029 (2019)
Projected year of payment for sales-based milestones and other amounts calculated as a percentage of annual sales	2019 to 2033 (2024)	2019 to 2033 (2024)

The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester, Avila and Quantical are estimated to be \$120.0 million, \$475.0 million and \$385.0 million respectively,

and \$1.865 billion plus other amounts calculated as a percentage of annual sales pursuant to the license agreement with Nogra.

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

	Balance at March 31, 2016	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	\$ 1,261.8	\$925.0	\$ 336.8	\$ —
Forward currency contracts	333.9	—	333.9	—
Purchased currency options	39.9	—	39.9	—
Interest rate swaps	122.4	—	122.4	—
Total assets	\$ 1,758.0	\$925.0	\$ 833.0	\$ —
Liabilities:				
Contingent value rights	\$ (56.7 )	\$ (56.7 )	\$ —	\$ —
Written currency options	(34.2 )	—	(34.2 )	—
Other acquisition related contingent consideration	(1,549.7 )	—	—	(1,549.7 )
Total liabilities	\$ (1,640.6 )	\$ (56.7 )	\$ (34.2 )	\$ (1,549.7 )

	Balance at December 31, 2015	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	\$ 1,671.6	\$1,235.9	\$ 435.7	\$ —
Forward currency contracts	606.0	—	606.0	—
Purchased currency options	46.7	—	46.7	—
Interest rate swaps	52.5	—	52.5	—
Total assets	\$ 2,376.8	\$1,235.9	\$ 1,140.9	\$ —
Liabilities:				
Contingent value rights	\$ (51.9 )	\$ (51.9 )	\$ —	\$ —
Written currency options	(19.1 )	—	(19.1 )	—
Other acquisition related contingent consideration	(1,521.5 )	—	—	(1,521.5 )
Total liabilities	\$ (1,592.5 )	\$ (51.9 )	\$ (19.1 )	\$ (1,521.5 )

There were no security transfers between Levels 1 and 2 during the three-month periods ended March 31, 2016 and 2015. The following table represents a roll-forward of the fair value of Level 3 instruments:

	Three-Month Periods Ended March 31,	
	2016	2015
Liabilities:		
Balance at beginning of period	\$(1,521.5)	\$(1,279.0)

Amounts acquired or issued	—	—
Net change in fair value	(28.2 )	(26.8 )
Settlements	—	—
Transfers in and/or out of Level 3	—	—
Balance at end of period	\$(1,549.7)	\$(1,305.8)

The \$28.2 million net increase in the fair value of Level 3 liabilities in 2016 was related to accretion of the fair value of our contingent consideration due to the passage of time. Changes to the fair value of contingent consideration are recorded on the Consolidated Statements of Income as Acquisition related charges and restructuring, net.

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

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.

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 and occasionally foreign currency put and call 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 at March 31, 2016 and December 31, 2015 had settlement dates within 36 months. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses are reported in other comprehensive income (OCI) and reclassified to operations 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. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in Other income (expense), net. The forward point components of these foreign currency forward contracts are not designated as cash flow hedges and all fair value adjustments of forward point amounts are recorded to Other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at March 31, 2016 and December 31, 2015:

	Notional Amount	
Foreign Currency	March 31, 2016	December 31, 2015

Australian Dollar	\$52.5	\$45.1
British Pound	252.8	289.3
Canadian Dollar	214.2	135.9
Euro	2,816.4	2,934.3
Japanese Yen	670.6	510.4
Swedish Krona	12.8	—
Total	\$4,019.3	\$3,915.0

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 March 31, 2016, credit risk did not materially change the fair value of our foreign currency forward contracts.

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

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 income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at March 31, 2016 and December 31, 2015 were \$676.1 million and \$920.0 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 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 at March 31, 2016 and December 31, 2015 had settlement dates within 51 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 at March 31, 2016 and December 31, 2015:

	Notional Amount <sup>1</sup>	
	March 31, 2016	December 31, 2015
Foreign currency option contracts designated as hedging activity:		
Purchased Put	\$782.3	\$ 641.5
Written Call	\$851.5	\$ 690.0

<sup>1</sup> 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.

#### Interest Rate Risk Management

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 treasury rate locks or forward starting swaps are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

Forward Starting Interest Rate Swaps and Treasury Rate Locks: During 2014, we entered into forward starting swaps that were designated as cash flow hedges to hedge against changes in interest rates that could impact an anticipated issuance of debt in 2015. During 2015, we entered into additional forward starting swaps and treasury rate locks. Forward starting swaps and treasury rate locks with a combined aggregate notional value of \$2.900 billion were settled upon the issuance of debt in August 2015, when the net fair value of the forward starting swaps and treasury rate locks in accumulated other comprehensive income was in a loss position of \$21.6 million. The net loss will be recognized as interest expense over the life of the associated senior notes. During 2015 and 2016, we entered into forward starting swaps with effective dates in 2017 and 2018 and maturing in ten years that were designated as cash



flow hedges to hedge against changes in interest rates that could impact anticipated future issuances of debt.

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 interest rates. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swap are recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense. 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 swap contracts at March 31, 2016 and December 31, 2015:

	Notional Amount	
	March 31, 2016	December 31, 2015
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
1.900% senior notes due 2017	300.0	300.0
2.300% senior notes due 2018	200.0	200.0
2.250% senior notes due 2019	500.0	500.0
3.950% senior notes due 2020	500.0	500.0
3.250% senior notes due 2022	1,000.0	1,000.0
4.000% senior notes due 2023	700.0	700.0
3.625% senior notes due 2024	100.0	100.0
3.875% senior notes due 2025	300.0	250.0
Total	\$3,600.0	\$3,550.0

The following tables summarize the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of March 31, 2016 and December 31, 2015:

Instrument	Balance Sheet Location	March 31, 2016 Fair Value	
		Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts <sup>(1)</sup>	Other current assets	\$293.7	\$ 28.6
	Accrued expenses and other current liabilities	0.9	6.6
	Other non-current assets	149.2	40.2
	Other non-current liabilities	14.8	24.5
Interest rate swap agreements	Other current assets	22.0	—
	Other non-current assets	121.5	19.2
	Other non-current liabilities	1.4	4.4
Derivatives not designated as hedging instruments:			
Foreign exchange contracts <sup>(1)</sup>	Other current assets	9.5	4.4
	Accrued expenses and other current liabilities	2.6	26.8
Interest rate swap agreements	Other current assets	0.7	0.6
	Other non-current assets	4.5	3.5
Total		\$620.8	\$ 158.8

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

Instrument	Balance Sheet Location	December 31, 2015 Fair Value	
		Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts <sup>(1)</sup>	Other current assets	\$356.2	\$ 18.0
	Other non-current assets	287.8	28.0
Interest rate swap agreements	Other current assets	30.7	—
	Other non-current assets	26.1	4.7
	Other non-current liabilities	0.2	0.9
Derivatives not designated as hedging instruments:			
Foreign exchange contracts <sup>(1)</sup>	Other current assets	46.0	5.9
	Accrued expenses and other current liabilities	2.9	7.4
Interest rate swap agreements	Other current assets	2.4	2.3
	Other non-current assets	2.4	1.4
Total		\$754.7	\$ 68.6

<sup>(1)</sup> 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.

The following tables summarize the effect of derivative instruments designated as cash-flow hedging instruments on the Consolidated Statements of Income for the three-month periods ended March 31, 2016 and 2015:

Instrument	Three-Month Period Ended March 31, 2016				
	(Effective Portion)		Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	(Ineffective Portion and Amount Excluded From Effectiveness Testing)	
	Amount of Gain/(Loss) Recognized in OCI on Derivative <sup>(1)</sup>	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income		Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
Foreign exchange contracts	\$(195.0)	Net product sales	\$ 88.4	Other income, net	\$ 14.3 (2)
Treasury rate lock agreements	\$—	Interest expense	\$ (1.3 )	Other income, net	—
Interest rate swap agreements	\$(26.0 )	Interest expense	\$ (0.4 )	Other income, net	—

<sup>(1)</sup> Net gains of \$248.9 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

<sup>(2)</sup> The amount of net gains recognized in income represents \$13.0 million of gains related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and \$1.3 million in gains related to the ineffective portion of the hedging relationships.



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

Three-Month Period Ended March 31, 2015

Instrument	(Effective Portion)		(Ineffective Portion and Amount Excluded From Effectiveness Testing)		
	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Recognized from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
Foreign exchange contracts	\$432.6	Net product sales	\$ 70.5	Other income, net	\$ 3.8 (1)
Treasury rate lock agreements	\$—	Interest expense	\$ (0.9 )	Other income, net	\$ —
Interest rate swap agreements	\$(25.7 )	Interest expense	\$ (0.4 )	Other income, net	\$ —

(1) The amount of net gains recognized in income represents \$7.2 million of gains related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and \$3.4 million in losses related to the ineffective portion of the hedging relationships.

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the three-month periods ended March 31, 2016 and 2015:

Instrument	Location of Gain (Loss) Recognized in Income on Derivative	Amount of Gain Recognized in Income on Derivative Three-Month Periods Ended	
		March 31, 2016	2015
Interest rate swap agreements	Interest expense	\$13.4	\$14.0

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the three-month periods ended March 31, 2016 and 2015:

Location of Gain (Loss) Recognized in Income on Derivative	Amount of Gain (Loss) Recognized in Income on Derivative Three-Month Periods Ended
--	--

Instrument		March 31,	
		2016	2015
Foreign exchange contracts	Other income (expense), net	\$(27.5)	\$74.5
Put options on our common stock	Other income (expense), net	\$4.4	\$3.9

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 income (expense), net for all periods presented. When we enter into foreign exchange contracts not designated as hedging instruments to mitigate the impact of exchange rate volatility in the translation of foreign earnings, gains and losses will generally be offset by fluctuations in the U.S. Dollar translated amounts of each Income Statement account in current and/or future periods.

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

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

Money market funds of \$1.815 billion and \$1.413 billion at March 31, 2016 and December 31, 2015, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security at March 31, 2016 and December 31, 2015 were as follows:

March 31, 2016	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 129.6	\$ 0.3	\$ —	\$ 129.9
U.S. government-sponsored agency MBS	19.6	0.1	(0.1 )	19.6
Corporate debt - global	161.5	0.6	(0.2 )	161.9
Asset backed securities	25.4	—	—	25.4
Marketable equity securities	875.1	171.5	(121.6 )	925.0
Total available-for-sale marketable securities	\$ 1,211.2	\$ 172.5	\$ (121.9 )	\$ 1,261.8

December 31, 2015	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 153.0	\$ —	\$ (0.4 )	\$ 152.6
U.S. government-sponsored agency MBS	29.8	0.1	(0.4 )	29.5
Corporate debt - global	219.7	—	(1.6 )	218.1
Asset backed securities	35.6	—	(0.1 )	35.5
Marketable equity securities	811.5	468.1	(43.7 )	1,235.9
Total available-for-sale marketable securities	\$ 1,249.6	\$ 468.2	\$ (46.2 )	\$ 1,671.6

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. Marketable equity securities consist of investments in publicly traded equity securities. The decrease in net unrealized gains in marketable equity securities during the three-month period ended March 31, 2016 primarily reflects the decrease in market value for certain equity investments subsequent to December 31, 2015.

Duration periods of available-for-sale debt securities at March 31, 2016 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	\$ 38.1	\$38.0
Duration of one through three years	287.7	288.4
Duration of three through five years	10.3	10.4
Total	\$ 336.1	\$336.8

9. Inventory

Inventories as of March 31, 2016 and December 31, 2015 are summarized by major category as follows:

	March 31, 2016	December 31, 2015
Raw materials	\$247.8	\$ 201.3
Work in process	95.7	120.0
Finished goods	127.1	122.1
Total	\$470.6	\$ 443.4



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

10. Intangible Assets and Goodwill

Intangible Assets: Our finite-lived intangible assets primarily consist of developed product rights and technology obtained from the Pharmion Corp. (Pharmion), Gloucester, Abraxis BioScience, Inc. (Abraxis), Avila and QuanticeL acquisitions. Our indefinite lived intangible assets consist of acquired IPR&D product rights from the Receptos, Nogra and Gloucester acquisitions. The remaining weighted-average amortization period for finite-lived intangible assets not fully amortized is approximately 9.4 years.

Intangible assets outstanding as of March 31, 2016 and December 31, 2015 are summarized as follows:

March 31, 2016	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$3,405.9	\$ (1,509.6 )	\$ 1,896.3
Technology	565.7	(227.1 )	338.6
Licenses	66.8	(23.4 )	43.4
Other	42.9	(28.3 )	14.6
	4,081.3	(1,788.4 )	2,292.9
Non-amortized intangible assets:			
Acquired IPR&D product rights	8,470.6	—	8,470.6
Total intangible assets	\$12,551.9	\$ (1,788.4 )	\$ 10,763.5

December 31, 2015	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$3,405.9	\$ (1,448.3 )	\$ 1,957.6
Technology	565.7	(197.1 )	368.6
Licenses	66.7	(22.3 )	44.4
Other	44.0	(27.1 )	16.9
	4,082.3	(1,694.8 )	2,387.5
Non-amortized intangible assets:			
Acquired IPR&D product rights	8,470.6	—	8,470.6
Total intangible assets	\$12,552.9	\$ (1,694.8 )	\$ 10,858.1

Amortization expense related to intangible assets was \$93.5 million and \$65.1 million for the three-month periods ended March 31, 2016 and 2015, respectively. The net amortization expense increase of \$28.4 million primarily related to the amortization of the technology platform received in the acquisition of QuanticeL and a reduction in the estimated useful lives of intangible assets related to the acquisition of Gloucester following the grant to Fresenius Kabi USA, LLC of a non-exclusive, royalty-free sublicense to manufacture and market a generic version of romidepsin for injection as of February 1, 2018. See Note 18 of Notes to Consolidated Financial Statements in our 2015 Annual Report on Form 10-K for additional details. Assuming no changes in the gross carrying amount of intangible assets, the future annual amortization expense related to intangible assets is expected to be approximately \$373.5 million in 2016, \$372.8 million in 2017, \$299.4 million in 2018, \$163.3 million in 2019, and \$154.2 million in 2020.

Goodwill: At March 31, 2016, our goodwill related to the 2015 acquisitions of Receptos and QuanticeL, the 2014 acquisition of Nogra, the 2012 acquisition of Avila, the 2010 acquisitions of Abraxis and Gloucester, the 2008 acquisition of Pharmion and the 2004 acquisition of Penn T Limited.

The carrying value of goodwill decreased by \$2.5 million to \$4.877 billion as of March 31, 2016 compared to December 31, 2015 due to the sale of our LifebankUSA business (see Note 3).

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

11. Debt

Short-Term Borrowings and Current Portion of Long-Term Debt: As of December 31, 2015 and March 31, 2016, we had no outstanding short-term borrowings or long-term debt due within one year.

Long-Term Debt: Summarized below are the carrying values of our senior notes at March 31, 2016 and December 31, 2015:

	March 31, December	
	2016	31, 2015
1.900% senior notes due 2017	\$501.0	\$499.9
2.125% senior notes due 2018	997.0	996.7
2.300% senior notes due 2018	402.2	400.2
2.250% senior notes due 2019	510.1	502.6
2.875% senior notes due 2020	1,491.3	1,490.9
3.950% senior notes due 2020	517.3	504.9
3.250% senior notes due 2022	1,046.3	1,010.5
3.550% senior notes due 2022	992.7	992.4
4.000% senior notes due 2023	734.6	706.0
3.625% senior notes due 2024	999.4	994.9
3.875% senior notes due 2025	2,475.5	2,461.8
5.700% senior notes due 2040	247.2	247.2
5.250% senior notes due 2043	392.9	392.8
4.625% senior notes due 2044	986.7	986.6
5.000% senior notes due 2045	1,974.1	1,974.0
Total long-term debt	\$14,268.3	\$14,161.4

At March 31, 2016, the fair value of our outstanding Senior Notes was \$14.939 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

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 March 31, 2016, a balance of \$66.1 million in 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.

At March 31, 2016, 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 at March 31, 2016 effectively convert 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 March 31, 2016, we had a balance of \$31.6 million of unamortized gains recorded as a component of our debt as a result of past swap contract settlements. There were no settlement of swap contracts during the three months ended March 31, 2016. As of December 31, 2015, we had a balance of \$33.1 million of unamortized gains recorded as a component of our debt as a result of past swap contract settlements.

Commercial Paper: As of March 31, 2016 and December 31, 2015 we had available capacity to issue up to \$1.750 billion of Commercial Paper and there were no borrowings under the program. In April 2016 our Board of Directors authorized an increase in the maximum amount of commercial paper issuable to \$2.000 billion.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of \$2.000 billion which was increased from \$1.750 billion in April 2016. In April 2016, the term of the Credit Facility was also extended from April 17, 2020 to April 17, 2021. 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. At March 31, 2016 and December 31, 2015 there was no outstanding borrowing against the Credit Facility.

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

The Credit Facility contains affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of March 31, 2016.

## 12. Share-Based Compensation

We have a stockholder-approved stock incentive plan, the 2008 Stock Incentive Plan (Amended and Restated as of April 15, 2015) (Plan) that provides for the granting of options, restricted stock units (RSUs), performance stock units (PSUs) and other share-based awards to our employees, officers and non-employee directors. The Management Compensation and Development Committee of the Board of Directors (Compensation Committee) may determine the type, amount and terms, including vesting, of any awards made under the Plan.

During 2015, we increased our usage of PSUs and began issuing PSUs to certain executive officers that are payable in shares of our common stock at the end of a three years performance measurement period. The number of shares to be issued at the end of the measurement period will vary, based on performance, from 0% to 200% of the target number of PSUs granted, depending on the achievement of specified performance and market targets for non-GAAP revenue (37.5% weighting), non-GAAP earnings per share (37.5% weighting), and relative total shareholder return (25% weighting). All shares delivered upon PSU vesting are restricted from trading for one year and one day from the vesting date.

The grant date fair value for the portion of the PSUs related to non-GAAP revenue and non-GAAP earnings per share was estimated using the fair market value of our common stock on the grant date. The grant date fair value for the portion of the PSUs related to relative total shareholder return was estimated using the Monte Carlo valuation model.

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three-month periods ended March 31, 2016 and 2015:

	Three-Month Periods Ended March 31,	
	2016	2015
Cost of goods sold (excluding amortization of acquired intangible assets)	\$9.0	\$6.7
Research and development	62.2	56.2
Selling, general and administrative	75.3	65.9
Total share-based compensation expense	146.5	128.8
Tax benefit related to share-based compensation expense	40.1	36.4
Reduction in income	\$106.4	\$92.4

The following table summarizes the activity for stock options, RSUs and PSUs for the three-month period ended March 31, 2016 (in millions unless otherwise noted):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units (in thousands)
Outstanding at December 31, 2015	75.7	7.7	334

Changes during the Year:

Granted	2.9	0.1	94
Exercised / Released	(1.6 )	(0.2 )	—
Forfeited	(0.7 )	(0.1 )	(17 )
Outstanding at March 31, 2016	76.3	7.5	411

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

Total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at March 31, 2016 were as follows (dollars in millions):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Unrecognized compensation cost	\$ 611.1	\$ 265.1	\$ 22.3
Expected weighted-average period in years of compensation cost to be recognized	2.0	1.2	1.8

### 13. Income Taxes

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

Unrecognized tax benefits, generally represented by liabilities on the Consolidated Balance Sheet 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 three-month period ended March 31, 2016 gross unrecognized tax benefits increased by \$2.7 million, primarily from an increase in unrecognized tax benefits related to current year operations of \$16.1 million, partially offset by a decrease in unrecognized tax benefits related to

settlements of tax positions taken in prior years of \$11.3 million, and a decrease in accrued interest of \$2.1 million. The liability for unrecognized tax benefits is expected to increase in the next 12 months relating to operations occurring in that period. Any settlements of examinations with taxing authorities or statute of limitations expirations would likely result in a decrease in our liability for unrecognized tax benefits and a corresponding increase in taxes paid or payable and/or a decrease in income tax expense. It is reasonably possible that the amount of the liability for unrecognized tax benefits could change by a significant amount during the next twelve-month period as a result of settlements or statute of limitations expirations. Finalizing examinations with the relevant taxing authorities can include formal administrative and legal proceedings and, as a result, it is difficult to estimate the timing and range of possible change related to the Company's unrecognized tax benefits. An estimate of the range of possible change cannot be made until issues are further developed or examinations close. Our estimates of tax benefits and potential tax benefits may not be representative of actual outcomes and variation from such estimates could materially affect our financial statements in the period of settlement or when the statutes of limitations expire.



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

14. Collaboration Agreements

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 for options to acquire rights to products and product candidates and other rights, as well as potential development, regulatory and commercial performance milestone payments, cost sharing arrangements, royalty payments, profit sharing and equity investments. These arrangements could include obligations for us to make 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 below. See Note 17 of Notes to Consolidated Financial Statements included in our 2015 Annual Report on Form 10-K for a description of certain other collaboration agreements entered into prior to January 1, 2016. The following is a brief description of significant developments in the relationships between Celgene and our collaboration partners during the three months ended March 31, 2016:

bluebird bio, Inc. (bluebird): In June 2015, we amended and restated the March 2013 collaboration agreement with bluebird. The amended and restated collaboration will focus on the discovery, development and commercialization of novel disease-altering gene therapy product candidates targeting B-cell maturation antigen (BCMA). BCMA is a cell surface protein that is expressed in normal plasma cells and in most multiple myeloma cells, but is absent from other normal tissues. The collaboration applies gene therapy technology to modify a patient's own T-cells, known as chimeric antigen receptor (CAR) T-cells, to target and destroy cancer cells that express BCMA. We have an option to license any anti-BCMA products resulting from the collaboration after the completion of a phase I clinical study by bluebird.

Under the amended and restated collaboration agreement we made an additional \$25.0 million payment for bluebird to develop the lead anti-BCMA product candidate (bb2121) through a phase I clinical study and to develop next-generation anti-BCMA product candidates. The payment was recorded as prepaid research and development on the balance sheet and is being recognized as expense as development work is performed. Upon exercising our option to license a product and achievement of certain milestones, we may be obligated to pay up to \$230.0 million per licensed product in aggregate potential option fees and clinical and regulatory milestone payments. bluebird also has the option to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and profit share in the United States in exchange for a reduction of milestone payments. Royalties would also be paid to bluebird in regions where there is no profit share, including in the United States, if bluebird declines to exercise their co-development and profit sharing rights. In February 2016, we exercised our option to license bb2121 and made a corresponding \$10 million license payment to bluebird.

We have the ability to terminate the collaboration at our discretion upon 90 days written notice to bluebird. If a product is optioned, the parties will enter into a pre-negotiated license agreement and potentially a co-development agreement should bluebird exercise its option to participate in the development and commercialization in the United States. The license agreement, if not terminated sooner, would expire upon the expiration of all applicable royalty terms under the agreement with respect to the particular product, and the co-development agreement, if not terminated sooner, would expire when the product is no longer being developed or commercialized in the United States. Upon the expiration of a particular license agreement, we will have a fully paid-up, royalty-free license to use bluebird intellectual property to manufacture, market, use and sell such licensed product.

Juno Therapeutics, Inc. (Juno): In June 2015, we announced a collaboration and investment agreement with Juno for the development and commercialization of immunotherapies for cancer and autoimmune diseases. The collaboration and investment agreement became effective on July 31, 2015 after an early termination of the Hart-Scott-Rodino Antitrust waiting period. Under the terms of the agreement, we have the option to be the commercialization partner for Juno's oncology and cell therapy auto-immune product candidates, including Juno's CD19 and CD22 directed CAR T-cell product candidates. For Juno-originated programs co-developed under the collaboration, (a) Juno will be responsible for research and development in North America and will retain commercialization rights in those territories, (b) we will be responsible for development and commercialization in the rest of the world, and will pay Juno a royalty on sales in those territories, and (c) we have certain co-promotion options for global profit sharing arrangements under which the parties will share worldwide expenses and profits equally, except in China.

Juno will have the option to enter into co-development and co-commercialization arrangements on certain Celgene-originated development candidates that target T-cells. For any such Celgene-originated programs co-developed under the collaboration, (a) the parties will share global costs and profits, with 70% allocated to us and 30% allocated to Juno, and (b) we will lead global development and commercialization, subject to a Juno co-promote option in the US and certain EU territories.

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

Upon closing, we made a \$1.000 billion payment to Juno and received 9.1 million shares of Juno common stock, amounting to approximately 9% of Juno's outstanding common stock. The value of our investment in Juno common stock of \$424.9 million was recorded as an available-for sale marketable security based on the market price of the stock on the date of closing and the remaining portion of the \$1.000 billion payment, which consists of both a \$150.0 million upfront payment and a \$425.1 million premium paid on our equity investment, was recorded to research and development expense.

The collaboration agreement has an initial term of ten years. If the parties enter into any pre-negotiated license or co-commercialization agreement during the initial term, the collaboration agreement will continue until all such license and co-commercialization agreements have expired. The collaboration agreement may be terminated at our discretion upon 120 days' prior written notice to Juno and by either party upon material breach of the other party, subject to cure periods.

In April 2016, we exercised our option to develop and commercialize Juno's CD19 program outside North America and China and entered into a pre-negotiated license agreement with Juno with respect to such program by making a \$50.0 million payment for such license.

A financial summary of certain period activity related to our collaboration agreements is presented below<sup>1,2</sup>:

	Three-Month Periods Ended March 31, Research and Development Expense				
	Upfront Fees	Milestones	Extension/Termination of Agreements	Amortization of Prepaid Research and Development	Equity Investments Made During Period
bluebird	2016 \$10.0	\$—	\$—	\$2.1	\$—
	2015 —	—	—	—	—
Juno <sup>3</sup>	2016 —	—	—	—	41.0
	2015 —	—	—	—	—
Other Collaboration Arrangements	2016 70.0	65.0	—	3.9	37.0
	2015 19.0	—	8.1	5.5	—

A financial summary of the period-end balances related to our collaboration agreements is presented below:

	Balances as of:	Intangible Asset Balance	Equity Investment Balance	Percentage of Outstanding Equity
Acceleron	March 31, 2016	\$—	\$142.8	15%
	December 31, 2015	—	224.9	14%
bluebird	March 31, 2016	18.1	N/A	N/A
	December 31, 2015	20.2	N/A	N/A
Juno	March 31, 2016	—	391.4	10%
	December 31, 2015	—	401.8	9%
Other Collaboration Arrangements	March 31, 2016	48.5	487.4	N/A
		52.4	702.4	N/A

December 31,  
2015

1 Activity and balances are presented specifically for notable new collaborations and for those collaborations which  
we have described in detail in our 2015 Annual Report on Form 10-K if there has been new significant activity  
during the periods presented. Amounts related to collaborations that are not specifically presented are included in  
the aggregate as Other Collaboration Arrangements.

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

3 Our equity investment in Juno made in the first quarter of 2016 was transacted at a price per share that exceeded the  
market value of Juno's publicly traded common stock on the transaction closing date, resulting in an expense for the  
premium of \$6.0 million that was recorded in the Consolidated Statements of Income as Other income (expense),  
net in the first quarter of 2016.

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

15. Commitments and Contingencies

**Collaboration Arrangements:** We have entered into certain research and development collaboration agreements with third parties that include the funding of certain development, manufacturing and commercialization efforts 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 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 are inherently uncertain, and accordingly no amounts have been recorded for the potential future achievement of these targets in our accompanying Consolidated Balance Sheets at March 31, 2016 and December 31, 2015. See Note 14 for additional details related to collaboration arrangements.

**Contingencies:** We believe we maintain insurance coverage adequate for our current needs. Our operations are subject to environmental laws and regulations, which 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 VAT 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, we are subject 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 future results of operations, (ii) our inability to continue to engage in certain activities, and (iii) significant liabilities, including payment of damages, royalties and/or license fees to any such third party.

Among the principal matters pending are the following:

Patent Related Proceedings:

**REVLIMID®:** In 2012, our European patent EP 1667682 (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, based primarily on procedural grounds, that the '682 patent was not valid. Celgene appealed the EPO ruling to the EPO Board of Appeal, which stays any revocation of the patent until the appeal is finally adjudicated. No appeal hearing date has been set.

We do not anticipate a decision from the EPO Board of Appeal for several years and intend to vigorously defend all of our intellectual property rights.

In 2010, Celgene's European patent EP1505973 (the '973 patent) relating to certain uses of lenalidomide expiring in 2023 was opposed in a proceeding before the EPO by Synthon B.V. and an anonymous party. On February 25, 2013, the EPO determined that the '973 patent was not valid. Celgene appealed the EPO ruling to the EPO Board of Appeal, which stays any revocation of the patent until the appeal is finally adjudicated. No appeal hearing date has been set. We do not anticipate a decision from the EPO Board of Appeal for several years and intend to vigorously defend all of our intellectual property rights.

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

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THALOMID® and REVLIMID®: On October 2, 2013, Andrulis Pharmaceuticals Corporation (Andrulis) filed a lawsuit against us in the United States District Court for the District of Delaware claiming infringement of U.S. Patent No. 6,140,346 (“the ’346 patent”). Andrulis alleges that we are liable for infringement of one or more claims of the ’346 patent, which covers the use of THALOMID® (and, as asserted by Andrulis, REVLIMID®) in combination with an alkylating agent (e.g., melphalan) to treat cancers. Andrulis is seeking an unspecified amount of damages, attorneys’ fees and injunctive relief. We disagree with Andrulis’ allegations and intend to vigorously defend against this infringement suit. On January 30, 2014, we filed a motion to dismiss Andrulis’ amended complaint. On April 11, 2014, the court denied our motion in part and granted our motion in part, dismissing two of Andrulis’ four infringement claims without leave to amend. We filed an answer to the remaining claims on April 25, 2014. In February 2015, we filed a partial summary judgment motion.

The court held hearings on claim construction and on the partial summary judgment motion on May 27, 2015 and May 28, 2015, respectively. On June 26, 2015, the court issued its claim construction ruling and held that certain claim terms were indefinite. On July 28, 2015, the court entered final judgment in favor of Celgene. On August 27, 2015, Andrulis filed a notice of appeal to the United States Court of Appeals for the Federal Circuit on the final judgment and its indefiniteness and claim construction rulings. Plaintiff’s opening brief was filed on December 2, 2015 and our response was filed on February 16, 2016. No hearing date has been scheduled.

ISTODAX® (romidepsin): On May 28, 2015, we received a Notice Letter from Teva Pharmaceuticals USA, Inc. (Teva) notifying us of Teva’s Abbreviated New Drug Application (ANDA) that seeks approval from the FDA to market a generic version of romidepsin for injection. The Notice Letter contains Paragraph IV certifications against U.S. Patent Nos. 7,608,280 and 7,611,724 (the ’280 and ’724 patents) that are listed in the Orange Book for ISTODAX®.

On July 10, 2015, we and Astellas Pharma Inc. (Astellas) filed an infringement action in the United States District Court for the District of Delaware against Teva. In its answer and counterclaims, Teva asserts that the ’280 and ’724 patents are invalid and/or not infringed by its proposed generic products. As a result of the filing of our action, the FDA cannot grant final approval of Teva’s ANDA until the earlier of (i) a final decision that each of the patents is invalid and/or not infringed; or (ii) November 28, 2017.

On October 30, 2015, we received a Notice Letter from Teva notifying us of Teva’s New Drug Application (NDA) pursuant to FDC Act § 505(b)(3)(D)(i) seeking approval to engage in the commercial manufacture, use or sale of romidepsin for injection. The Notice Letter contains Paragraph IV certifications against the ’280 and ’724 patents.

On December 10, 2015, we and Astellas filed an infringement action in the United States District Court for the District of Delaware against Teva. In its answer and counterclaims, Teva asserts that the ’280 and ’724 patents are invalid and/or not infringed by its proposed products. As a result of the filing of our action, the FDA cannot grant final approval of Teva’s NDA until the earlier of (i) a final decision that each of the patents is invalid and/or not infringed; or (ii) April 30, 2018.

On March 2, 2016, the cases were consolidated. Fact discovery is set to close on August 31, 2016. A claim construction hearing is scheduled for August 23, 2016. Expert discovery is set to close on April 18, 2017 and trial is scheduled to begin on June 19, 2017.

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

7,435,745; 7,874,984; 7,959,566; 8,204,763; 8,315,886; 8,589,188; and 8,626,531 that are listed in the Orange Book for THALOMID® (thalidomide). Lannett is seeking to market a generic version of 50mg, 100mg, 150mg and 200mg of THALOMID® capsules.

On January 30, 2015, we filed an infringement action against Lannett in the United States District Court for the District of New Jersey. As a result of the filing of our action, the FDA cannot grant final approval of Lannett's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) June 22, 2017. On March 27, 2015, Lannett filed a motion to dismiss our complaint for lack of personal jurisdiction and we filed a response to the motion on April 20, 2015. A hearing was held on July 27, 2015 and the Court decided to administratively terminate the motion to dismiss in order to allow us to conduct jurisdictional discovery. On November 17, 2015, Lannett withdrew its motion to dismiss.

On December 8, 2015, Lannett filed an answer and counterclaims asserting that the patents-in-suit are invalid, unenforceable, and/or not infringed and on January 19, 2016 we filed a reply to Lannett's counterclaims. On April 18, 2016, Lannett amended its answer to narrow the scope of its unenforceability counterclaims. Our reply to Lannett's amended answer is due on May 12, 2016.



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Fact discovery is currently set to close on January 20, 2017. Markman briefing is currently scheduled to be completed on December 20, 2016. The Court has not yet set dates for a Markman hearing, close of expert discovery, or trial.

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

On April 6, 2016, we filed an infringement action against Actavis in the United States District Court for the District of New Jersey. As a result of the filing of our action, the FDA cannot grant final approval of Actavis's ANDA until the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed; or (ii) August 24, 2018. Actavis has yet to file its Answer and no scheduling order has been entered. At this time, we cannot predict the ultimate outcome of this lawsuit. We intend to vigorously defend our patent rights.

Proceedings involving the USPTO:

Under the America Invents Act (AIA), any person may seek to challenge an issued patent by petitioning the United States Patent and Trademark Office (USPTO) to institute a post grant review. On April 23, 2015, we were informed that Coalition for Affordable Drugs VI LLC filed petitions for Inter Partes Review (IPRs) challenging the validity of Celgene's patents US 6,045,501 and US 6,315,720 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 has been scheduled for July 21, 2016 and a decision is expected by October 27, 2016.

In accordance with the requirements of the AIA, we expect final decisions from the PTAB not later than one year after the institution of the IPRs. Any patent claim the PTAB determines to be unpatentable is stricken from the challenged patent. Any party may appeal final written decisions of the PTAB to the United States Court of Appeals for the Federal Circuit. We intend to continue to vigorously defend our patent claims.

Other Proceedings:

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

On April 3, 2014, Mylan Pharmaceuticals Inc. (Mylan) filed a lawsuit against us in the United States District Court for the District of New Jersey alleging that we violated various federal and state antitrust and unfair competition laws by allegedly refusing to sell samples of our THALOMID<sup>®</sup> and REVLIMID<sup>®</sup> brand drugs so that Mylan can conduct the bioequivalence testing necessary for ANDAs to be submitted to the FDA for approval to market generic versions of these products. Mylan is seeking injunctive relief, damages and declaratory judgment. We filed a motion to dismiss Mylan's complaint on May 25, 2014. Mylan filed its opposition to our motion to dismiss on June 16, 2014. The Federal Trade Commission filed an amicus curiae brief in opposition to our motion to dismiss on June 17, 2014. On December 22, 2014, the court granted Celgene's motion to dismiss (i) Mylan's claims based on Section 1 of the Sherman Act (without prejudice), and (ii) Mylan's claims arising under the New Jersey Antitrust Act. The court denied

our motion to dismiss the rest of the claims which primarily relate to Section 2 of the Sherman Act. On January 6, 2015 we filed a motion to certify for interlocutory appeal the order denying our motion to dismiss with respect to the claims relating to Section 2 of the Sherman Act, which appeal was denied by the United State Court of Appeals for the Third Circuit on March 5, 2015. On January 20, 2015, we filed an answer to Mylan's complaint. Fact discovery closed on April 8, 2016 and expert discovery is set to be completed by October 24, 2016. No trial date has been set. We intend to vigorously defend against Mylan's claims.

In 2011, the United States Attorney's Office for the Central District of California informed us that they were investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In 2012, we learned that two other United States Attorneys' offices (the Northern District of Alabama and the Eastern District of Texas) and various state Attorneys General were conducting related investigations. In February 2014, three civil qui tam actions related

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to those investigations brought by three former Celgene employees on behalf of the federal and various state governments under the federal false claims act and similar state laws were unsealed after the United States Department of Justice (DOJ) declined to intervene in any of these actions. The DOJ retains the right to intervene in these actions at any time. Additionally, while several states have similarly declined to intervene in some of these actions, they also retain the right to intervene in the future. The plaintiffs in the Northern District of Alabama and Eastern District of Texas actions have voluntarily dismissed their cases. On April 25, 2014, we filed a motion to dismiss the complaint in the remaining (Central District of California) action, United States of America ex. rel. Beverly Brown V. Celgene Corp., unsealed February 5, 2014 (the Brown Action), which was denied except with respect to certain state claims. The complaint seeks, among other things, treble damages, civil penalties and attorneys' fees and costs. We filed our answer to the complaint on August 28, 2014. Fact discovery closed on September 25, 2015. Expert discovery is set to close on June 30, 2016. Summary judgment motions are to be filed with the court by August 29, 2016. No trial date has been set. At this time, we are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and cannot reasonably estimate the possible loss or range of loss, if any. We intend to vigorously defend against the claims in the Brown Action.

In February 2014, we received a letter purportedly on behalf of a stockholder demanding access to certain books and records of the Company for the purpose of investigating matters pertaining to the Brown Action. The Company complied with the demand, as modified through negotiation with counsel for the purported stockholder. In July 2014, we received a letter purportedly on behalf of two stockholders (one of which was referenced in the February 2014 letter) that demands, primarily on the basis of the allegations in the Brown Action, that our board of directors take action on the Company's behalf to correct alleged deficiencies in the Company's internal controls and to recover from current and past directors and officers damages those stockholders allege to have resulted from breaches of fiduciary duties related to the matters alleged in the Brown Action (the Demand). Our Board formed a Demand Investigation Committee, and with the assistance of independent counsel retained by it, the Demand Investigation Committee considered the issues raised in the stockholders' letter. In October 2015, the Demand Investigation Committee reported to the Board of Directors, and the Board of Directors accepted the Committee's recommendation, that the Company take no action at this time, legal or otherwise, in response to the stockholders' demands. In November 2015, we received another letter purportedly on behalf of the same two stockholders that demands access to certain books and records of the Company for the purpose of investigating whether the Demand was wrongfully refused, the independence, good faith and due care of the Demand Investigation Committee, and whether the Demand Investigation Committee conducted a reasonable investigation of the Demand. On February 22, 2016, the Company produced additional documents pursuant to the November 2015 letter.

In November 2014, we received another letter purportedly on behalf of a stockholder demanding access to certain books and records of the Company for the purpose of investigating matters pertaining to the Brown Action. The Company complied with the demand, as modified through negotiation with counsel for the purported stockholder, and in November 2015 the stockholder filed a complaint in Delaware Chancery Court asserting derivative claims on behalf of the Company against eight current, and four former members of the Board of Directors. The complaint alleges, largely on the basis of allegations in the Brown Action, that the defendant directors breached their fiduciary duties by allowing the Company to engage in unlawful activity in its marketing of THALOMID® and REVLIMID®, and seeks from the defendant directors unspecified damages, including Celgene's costs of defending against government and civil investigations and lawsuits and alleged reputational harm, and disgorgement of compensation paid to the defendant directors. On January 22, 2016, the Company filed a motion to dismiss the complaint on the basis that prior to filing the complaint asserting derivative claims the plaintiff was required under Delaware law and failed to demand that our board of directors take action on the Company's behalf. On March 21, 2016, plaintiff filed an amended complaint. On April 5, 2016, the Company filed a motion to dismiss the amended complaint. A schedule for briefing and oral argument has not been set.

On June 7, 2013, Children's Medical Center Corporation (CMCC) filed a lawsuit against us in the Superior Court of the Commonwealth of Massachusetts alleging that our obligation to pay a 1% royalty on REVLIMID® net sales revenue and a 2.5% royalty on POMALYST®/IMNOVID® net sales revenue under a license agreement entered into in December 2002 extended beyond February 28, 2013 and that our failure to make royalty payments to CMCC subsequent to February 28, 2013 breached the license agreement. CMCC is seeking unspecified damages and a declaration that the license agreement remains in full force and effect. In July 2013, we removed these proceedings to the United States District Court for the District of Massachusetts. On August 5, 2013, we filed an answer to CMCC's complaint and a counterclaim for declaratory judgment that our obligations to pay royalties have expired. On August 26, 2013, CMCC filed an answer to our counterclaim.

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

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Discovery in this matter has been completed. On August 4, 2015, Plaintiffs filed a motion for summary judgment on certain claims, including breach of contract, declaratory judgment and, with respect to Celgene's counterclaims, patent misuse. Oral argument on the motion was held on October 21, 2015.

On February 23, 2016, the Magistrate Judge issued a Report and Recommendation that the Court allow-in-part and deny-in-part the plaintiffs' motion for summary judgment. The Magistrate Judge recommended to the Court to allow royalties on sales of REVLIMID® during the period from March 1, 2013 through May 11, 2016, and to deny the remainder of plaintiffs' motion, including seeking royalties on sales of POMALYST®/IMNOVID®. On March 8, 2016, we filed objections to the Report and Recommendation. No trial date has been set by the court.

We intend to vigorously defend against CMCC's and CR Rev's claims. As of March 31, 2016, we consider the range of reasonably possible loss relating to this lawsuit to be between zero and \$156.5 million, with the high end of the range being the royalty payments on REVLIMID® we would have made to CMCC under the license agreement through March 31, 2016, if our obligation to pay royalties remained in effect. CMCC contends that our royalty obligation continues on net sales of REVLIMID®, as well as POMALYST®/IMNOVID®, at least until May 2016. If CMCC prevails, we may be obligated to continue to pay royalties on sales for periods after March 31, 2016.

On November 7, 2014, the International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund (IUB) filed a putative class action lawsuit against us in the United States District Court for the District of New Jersey alleging that we violated various state 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 (Barr) 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 Mylan Pharmaceuticals, Lannett Company, and Dr. Reddy's Laboratories so that those companies can conduct the 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 against Barr and Natco Pharma Limited in order to allegedly delay those companies from obtaining 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. On February 6, 2015, we filed a motion to dismiss IUB's complaint. On March 3, 2015, the City of Providence ("Providence") filed a similar putative class action making similar allegations. Both IUB and Providence, on behalf of themselves and a putative class of third party payers, are seeking injunctive relief and damages. Providence agreed that the decision in the motion to dismiss IUB's complaint would apply to the identical claims in Providence's complaint. A supplemental motion to dismiss Providence's state law claims was filed on April 20, 2015. On October 30, 2015, the court denied our motion to dismiss on all grounds.

Celgene filed its Answer to the IUB and Providence complaints on January 11, 2016. The completion of fact discovery and expert discovery is scheduled for August 1, 2017 and December 15, 2017, respectively. No trial date has been set. We intend to vigorously defend against IUB's claims.

On July 20, 2015, a putative class action lawsuit, *Scott v. Receptos, Inc.*, related to our acquisition of Receptos, was commenced by the filing of a complaint in the Court of Chancery for the State of Delaware, Case No. 11316, against Receptos, members of the Receptos Board, Celgene and Celgene's wholly-owned subsidiary, Strix Corporation, which is a party to the acquisition agreement. Four other complaints, *Cacioppo v. Hasnain and Rosenberg v. Receptos, Inc.* (Cases Nos. 11324 and 11325) filed on July 23, and *Kadin v. Receptos, Inc.*, filed on July 27 (Case No. 11337), and *Rockaway v. Hasnain* (Case No. 11346) filed on July 28, 2015 raise similar putative class claims in the Court of Chancery for the State of Delaware against some or all of Receptos, members of the Receptos Board, Celgene, and

Strix Corporation. These complaints generally allege breaches of fiduciary duty by members of the Receptos Board in connection with the Merger Agreement. In the Scott, Rosenberg and Kadin actions, the plaintiffs also allege that Celgene and Strix Corporation aided and abetted the purported breaches of fiduciary duty. On August 17, 2015, all parties to these actions entered into a Memorandum of Understanding (MOU), which sets forth the parties' agreement in principle for a settlement of the actions. As part of the proposed settlement, prior to the closing, Receptos made certain additional disclosures related to the acquisition. The parties have since terminated settlement discussions. Plaintiff voluntarily dismissed the action without prejudice to plaintiff's right to seek an award of attorneys' fees. The briefing for plaintiff's motion for attorneys' fees is to be completed by June 29, 2016. Oral argument on the motion for attorneys' fees will be held on July 21, 2016.

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

### Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “aims,” “plans,” “could,” “will,” “will continue,” “seeks,” “should,” “predicts,” “potential,” “outlook,” “guidance,” “target,” “forecast,” “probable,” and the negative of such terms and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions and projections, which are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws. We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements and therefore you should not place too much reliance on them. These factors include, among others, those described in the sections “Forward-Looking Statements” and “Risk Factors” contained in our 2015 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in this report and our other public reports filed with the SEC. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

### Executive Summary

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

Our primary commercial stage products include REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, ABRAXANE<sup>®</sup>, OTEZLA<sup>®</sup>, VIDAZA<sup>®</sup>, azacitidine for injection (generic version of VIDAZA<sup>®</sup>), THALOMID<sup>®</sup> (sold as THALOMID<sup>®</sup> or Thalidomide Celgene<sup>™</sup> outside of the U.S.), and ISTODAX<sup>®</sup>. In addition, we earn revenue through licensing arrangements.

We continue to invest substantially in research and development in support of multiple ongoing proprietary clinical development programs which support our existing products and pipeline of new drug candidates. Our clinical trial activity includes trials across the disease areas of hematology, oncology, and inflammation and immunology. REVLIMID<sup>®</sup> is in several phase III trials covering a range of hematological malignancies that include multiple myeloma, lymphomas, chronic lymphocytic leukemia (CLL) and myelodysplastic syndromes (MDS). POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> was approved in the United States and the European Union (EU) for indications in multiple myeloma based on phase II and phase III trial results, respectively, and an additional phase III trial is underway with POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> in relapsed and refractory multiple myeloma. In solid tumors, ABRAXANE<sup>®</sup> is currently in various stages of investigation for breast, pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA<sup>®</sup> is being evaluated in phase III trials for Behçet's disease and expanded indications in psoriatic arthritis and plaque psoriasis. We also have a growing number of potential products in phase III trials across multiple diseases. In the inflammation and immunology therapeutic area, we have phase III trials

underway for ozanimod in ulcerative colitis (UC) and relapsing multiple sclerosis (RMS) and for GED-0301 in Crohn's disease. In hematology, phase III trials are underway for CC-486 in MDS and acute myeloid leukemia (AML), for AG-221 in AML, and for luspatercept in MDS.

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, regulatory approvals of new products and expanded use of existing products will provide the catalysts for future growth.

The diseases that our primary commercial stage products are approved to treat are described below for the major markets of the United States, the European Union and Japan. Approvals in other international markets are indicated in the aggregate for the disease indication that most closely represents the majority of the other international approvals.



REVLIMID® (lenalidomide): REVLIMID® is an oral immunomodulatory drug marketed in the United States and many international markets for the treatment of patients with the following indications:

Disease	Geographic Approvals
Multiple myeloma (MM)	- United States - European Union
Multiple myeloma in combination with dexamethasone, in patients who have received at least one prior therapy	- Japan - Other international markets - United States - Japan - Other international markets
Multiple myeloma in combination with dexamethasone for newly diagnosed patients	- Other international markets - European Union
Adult patients with previously untreated multiple myeloma who are not eligible for transplant Myelodysplastic syndromes (MDS)	- United States - Other international markets
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities	- European Union
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS in patients with isolated deletion 5q cytogenetic abnormality when other options are insufficient or inadequate MDS with a deletion 5q cytogenetic abnormality. The efficacy or safety of REVLIMID® for International Prognostic Scoring System (IPSS) intermediate-2 or high risk MDS has not been established.	- Japan
Mantle cell lymphoma (MCL) in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib	- United States
In January 2016, the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for treatment with REVLIMID® in adult patients with relapsed or refractory mantle cell lymphoma.	

ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension): ABRAXANE® is a solvent-free chemotherapy product which was developed using our proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. ABRAXANE® is approved for the treatment of patients with the following indications:

Disease	Geographic Approvals
Breast Cancer	
Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.	- United States - Other international markets
Metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease for whom standard, anthracycline containing therapy is not indicated	- European Union
Breast cancer	- Japan
Non-Small Cell Lung Cancer (NSCLC)	
Locally advanced or metastatic NSCLC, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy	- United States - European Union - Other international markets
NSCLC	- Japan
Pancreatic Cancer	
Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, as first line treatment in combination with gemcitabine	- United States - European Union - Other international markets
Unresectable pancreatic cancer	- Japan
Gastric cancer	- Japan

POMALYST®/IMNOVID® (pomalidomide)<sup>1</sup>: POMALYST®/IMNOVID® is a proprietary, distinct, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST®/IMNOVID® is approved for the treatment of patients with the following indications:

Disease	Geographic Approvals
Multiple myeloma, in combination with dexamethasone, for patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy	- United States
Relapsed and refractory multiple myeloma, in combination with dexamethasone, for adult patients who have received at least two prior therapies including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy	- European Union
Relapsed and refractory multiple myeloma for patients who have received REVLIMID or bortezomib	- Japan

<sup>1</sup> We received regulatory approval for pomalidomide under the trade name POMALYST® in the United States and Japan and under the trade name IMNOVID® in the European Union.

OTEZLA® (apremilast): OTEZLA® is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. OTEZLA® is approved for the treatment of patients with the following indications:

Disease	Geographic Approvals
Psoriatic arthritis	
Adult patients with active psoriatic arthritis	- United States
Adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior DMARD therapy	- European Union
Psoriasis	
	- United States
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- Other international markets
Adult patients with moderate to severe chronic plaque psoriasis who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light	- European Union

VIDAZA® (azacitidine for injection): VIDAZA® is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA® is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS, according to the National Comprehensive Cancer Network. The U.S. regulatory exclusivity for VIDAZA® expired in May 2011. After the launch of a generic version of VIDAZA® in the United States by a competitor in September 2013, we experienced a significant reduction in our U.S. sales of VIDAZA®. In 2013, we contracted with Sandoz AG (Sandoz) to sell a generic version of VIDAZA® in the United States, which we supply, and we recognize net product sales from our sales to Sandoz. Regulatory exclusivity for VIDAZA® is expected to continue in Europe through 2019. VIDAZA® is marketed in the United States and many international markets for the treatment of patients with the following indications:

Disease	Geographic Approvals
Myelodysplastic syndromes (MDS)	
All French-American-British (FAB) subtypes	- United States
	- European Union
Intermediate-2 and high-risk MDS	- Other international markets
MDS	
	- Japan
	- European Union
Chronic myelomonocytic leukemia with 10% to 29% marrow blasts without myeloproliferative disorder	- Other international markets
	- European Union
Acute myeloid leukemia (AML) with 20% to 30% blasts and multi-lineage dysplasia	- Other international markets
Acute myeloid leukemia with >30% bone marrow blasts according to the WHO classification in patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation.	- European Union



THALOMID® (thalidomide): THALOMID®, sold as THALOMID® or Thalidomide Celgene™ outside of the United States, is administered orally for the treatment of patients with the following indications:

Disease	Geographic Approvals
Multiple myeloma	
Newly diagnosed multiple myeloma, in combination with dexamethasone	- United States
Thalomid in combination with dexamethasone is indicated for induction therapy prior to high dose chemotherapy with autologous stem cell rescue, for the treatment of patients with untreated multiple myeloma	- Other international markets - Other international markets
Multiple myeloma after failure of standard therapies (relapsed or refractory)	- European Union - Other international markets
Thalidomide Celgene™ in combination with melphalan and prednisone as a first line treatment for patients with untreated multiple myeloma who are aged sixty-five years of age or older or ineligible for high dose chemotherapy	- European Union - Other international markets
Erythema nodosum leprosum	
Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), an inflammatory complication of leprosy	- United States - Other international markets
Maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence	- United States - Other international markets

ISTODAX® (romidepsin): ISTODAX® is administered by intravenous infusion for the treatment of patients with the diseases as indicated below and has received orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, including CTCL and PTCL.

Disease	Geographic Approvals
Cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy	- United States - Other international markets
Peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy	- United States - Other international markets

The following table summarizes total revenue and earnings for the three-month periods ended March 31, 2016 and 2015 (dollar amounts in millions, except per share data):

	Three-Month		Increase	Percent Change
	Periods Ended	Periods Ended		
	March 31,	March 31,		
	2016	2015		
Total revenue	\$2,511.6	\$2,080.8	\$ 430.8	20.7 %
Net income	\$800.7	\$718.9	\$ 81.8	11.4 %
Diluted earnings per share	\$0.99	\$0.86	\$ 0.13	15.1 %

Total revenue increased by \$430.8 million in the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to the continued growth in sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA®. The \$81.8 million increase in net income and \$0.13 increase in diluted

earnings per share in the current three-month period were primarily due to a higher level of net product sales, partly offset by an increase in research and development expenses of \$227.2 million which includes a \$118.4 million increase in expenses related to collaboration arrangements as well as an increase in drug discovery and clinical trial activity, and a \$72.7 million increase in interest expense.

## Results of Operations

## Three-Month Periods Ended March 31, 2016 and 2015

Total Revenue: Total revenue and related percentages for the three-month periods ended March 31, 2016 and 2015 were as follows (dollar amounts in millions):

	Three-Month		Increase (Decrease)	Percent Change
	Periods Ended March 31, 2016	2015		
Net product sales:				
REVLIMID®	\$1,573.6	\$1,342.9	\$ 230.7	17.2 %
ABRAXANE®	224.9	223.4	1.5	0.7 %
POMALYST®/IMNOVID®	274.0	198.5	75.5	38.0 %
OTEZLA®	195.6	60.3	135.3	N/M
VIDAZA®	146.7	143.6	3.1	2.2 %
azacitidine for injection	18.5	20.6	(2.1)	(10.2)%
THALOMID®	41.0	46.9	(5.9)	(12.6)%
ISTODAX®	18.5	16.5	2.0	12.1 %
Other	1.9	2.5	(0.6)	(24.0)%
Total net product sales	\$2,494.7	\$2,055.2	\$ 439.5	21.4 %
Other revenue	16.9	25.6	(8.7)	(34.0)%
Total revenue	\$2,511.6	\$2,080.8	\$ 430.8	20.7 %

N/M - Not meaningful

Total revenue increased by \$430.8 million, or 20.7%, to \$2.512 billion for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, reflecting increases of \$311.7 million, or 24.8%, in the United States and \$119.1 million, or 14.4%, in international markets.

Net Product Sales: Total net product sales for the three-month period ended March 31, 2016 increased by \$439.5 million, or 21.4%, to \$2.495 billion compared to the three-month period ended March 31, 2015. The increase was comprised of net volume increases of \$395.7 million and net price increases of \$75.0 million, offset in part by a \$31.2 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity.

REVLIMID® net sales increased by \$230.7 million, or 17.2%, to \$1.574 billion for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to increased unit sales in both U.S. and international markets and price increases in the U.S. market. Increases in market penetration and treatment duration of patients using REVLIMID® in multiple myeloma contributed to the increase in U.S. unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains. Launch activities in the U.S. and EU for the Newly Diagnosed Multiple Myeloma indication, which was approved in both the U.S. and the EU in February 2015, commenced in 2015.

ABRAXANE® net sales increased by \$1.5 million, or 0.7%, to \$224.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015. U.S. sales of \$143.8 million and international sales of \$81.1 million decreased 10 percent and increased 26 percent, respectively. The decrease in sales in the U.S. reflects quarterly customer buying patterns and increased competition in breast cancer and lung cancer from new market entrants.

POMALYST®/IMNOVID® net sales increased by \$75.5 million, or 38.0%, to \$274.0 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, reflecting net sales of \$170.7 million in the United States and \$103.3 million in international markets. Increases in market share and treatment duration contributed to the increase in U.S. and international net sales of POMALYST®/IMNOVID®. Achieving reimbursement in additional countries, notably in Japan, also continues to contribute to the growth of POMALYST®/IMNOVID® net sales in international markets.

OTEZLA® net sales increased by \$135.3 million to \$195.6 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015 reflecting net sales of \$174.8 million in the United States and \$20.8 million in international markets. OTEZLA® was approved by the U.S. Food and Drug Administration (FDA) in March 2014 for the treatment



of adult patients with active psoriatic arthritis and in September 2014 for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. OTEZLA<sup>®</sup> was approved for plaque psoriasis and psoriatic arthritis in the European Union in January 2015.

VIDAZA<sup>®</sup> net sales increased by \$3.1 million, or 2.2%, to \$146.7 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to a \$5.5 million increase in international markets resulting from increased unit sales which was partly offset by volume decreases in U.S. sales.

Azacitidine for injection net sales decreased by \$2.1 million, or 10.2%, to \$18.5 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to price decreases slightly offset by an increase in unit volumes.

THALOMID<sup>®</sup> net sales decreased by \$5.9 million, or 12.6%, to \$41.0 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily resulting from lower unit volumes in both U.S. and international markets.

ISTODAX<sup>®</sup> net sales increased by \$2.0 million, or 12.1%, to \$18.5 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to an increase in unit volume.

Other Revenue: Other revenue decreased by \$8.7 million to \$16.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015 primarily due to a \$7.4 million decrease in royalty revenue from Novartis based upon its sales of both RITALIN<sup>®</sup> and FOCALIN XR<sup>®</sup>, which have both been negatively impacted by generic competition in certain markets and we expect that trend to accelerate throughout the remainder of 2016.

Gross to Net Sales Accruals: We record gross to net sales accruals for sales returns and allowances, sales discounts, government rebates, chargebacks and distributor service fees.

REVLIMID<sup>®</sup>, POMALYST<sup>®</sup> and THALOMID<sup>®</sup> are distributed in the United States primarily through contracted pharmacies under the REVLIMID<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS), POMALYST REMS<sup>™</sup> and THALOMID REMS<sup>™</sup> programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup> and THALOMID<sup>®</sup>. Internationally, REVLIMID<sup>®</sup>, THALOMID<sup>®</sup>/Thalidomide Celgene<sup>™</sup> and IMNOVID<sup>®</sup> 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. VIDAZA<sup>®</sup>, ABRAXANE<sup>®</sup>, ISTODAX<sup>®</sup> and OTEZLA<sup>®</sup> are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and THALOMID<sup>®</sup>/Thalidomide Celgene<sup>™</sup>.

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. As noted above, REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and THALOMID<sup>®</sup>/Thalidomide Celgene<sup>™</sup> are distributed primarily through hospitals and contracted pharmacies, which are typically subject to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. 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. Subsequent to implementation of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the 2010 U.S. Health Care Reform Law), certain states have not completed their Medicaid Managed Care Organization billing for the years of 2010 through 2015. Our accruals for these Medicaid Managed Care Organization rebates had been at elevated levels given the delays in the receipt of complete invoices from certain states. Due to the receipt of more complete claims data during 2013, 2014 and 2015, the accruals for certain states were reduced from these elevated levels as a result of both payments being applied to the accrual during 2013, 2014 and 2015 and changes in estimate of the ultimate obligation during the fourth quarters of 2013, 2014 and 2015. We will continue to adjust the rebate accruals as more information becomes available and to reflect actual claims experience. 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.

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 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.

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.

See Critical Accounting Estimates and Significant Accounting Policies in our 2015 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended March 31, 2016 and 2015 were as follows (in millions):

	Sales Returns	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at December 31, 2015	\$ 17.4	\$ 12.2	\$ 225.1	\$ 141.7	\$ 396.4
Allowances for sales during prior periods	(4.5 )	—	9.9	(5.7 )	(0.3 )
Allowances for sales during 2016	1.9	35.5	160.4	159.9	357.7
Credits/deductions issued for prior year sales	(1.3 )	(10.4 )	(78.0 )	(44.6 )	(134.3 )
Credits/deductions issued for sales during 2016	(0.6 )	(22.4 )	1.3	(102.7 )	(124.4 )
Balance at March 31, 2016	\$ 12.9	\$ 14.9	\$ 318.7	\$ 148.6	\$ 495.1
Balance at December 31, 2014	\$ 10.2	\$ 11.5	\$ 138.5	\$ 94.4	\$ 254.6

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Allowances for sales during prior periods	—	—	(4.9	) (3.0	) (7.9	)
Allowances for sales during 2015	1.6	26.1	116.1	118.1	261.9	
Credits/deductions issued for prior year sales	(0.7	) (8.1	) (40.1	) (41.7	) (90.6	)
Credits/deductions issued for sales during 2015	(0.8	) (16.8	) (19.1	) (67.3	) (104.0	)
Balance at March 31, 2015	\$ 10.3	\$ 12.7	\$ 190.5	\$ 100.5	\$ 314.0	

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended March 31, 2016 and 2015 follows:

Provisions for sales returns decreased by \$4.2 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to a \$5.0 million reduction in the ABRAXANE® returns reserve allowance related to inventory levels held by certain distributors at the end of 2015 which was sold to end customers during the first quarter of 2016. This reduction was partially offset by \$0.5 million increase in the returns allowance related to OTEZLA®.

Discount provisions increased by \$9.4 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to increased sales volumes. The \$9.4 million increase consisted of a \$9.0 million increase in the United States, which included increases of \$4.8 million of cash discounts related to REVLIMID® and \$4.2 million related to OTEZLA®.

Government rebates provisions increased by \$59.1 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily due to a \$39.3 million increase in international government rebates. The increase in international government rebates was primarily driven by an adjustment of our accrual to reflect higher rebate rates for IMNOVID® in France, as well as higher sales volumes for our primary products in Europe and increased rebate rates in other countries. The increase in the allowance for sales of IMNOVID® in France during prior periods was \$15.1 million and the increase for sales in the current quarter was \$4.4 million. The \$19.8 million increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with \$11.0 million reflected in an increase in expense related to Medicare Part D Coverage Gap and \$8.8 million reflected in an increase in Medicaid rebates.

Chargebacks and distributor service fees provisions increased by \$39.1 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015. Chargebacks increased by approximately \$18.2 million and distributor service fees increased by approximately \$20.9 million. The chargeback increases were primarily due to higher sales volumes. The distributor service fee increase was primarily attributable to OTEZLA®, which increased by \$21.6 million for the three-month period ended March 31, 2016.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended March 31, 2016 and 2015 were as follows (dollar amounts in millions):

	Three-Month Periods Ended		Increase	Percent Change
	March 31, 2016	2015		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$105.9	\$104.0	\$ 1.9	1.8 %
Percent of net product sales	4.2 %	5.1 %		
Research and development	\$733.2	\$506.0	\$ 227.2	44.9 %
Percent of total revenue	29.2 %	24.3 %		
Selling, general and administrative	\$543.0	\$529.2	\$ 13.8	2.6 %
Percent of total revenue	21.6 %	25.4 %		
Amortization of acquired intangible assets	\$91.8	\$63.6	\$ 28.2	44.3 %
Acquisition related charges and restructuring, net	\$36.2	\$19.0	\$ 17.2	90.5 %

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$1.9 million to \$105.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015. The increase was primarily due to the higher level of net product sales. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 4.2% for the three-month period ended March 31, 2016 compared to 5.1% for the three-month period ended March 31, 2015, primarily due to OTEZLA® and POMALYST®, which have lower cost, making up a higher percentage of net product sales, while sales of ABRAXANE® and azacitidine for injection, which have a lower

gross margin, made up a lower percentage of net product sales.

Research and Development: Research and development expenses increased by \$227.2 million to \$733.2 million for the three-month period ended March 31, 2016, compared to the three-month period ended March 31, 2015. The increase was primarily due to a \$118.4 million increase in expenses related to collaboration arrangements as well as an increase in drug discovery and clinical trial activity.

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

	Three-Month		
	Periods Ended		Increase
	March 31,		(Decrease)
	2016	2015	
Human pharmaceutical clinical programs	\$254.4	\$212.6	\$ 41.8
Other pharmaceutical programs	186.4	169.5	16.9
Drug discovery and development	136.4	84.6	51.8
Collaboration arrangements	151.0	32.6	118.4
Cellular therapy	5.0	6.7	(1.7 )
Total	\$733.2	\$506.0	\$ 227.2

The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended March 31, 2016, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

New phase III trials:

Product	Disease Indication
AG-221 <sup>1</sup>	Acute myeloid leukemia
luspaterecept <sup>2</sup>	Myelodysplastic syndrome

<sup>1</sup> In collaboration with Agios Pharmaceuticals, Inc.

<sup>2</sup> In collaboration with Acceleron Pharma, Inc.

Regulatory approval requests in major markets:

Product	Disease Indication	Major Market	Regulatory Agency	Date of Submission or Filing
OTEZLA <sup>®</sup>	Psoriasis and Psoriatic Arthritis	Japan	PMDA <sup>1</sup>	Q1 2016 (filed)

<sup>1</sup> Pharmaceuticals and Medical Devices Agency

**Selling, General and Administrative:** Selling, general and administrative expenses increased by \$13.8 million to \$543.0 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015. The increase was primarily due to an increase in expenses associated with our growing organization to support inflammation and immunology products and product candidates, such as OTEZLA<sup>®</sup>, ozanimod, and GED-0301, as well as increases in selling and marketing activities related to recently approved indications as well as the expansion of sales into new geographic regions for OTEZLA<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>.

**Amortization of Acquired Intangible Assets:** Amortization of intangible assets acquired as a result of business combinations is summarized below for the three-month period ended March 31, 2016 and 2015 (in millions):

	Three-Month	
	Periods	
	Ended	
	March 31,	
	2016	2015
Acquisitions		
Abraxis	\$38.0	\$38.0
Avila	11.8	11.8
Gloucester	22.9	12.8
Pharmion	1.0	1.0
Quanticel	18.1	—
Total amortization	\$91.8	\$63.6

The increase in amortization expense primarily related to the amortization of the technology platform received in the acquisition of Quantice and a reduction in the estimated useful lives of intangible assets related to the acquisition of Gloucester following the grant to Fresenius Kabi USA, LLC of a non-exclusive, royalty-free sublicense to manufacture and market a generic version of romidepsin for injection as of February 1, 2018. See Note 18 of Notes to Consolidated Financial Statements in our 2015 Annual Report on Form 10-K for additional details.



Acquisition Related Charges and Restructuring, net: Acquisition related charges and restructuring, net were a net expense of \$36.2 million and \$19.0 million for the three-month periods ended March 31, 2016 and 2015, respectively. The \$17.2 million increase in the current year three-month period was primarily due to a \$12.6 million increase in expense in the current year three-month period compared to the prior year three-month period for the fair value of our liability related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis, a \$2.8 million increase in expense in the current year three-month period related to our contingent liabilities for the Nogra Pharma Limited (Nogra) acquisition, and \$3.1 million of restructuring charges in the current year three-month period related to our relocation of certain operations into our two Summit, NJ locations as well as costs associated with certain headcount reductions. These increases in expense were partly offset by a \$2.3 million reduction in the current year three-month period for our contingent liabilities related to the Avila acquisition compared to the prior year three-month period.

Interest and Investment Income, Net: Interest and investment income, net decreased by \$2.2 million to \$6.8 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015 primarily due to lower investment balances compared to the prior year.

Interest (Expense): Interest (expense) increased by \$72.7 million to \$121.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015 primarily due to interest expense associated with the issuance of \$8.000 billion of senior notes in August 2015.

Other Income (Expense), Net: Other income (expense), net and fluctuations in the components of Other income (expense), net is summarized below for the three-month period ended March 31, 2016 and 2015 (in millions):

	Three-Month Periods Ended March 31,		
	2016	2015	Change
Foreign exchange gains (losses), including foreign exchange derivative instruments not designated as hedging instruments	\$0.8	\$2.1	\$(1.3 )
Premium paid on equity investment	(6.0 )	—	(6.0 )
Fair value adjustments of forward point amounts	13.0	7.2	5.8
Gain from sale of put options	4.4	3.9	0.5
Impairment charges	(15.1 )	(2.1 )	(13.0 )
Gain on sale of LifebankUSA business	37.5	—	37.5
Other	0.6	(2.8 )	3.4
Total Other income (expense), net	\$35.2	\$8.3	\$26.9

Other income (expense), net was a net income of \$35.2 million and \$8.3 million for the three-month periods ended March 31, 2016 and 2015, respectively. The \$26.9 million increase in other income was primarily due to a gain on the sale of our LifebankUSA business and a favorable change in spreads between forward and spot rates related to foreign exchange contracts partly offset by increased impairment charges related to certain investments recorded in the 2016 period and a premium paid on an equity investment.

Income Tax Provision: The income tax provision increased by \$12.7 million to \$120.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015, primarily as a result of an increase in income before taxes and an increase in the effective tax rate. The estimated full year 2016 underlying effective tax rate of 14.2% reflects the impact of our global business footprint. The increase in the estimated underlying effective tax rate from the first quarter of 2015 reflects a projected unfavorable tax impact of changes in

the jurisdictional mix of income before taxes from operations in the ordinary course of business. The effective tax rate for the first quarter of 2016 was reduced by 1.1 percentage points as a result of a decrease in unrecognized tax benefits related to settlements of tax positions taken in prior years. The income tax provision for the three-month period ended March 31, 2015 included an estimated full year 2015 underlying effective tax rate of 13.1% (which subsequently increased to 20.0% when the actual 2015 full year results were achieved).

## Liquidity and Capital Resources

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

	March 31, 2016	December 31, 2015	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	\$4,445.5	\$4,880.3	\$ (434.8 )
Marketable securities available for sale	1,261.8	1,671.6	(409.8 )
Total financial assets	\$5,707.3	\$6,551.9	\$ (844.6 )
Debt:			
Long-term debt, net of discount	14,268.3	14,161.4	106.9
Total debt	\$14,268.3	\$14,161.4	\$ 106.9
Working capital <sup>(1)</sup>	\$6,609.9	\$7,492.6	\$ (882.7 )

Includes cash, cash equivalents and marketable securities available for sale, accounts receivable, net of allowances, <sup>(1)</sup> inventory and other current assets, less accounts payable, accrued expenses and other current liabilities, and income taxes payable.

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

Many of our operations are conducted outside the United States and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of March 31, 2016, we held approximately \$3.399 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business, including intercompany transactions, as well as for other reasons, such as repurchases of our common stock, internal reorganizations, business-development activities and debt issuances. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the United States, no accrual for U.S. taxes is provided. Approximately \$900.0 million of our foreign earnings, included in the \$3.399 billion of short-term funds in foreign tax jurisdictions, may not be required for use in offshore operations and may be available for use in the United States. These earnings are not treated as permanently reinvested and accordingly, our deferred tax liabilities as of March 31, 2016 and December 31, 2015 included \$316.5 million for the estimated U.S. federal and state income taxes that may be incurred should these earnings be repatriated. The remaining foreign earnings are unremitted and expected to be permanently reinvested outside the United States. We do not rely on these earnings as a source of funds for our domestic business as we expect to have sufficient current cash resources combined with future cash flows in the United States to fund our U.S. operational and strategic needs.

Share Repurchase Program: Our Board of Directors approved an aggregate \$17.500 billion common stock repurchase program of which we have approximately \$2.481 billion remaining for future share repurchases as of March 31, 2016. During the three-month period ended March 31, 2016 we used \$1.410 billion for purchases of our common stock,

measured on a settlement date basis.

#### Components of Working Capital

**Cash, Cash Equivalents and Marketable Securities Available for Sale:** We invest our excess cash primarily in money market funds, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government agency and supranational securities, global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as marketable securities available for sale. The \$844.6 million decrease in cash, cash equivalents and marketable securities available for sale at March 31, 2016 compared to December 31, 2015 was primarily due to \$1.410 billion of payments under our share repurchase program, \$381.8

million of net unrealized holding losses on marketable securities available for sale, partially offset by \$974.9 million of net cash from operating activities.

Accounts Receivable, Net: Accounts receivable, net decreased by \$0.6 million to \$1.420 billion at March 31, 2016 compared to December 31, 2015. 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 crisis in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. 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.

The credit and economic conditions within Spain, Italy, Portugal and Greece, as well as increasing sales levels in those countries have in the past resulted in, and may continue to result in, an increase in the average length of time it takes to collect accounts receivable. Our total net receivables in Spain, Italy and Portugal are composed almost entirely of amounts receivable from government-owned or controlled hospitals and the public sector and amounted to \$228.3 million at March 31, 2016 compared to \$187.8 million at December 31, 2015. Approximately \$34.0 million of the \$228.3 million receivable balance at March 31, 2016 was greater than one year past due. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of receivables in Greece. We maintain timely and direct communication with hospital customers in Spain, Italy and Portugal regarding both the current and past due receivable balances. We continue to receive payments from these countries and closely monitor the plans for payment at the regional government level. Payments from customers in these countries are not received on regular intervals and several months could elapse between significant payments. We also regularly request and receive positive confirmation of the validity of our receivables from most of the regional governmental authorities.

In determining the appropriate allowance for doubtful accounts for Spain, Italy and Portugal, we considered the balance of past due receivables related to sales made to government-owned or supported customers. We regularly monitor developments in Europe to assess whether the level of risk of default for any customers has increased and note the ongoing efforts by the European Union, European Monetary Union and International Monetary Fund to support countries with large public deficits and outstanding debt balances. We also monitor the efforts of individual countries to support their regions with large public deficits and outstanding debt balances. We have not experienced significant losses or write-offs with respect to the collection of our accounts receivable in these countries as a result of their economic difficulties and we do not expect to have write-offs or adjustments to accounts receivable that would have a material adverse impact on our financial position or results of operations.

Inventory: Inventory balances increased by \$27.2 million to \$470.6 million at March 31, 2016 compared to December 31, 2015. The increase was primarily due to an increase in ABRAXANE<sup>®</sup> raw materials.

Other Current Assets: Other current assets decreased by \$196.9 million to \$787.8 million at March 31, 2016 compared to December 31, 2015 primarily due to a \$116.8 million decrease in the fair value of derivative instruments and a \$80.8 million decrease in prepaid taxes.

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 March 31, 2016, we had available capacity to issue up to \$1.750 billion of Commercial Paper and there were no borrowings under the Program. In April 2016 our Board of Directors authorized an increase in the maximum amount of commercial paper issuable to \$2.000 billion. 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 \$2.000 billion which was increased from \$1.750 billion in April 2016. In April 2016, the term of the Credit Facility was also extended from April 17, 2020 to April 17, 2021. 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. At March 31, 2016 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 March 31, 2016.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities decreased by \$127.0 million to \$1.762 billion at March 31, 2016 compared to December 31, 2015. The decrease was primarily due to decreases of \$163.6 million for compensation related accrued expenses and \$69.8 million for accrued interest. These decreases were partially offset by increases of \$96.0 million for sales adjustment accruals and \$10.3 million of other increases.

Income Taxes Payable (Current and Non-Current): Income taxes payable decreased by \$2.5 million to \$341.5 million at March 31, 2016 compared to December 31, 2015, primarily from the current provision for income taxes of \$164.2 million and net deferred intercompany credits of \$8.7 million, offset by income tax payments of \$102.1 million, tax benefits of share-based compensation of \$24.7 million, and a decrease in refundable income taxes of \$48.6 million.

#### Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the three-month periods ended March 31, 2016 and 2015 were as follows (in millions):

	Three-Month Periods Ended		
	March 31,		
	2016	2015	Change
Net cash provided by operating activities	\$974.9	\$856.5	\$118.4
Net cash (used in) provided by investing activities	\$(110.2 )	\$338.0	\$(448.2)
Net cash used in financing activities	\$(1,319.7)	\$(908.1)	\$(411.6)

Operating Activities: Net cash provided by operating activities increased by \$118.4 million to \$974.9 million for the three-month period ended March 31, 2016 compared to the three-month period ended March 31, 2015. The increase in net cash provided by operating activities was primarily attributable to an increase net income of \$81.8 million in 2016 compared to 2015 and an increase in cash collections on accounts receivable, partially offset by increased payments of accounts payable and other operating liabilities.

Investing Activities: Net cash used in investing activities for the three-month period ended March 31, 2016 amounted to \$110.2 million compared to net cash provided by investing activity of \$338.0 million for the three-month period ended March 31, 2015. The increase in net cash used in investing activities was primarily due to the net proceeds of \$28.5 million from net sales of marketable securities available for sale during 2016 compared to \$401.0 million of net sales of marketable securities available for sale during 2015 as well as \$79.1 million of net purchases of equity investments during 2016 compared to \$20.7 million of net purchases of equity investments during 2015.

Financing Activities: Net cash used in financing activities amounted to \$1.320 billion for the three-month period ended March 31, 2016, compared to net cash used in financing activities of \$908.1 million for the three-month period ended March 31, 2015. The \$411.6 million increase in net cash used in financing activities was primarily attributable to the \$1.410 billion of payments under our share repurchase program during 2016 compared to \$1.013 billion of payments under our share repurchase program during 2015.

#### Contractual Obligations

For a discussion of our contractual obligations, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in our 2015 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2015 aside from those disclosed in Note 14 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

#### 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 2015 Annual Report on Form 10-K. There have not been any material changes to such critical accounting estimates since December 31, 2015.

## 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. At March 31, 2016, our market risk sensitive instruments consisted of marketable securities available for sale, our long-term debt and certain derivative contracts.

**Marketable Securities Available for Sale:** At March 31, 2016, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency mortgage-backed (MBS) securities, global corporate debt securities, asset backed securities and marketable equity securities. 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.

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

As of March 31, 2016, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as marketable securities available for sale were as follows (dollar amounts in millions):

	Duration			
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	Total
Principal amount	\$37.7	\$286.4	\$10.0	\$334.1
Fair value	\$38.0	\$288.4	\$10.4	\$336.8
Weighted average interest rate	1.4 %	1.2 %	2.2 %	1.3 %

**Short-Term Borrowings and Current Portion of Long-Term Debt:** As of March 31, 2016 and December 31, 2015 we had no outstanding short-term borrowings or long-term debt due within one year.

Long-Term Debt: We have issued an aggregate \$14.250 billion principal amount of senior notes at varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of March 31, 2016 are summarized below (in millions):

	Principal Amount	Carrying Value
1.900% senior notes due 2017	\$500.0	\$501.0
2.125% senior notes due 2018	1,000.0	997.0
2.300% senior notes due 2018	400.0	402.2
2.250% senior notes due 2019	500.0	510.1
2.875% senior notes due 2020	1,500.0	1,491.3
3.950% senior notes due 2020	500.0	517.3
3.250% senior notes due 2022	1,000.0	1,046.3
3.550% senior notes due 2022	1,000.0	992.7
4.000% senior notes due 2023	700.0	734.6
3.625% senior notes due 2024	1,000.0	999.4
3.875% senior notes due 2025	2,500.0	2,475.5
5.700% senior notes due 2040	250.0	247.2
5.250% senior notes due 2043	400.0	392.9
4.625% senior notes due 2044	1,000.0	986.7
5.000% senior notes due 2045	2,000.0	1,974.1
Total long-term debt	\$14,250.0	\$14,268.3

At March 31, 2016, the fair value of our senior notes outstanding was \$14.939 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 and occasionally foreign currency put and call 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 at March 31, 2016 and December 31, 2015 had settlement dates within 36 months. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses are reported in other comprehensive income (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect earnings.

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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. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in other income (expense), net. The forward point components of these foreign currency forward contracts are not designated as cash flow hedges and all fair value adjustments of forward point amounts are recorded to other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at March 31, 2016 and December 31, 2015 (in millions):

Foreign Currency	Notional Amount	
	March 31, 2016	December 31, 2015
Australian Dollar	\$52.5	\$45.1
British Pound	252.8	289.3
Canadian Dollar	214.2	135.9
Euro	2,816.4	2,934.3
Japanese Yen	670.6	510.4
Swedish Krona	12.8	—
Total	\$4,019.3	\$3,915.0

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 March 31, 2016, 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 income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at March 31, 2016 and December 31, 2015 were \$676.1 million and \$920.0 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 March 31, 2016 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$471.6 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 other comprehensive income 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 at March 31, 2016 and December 31, 2015 had settlement dates within 51 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 at March 31, 2016 and December 31, 2015 (in millions):

	Notional Amount <sup>1</sup>	
	March 31, 2016	December 31, 2015
Foreign currency option contracts designated as hedging activity:		
Purchased Put	\$782.3	\$ 641.5
Written Call	\$851.5	\$ 690.0

<sup>1</sup> 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.

Assuming that the March 31, 2016 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately \$63.0 million if the U.S. Dollar were to strengthen and decrease by approximately \$63.7 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 other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings.

#### Interest Rate Risk Management

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 treasury rate locks or forward starting swaps are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

**Forward Starting Interest Rate Swaps and Treasury Rate Locks:** During 2014, we entered into forward starting swaps that were designated as cash flow hedges to hedge against changes in interest rates that could impact an anticipated issuance of debt in 2015. During 2015, we entered into additional forward starting swaps and treasury rate locks. Forward starting swaps and treasury rate locks with a combined aggregate notional value of \$2.900 billion were settled upon the issuance of debt in August 2015, when the net fair value of the forward starting swaps and treasury rate locks in accumulated other comprehensive income was in a loss position of \$21.6 million. The net loss will be recognized as interest expense over the life of the associated senior notes. During 2015 and 2016, we entered into forward starting swaps with effective dates in 2017 and 2018 and maturing in ten years that were designated as cash flow hedges to hedge against changes in interest rates that could impact anticipated future issuances of debt.

A sensitivity analysis to measure potential changes in the market value of our forward starting interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at March 31, 2016 would have increased the fair value of our contracts by \$44.0 million. A one percentage point decrease at March 31, 2016 would have decreased the aggregate fair value of our contracts by \$49.8 million.

**Interest Rate Swap Contracts:** From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swap are recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense. 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 swap contracts at March 31, 2016 and December 31, 2015 (in millions):

	Notional Amount	
	March 31, 2016	December 31, 2015
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
1.900% senior notes due 2017	300.0	300.0
2.300% senior notes due 2018	200.0	200.0
2.250% senior notes due 2019	500.0	500.0
3.950% senior notes due 2020	500.0	500.0
3.250% senior notes due 2022	1,000.0	1,000.0
4.000% senior notes due 2023	700.0	700.0
3.625% senior notes due 2024	100.0	100.0
3.875% senior notes due 2025	300.0	250.0
Total	\$3,600.0	\$3,550.0

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 at March 31, 2016 would have reduced the aggregate fair value of our net payable by \$930.1 million. A one percentage point decrease at March 31, 2016 would have increased the aggregate fair value of our net payable by \$1.098 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 March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

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

Our operating results may be subject to significant fluctuations.

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

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 and occasionally foreign currency put and call options to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful. As a result, currency fluctuation among our reporting currency, the U.S. dollar, and the currencies in which we do business will affect our operating results. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency and other hedge transactions. In particular, we may incur higher than expected charges from hedge ineffectiveness or from the termination of a hedge arrangement. For more information, see Item 3. "Quantitative and Qualitative Disclosures About Market Risk."

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

Our business is largely dependent on the commercial success of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, ABRAXANE<sup>®</sup>, OTEZLA<sup>®</sup>, VIDAZA<sup>®</sup> and THALOMID<sup>®</sup>. REVLIMID<sup>®</sup> currently accounts for over half of our total revenue. As new products, such as POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup>, have obtained regulatory approval and gained market acceptance, our dependence on REVLIMID<sup>®</sup> has decreased, a trend that we expect to continue. A significant decline in REVLIMID<sup>®</sup> 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 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. Certain of our pharmaceutical products, such as FOCALIN<sup>®</sup>, also require authorization by the U.S. Drug Enforcement Agency (DEA) of the U.S. Department of Justice. 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<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, 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<sup>™</sup> 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;

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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 legislation may affect our pricing policies and government reimbursement of our products that may adversely impact our revenues and profitability.

In the U.S. there have been and may continue to be a number of legislative and regulatory proposals and enactments related to drug pricing and reimbursement 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. Although these reforms have significantly impacted the pharmaceutical industry, the full effects of these provisions will become apparent over time as these laws are implemented and the Centers for Medicare & Medicaid Services (CMS) and other agencies issue applicable regulations or guidance as required by the Healthcare Reform Acts. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the profitability of our products.

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 increasing the category of entities qualified to participate in the program

and benefit from its deeply discounted drug pricing. We have received inquiries from the Health Resources and Services Administration of the Department of Health & Human Services (“HRSA”) regarding our compliance with the 340B program. We have responded to these inquiries and believe that we have complied with applicable legal requirements. If, however, we are ultimately required to change our sales or pricing practices, 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

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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, 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 Item 1. "Legal Proceedings".

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

Our intellectual property rights may be affected in ways that are difficult to anticipate at this time under the provisions of the America Invents Act enacted in 2011. This law represents a significant change to the US patent system. Uncertainty exists in the application and interpretation of various aspects of the America Invents Act. For example, post grant review procedures have been implemented that potentially represent a significant threat to a company's patent portfolio. Members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant review. Once instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. For example, on April 23, 2015, a party filed a petition to institute an Inter Partes Review (IPR) challenging the validity of our patent US 6,045,501 and three petitions challenging patent US 6,315,720. On October 27, 2015, the USPTO granted all four petitions. In addition, on May 7, 2015 another IPR was filed against our compound patent US 5,635,517 for lenalidomide, set to expire in 2019. On November 15, 2015, the USPTO rejected this challenge by denying the institution of the IPR procedure. For more information with respect to IPRs, see Item 1. "Legal Proceedings". A procedure similar to the IPR has existed in Europe for many years and we have defended our European patents in certain of those proceedings. For example, the validity of our patent EP 1 667 682 is currently the subject of an opposition proceeding before the EPO. We cannot predict whether any other Celgene patents will ever become the subject of a post grant review. If a significant product patent is successfully challenged in a post grant review proceeding it may be revoked, which would have a serious negative impact on our ability to maintain exclusivity in the market-place for our commercial products affected by such revocation and could adversely affect our future revenues and profitability.



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

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

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

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

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

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

Manufacturers of generic drugs are seeking to compete with our drugs and present a significant challenge to us. Those manufacturers may challenge the scope, validity or enforceability of our patents in court, requiring us to engage in complex, lengthy and costly litigation. If any of our owned or licensed patents are infringed or challenged, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on our sales of that product. In addition, manufacturers of innovative drugs as well as generic drug manufacturers may be able to design their products around our owned or licensed patents and compete with us using the resulting alternative technology. For more information concerning certain pending proceedings relating to our intellectual property rights and settlements of certain challenges, see Item 1. "Legal Proceedings".

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

Our business operates in an extremely competitive environment.

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

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

• Inflammation and Immunology: AbbVie, Amgen, Biogen, Eisai, Eli Lilly, Johnson & Johnson, Merck, Pfizer, Novartis 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 amounts receivable from the government-owned or -controlled hospitals in Spain, Italy and Portugal, see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

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

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

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

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

For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Item 1. "Legal Proceedings".

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

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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.

The stem cell products that we are developing through our CCT subsidiary may represent substantial departures from established treatment methods and will compete with a number of traditional products and therapies which are now, or may be in the future, manufactured and marketed by major pharmaceutical and biopharmaceutical companies.

Furthermore, public attitudes may be influenced by claims that stem cell therapy is unsafe and stem cell therapy may not gain the acceptance of the public or the medical community.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may face significant challenges in effectively integrating entities and businesses that we acquire and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquired businesses, such as the recent acquisition of Receptos, 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 Item 1. "Legal Proceedings".

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.

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

Product liability claims could result in significant damage awards or settlements. Such claims can also be accompanied by consumer fraud claims or claims by third-party payers seeking reimbursement of the cost of our products. In addition, adverse determinations or settlements of product liability claims may result in suspension or withdrawal of a product marketing authorization or changes to our product labeling, including restrictions on therapeutic indications, inclusion of new contraindications, warnings or precautions, which would have a material adverse effect on sales of such product. We have historically purchased product liability coverage from third-party carriers for a portion of our potential liability. Such insurance has become increasingly difficult and costly to obtain. In this context and in light of the strength of our balance sheet, commencing in the second quarter of 2016, we will self-insure these risks. 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. The impact on our income tax provision resulting from the above-mentioned factors and others could have a material impact on our results of operations.

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

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

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

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

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. In addition, 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.

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 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. There can be no assurance that our efforts to protect our data and information technology

systems will prevent breakdowns or breaches in our systems that could adversely affect our business and result in financial and reputational harm to us, 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 milestone and 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 clinical approval milestones or 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 March 2016, our Board of Directors approved purchases of up to \$17.500 billion of our common stock. Approved amounts exclude share purchase transaction fees.

The following table presents the number of shares purchased during the three-month period ended March 31, 2016, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs
January 1 - January 31	2,925,277	\$101.15	2,925,277	\$3,594,005,881
February 1 - February 29	6,706,978	\$99.84	6,706,978	\$2,924,352,835
March 1 - March 31	4,447,997	\$99.62	4,447,997	\$2,481,226,505
Total	14,080,252	\$100.05	14,080,252	

During the three-month period ended March 31, 2016, we purchased 14.1 million shares of common stock under the share repurchase program at a cost of \$1.409 billion, excluding commissions. As of March 31, 2016, we had a remaining purchase authorization of \$2.481 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

10.1\* First Amendment to Second Amended and Restated Credit Agreement, dated as of April 17, 2015, among Celgene Corporation, the lender parties named therein, and Citibank, N.A., as administrative agent.

10.2\* Amendment No. 2 to Second Amended and Restated Credit Agreement, dated as of April 17, 2015, among Celgene Corporation, the lender parties named therein, and Citibank, N.A., as administrative agent.

Amendment No. 3, effective April 16, 2014, to Amended and Restated Employment Agreement effective  
10.3\* May 1, 2006, as amended, between the Company and Robert J. Hugin.

Amendment No. 4, effective March 1, 2016, to Amended and Restated Employment Agreement effective  
10.4\* May 1, 2006, as amended, between the Company and Robert J. Hugin.

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 March 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) Notes to Unaudited Consolidated Financial Statements.

\* Filed herewith.



SIGNATURE

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

CELGENE  
CORPORATION

Date: May 3, 2016 By: /s/ Peter N. Kellogg  
Peter N. Kellogg  
Executive Vice  
President and Chief  
Financial Officer  
(principal financial  
and accounting  
officer)