CELGENE CORP /DE/
Form 10-Q
November 05, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark one)

[x] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____to _____

Commission File Number 001-34912
CELGENE CORPORATION
(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No

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

At October 30, 2015, 785,654,567 shares of Common Stock, par value $.01 per share, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In millions, except per share amounts)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Net product sales	$2,312.6	$1,956.8	$6,621.9	$5,508.9
Other revenue	21.5	25.4	70.8	76.0
Total revenue	2,334.1	1,982.2	6,692.7	5,584.9
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	109.9	97.7	314.7	282.7
Research and development	1,304.5	675.1	2,920.5	1,845.7
Selling, general and administrative	550.3	497.6	1,696.3	1,483.5
Amortization of acquired intangible assets	63.6	63.7	190.9	194.7
Acquisition related charges and restructuring, net	226.2	1.5	215.9	11.0
Total costs and expenses	2,254.5	1,335.6	5,338.3	3,817.6
Operating income	79.6	646.6	1,354.4	1,767.3
Other income and (expense):				
Interest and investment income, net	8.6	6.9	26.4	20.6
Interest (expense)	(88.5)	(53.5)	(186.0)	(124.4)
Other income (expense), net	(19.6)	(22.5)	83.2	(46.9)
Income (loss) before income taxes	(19.9)	577.5	1,278.0	1,616.6
Income tax provision	14.2	69.0	237.0	230.6
Net income (loss)	$(34.1)	$508.5	$1,041.0	$1,386.0
Net income (loss) per common share:				
Basic	$(0.04)	$0.64	$1.31	$1.72
Diluted	$(0.04)	$0.61	$1.26	$1.66
Weighted average shares:				
Basic	791.1	799.6	794.3	803.5
Diluted	791.1	832.8	827.7	836.4

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2015	2014	2015	2014
Net income (loss)	$(34.1)	$508.5	$1,041.0	$1,386.0
Other comprehensive income (loss):				
Foreign currency translation adjustments	(4.2)	(36.6)	(11.9)	(32.5)
Pension liability adjustment	—	—	(7.6)	—
Net unrealized gains (losses) related to cash flow hedges:				
Unrealized holding gains (losses)	(67.1)	382.8	277.0	342.5
Tax benefit	29.9	—	8.3	12.6
Unrealized holding gains (losses), net of tax	(37.2)	382.8	285.3	355.1
Reclassification adjustment for (gains) losses included in net income	(91.4)	(0.1)	(249.6)	4.8
Tax (benefit)	(0.5)	(0.5)	(1.5)	(1.2)
Reclassification adjustment for (gains) losses included in net income, net of tax	(91.9)	(0.6)	(251.1)	3.6
Net unrealized gains (losses) on marketable securities available for sale:				
Unrealized holding gains (losses)	(426.3)	64.6	(434.6)	196.9
Tax (expense) benefit	133.7	(22.2)	136.8	(67.3)
Unrealized holding gains (losses), net of tax	(292.6)	42.4	(297.8)	129.6
Reclassification adjustment for losses included in net income	10.9	1.2	11.6	4.2
Tax (benefit)	(3.9)	(0.4)	(4.1)	(1.5)
Reclassification adjustment for losses included in net income, net of tax	7.0	0.8	7.5	2.7
Total other comprehensive income (loss)	(418.9)	388.8	(275.6)	458.5
Comprehensive income (loss)	$(453.0)	$897.3	$765.4	$1,844.5

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$6,016.5	$4,121.6
Marketable securities available for sale	1,489.1	3,425.1
Accounts receivable, net of allowances of $31.5 and $32.1 at September 30, 2015 and December 31, 2014, respectively	1,272.4	1,166.7
Inventory	420.9	393.1
Deferred income taxes	249.6	11.7
Other current assets	703.9	594.4
Total current assets	10,152.4	9,712.6
Property, plant and equipment, net	702.0	642.6
Intangible assets, net	10,715.8	4,067.6
Goodwill	4,742.0	2,191.2
Other assets	1,057.0	726.1
Total assets	$27,369.2	$17,340.1
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	$1,199.7	$605.9
Accounts payable	189.4	198.2
Accrued expenses	1,504.8	991.1
Income taxes payable	5.9	12.7
Current portion of deferred revenue	74.8	28.5
Other current liabilities	169.3	275.8
Total current liabilities	3,143.9	2,112.2
Deferred revenue, net of current portion	29.4	27.8
Income taxes payable	322.8	272.9
Deferred income taxes	2,632.4	555.6
Other non-current liabilities	1,567.3	1,581.1
Long-term debt, net of discount	14,297.9	6,265.7
Total liabilities	21,993.7	10,815.3
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Preferred stock, $.01 par value per share, 5.0 million shares authorized; none outstanding at September 30, 2015 and December 31, 2014, respectively	—	—
Common stock, $.01 par value per share, 1,150.0 million shares authorized; issued 936.8 million and 924.8 million shares at September 30, 2015 and December 31, 2014, respectively	9.4	9.2
Common stock in treasury, at cost; 149.6 million and 124.6 million shares at September 30, 2015 and December 31, 2014, respectively	(13,613.4)	(10,698.8)
Additional paid-in capital	10,826.9	9,827.2
Retained earnings	7,513.4	6,472.4
Accumulated other comprehensive income	639.2	914.8

Total stockholders' equity	5,375.5	6,524.8
Total liabilities and stockholders' equity	$27,369.2	$17,340.1

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	Nine-Month Periods Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net income	$1,041.0	$1,386.0
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	86.6	78.1
Amortization	198.5	203.3
Deferred income taxes	(413.1)	(248.6)
Impairment charges	26.6	133.2
Change in value of contingent consideration	(17.2)	11.0
Net (gain) loss on sale of investments	(84.1)	4.2
Share-based compensation expense	426.4	319.2
Share-based employee benefit plan expense	24.1	29.3
Reclassification adjustment for cash flow hedges included in net income	(249.6)	4.8
Unrealized change in value of derivative instruments	209.8	(27.8)
Other, net	17.9	(3.5)
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(145.8)	(46.0)
Inventory	(27.1)	(33.6)
Other operating assets	(17.6)	55.7
Accounts payable and other operating liabilities	256.2	74.3
Income tax payable	43.9	27.7
Payment of contingent consideration	—	(5.0)
Deferred revenue	49.3	11.4
Net cash provided by operating activities	1,425.8	1,973.7
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	3,661.7	1,662.2
Purchases of marketable securities available for sale	(1,699.4)	(2,137.0)
Payments for acquisition of businesses, net of cash acquired	(7,579.3)	(710.0)
Capital expenditures	(145.5)	(100.9)
Purchases and sales of investment securities, net	(130.8)	(58.4)
Other investing activities	(4.5)	(21.0)
Net cash used in investing activities	(5,897.8)	(1,365.1)
Cash flows from financing activities:		
Payment for treasury shares	(2,574.1)	(2,433.8)
Proceeds from short-term borrowing	2,230.9	2,436.9
Principal repayments on short-term borrowing	(1,630.8)	(2,881.9)
Proceeds from issuance of long-term debt	7,913.3	2,470.6
Proceeds from sale of common equity put options	10.2	5.8
Payment of contingent consideration	—	(15.0)
Net proceeds from share-based compensation arrangements	204.2	205.1
Excess tax benefit from share-based compensation arrangements	243.7	146.4
Net cash provided by (used in) financing activities	6,397.4	(65.9)
Effect of currency rate changes on cash and cash equivalents	(30.5)	(34.6)

Net increase (decrease) in cash and cash equivalents	1,894.9	508.1
Cash and cash equivalents at beginning of period	4,121.6	3,234.4
Cash and cash equivalents at end of period	$6,016.5	$3,742.5

See accompanying Notes to Unaudited Consolidated Financial Statements

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

	Nine-Month Periods Ended September 30,	
	2015	2014
Supplemental schedule of non-cash investing and financing activity:		
Fair value of contingent consideration issued in business combinations	$—	$1,060.0
Change in net unrealized (gain) loss on marketable securities available for sale	$434.6	$(196.9)
Investment in NantBioScience, Inc. preferred equity	$—	$90.0
Supplemental disclosure of cash flow information:		
Interest paid	$171.1	$126.2
Income taxes paid	$345.6	$275.0

See accompanying Notes to Unaudited Consolidated Financial Statements

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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 gene and protein regulation. We are dedicated to innovative research and development designed to bring new therapies to market and we are involved in research in several scientific areas designed to deliver proprietary next-generation therapies, targeting areas including intracellular signaling pathways, protein homeostasis and epigenetics in cancer and immune cells, immunomodulation in cancer and autoimmune diseases and therapeutic application of cell therapies.

Our primary commercial stage products include REVLIMID®, ABRAXANE®, POMALYST®/IMNOVID®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®), THALOMID® (sold as THALOMID® or Thalidomide Celgene™ outside of the U.S.), OTEZLA® and ISTODAX®. 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. In January 2015, OTEZLA® was approved by the European Commission (EC) for the treatment of both psoriasis and psoriatic arthritis in certain adult patients. We began recognizing revenue related to OTEZLA® during the second quarter of 2014. Additional sources of revenue include royalties from Novartis Pharma AG (Novartis) on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of products and services through our Celgene Cellular Therapeutics (CCT) subsidiary and other 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, 2014 (2014 Annual Report on Form 10-K).

New Accounting Pronouncements: In May 2014, the Financial Accounting Standards Board (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 will have on our consolidated financial statements and related disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs" (ASU 2015-03). ASU 2015-03 will more closely align 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

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. This accounting guidance is effective for us beginning in the first quarter of 2016. We do not expect the adoption of this updated standard to have a material impact on our consolidated financial statements and related disclosures.

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 is effective for us beginning in the first quarter of 2016. We are currently evaluating the effect that the updated standard 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 August 2015, the FASB issued Accounting Standards Update No. 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements" (ASU 2015-15). ASU 2015-15 clarifies the presentation and subsequent measurement of debt issuance costs associated with lines of credit. These costs may be presented as an asset and amortized ratably over the term of the line of credit arrangement, regardless of whether there are outstanding borrowings on the arrangement. The effective date will be the first quarter of fiscal year 2017 and will be applied retrospectively. We are currently evaluating the effect that the updated standard will have 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 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 will be effective is effective for us beginning in the first quarter of 2016. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. We do not expect the adoption of this updated standard to have a material impact on our consolidated financial statements and related disclosures.

3. Acquisitions

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 the first half of 2017. Receptos is also developing RPC4046, for the treatment of an allergic/immune-mediated disorder, Eosinophilic Esophagitis (EoE), which has been designated as an orphan disease. RPC4046 was licensed from AbbVie Bahamas Ltd. and AbbVie Inc. (collectively referred to as AbbVie) and is currently in phase II testing for EoE. The results of operations 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 will pay $0.197 billion for the portion of equity compensation attributable to the post-combination service period, which will be recorded as expense over the required service period ending in the fourth quarter of 2015.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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 in-process research and development (IPR&D) to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. A preliminary purchase price allocation has been performed and the recorded amounts for intangible assets, 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 was $7,626.2 million, consisting of cash and is summarized as follows:

	Total Consideration
Cash paid for outstanding common stock	$7,311.3
Cash for equity compensation attributable to pre-combination service[1]	314.9
Total consideration	$7,626.2

[1] $28.6 million for equity compensation attributable to pre-combination service remained payable at September 30, 2015 and will be paid prior to December 31, 2015.

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

	Amounts Recognized as of the Acquisition Date (Provisional)
Working capital [1]	$479.2
Current deferred tax assets	238.2
Property, plant and equipment	5.0
In-process research and development product rights	6,842.0
Other non-current assets	7.9
Non-current deferred tax liabilities	(2,497.0)
Total identifiable net assets	5,075.3
Goodwill	2,550.9
Total net assets acquired	$7,626.2

[1] Includes cash and cash equivalents, available for sale marketable securities, other current assets, accounts payable and other current liabilities.

The fair values of 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.

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

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 and the assembled workforce. 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 following the availability of results from the current phase II study. If AbbVie does not exercise its option, we will have an exclusive worldwide license for the development and commercialization of RPC4046 that will be unlimited as to indications. We do not consider this potential collaboration arrangement to be significant.

From the Acquisition Date through September 30, 2015, our Consolidated Statements of Operations included expenses of $235.3 million associated with the acquisition and operations of Receptos as follows[1]:

Statements of Operations Location	Acquisition Date Through September 30, 2015
Research and development	$21.9
Selling, general and administrative	1.1
Acquisition related (gains) charges and restructuring, net [2]	211.7
Other income (expense), net	0.6
Total	$235.3

[1] In addition, Celgene incurred $19.9 million of acquisition related costs prior to the acquisition date.
[2] Consists of acquisition-related compensation expense and transaction costs.

Pro Forma Financial Information:
The following table provides unaudited pro forma financial information for the three- and nine-month periods ended September 30, 2015 and 2014 as if the acquisition of Receptos had occurred on January 1, 2014.

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2015	2014	2015	2014
Total revenue	$2,334.1	$1,985.7	$6,692.7	$5,590.8
Net income	$107.3	$445.4	$1,029.8	$952.2
Net income per common share: basic	$0.14	$0.56	$1.30	$1.19
Net income per common share: diluted	$0.13	$0.53	$1.24	$1.14

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 pro-forma financial information assumes that the acquisition-related transaction fees and costs incurred were removed from the three-month period ended September 30, 2015 and were assumed to have been incurred during the first quarter of 2014. 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.

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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 $100.0 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 will be 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 will be included in our consolidated financial statements from the date of acquisition.

Due to the limitations on access to Quanticel information prior to the acquisition date and the limited time since the acquisition date, the initial accounting for the business combination is incomplete at this time. As a result, we are unable to provide contingent consideration disclosures and the amounts recognized as of the acquisition date for the major classes of assets acquired and liabilities assumed, including the information required for net working capital, pre-acquisition contingencies, intangible assets and goodwill. This information will be included in our 2015 Annual Report on Form 10-K.

Nogra Pharma Limited (Nogra): On April 23, 2014, we entered into a license agreement with Nogra, pursuant to which Nogra granted us an exclusive, royalty-bearing license in its intellectual property relating to GED-0301, an antisense oligonucleotide targeting Smad7, to develop and commercialize products containing GED-0301 for the treatment of Crohn's disease and other indications. Based on our evaluation of the license agreement, our level of control and decision making authority over the development and application of the intellectual property, the associated transfer of manufacturing agreements and knowhow, and access to employees of Nogra, we concluded that the acquired assets met the definition of a business and we have accounted for the GED-0301 license as IPR&D acquired in a business combination. The assets acquired and liabilities assumed of Nogra were recorded on our balance sheet as of May 14, 2014 (Effective Date), at their respective fair values. Nogra's results of operations are included in our consolidated financial statements from the Effective Date.

We made an upfront payment of $710.0 million and may make additional contingent developmental, regulatory and sales milestone payments as well as payments based on percentages of annual sales of licensed products. The maximum aggregate amount payable for development and regulatory milestones is approximately $815.0 million, which covers such milestones relating to Crohn's disease and other indications. Starting from global annual net sales of $500.0 million, aggregate tiered sales milestone payments could total a maximum of $1.050 billion if global annual net sales reach $4.000 billion.

Subsequent to the Effective Date, we have measured the contingent consideration at fair value each period with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the IPR&D assets and the passage of time. At September 30, 2015, the balance of the contingent consideration was $1.213 billion, of which $25.0 million is included in other current liabilities and $1.188 billion included in other non-current liabilities.

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4. Earnings Per Share

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
(Amounts in millions, except per share)	2015	2014	2015	2014
Net income (loss)	$(34.1)	$508.5	$1,041.0	$1,386.0
Weighted-average shares:				
Basic	791.1	799.6	794.3	803.5
Effect of dilutive securities:				
Options, restricted stock units and other incentives	—	33.2	33.4	32.9
Diluted	791.1	832.8	827.7	836.4
Net income (loss) per share:				
Basic	$(0.04)	$0.64	$1.31	$1.72
Diluted	$(0.04)	$0.61	$1.26	$1.66

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 32.5 million and 13.7 million for the three-month periods ended September 30, 2015 and 2014, respectively. The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 11.6 million and 17.9 million shares for the nine-month periods ended September 30, 2015 and 2014, respectively. All of the potentially dilutive securities for the three-month period ended September 30, 2015 were determined to be anti-dilutive due to the net loss reported.

Share Repurchase Program: In June 2015, our Board of Directors approved an increase of $4.000 billion to our authorized share repurchase program, bringing the total amount authorized since April 2009 to an aggregate of up to $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 and nine-month periods ended September 30, 2015 and 2014, we recorded losses and gains from put option activity on our Consolidated Statements of Operations in other income (expense), net as follows:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2015	2014	2015	2014
Gain (loss) from sale of put options	$(18.8)	$3.6	$(9.9)	$9.9

At September 30, 2015, we had no outstanding put options.

We have purchased 7.1 million and 24.5 million shares of common stock under the share repurchase program from all sources at a total cost of $815.4 million and $2.849 billion during the three- and nine-month periods ended September 30, 2015, respectively. As of September 30, 2015, we had a remaining share repurchase authorization of $4.297 billion.

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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, 2014	$(15.5)	$460.9	$519.6	$(50.2)	$914.8
Other comprehensive income (loss) before reclassifications	(7.6)	(297.8)	285.3	(11.9)	(32.0)
Amounts reclassified from accumulated other comprehensive income	—	7.5	(251.1)	—	(243.6)
Net current-period other comprehensive income (loss)	(7.6)	(290.3)	34.2	(11.9)	(275.6)
Balance September 30, 2015	$(23.1)	$170.6	$553.8	$(62.1)	$639.2
Balance December 31, 2013	$(6.9)	$137.3	$(36.0)	$(0.4)	$94.0
Other comprehensive income (loss) before reclassifications	—	129.6	355.1	(32.5)	452.2
Amounts reclassified from accumulated other comprehensive income	—	2.7	3.6	—	6.3
Net current-period other comprehensive income (loss)	—	132.3	358.7	(32.5)	458.5
Balance September 30, 2014	$(6.9)	$269.6	$322.7	$(32.9)	$552.5

		Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income			
Accumulated Other Comprehensive Income Components	Affected Line Item in the Consolidated Statements of Operations	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2015	2014	2015	2014
Gains (losses) from cash-flow hedges:					
Foreign exchange contracts	Net product sales	$92.9	$1.3	$253.6	$(1.7)
Treasury rate lock agreements	Interest (expense)	(1.1)	(0.9)	(2.9)	(2.6)
Interest rate swap agreements	Interest (expense)	(0.4)	(0.3)	(1.1)	(0.5)
	Income tax benefit	0.5	0.5	1.5	1.2
Gains (losses) from available-for-sale marketable securities:					
		(10.9)	(1.2)	(11.6)	(4.2)

Realized income (loss) on sales of marketable securities	Interest and investment income, net				
	Income tax benefit	3.9	0.4	4.1	1.5
Total reclassification, net of tax		$84.9	$(0.2)	$243.6	$(6.3)

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6. Financial Instruments and Fair Value Measurement

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of September 30, 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 2014 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 resulting from the acquisitions of Gloucester Pharmaceuticals, Inc. (Gloucester) and Nogra in addition to contingent consideration related to the undeveloped product rights and technology platform acquired as part of the acquisition of Avila Therapeutics, Inc. (now known as Celgene Avilomics Research, Inc.) (Avila). The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester and Avila are estimated to be $120.0 million and $555.0 million, respectively, and $1.865 billion plus amounts based on sales pursuant to the license agreement with Nogra.

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	Balance at September 30, 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	$1,489.1	$1,111.3	$377.8	$—
Forward currency contracts	599.9	—	599.9	—
Purchased currency options	36.3	—	36.3	—
Interest rate swaps	89.8	—	89.8	—
Total assets	$2,215.1	$1,111.3	$1,103.8	$—
Liabilities:				
Contingent value rights	$(69.7)	$(69.7)	$—	$—
Written currency options	(18.7)	—	(18.7)	—
Other acquisition related contingent consideration	(1,328.5)	—	—	(1,328.5)
Total liabilities	$(1,416.9)	$(69.7)	$(18.7)	$(1,328.5)

	Balance at December 31, 2014	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	$3,425.1	$1,051.3	$2,373.8	$—
Forward currency contracts	550.7	—	550.7	—
Purchased currency options	9.8	—	9.8	—
Interest rate swaps	20.0	—	20.0	—
Total assets	$4,005.6	$1,051.3	$2,954.3	$—
Liabilities:				
Contingent value rights	$(136.3)	$(136.3)	$—	$—
Written currency options	(4.6)	—	(4.6)	—
Other acquisition related contingent consideration	(1,279.0)	—	—	(1,279.0)
Total liabilities	$(1,419.9)	$(136.3)	$(4.6)	$(1,279.0)

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There were no security transfers between Levels 1 and 2 during the nine-month periods ended September 30, 2015 and 2014. The following table represents a roll-forward of the fair value of Level 3 instruments:

	Nine-Month Periods Ended September 30,	
	2015	2014
Liabilities:		
Balance at beginning of period	$(1,279.0)	$(228.5)
Amounts acquired or issued	—	(1,060.0)
Net change in fair value	(49.5)	17.6
Settlements	—	20.0
Transfers in and/or out of Level 3	—	—
Balance at end of period	$(1,328.5)	$(1,250.9)

Level 3 liabilities outstanding as of September 30, 2015 primarily consisted of contingent consideration related to the acquisitions of Avila and Nogra. The $49.5 million net increase in the fair value of Level 3 liabilities in 2015 was related to accretion of the fair value of our contingent consideration due to the passage of time, which was partly offset by reductions in the probability and delays in the assumed timing of certain contingent consideration milestones related to the acquisition of Avila. Changes to the fair value of contingent consideration are recorded on the Consolidated Statements of Operations as acquisition related charges and restructuring, net.

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. 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 September 30, 2015 and December 31, 2014 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 Operations in other income (expense), net. The forward point components of these

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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 September 30, 2015 and December 31, 2014:

Foreign Currency	Notional Amount	
	September 30, 2015	December 31, 2014
Australian Dollar	$38.6	$18.8
British Pound	332.6	304.8
Canadian Dollar	84.4	43.7
Euro	3,290.3	3,375.7
Japanese Yen	555.2	541.1
Total	$4,301.1	$4,284.1

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2015, 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 Operations in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2015 and December 31, 2014 were $831.8 million and $835.5 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. 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 September 30, 2015 and December 31, 2014:

	Notional Amount[1]	
	September 30, 2015	December 31, 2014
Foreign currency option contracts designated as hedging activity:		
Purchased Put	$524.1	$152.6
Written Call	$562.4	$160.9

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

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: In anticipation of issuing debt in 2015, we entered into forward starting swaps and treasury rate locks, that were designated as cash flow hedges, with aggregate notional value of $1.300 billion

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and $1.600 billion, respectively. All forward starting swaps and treasury rate locks 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 October 2015, we entered into forward starting swaps with effective dates in September 2017 and maturing in ten years.

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.

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes and also terminated the hedging relationship by settling certain of those swap contracts during 2014 and 2015. The settlement of swap contracts resulted in the receipt of net proceeds of $7.7 million and $15.3 million during the nine-month periods ended September 30, 2015 and 2014, respectively, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 for additional details related to reductions of current and future interest expense.

The following table summarizes the notional amounts of our outstanding swap contracts at September 30, 2015 and December 31, 2014:

	Notional Amount	
	September 30, 2015	December 31, 2014
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
2.450% senior notes due 2015	$300.0	$300.0
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	750.0
4.000% senior notes due 2023	700.0	150.0
3.625% senior notes due 2024	100.0	—
Total	$3,600.0	$2,700.0

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The following tables summarize the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of September 30, 2015 and December 31, 2014:

Instrument	Balance Sheet Location	September 30, 2015 Fair Value Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	$329.5	$28.1
	Other current liabilities	0.5	1.8
	Other non-current assets	321.3	33.3
Interest rate swap agreements	Other current assets	23.6	—
	Other non-current assets	65.1	—
Derivatives not designated as hedging instruments:			
Foreign exchange contracts[1]	Other current assets	39.4	9.1
	Other current liabilities	—	0.9
Interest rate swap agreements	Other current assets	0.7	0.7
	Other non-current assets	1.4	0.3
Total		$781.5	$74.2

Instrument	Balance Sheet Location	December 31, 2014 Fair Value Asset Derivatives	Liability Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts(1)	Other current assets	$264.9	$44.9
	Other current liabilities	0.1	1.7
	Other non-current assets	322.3	17.5
Interest rate swap agreements	Other current assets	17.9	—
	Other non-current assets	4.8	0.3
	Other non-current liabilities	—	3.8
Derivatives not designated as hedging instruments:			
Foreign exchange contracts(1)	Other current assets	39.7	6.0
	Other current liabilities	0.1	1.1
Interest rate swap agreements	Other current assets	0.1	—
	Other non-current assets	1.3	—
Total		$651.2	$75.3

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

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The following tables summarize the effect of derivative instruments designated as cash-flow hedging instruments on the Consolidated Statements of Operations for the three-month periods ended September 30, 2015 and 2014:

	Three-Month Period Ended September 30, 2015					
	(Effective Portion)			(Ineffective Portion and Amount Excluded From Effectiveness Testing)		
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative[1]	Location of Gain/(Loss) Reclassified 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	$10.8	Net product sales	$92.9	Other income, net	$14.8	(2)
Treasury rate lock agreements	$(27.9)	Interest expense	$(1.1)	Other income, net	$(0.2)	(3)
Interest rate swap agreements	$(50.0)	Interest expense	$(0.4)	Other income, net	$0.3	(3)

(1) Net gains of $320.3 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.
(2) The amount of net gains recognized in income represents $14.7 million of gains related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and $0.1 million in gains related to the ineffective portion of the hedging relationships.
(3) The amount of net gain recognized in income relates to the ineffective portion of the hedging relationships.

	Three-Month Period Ended September 30, 2014					
	(Effective Portion)			(Ineffective Portion and Amount Excluded From Effectiveness Testing)		
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified 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	$382.8	Net product sales	$1.3	Other income, net	$(16.4)	(1)
Treasury rate lock agreements	$—	Interest expense	$(0.9)	Other income, net	$—	
Interest rate swap agreements	$—	Interest expense	$(0.3)	Other income, net	$—	

(1) The amount of net losses recognized in income represents $18.6 million of losses related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and $2.2 million in gains

related to the ineffective portion of the hedging relationships.

The following tables summarize the effect of derivative instruments designated as cash-flow hedging instruments on the Consolidated Statements of Operations for the nine-month periods ended September 30, 2015 and 2014:

	Nine-Month Period Ended September 30, 2015					
	(Effective Portion)			(Ineffective Portion and Amount Excluded From Effectiveness Testing)		
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative[1]	Location of Gain/(Loss) Reclassified 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	$298.7	Net product sales	$253.6	Other income, net	$32.2	(2)
Treasury rate lock agreements	$(27.9)	Interest expense	$(2.9)	Other income, net	(0.2)	(3)
Interest rate swap agreements	$6.2	Interest expense	$(1.1)	Other income, net	0.3	(3)

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(1) Net gains of $320.3 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.
(2) The amount of net gains recognized in income represents $35.5 million of gains related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and $3.3 million in losses related to the ineffective portion of the hedging relationships.
(3) The amount of net gain recognized in income relates to the ineffective portion of the hedging relationships.

	Nine-Month Period Ended September 30, 2014					
	(Effective Portion)			(Ineffective Portion and Amount Excluded From Effectiveness Testing)		
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified 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	$374.9	Net product sales	$(1.7)	Other income, net	$(19.2)	(1)
Treasury rate lock agreements	$—	Interest expense	$(2.6)	Other income, net	$—	
Interest rate swap agreements	$(32.4)	Interest expense	$(0.5)	Other income, net	$(3.6)	(2)

(1) The amount of net losses recognized in income represents $22.1 million of losses related to amounts excluded from the assessment of hedge effectiveness (fair value adjustments of forward point amounts) and $2.9 million in gains related to the ineffective portion of the hedging relationships.
(2) The amount of net loss recognized in income relates 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 Operations for the three- and nine-month periods ended September 30, 2015 and 2014:

		Amount of Gain (Loss) Recognized in Income on Derivative			
	Location of Gain (Loss) Recognized in Income on	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Instrument	Derivative	2015	2014	2015	2014
Interest rate swap agreements	Interest expense	$16.2	$10.3	$45.5	$31.2

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2015 and 2014:

		Amount of Gain (Loss) Recognized in Income on Derivative			
	Location of Gain (Loss) Recognized in Income on	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Instrument	Derivative	2015	2014	2015	2014

Foreign exchange contracts	Other income (expense), net	$14.4	$55.4	$69.3	$44.3
Put options on our common stock	Other income (expense), net	$(18.8)	$3.6	$(9.9)	$9.9

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 Operations 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.

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

Money market funds of $2.101 billion and $2.251 billion at September 30, 2015 and December 31, 2014, 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 September 30, 2015 and December 31, 2014 were as follows:

September 30, 2015	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	$92.8	$—	$—	$92.8
U.S. government-sponsored agency MBS	34.0	—	(0.2)	33.8
Corporate debt - global	213.4	0.2	(1.0)	212.6
Asset backed securities	38.6	—	—	38.6
Marketable equity securities	820.3	365.8	(74.8)	1,111.3
Total available-for-sale marketable securities	$1,199.1	$366.0	$(76.0)	$1,489.1

December 31, 2014	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	$1,044.7	$0.3	$(0.8)	$1,044.2
U.S. government-sponsored agency securities	145.1	0.1	(0.1)	145.1
U.S. government-sponsored agency MBS	531.1	1.0	(2.7)	529.4
Non-U.S. government, agency and Supranational securities	32.4	—	(0.1)	32.3
Corporate debt - global	446.3	0.6	(1.2)	445.7
Asset backed securities	177.3	—	(0.2)	177.1
Marketable equity securities	335.2	716.3	(0.2)	1,051.3
Total available-for-sale marketable securities	$2,712.1	$718.3	$(5.3)	$3,425.1

U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. Government Sponsored Enterprises. U.S. government-sponsored agency MBS include mortgage-backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and supranational securities consist of direct obligations of highly rated governments of nations other than the United States and obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. 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 nine-month period ended September 30, 2015 primarily reflects the decrease in market value for certain equity investments subsequent to December 31, 2014.

Duration periods of available-for-sale debt securities at September 30, 2015 were as follows:

	Amortized	Fair

	Cost	Value
Duration of one year or less	$68.1	$67.9
Duration of one through three years	292.6	291.9
Duration of three through five years	18.1	18.0
Total	$378.8	$377.8

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9. Inventory

Inventories as of September 30, 2015 and December 31, 2014 are summarized by major category as follows:

	September 30, 2015	December 31, 2014
Raw materials	$109.8	$200.0
Work in process	131.4	101.5
Finished goods	179.7	91.6
Total	$420.9	$393.1

The decrease in raw materials and increase in finished goods during the nine-month period ended September 30, 2015 was primarily related to the production of ABRAXANE® to support recently launched new indications. Raw materials for ABRAXANE® had been at elevated levels at December 31, 2014 and during the nine-month period ended September 30, 2015 many of those materials were converted into finished goods.

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) and Avila 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 10.5 years.

Intangible assets outstanding as of September 30, 2015 and December 31, 2014 are summarized as follows:

September 30, 2015	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	$3,405.9	$(1,387.1)	$2,018.8
Technology	333.7	(170.8)	162.9
Licenses	66.7	(21.2)	45.5
Other	44.0	(26.1)	17.9
	3,850.3	(1,605.2)	2,245.1
Non-amortized intangible assets:			
Acquired IPR&D product rights	8,470.7	—	8,470.7
Total intangible assets	$12,321.0	$(1,605.2)	$10,715.8

December 31, 2014	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	$3,405.9	$(1,234.1)	$2,171.8
Technology	333.7	(135.1)	198.6
Licenses	67.0	(18.1)	48.9
Other	42.5	(22.9)	19.6
	3,849.1	(1,410.2)	2,438.9
Non-amortized intangible assets:			
Acquired IPR&D product rights	1,628.7	—	1,628.7
Total intangible assets	$5,477.8	$(1,410.2)	$4,067.6

The $6.843 billion increase in the gross carrying value of intangible assets during the nine-month period ended September 30, 2015 was primarily due to the addition of $6.842 billion of IPR&D from the Receptos acquisition.

Amortization expense related to intangible assets was $65.0 million and $65.0 million for the three-month periods ended September 30, 2015 and 2014, respectively, and $195.0 million and $198.8 million for the nine-month periods ended September 30,

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2015 and 2014, respectively. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for years 2015 through 2019 is estimated to be in the range of approximately $163.7 million to $306.5 million annually.

Goodwill: At September 30, 2015, our goodwill related to the 2015 acquisition of Receptos, 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 increased by $2.551 billion to $4.742 billion as of September 30, 2015 compared to December 31, 2014 due to the Receptos acquisition.

11. Debt

Short-Term Borrowings and Current Portion of Long-Term Debt: The carrying value of short-term borrowings and current portion of long-term debt outstanding at September 30, 2015 and December 31, 2014 includes:

	September 30, 2015	December 31, 2014
Commercial paper	$699.4	$99.6
2.450% senior notes due 2015	500.3	506.3
Total	$1,199.7	$605.9

Long-Term Debt: Summarized below are the carrying values of our senior notes at September 30, 2015 and December 31, 2014:

	September 30, 2015	December 31, 2014
1.900% senior notes due 2017	$503.0	$501.0
2.125% senior notes due 2018	999.9	—
2.300% senior notes due 2018	403.8	401.2
2.250% senior notes due 2019	511.3	502.5
2.875% senior notes due 2020	1,497.4	—
3.950% senior notes due 2020	514.6	502.8
3.250% senior notes due 2022	1,032.3	1,010.2
3.550% senior notes due 2022	997.3	—
4.000% senior notes due 2023	722.2	708.5
3.625% senior notes due 2024	1,003.4	996.8
3.875% senior notes due 2025	2,476.1	—
5.700% senior notes due 2040	249.6	249.5
5.250% senior notes due 2043	396.7	396.7
4.625% senior notes due 2044	996.5	996.5
5.000% senior notes due 2045	1,993.8	—
Total long-term debt	$14,297.9	$6,265.7

At September 30, 2015, the fair value of our outstanding Senior Notes was $14.847 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

In August 2015, we issued an additional $8.000 billion principal amount of senior notes consisting of $1.000 billion aggregate principal amount of 2.125% Senior Notes due 2018 (the 2018 notes), $1.500 billion aggregate principal amount of 2.875% Senior Notes due 2020 (the 2020 notes), $1.000 billion aggregate principal amount of 3.550% Senior Notes due 2022 (the 2022 notes), $2.500 billion aggregate principal amount of 3.875% Senior Notes due 2025 (the 2025 notes) and $2.000 billion aggregate principal amount of 5.000% Senior Notes due 2045 (the 2045 notes and together with the 2018 notes, the 2020 notes, the 2022 notes, and the 2025 notes, referred to herein as the "2015 issued notes"). The 2015 issued notes were issued at 99.994%, 99.819%, 99.729%, 99.034%, and 99.691% of par, respectively, and the discount is being amortized as additional interest expense over the period from

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issuance through maturity. Offering costs of approximately $50.0 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the 2015 issued notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2016 and the principal on each 2015 issued note is due in full at their respective maturity dates. The 2015 issued notes may be redeemed at our option, in whole or in part; the 2018 notes, the 2020 notes, and the 2022 notes may be redeemed at any time, the 2025 notes and 2045 notes may be redeemed at three months and six months prior to the maturity dates, respectively. Early redemption would be at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the 2015 issued notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2018 notes, 20 basis points in the case of the 2020 notes, 25 basis points in the case of the 2022 notes, 30 basis points in the case of the 2025 notes, and 35 basis points in the case of the 2045 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the 2015 issued notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.
From time to time, we have used treasury rate locks and forward starting interest rate swap contracts to hedge against changes in interest rates in anticipation of issuing fixed-rate notes. As of September 30, 2015, a balance of $69.7 million in losses remained in accumulated OCI related to these derivative instruments and will be recognized as interest expense over the life of the notes.

At September 30, 2015, 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 September 30, 2015 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 September 30, 2015, we had a balance of $34.8 million of unamortized gains recorded as a component of our debt as a result of past swap contract settlements, including $6.0 million related to the settlement of swap contracts during the nine months ended September 30, 2015. As of December 31, 2014, we had a balance of $38.6 million of unamortized gains recorded as a component of our debt as a result of past swap contract settlements.

Commercial Paper: The carrying value of Commercial Paper as of September 30, 2015 and December 31, 2014 was $699.4 million and $99.6 million, respectively, and approximated its fair value. The effective interest rate on our outstanding Commercial Paper at September 30, 2015 was 0.5%. In October 2015, our Board of Directors authorized an increase in the size of our Commercial Paper program from $1.750 billion to $2.750 billion.

Credit Facility and Revolving Credit: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of $1.750 billion, which was increased from $1.500 billion in April 2015. Also in April 2015, the term of the Credit Facility was extended from April 18, 2018 to April 17, 2020. Subject to certain conditions, we have the right to increase the amount of the Credit Facility (but in no event more than one time per annum) up to a maximum aggregate amount of $2.000 billion. Amounts may be borrowed in U.S. dollars for general corporate purposes. In October 2015, we entered into a revolving credit agreement (Revolving Credit Agreement) with JPMorgan Chase Bank, N.A., under which we may borrow up to a maximum aggregate principal amount of $1.000 billion. The maturity date of any borrowings under the Revolving Credit Agreement and the expiration date of the agreement is December 31, 2015. The Credit Facility and Revolving Credit Agreement currently serve as backup liquidity for our Commercial Paper borrowings. At September 30, 2015, there was no outstanding

borrowing against the Credit Facility or the Revolving Credit Agreement.

The Credit Facility and the Revolving Credit Agreement contain affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2015.

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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 and officers. 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-year 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 revenue (37.5% weighting), 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 revenue and 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 weighted average grant date fair value per share of the PSUs granted to certain executive officers during the nine-month period ended September 30, 2015 was $122.90.

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2015 and 2014:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2015	2014	2015	2014
Cost of goods sold (excluding amortization of acquired intangible assets)	$8.5	$6.8	$23.3	$18.8
Research and development	65.2	48.4	185.0	141.2
Selling, general and administrative	76.2	56.2	218.1	159.2
Total share-based compensation expense	149.9	111.4	426.4	319.2
Tax benefit related to share-based compensation expense	42.8	31.4	124.0	92.4
Reduction in income	$107.1	$80.0	$302.4	$226.8

The following table summarizes the activity for stock options, RSUs and PSUs for the nine-month period ended September 30, 2015 (in millions unless otherwise noted):

	Stock Options	Restricted Stock Units	Performance-Based Restricted Stock Units (in thousands)
Outstanding at December 31, 2014	77.2	9.4	133
Changes during the Year:			
Granted	8.7	1.8	211
Exercised / Released	(9.0)	(3.0)	—
Forfeited	(1.3)	(0.3)	(7)
Outstanding at September 30, 2015	75.6	7.9	337

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 September 30, 2015 were as follows (dollars in millions):

	Stock Options	Restricted Stock Units	Performance-Based Restricted Stock Units
Unrecognized compensation cost	$613.4	$304.3	$20.4
Expected weighted-average period in years of compensation cost to be recognized	2.0	1.3	1.7

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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, which may conclude within the next twelve months. We are also subject to audits by various state and foreign taxing authorities, including, but not limited to, most U.S. states and major European and Asian 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 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 nine-month period ended September 30, 2015 gross unrecognized tax benefits increased by $49.8 million, primarily from unrecognized tax benefits related to current year operations of $42.2 million and accrued interest of $7.6 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. Certain examinations may conclude within the next twelve months. 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.

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 product 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 purchase licenses of additional rights, as well as potential development, regulatory and commercial performance milestone payments, cost sharing arrangements, royalty payments, profit sharing and equity investments. Certain of these arrangements obligate us to make additional 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 2014 Annual Report on Form 10-K for a description of certain other collaboration agreements entered into prior to January 1, 2015. The following is a brief description of significant developments in the relationships between Celgene and our collaboration partners during the nine months ended September 30, 2015:

Agios Pharmaceuticals, Inc. (Agios): During 2010, we entered into a discovery and development collaboration and license agreement with Agios that focuses on cancer metabolism targets and the discovery, development and commercialization of associated therapeutics. We have an exclusive option to license any potential products that result from the Agios cancer metabolism research platform through the end of phase I clinical trials.

With respect to each product that we choose to license, Agios could receive up to approximately $120.0 million upon achievement of certain milestones and other payments plus royalties on worldwide sales, and Agios may also participate in the development and commercialization of certain products in the United States. In December 2014, we elected to extend the collaboration and license agreement for an additional year for a payment of $20.0 million. Our option to license products will terminate on April 14, 2016.

In June 2014, we exercised our option to license AG-221 from Agios on an exclusive worldwide basis, with Agios retaining the right to conduct a portion of commercialization activities for AG-221 in the United States. AG-221 is currently in a phase I study in patients that present an isocitrate dehydrogenase-2 (IDH2) mutation with advanced hematologic malignancies, including acute myeloid leukemia (AML).

In January 2015, we exercised our option, subject to applicable regulatory approvals which were subsequently achieved, to an exclusive license from Agios to AG-120 outside the United States, with Agios retaining the right to conduct development and commercialization within the United States. AG-120 is an orally available, selective inhibitor of the mutated isocitrate dehydrogenase-1 (IDH1) protein for the treatment of patients with cancers that harbor an IDH1 mutation. AG-120 is currently being evaluated in two phase I dose escalation trials, one in advanced hematological malignancies and the other in advanced solid tumors.

In April 2015, we and Agios entered into a new joint worldwide development and profit share collaboration for AG-881. AG-881 is a small molecule that has shown in preclinical studies to fully penetrate the blood brain barrier and inhibit IDH1 and IDH2 mutant cancer cells. Under the terms of the AG-881 collaboration, Agios received an initial payment of $10.0 million and is eligible to receive contingent payments of up to $70.0 million based on the attainment of specified regulatory goals. The upfront payment to Agios was accounted for as $9.0 million of upfront research and development collaboration expense and $1.0 million of prepaid manufacturing rights recorded on the balance sheet. We and Agios will jointly collaborate on the worldwide development program for AG-881, sharing development costs equally. The two companies will share profits equally, with Celgene recording commercial sales worldwide. Agios will lead commercialization in the U.S. with both companies sharing equally in field-based commercial activities, and we will lead commercialization ex-U.S. with Agios providing one third of field-based commercial activities in the major EU markets.

Epizyme Inc. (Epizyme): In July 2015 we entered into an amendment and restatement of the collaboration and license agreement dated April 2, 2012 with Epizyme (the “Amended Agreement”). Under the original agreement, we had an exclusive license, for all countries other than the United States, to small molecule HMT inhibitors targeting DOT1L, including pinometostat (EPZ-5676), and an option, on a target-by-target basis, to exclusively license, for all countries other than the United States, rights to small molecule HMT inhibitors targeting any other HMT targets. Under the

Amended Agreement:

- We retain our exclusive license to small molecule HMT inhibitors targeting DOT1L outside of the United States, including pinometostat (EPZ-5676),
- We have narrowed our option rights to HMT inhibitors targeting three predefined targets (the “Option Targets”),
- The exclusive licenses to HMT inhibitors targeting two of the Option Targets that we may acquire have been expanded to include the United States, with the exclusive license to the third Option Target continuing to be for all countries other than the United States,
- Our option period has been extended for each of the Option Targets and is exercisable at the time of Epizyme's IND filing for an HMT inhibitor targeting the applicable Option Target,
- Epizyme may complete phase I clinical trials as to each Option Target following our exercise of our option at IND filing. If Epizyme chooses not to complete phase I clinical trials to an Optioned Target, future milestones and royalties on products developed for such Option Targets will be reduced.

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Under the terms of the Amended Agreement, we made a $10.0 million payment to Epizyme. In addition, Epizyme may earn up to $75.0 million in development milestone payments, up to $365.0 million in regulatory milestone payments and up to $170.0 million in sales milestone payments related to the Option Targets. For the DOT1L program, Epizyme remains eligible to earn $35.0 million in clinical development milestone payments and up to $100.0 million in regulatory milestone payments. Epizyme is also entitled to tiered royalties ranging from the mid-single digits to the mid-teens on annual net product sales in our territory, subject to reductions in specified circumstances.

The Amended Agreement extends the research and development collaboration for at least an additional three years until July 8, 2018, subject to our exercise of our options at IND filing. The Amended Agreement will expire on a product-by-product and country-by-country basis on the date of the expiration of the applicable royalty term with respect to each licensed product in each country and in its entirety upon the expiration of all applicable royalty terms for all licensed products in all countries. We have the right to terminate the Amended Agreement in its entirety or with respect to one or more Optioned Targets upon 120 days' notice. Upon the expiration of the royalty term of a particular license product, we will have a fully paid-up, royalty-free license to use Epizyme intellectual property to manufacture, market, use and sell such licensed products in our territory.

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.

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.

FORMA Therapeutics Holdings, LLC (FORMA): In April 2013, we entered into a collaboration agreement with FORMA to discover, develop and commercialize drug candidates to regulate protein homeostasis targets. Protein homeostasis, which is important in oncology, neurodegenerative and other disorders, involves a tightly regulated network of pathways controlling the biogenesis, folding, transport and degradation of proteins.

The collaboration was launched with an upfront payment that enables us to evaluate selected targets and lead assets in protein homeostasis pathways during the pre-clinical phase. Based on such evaluation, we have the right to obtain exclusive licenses with respect to the development and commercialization of multiple drug candidates outside of the United States, in exchange for research and early development payments of up to approximately $200.0 million to FORMA. Under the terms of the collaboration agreement, FORMA is incentivized to advance the full complement of drug candidates through phase I, while Celgene is responsible for all further global clinical development for each licensed candidate. FORMA is eligible to receive up to an additional $315.0 million in potential payments based upon development, regulatory and sales objectives for the first ex-U.S. license. FORMA is also eligible to receive potential payments for successive licenses, which escalate for productivity, increasing up to a maximum of an additional $430.0 million per program. In addition, FORMA will receive royalties on ex-U.S. sales and additional payments if multiple drug candidates reach defined cumulative sales objectives. The collaboration agreement includes provisions for Celgene to obtain rights with respect to development and commercialization of drug candidates inside the United States in exchange for additional payments.

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Under the collaboration, the parties perform initial research and development for a term of four years. If, during such research term, a drug candidate meets certain criteria, then the parties enter into a pre-negotiated license agreement and the collaboration continues until all license agreements have expired and all applicable royalty terms under the collaboration with respect to the particular products have expired. Each license agreement, if not terminated sooner, expires upon the expiration of all applicable royalty terms under such agreement. Upon the expiration of each license agreement, we will have an exclusive, fully-paid, royalty-free license to use the applicable FORMA intellectual property to manufacture, market, use and sell the product developed under such agreement outside of the United States. In October, 2013, we entered into the first ex-US license with FORMA and paid the applicable upfront payment under such license. In February, 2015, we entered into the second ex-US license with FORMA and made a $19.0 million upfront payment for the license.

On March 21, 2014, we entered into a second collaboration arrangement with FORMA, pursuant to which FORMA granted us an option, for an additional fee, to license the rights to select current and future FORMA drug candidates during a term of three and one half years. We agreed to pay an upfront payment of $225.0 million. In addition, with respect to each subsequently licensed drug candidate, we have the obligation to pay designated amounts when certain development, regulatory and sales milestone events occur, with such amounts being variable and contingent on various factors. With respect to each licensed drug candidate, we assume responsibility for all global development activities and costs after completion of phase I clinical trials. FORMA retains U.S. rights to all such licensed assets, including responsibility for manufacturing and commercialization.

Under this collaboration arrangement, we also have an option to enter into up to two additional collaborations with successive terms of two years each for additional payments totaling approximately $375.0 million. If we exercise our option to enter into both of these additional collaborations, we will receive an exclusive option to acquire FORMA, including the U.S. rights to all licensed drug candidates, and worldwide rights to other wholly owned assets within FORMA at that time. In April, 2015, we entered into the first license with FORMA under the second collaboration and made a $20.0 million upfront payment for the license.

MorphoSys AG (MorphoSys): On March 26, 2015, we and MorphoSys agreed to terminate our collaboration, license and equity purchase agreement for the co-development and co-promotion of the anti-CD38 antibody, MOR202. As part of the termination, we made a final payment of $8.1 million to settle all obligations. The termination of our agreement eliminates all potential future payments for development, regulatory and sales milestones. We have retained our equity interest in MorphoSys.

AstraZeneca PLC (AstraZeneca): In April 2015, we entered into a strategic collaboration agreement with MedImmune Limited (MedImmune), a subsidiary of AstraZeneca, to develop and commercialize MEDI4736, a novel anti-PD-L1 monoclonal antibody, for hematologic malignancies. The agreement provides for a negotiation period to expand the agreement for other immuno-therapeutics. Under the terms of the agreement, we made an upfront payment of $450.0 million to MedImmune. We lead clinical development across all new clinical trials within the collaboration and are responsible for all costs associated with such trials until December 31, 2016, after which we will be responsible for 75 percent of those costs. We also will be responsible for the global commercialization of approved MEDI4736 indications in hematology, and will receive royalty rates starting at 70 percent of worldwide sales from all uses in hematology. Royalty rates will decrease gradually to 50 percent over a period of 4 years after the start of commercial sales. The agreement may be terminated at our discretion upon nine months' prior written notice to MedImmune, and by either party upon material breach of the other party, subject to cure periods. The agreement, if not terminated sooner, expires upon the expiration of all applicable royalty terms under such agreement.

Lycera Corp. (Lycera): In June 2015, we entered into a collaboration and option agreement with Lycera. Under the agreement, the parties will support the development of Lycera's portfolio of immune modulator assets, including (1) oral agonists that target RORy, a master control switch of immune system activation, for the potential treatment of a broad range of cancers, and (2) LYC-30937, an oral gut-directed ATPase modulator currently in phase I clinical studies.

Lycera has developed orally bioavailable RORy agonists that have demonstrated single agent therapeutic activity in multiple animal models of cancer. Ex-vivo treatment with RORy agonist compounds has been shown to enhance the therapeutic benefit of adoptive T-cell therapy by improving both immune cell persistence and activation. Development of LYC-30937 is focused on the treatment of inflammatory bowel disease, with the goal of delivering significant disease improvement without global immune suppression. Under the collaboration, Lycera also will continue to advance its other programs, including a Rho-associated protein kinase 2 (ROCK2) inhibitor.

Under the terms of the agreement, we made an upfront payment of $82.5 million to Lycera. We received an exclusive option for an additional fee to license Lycera's portfolio of ex-vivo RORy agonist compounds, an equity interest and an exclusive right to acquire Lycera. If we exercise the acquisition right, Lycera shareholders will be also eligible to receive future success-based milestone payments of up to $190.0 million. The upfront payment to Lycera was accounted for as $69.5 million of upfront

collaboration payment included in research and development expense and $13.0 million as non-current assets consisting of $10.0 million for an equity investment and $3.0 million for a warrant to acquire the remaining shares outstanding.

The agreement has an initial term of 3 years and may be terminated earlier at our discretion upon 6 months' prior written notice to Lycera and by either party upon material breach of the other party, subject to cure periods.

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 percent allocated to us and 30 percent 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.

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 percent 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.

Nurix, Inc. (Nurix): In September 2015, we entered into a strategic collaboration agreement with Nurix for the discovery, development and commercialization of novel small molecule therapeutics in oncology and inflammation and immunology. Nurix will work exclusively with us in these therapeutic areas to advance new therapies that function through the ubiquitin proteasome system (UPS) to modulate protein homeostasis, a fundamental cellular process controlling protein levels.

Under the terms of the collaboration, we made an upfront payment to Nurix of $149.8 million, plus an equity investment of $17.0 million, which amounted to approximately 13 percent of Nurix outstanding equity, for an option to license future programs. The option term for each of these programs is the earlier of either (a) 45 days after the delivery of a phase I data package, or (b) four years, which period we may extend twice for the payment of additional

fees. During the term, Nurix may focus on investigating E3 ubiquitin ligases and E2 conjugating enzymes to identify the most promising drug discovery programs for use in oncology or inflammation and immunology therapeutic applications. Nurix will control and is responsible for all drug discovery and development activities through the end of phase I clinical trials.

We may opt to license global development and commercialization rights to a program in exchange for an option fee, potential clinical, regulatory and sales milestone payments totaling up to $405.0 million, as well as future tiered single-digit to low double-digit royalties on global sales. We would also have worldwide rights to collaboration products, with the exception of certain collaboration products for which Nurix would retain U.S. development and commercialization rights. These rights include the opportunity for the companies to co-develop and co-commercialize up to two programs in the U.S., sharing profits and losses equally, and we would retain ex-US rights, in exchange for an option fee, milestone payments and royalties on ex-U.S. sales on a program-by-program basis. For candidates not optioned by us under the collaboration, Nurix would retain worldwide rights.

Acetylon Pharmaceuticals, Inc. (Acetylon): In August 2015, we entered into an amendment to the collaboration and option agreement with Acetylon to extend the expiration date of the agreement to May 2, 2016 and remove our right to further extend the expiration date.

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In addition to the collaboration arrangements described above, we entered into a number of collaborative arrangements during the nine-months ended September 30, 2015 that include the potential for future milestone payments of up to an aggregate $120.0 million related to the attainment of specified developmental, regulatory and sales milestones over a period of several years. Our obligation to fund these efforts is contingent upon our continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs.

A financial summary of certain period activity related to our collaboration agreements is presented below[1,2]:

		Three-Month Periods Ended September 30, Research and Development Expense				
		Upfront Fees	Milestones	Extension/Termination of Agreements	Amortization of Prepaid Research and Development	Equity Investments Made During Period
Acetylon	2015	$—	$—	$—	$5.4	$—
	2014	—	—	—	4.3	—
bluebird	2015	—	—	—	2.1	—
	2014	—	—	—	0.1	—
Epizyme	2015	—	—	10.0	—	—
	2014	—	—	—	—	—
Juno	2015	575.1	—	—	—	424.9
Nurix	2015	149.8	—	—	—	17.0
Sutro	2015	—	—	—	1.4	—
	2014	72.6	—	—	0.1	11.9
Other Collaboration Arrangements	2015	26.9	—	—	—	—
	2014	6.0	6.8	—	0.4	27.0

		Nine-Month Periods Ended September 30, Research and Development Expense				
		Upfront Fees	Milestones	Extension/Termination of Agreements	Amortization of Prepaid Research and Development	Equity Investments Made During Period
Acceleron	2015	$—	$—	$—	$—	$—
	2014	—	—	—	—	52.4
Acetylon	2015	—	—	—	14.6	—
	2014	—	—	—	11.4	—
Agios	2015	9.0	—	—	—	—
	2014	—	—	—	—	13.0
AstraZeneca	2015	450.0	—	—	—	—
bluebird	2015	—	—	—	2.8	—
	2014	—	—	—	0.1	—
Epizyme	2015	—	—	10.0	—	—
	2014	—	—	—	—	9.9
FORMA	2015	39.0	—	—	—	—
	2014	225.0	—	—	0.1	—
Juno	2015	575.1	—	—	—	424.9

Lycera	2015	69.5	—	—	—	10.0
MorphoSys	2015	—	—	8.1	—	—
	2014	—	—	—	—	—
NantBioScience[3]	2015	—	—	—	—	—
	2014	50.0	—	—	—	90.0
Nurix	2015	149.8	—	—	—	17.0
Sutro	2015	—	—	—	3.4	—
	2014	72.6	—	—	0.2	11.9
Other Collaboration Arrangements	2015	47.9	8.0	—	0.9	50.0
	2014	54.0	7.3	—	6.9	47.9

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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	September 30, 2015	$—	$114.8	14%
	December 31, 2014	—	179.7	14%
Acetylon	September 30, 2015	5.8	25.0	11%
	December 31, 2014	20.4	25.0	10%
Agios	September 30, 2015	1.0	370.1	13%
	December 31, 2014	—	587.4	14%
bluebird	September 30, 2015	22.3	N/A	N/A
	December 31, 2014	0.1	N/A	N/A
Epizyme	September 30, 2015	—	47.3	8%
	December 31, 2014	—	69.3	11%
FORMA	September 30, 2015	0.1	N/A	N/A
	December 31, 2014	0.1	N/A	N/A
Juno	September 30, 2015	—	371.8	9%
Lycera	September 30, 2015	3.0	10.0	8%
MorphoSys	September 30, 2015	—	53.1	3%
	December 31, 2014	—	73.9	3%
NantBioScience	September 30, 2015	—	90.0	13%
	December 31, 2014	—	90.0	14%
Nurix	September 30, 2015	0.2	17.0	13%
Sutro	September 30, 2015	24.4	17.6	15%
	December 31, 2014	12.8	17.6	15%

Other Collaboration Arrangements	September 30, 2015	22.1	130.1	N/A
	December 31, 2014	34.4	90.8	N/A

[1] Activity and balances are presented specifically for notable new collaborations and for those collaborations which we have described in detail in our 2014 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 described are presented 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] $25.0 million of expense related to the settlement of contingent matching contributions was also recognized at the 2014 inception of the collaboration agreement with NantBioScience and included in Selling, General and Administrative expense.

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 and uncertainty of these arrangements and any future potential payments, no amounts have been recorded in our accompanying Consolidated Balance Sheets at September 30, 2015 and December 31, 2014. 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

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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

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®: We received Notice Letters, dated August 30, 2010 and June 12, 2012 from Natco Pharma Limited of India (Natco) notifying us of Natco's Abbreviated New Drug Application (ANDA), which contain Paragraph IV certifications against certain of Celgene's patents that are listed in the FDA Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") for REVLIMID® (lenalidomide). Natco's Notice Letters were sent in connection with its filing of an ANDA seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg REVLIMID® capsules. We filed separate infringement actions (which were subsequently consolidated) in the United States District Court for the District of New Jersey against Natco, Natco's U.S. partner, Arrow International Limited (Arrow), and Arrow's parent company, Watson Laboratories, Inc. (Watson, a wholly-owned subsidiary of Allergan plc (formerly known as Actavis, Inc.) and formerly known as Watson Pharmaceuticals, Inc.) (Natco, Arrow and Watson are collectively referred to hereinafter as "Natco"). In its answer and counterclaim, Natco asserts that our patents are invalid, unenforceable and/or not infringed by Natco's proposed generic products.

The patents in dispute include United States Patent Nos. 5,635,517; 6,045,501; 6,315,720; 6,555,554; 6,561,976; 6,561,977; 6,755,784; 7,119,106; 7,465,800; 6,281,230; 7,189,740; 7,968,569; 8,288,415; 8,315,886 and 8,404,717, plus three non-Orange Book listed patents, United States Patent Nos. 7,977,357; 8,193,219 and 8,431,598.

A claim construction decision was issued on May 27, 2014, and fact discovery closed on August 4, 2014. On November 18, 2014, the court granted-in-part Natco's motion to amend its invalidity contentions, and denied Celgene's appeal of that decision on July 9, 2015. Expert discovery has been extended and is set to close on January 15, 2016.

No trial date has been set.

We received a third Notice Letter from Natco dated April 3, 2014, notifying us of Natco's Paragraph IV certifications against five patents, including United States Patent Nos. 8,404,717 (already in suit), 8,530,498; 8,589,188; 8,626,531; and 8,648,095. On May 15, 2014, we filed an infringement action in the United States District Court for the District of New Jersey against Natco, Arrow and Watson. Natco filed its answer and counterclaim on June 13, 2014, and asserts that our patents are invalid, unenforceable and/or not infringed by Natco's proposed generic products. Fact discovery is set to close on November 6, 2015. No trial date has been set.

We believe that Natco's defenses and counterclaims in both cases are unlikely to be sustained and we intend to vigorously assert our patent rights. Although there can be no assurance as to the ultimate outcomes of these proceedings, we currently expect that they will not have a material adverse effect on our financial condition or results of operations. However, if Natco is successful in challenging all the patents in dispute or if the court rules that certain of our key patent claims are invalid or not infringed, such events could have a material adverse effect on our financial condition and results of operations.

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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.

ISTODAX® (romidepsin): We received a Notice Letter dated March 17, 2014 from Fresenius Kabi USA, LLC (Fresenius) notifying us of Fresenius's 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 April 30, 2014, Celgene and Astellas Pharma Inc. (Astellas), filed an infringement action in the United States District Court for the District of Delaware against Fresenius. In its answer and counterclaim, Fresenius 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 Fresenius's ANDA until the earlier of (i) a final decision that each of the patents is invalid and/or not infringed; or (ii) May 5, 2017.

Celgene and Astellas have reached an agreement to settle all claims and counterclaims with Fresenius. Under the terms of the settlement agreement, which was approved by the court, the parties have stipulated to dismiss the case and Celgene will provide Fresenius a non-exclusive, royalty-free sublicense to manufacture and market the Fresenius generic product as of February 1, 2018. The settlement agreement has been submitted to the Federal Trade Commission for review.

On August 4, 2014, we received a Notice Letter from InnoPharma, Inc. (InnoPharma) notifying us of Innopharma's ANDA that seeks approval from the FDA to market a generic version of romidepsin for injection. The Notice Letter contains Paragraph IV certifications against the '280 and '724 patents.

On September 12, 2014, we and Astellas, filed an infringement action in the United States District Court for the District of Delaware against InnoPharma. In its answer and counterclaim, InnoPharma 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 InnoPharma's ANDA until the earlier of (i) a final decision that each of the patents is invalid and/or not infringed; or (ii) May 5, 2017.

Fact discovery is set to close on November 6, 2015 and the claim construction hearing is scheduled for November 17, 2015. Expert discovery is set to close on July 13, 2016 and trial is scheduled to begin on September 19, 2016.

On May 28, 2015, we received a Notice Letter from Teva Pharmaceuticals USA, Inc. (Teva) notifying us of Teva's ANDA that seeks approval from the FDA to market a generic version of romidepsin for injection. The Notice Letter contains Paragraph IV certifications against the '280 and '724 patents.

On July 10, 2015, we and Astellas filed an infringement action in the United States District Court for the District of Delaware against Teva. Teva has not yet responded. 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. Fact discovery is set to close on August 9, 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.

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

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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 generic versions of 50mg, 100mg, 150mg and 200mg of THALOMID® capsules. On January 30, 2015, we filed an infringement action against Lannett in the United States District Court for the District of New Jersey. On March 27, 2015, Lannett filed a motion to dismiss our complaint for lack of personal jurisdiction. Following oral argument on July 27, 2015, the court ordered Lannett to provide jurisdictional discovery.

Other Proceedings:

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

On April 3, 2014, Mylan 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® and REVLIMID® brand drugs so that Mylan can conduct the bioequivalence testing needed to submit ANDAs 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 is set to close February 2, 2016 and expert discovery is set to be completed by July 31, 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 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. We filed our answer to the complaint on August 28, 2014. Expert discovery is set to close on November 20, 2015. Summary judgment motions are due January 29, 2016. No trial date has been set. We intend to vigorously defend against the remaining claims in the Brown Action.

In a related matter, in July 2014, we received a letter purportedly on behalf of two stockholders 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. 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.

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

In November 2014, we received another letter purportedly on behalf of a stockholder that demanded access to certain books and records of the Company for the purpose of investigating matters pertaining to the Brown Action. The Company has complied with the demand to the extent it considers reasonable in view of the Demand Investigation Committee's consideration of matters pertaining to the Brown Action.

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.

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 Plaintiffs' motion for summary judgment was held on October 21, 2015. No trial date has as yet been set by the court.

We intend to vigorously defend against CMCC's and CR Rev's claims. As of September 30, 2015, we consider the range of reasonably possible loss relating to this lawsuit to be between zero and $126.3 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 September 30, 2015, 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 and if CMCC prevails, we may be obligated to continue to pay royalties on sales for periods after September 30, 2015.

In the second quarter of 2014, we received a Health Insurance Portability and Accountability Act (HIPAA) subpoena from the United States Attorney's Office for the District of Massachusetts requesting certain documents relating to an investigators meeting in 2011 with respect to a clinical study relating to ABRAXANE®. The Company cooperated with the United States Attorney's Office in connection with this subpoena and we understand that the matter is no longer active.

On October 2, 2014, a complaint was filed in Delaware Chancery Court by a stockholder asserting derivative claims on behalf of the Company against the non-employee members of the Board of Directors. The complaint, as subsequently amended, alleged that equity grants made to non-employee directors in 2012, 2013 and 2014 were excessive compared to the equity grants to directors of peer companies, and that the award of such allegedly excessive compensation constituted a breach of fiduciary duty, waste of corporate assets, and unjust enrichment. On September 14, 2015, the parties agreed to settle all claims in the case, subject to the Chancery Court's approval of the settlement. A hearing on the settlement is scheduled for December 9, 2015. The settlement provides prospective relief only, setting limits on equity grants to non-employee directors for at least four years and requiring certain changes in the charter of the Board's compensation committee and in the timing of disclosures concerning non-employee director

compensation.

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" who at one time held an ANDA for THALOMID®) 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 could conduct the bioequivalence testing needed to submit ANDAs 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 payors, 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 payors,

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 as well. On October 30, 2015, the court denied our motion to dismiss on all grounds.

The Court entered an Order on July 6, 2015 scheduling the production of certain discovery for the case through October 1, 2015. A status conference is scheduled for January 5, 2016. Dates for the completion of fact and expert discovery have not 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. The MOU contemplates that the parties will seek to enter into a stipulation of settlement providing for a global release of claims relating to the acquisition as set forth in the MOU. The claims will not be released until such stipulation of settlement is approved by the Court of Chancery of the State of Delaware. There can be no assurance that the parties will ultimately enter into a stipulation of settlement or that the court will approve such settlement even if the parties were to enter into such stipulation. The settlement did not affect the consideration received by Receptos' stockholders in connection with the acquisition. As part of the settlement, Receptos agreed to make certain additional disclosures related to the acquisition.

Under the America Invents Act (AIA) enacted in 2011, members of the public 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 several petitions seeking to institute Inter Partes Review (IPRs) challenging the validity of Celgene's patent US 6,045,501 and US 6,315,720 having claims that cover 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. 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. Discovery, briefing and oral arguments will be scheduled in the near future. 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.

17. Subsequent Event

In October 2015, we completed the purchase of real property in Summit, New Jersey that includes 12 buildings. The site has approximately 850,000 square feet of administrative office space and 450,000 square feet of R&D space.

The purchase of the Summit New Jersey campus together with the construction of a 550,000 square foot addition at our global headquarters will enable us to consolidate our New Jersey operations into our two Summit, New Jersey campuses. We expect to incur restructuring expenses associated with the relocation of operations into the two campuses during 2015 and 2016.

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

Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words "expects," "anticipates," "believes," "intends," "estimates," "aims," "plans," "
"could," "will," "will continue," "seeks," "should," "predicts," "potential," "outlook," "guidance," "target," "forecast," "probab
the negative of such terms and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions and projections, which are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws. We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements and therefore you should not place too much reliance on them. These factors include, among others, those described in the sections "Forward-Looking Statements" and "Risk Factors" contained in our 2014 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 gene and protein regulation. We are dedicated to innovative research and development designed to bring new therapies to market and we are involved in research in several scientific areas designed to deliver proprietary next-generation therapies, targeting areas including intracellular signaling pathways, protein homeostasis and epigenetics in cancer and immune cells, immunomodulation in cancer and autoimmune diseases and therapeutic application of cell therapies.

Our primary commercial stage products include REVLIMID®, ABRAXANE®, POMALYST®/IMNOVID®, OTEZLA®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®), THALOMID® (sold as THALOMID® or Thalidomide Celgene™ outside of the U.S.), and ISTODAX®. Additional sources of revenue include royalties from Novartis Pharma AG (Novartis) on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of products and services through our Celgene Cellular Therapeutics (CCT) subsidiary and other 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. REVLIMID® is in several phase III trials across a range of hematological malignancies that include multiple myeloma, lymphomas, chronic lymphocytic leukemia (CLL) and myelodysplastic syndromes (MDS). POMALYST®/IMNOVID® 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®/IMNOVID® in relapsed and refractory multiple myeloma. Phase III trials are also underway for CC-486 in MDS and acute myeloid leukemia (AML) and ISTODAX® in first-line peripheral T-cell lymphoma

(PTCL). In solid tumors, ABRAXANE® is currently in various stages of investigation for breast, pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA® is being evaluated in phase III trials for Behçet's disease and expanded indications in psoriatic arthritis and psoriasis. Also in the inflammation and immunology therapeutic area, we have initiated a phase III registration program with GED-0301 in patients with active Crohn’s disease.

On August 27, 2015 (Acquisition Date), we acquired all of the outstanding common stock of Receptos, Inc. (Receptos) which resulted 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).

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Receptos is also developing RPC4046, an anti-interleukin-13 (IL-13) antibody for eosinophilic esophagitis, an allergic/immune-mediated orphan disease, as well as other pipeline and pre-clinical stage compounds. See Note 3 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report for more information related to our acquisition of Receptos. 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 the first half of 2017.

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 as indicated below:

Disease	Geographic Approvals
Multiple myeloma (MM)	
Multiple myeloma in combination with dexamethasone, in patients who have received at least one prior therapy	- United States - European Union - Japan - Other international markets
Multiple myeloma in combination with dexamethasone for newly diagnosed patients	- United States (Approved February 2015)
Adult patients with previously untreated multiple myeloma who are not eligible for transplant	- European Union (Approved February 2015)
Myelodysplastic syndromes (MDS)	
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities	- United States - Other international markets
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	- European Union
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

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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 as indicated below:

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 (Approved March 2015) - 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)[1]: 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 as indicated below:

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 (Approved March 2015)

[1] We received approval for pomalidomide under the trade name POMALYST® in the United States and Japan. We received approval for pomalidomide under the trade name IMNOVID® in the European Union.

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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. During 2014 and January 2015, OTEZLA® received initial approvals in the U.S. and EU as indicated below:

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 (Approved January 2015)
Psoriasis	
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- United States - 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 (Approved January 2015)

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 also contracted with Sandoz AG to sell a generic version of VIDAZA® in the United States, which we supply. We recognize net product sales from our sales of azacitidine for injection to Sandoz AG. 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 as indicated below:

Disease	Geographic Approvals
Myelodysplastic syndromes (MDS)	
All French-American-British (FAB) subtypes	- United States
Intermediate-2 and high-risk MDS	- European Union - Other international markets
MDS	- Japan
Chronic myelomonocytic leukemia with 10% to 29% marrow blasts without myeloproliferative disorder	- European Union - Other international markets
Acute myeloid leukemia (AML) with 20% to 30% blasts and multi-lineage dysplasia	- European Union - 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

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THALOMID® (thalidomide): THALOMID®, sold as THALOMID® or Thalidomide Celgene™ outside of the United States, is administered orally for the treatment of diseases as indicated below:

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
Multiple myeloma after failure of standard therapies (relapsed or refractory)	- 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 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 September 30, 2015 and 2014 (dollar amounts in millions, except per share data):

	Three-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Total revenue	$2,334.1	$1,982.2	$351.9	17.8 %
Net income (loss)	$(34.1)	$508.5	$(542.6)	(106.7)%
Diluted earnings (loss) per share	$(0.04)	$0.61	$(0.65)	(106.6)%

Revenue increased by $351.9 million in the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to the continued growth in sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA®. OTEZLA® was approved by the 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. In January 2015, OTEZLA® was approved by the European Commission (EC) for the treatment of both psoriasis and psoriatic arthritis in certain adult patients. We began recognizing revenue related to OTEZLA® during the second quarter of 2014. The $542.6 million decrease in net income and $0.65 decrease in diluted earnings per share in the current three-month period were primarily due to higher research and development collaboration related

expenses, which included $575.1 million of upfront expense for our collaboration with Juno and $149.8 million of upfront expense for our collaboration with Nurix Inc. (Nurix), as well as $255.3 million of expenses associated with the acquisition and operations of Receptos. The increase in collaboration and acquisition related expenses in the current three-month quarter were partly offset by higher net product sales.

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The following table summarizes total revenue and earnings for the nine-month periods ended September 30, 2015 and 2014 (dollar amounts in millions, except per share data):

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Total revenue	$6,692.7	$5,584.9	$1,107.8	19.8 %
Net income	$1,041.0	$1,386.0	$(345.0)	(24.9)%
Diluted earnings per share	$1.26	$1.66	$(0.40)	(24.1)%

Revenue increased by $1.108 billion in the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to the continued growth in sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA®. OTEZLA® was approved by the 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. In January 2015, OTEZLA® was approved by the EC for the treatment of both psoriasis and psoriatic arthritis in certain adult patients. We began recognizing revenue related to OTEZLA® during the second quarter of 2014. The $345.0 million decrease in net income and $0.40 decrease in diluted earnings per share in the current nine-month period were primarily due to higher research and development collaboration related expenses,which included upfront expenses of $575.1 million, $450.0 million, and $149.8 million for our collaborations with Juno, AstraZeneca and Nurix, respectively, as well as $255.3 million of expenses associated with the acquisition and operations of Receptos. The increased collaboration and acquisition related expenses in the current nine-month period were partly offset by higher net product sales as well as a $85.9 million realized gain on the sale of our equity investment in Flexus Biosciences, Inc. in April 2015.

Results of Operations

Three-Month Periods Ended September 30, 2015 and 2014

Total Revenue: Total revenue and related percentages for the three-month periods ended September 30, 2015 and 2014 were as follows (dollar amounts in millions):

	Three-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Net product sales:				
REVLIMID®	$1,453.5	$1,300.0	$153.5	11.8 %
ABRAXANE®	229.9	212.2	17.7	8.3 %
POMALYST®/IMNOVID®	256.5	181.1	75.4	41.6 %
OTEZLA®	138.7	17.6	121.1	N/M
VIDAZA®	147.6	157.8	(10.2)	(6.5)%
azacitidine for injection	21.3	19.9	1.4	7.0 %
THALOMID®	45.1	51.9	(6.8)	(13.1)%
ISTODAX®	17.3	15.7	1.6	10.2 %
Other	2.7	0.6	2.1	350.0 %
Total net product sales	$2,312.6	$1,956.8	$355.8	18.2 %
Other revenue	21.5	25.4	(3.9)	(15.4)%
Total revenue	$2,334.1	$1,982.2	$351.9	17.8 %

N/M - Not meaningful

Total revenue increased by $351.9 million, or 17.8%, to $2.334 billion for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, reflecting increases of $264.5 million, or 23.1%, in the United States and $87.4 million, or 10.5%, in international markets.

Net Product Sales: Total net product sales for the three-month period ended September 30, 2015 increased by $355.8 million, or 18.2%, to $2.313 billion compared to the three-month period ended September 30, 2014. The increase was comprised of net volume increases of $315.0 million and net price increases of $70.9 million, offset in part by a $30.1 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity.

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REVLIMID® net sales increased by $153.5 million, or 11.8%, to $1.454 billion for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, 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, are in progress and are expected to continue through the remainder of 2015.

ABRAXANE® net sales increased by $17.7 million, or 8.3%, to $229.9 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to increased unit volumes in international markets.

POMALYST®/IMNOVID® net sales increased by $75.4 million, or 41.6%, to $256.5 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, reflecting net sales of $150.1 million in the United States and $106.4 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®. The finalization of access, pricing and reimbursement in additional countries also continues to contribute to the growth of POMALYST®/IMNOVID® net sales in international markets.

OTEZLA® net sales increased by $121.1 million to $138.7 million for the three-month period ended September 30, 2015 compared to the three- month period ended September 30, 2014 reflecting net sales of $128.4 million in the United States and $10.3 million in international markets. OTEZLA® was approved by the 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® was approved for plaque psoriasis and psoriatic arthritis in the European Union in January 2015. Launch activities for OTEZLA® commenced in March 2014 and we began recognizing revenue related to OTEZLA® during the second quarter of 2014.

VIDAZA® net sales decreased $10.2 million, or 6.5%, to $147.6 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to the effect of an unfavorable foreign exchange impact as well as a decrease in U.S. sales offset by volume increases in international markets.

Azacitidine for injection net sales increased by $1.4 million, or 7.0%, to $21.3 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014 primarily due to increased unit volumes offset by price decreases in the United States. Azacitidine for injection is a generic version of VIDAZA® supplied by Celgene to Sandoz AG.

THALOMID® net sales decreased by $6.8 million, or 13.1%, to $45.1 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily resulting from lower unit volumes in both U.S. and international markets.

ISTODAX® net sales increased by $1.6 million, or 10.2%, to $17.3 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to an increase in unit volume.

Other Revenue: Other revenue decreased by $3.9 million to $21.5 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014 primarily due to a $3.7 million

decrease in royalty revenue related to lower royalties earned from Novartis based upon its sales of both RITALIN® and FOCALIN XR®.

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®, POMALYST® and THALOMID® are distributed in the United States primarily through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS), POMALYST REMS™ and THALOMID REMS™ programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®, POMALYST® and THALOMID®. Internationally, REVLIMID®, THALOMID®/Thalidomide Celgene™ and IMNOVID® are distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the product's safe and appropriate distribution and use. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA®, ABRAXANE®, ISTODAX® and OTEZLA® are distributed through the more traditional

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pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene™.

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®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene™ 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 2014. 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 and 2014, the accruals for certain states were reduced from these elevated levels as a result of both payments being applied to the accrual during 2013 and 2014 and changes in estimate of the ultimate obligation during the fourth quarters of both 2013 and 2014. We will continue to adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Effective January 1, 2011, 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 2014 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

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Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2015 and 2014 were as follows (in millions):

	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at June 30, 2015	$12.3	$12.4	$169.6	$119.7	$314.0
Allowances for sales during prior periods	—	—	9.2	—	9.2
Allowances for sales during 2015	2.7	30.5	89.5	125.3	248.0
Credits/deductions issued for prior year sales	(1.2)	—	(3.5)	(0.1)	(4.8)
Credits/deductions issued for sales during 2015	(1.8)	(31.4)	(57.9)	(127.6)	(218.7)
Balance at September 30, 2015	$12.0	$11.5	$206.9	$117.3	$347.7
Balance at June 30, 2014	$12.7	$11.9	$120.4	$86.8	$231.8
Allowances for sales during prior periods	—	—	(0.6)	(1.7)	(2.3)
Allowances for sales during 2014	1.9	23.2	69.8	95.8	190.7
Credits/deductions issued for prior year sales	(0.2)	—	(3.2)	(0.1)	(3.5)
Credits/deductions issued for sales during 2014	(0.8)	(23.7)	(52.3)	(102.0)	(178.8)
Balance at September 30, 2014	$13.6	$11.4	$134.1	$78.8	$237.9

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2015 and 2014 follows:

Returns and allowances provisions increased by $0.8 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to higher net product sales volumes.

Discounts provisions increased by $7.3 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to increased sales volumes. The $7.3 million increase consisted of a $7.0 million increase in the United States, which included a $2.8 million increase in cash discounts in the third quarter of 2015 relating to OTEZLA® and a $3.8 million increase related to REVLIMID®.

Government rebates provisions increased by $29.5 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily due to a $22.2 million increase in international government rebates due to higher sales volumes and increased rebate rates, a $3.2 million increase related to Medicaid rebates due to increased sales and Medicaid expansion and a $4.1 million increase in expense related to Medicare Part D Coverage Gap due to increased sales volumes.

Chargebacks and distributor service fees provisions increased by $31.2 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014. Chargebacks increased by approximately $15.9 million and distributor service fees increased by approximately $15.3 million. The chargeback increases were primarily due to higher sales volumes, increased rebate rates and a greater portion of sales qualifying for chargeback rebates. The distributor service fee increase was primarily attributable to sales increases in the United States, including $15.4 million of service fees related to increased sales of OTEZLA® in the three-month period ended September 30, 2015.

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Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended September 30, 2015 and 2014 were as follows (dollar amounts in millions):

	Three-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Cost of goods sold (excluding amortization of acquired intangible assets)	$109.9	$97.7	$12.2	12.5 %
Percent of net product sales	4.8 %	5.0 %		
Research and development	$1,304.5	$675.1	$629.4	93.2 %
Percent of total revenue	55.9 %	34.1 %		
Selling, general and administrative	$550.3	$497.6	$52.7	10.6 %
Percent of total revenue	23.6 %	25.1 %		
Amortization of acquired intangible assets	$63.6	$63.7	$(0.1)	(0.2)%
Acquisition related charges and restructuring, net	$226.2	$1.5	$224.7	N/M

N/M - Not meaningful

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by $12.2 million to $109.9 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014. 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 4.8% for the three-month period ended September 30, 2015 compared to 5.0% for the three-month period ended September 30, 2014, 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 $629.4 million to $1.305 billion for the three-month period ended September 30, 2015, compared to the three-month period ended September 30, 2014. The increase was primarily due to a $680.4 million increase in expenses related to collaboration arrangements, as well as an increase in activity in support of our early- to mid-stage product pipeline, partly offset by a decrease in general research activity.

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

	Three-Month Periods Ended September 30,		Increase (Decrease)
	2015	2014	
Human pharmaceutical clinical programs	$263.7	$209.9	$53.8
Other pharmaceutical programs	170.9	295.1	(124.2)
Drug discovery and development	94.4	72.6	21.8
Collaboration arrangements	770.7	90.3	680.4
Cellular therapy	4.8	7.2	(2.4)
Total	$1,304.5	$675.1	$629.4

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The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended September 30, 2015, 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
GED-0301	Crohn's Disease
ozanimod	Ulcerative Colitis (Receptos trial initiated in Q3 2015)
ozanimod	Relapsing Multiple Sclerosis (Two Receptos trials initiated in Q4 2013 and Q4 2014, respectively)

Regulatory approval requests in major markets:

Product	Disease Indication	Major Market	Regulatory Agency	Date of Submission or Filing
REVLIMID®	Non-del 5q MDS	US	FDA	Q3 2015 (Filed)

Regulatory agency actions:

Product	Disease Indication	Major Market	Regulatory Agency	Action
VIDAZA®	Expanded indication for the treatment of elderly AML patients who are not eligible for haematopoietic stem cell transplantation and have >30% myeloblasts in their bone marrow	EU	EC	Approval

Selling, General and Administrative: Selling, general and administrative expenses increased by $52.7 million to $550.3 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014. The increase was primarily due to increases in expenses associated with our growing organization to support inflammation and immunology products and product candidates, such as OTEZLA® and GED-0301, as well as increases in selling and marketing activities related to recently approved indications for OTEZLA®, POMALYST®/IMNOVID® and ABRAXANE®.

Amortization of Acquired Intangible Assets: Amortization of intangible assets acquired as a result of business combinations is summarized below for the three-month periods ended September 30, 2015 and 2014 (in millions):

	Three-Month Periods Ended September 30,	
Acquisitions	2015	2014
Abraxis	$38.0	$37.9
Avila	11.8	11.8
Gloucester	12.8	13.0
Pharmion	1.0	1.0
Total amortization	$63.6	$63.7

Acquisition Related Charges and Restructuring, net: Acquisition related charges and restructuring, net were a net expense of $226.2 million and $1.5 million for the three-month periods ended September 30, 2015 and 2014, respectively. The $224.7 million increase in the current year three-month period was primarily due to $231.6 million in net costs related to the acquisition of Receptos in August 2015 and a $43.4 million increase for our contingent liabilities related to the Avila acquisition compared to the third quarter of 2014. These increases were partly offset by a $54.5 million reduction 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. The increase related to Receptos included acquisition related fees of $60.3 million, and acquisition related expenses for equity compensation and severance of $171.3 million. The increase related to the Avila acquisition was due to changes in the probability and timing of achieving milestones.

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Interest and Investment Income, Net: Interest and investment income, net increased by $1.7 million to $8.6 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014 primarily due to interest earned and collected on certain international receivables.

Interest (Expense): Interest (expense) increased by $35.0 million to $88.5 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014 primarily due to interest expense associated with the issuance of senior notes in August 2015. We anticipate an increase in interest expense for the remainder of 2015 due to our issuance of senior notes in August 2015. For more information related to our debt issuance, see Note 11 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

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 periods ended September 30, 2015 and 2014 (in millions):

	Three-Month Periods Ended September 30,		
	2015	2014	Change
Foreign exchange gains (losses) including foreign exchange derivative instruments not designated as hedging instruments	$(3.2)	$(4.3)	$1.1
Fair value adjustments of forward point amounts	14.7	(18.6)	33.3
Celgene puts sold	(18.8)	3.6	(22.4)
Milestones received	12.0	—	12.0
Impairment charges	(21.5)	(2.0)	(19.5)
Other	(2.8)	(1.2)	(1.6)
Total other income (expense), net	$(19.6)	$(22.5)	$2.9

Other income (expense), net was a net expense of $19.6 million for the three-month period ended September 30, 2015 and a net expense of $22.5 million for the three-month period ended September 30, 2014. The $2.9 million decrease in expense was primarily due to currency fluctuations offset by a loss on Celgene puts sold and impairment charges.

Income Tax Provision: The income tax provision decreased by $54.8 million to $14.2 million for the three-month period ended September 30, 2015 compared to the three-month period ended September 30, 2014, primarily as a result of a decrease in income before taxes to a net loss, offset by an increase in the effective tax rate. The estimated full year 2015 underlying effective tax rate of 19.3% reflects the impact of our global business footprint. The increase in the estimated underlying effective tax rate from the third quarter of 2014 reflects a projected increase in tax expense related to collaborations, primarily our collaboration with Juno, partially offset by a projected decrease in tax expense related to our acquisition of Receptos, both of which occurred in the third quarter, and a non-recurring tax expense from the launch of new products. The effective tax rate for the third quarter of 2015 was increased from a tax benefit of 19.3% to a tax expense of 71.4% primarily as a result of the impact of the increase in the estimated full year 2015 underlying effective tax rate from the second quarter applied to cumulative income before taxes. The income tax provision for the three-month period ended September 30, 2014 included an estimated full year 2014 underlying effective tax rate of 14.4% (which subsequently decreased to 14.3% when the actual 2014 full year results were achieved). The effective tax rate for the third quarter of 2014 was decreased by 0.2 percentage points primarily resulting from a net decrease in unrecognized tax benefits related to ongoing examinations and settlements of tax positions taken in prior years.

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Nine-Month Periods Ended September 30, 2015 and 2014

Total Revenue: Total revenue and related percentages for the nine-month periods ended September 30, 2015 and 2014 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Net product sales:				
REVLIMID®	$4,240.4	$3,657.5	$582.9	15.9 %
ABRAXANE®	697.5	612.3	85.2	13.9 %
POMALYST®/IMNOVID®	689.5	477.6	211.9	44.4 %
OTEZLA®	288.7	22.2	266.5	N/M
VIDAZA®	443.3	458.2	(14.9)	(3.3)%
azacitidine for injection	64.2	62.7	1.5	2.4 %
THALOMID®	139.9	164.2	(24.3)	(14.8)%
ISTODAX®	51.7	48.9	2.8	5.7 %
Other	6.7	5.3	1.4	26.4 %
Total net product sales	$6,621.9	$5,508.9	$1,113.0	20.2 %
Other revenue	70.8	76.0	(5.2)	(6.8)%
Total revenue	$6,692.7	$5,584.9	$1,107.8	19.8 %

N/M - Not meaningful

Total revenue increased by $1.108 billion, or 19.8%, to $6.693 billion for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, reflecting increases of $812.5 million, or 25.2%, in the United States and $295.3 million, or 12.5%, in international markets.

Net Product Sales: Total net product sales for the nine-month period ended September 30, 2015 increased by $1.113 billion, or 20.2%, to $6.622 billion compared to the nine-month period ended September 30, 2014. The increase was comprised of net volume increases of $1.044 billion and net price increases of $161.8 million, offset in part by a $93.0 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity.

REVLIMID® net sales increased by $582.9 million, or 15.9%, to $4.240 billion for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, 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, are in progress and expected to continue through the remainder of 2015.

ABRAXANE® net sales increased by $85.2 million, or 13.9%, to $697.5 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to increased unit volumes based on demand in both U.S. and international markets.

POMALYST®/IMNOVID® net sales increased by $211.9 million, or 44.4%, to $689.5 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, reflecting net sales of $422.1 million in the United States and $267.4 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®. The finalization of access, pricing and reimbursement in additional countries also continues to contribute to the growth of

POMALYST®/IMNOVID® net sales in international markets.

OTEZLA® net sales increased by $266.5 million to $288.7 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014 reflecting net sales of $272.5 million in the United States and $16.2 million in international markets. OTEZLA® was approved by the 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® was approved for plaque psoriasis and psoriatic arthritis in the European Union in

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January 2015. Launch activities for OTEZLA® commenced in March 2014 and we began recognizing revenue related to OTEZLA® during the second quarter of 2014.

VIDAZA® net sales decreased by $14.9 million, or 3.3%, to $443.3 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to a $17.6 million decrease in U.S. sales which was partly offset by volume increases in international markets.

Azacitidine for injection net sales increased by $1.5 million, or 2.4% for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to increased unit sales which were offset by price decreases.

THALOMID® net sales decreased by $24.3 million, or 14.8%, to $139.9 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily resulting from lower unit volumes and price decreases in both U.S. and international markets.

ISTODAX® net sales increased by $2.8 million, or 5.7%, to $51.7 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to an increase in unit volume.

Other Revenue: Other revenue decreased by $5.2 million to $70.8 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014 primarily due to a $4.8 million decrease in royalty revenue related to lower royalties earned from Novartis based upon its sales of both RITALIN® and FOCALIN XR®.

Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2015 and 2014 were as follows (in millions):

	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at December 31, 2014	$10.2	$11.5	$138.5	$94.4	$254.6
Allowances for sales during prior periods	1.1	—	1.8	(3.1)	(0.2)
Allowances for sales during 2015	7.5	84.0	294.5	381.5	767.5
Credits/deductions issued for prior year sales	(3.9)	(8.2)	(70.5)	(50.6)	(133.2)
Credits/deductions issued for sales during 2015	(2.9)	(75.8)	(157.4)	(304.9)	(541.0)
Balance at September 30, 2015	$12.0	$11.5	$206.9	$117.3	$347.7
Balance at December 31, 2013	$15.5	$12.1	$134.1	$83.2	$244.9
Allowances for sales during prior periods	(1.9)	—	(5.7)	(8.4)	(16.0)
Allowances for sales during 2014	6.3	63.9	216.5	272.2	558.9
Credits/deductions issued for prior year sales	(3.9)	(7.9)	(74.3)	(41.9)	(128.0)
Credits/deductions issued for sales during 2014	(2.4)	(56.7)	(136.5)	(226.3)	(421.9)
Balance at September 30, 2014	$13.6	$11.4	$134.1	$78.8	$237.9

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2015 and 2014 follows:

Returns and allowances provisions increased by $4.2 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to higher net product sales volumes in the U.S. market and a $2.9 million expense recorded in 2015 relating to increased anticipated returns of products that have reached their expiration dates. In addition, a $1.3 million decrease in the returns allowance related to VIDAZA® inventory held by distributors was recorded in 2014 due to reductions in inventory levels resulting from competition from generic versions of VIDAZA®.

Discounts provisions increased by $20.1 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to increased sales volumes. The $20.1 million increase consisted of a $18.5 million increase in the United States, which included increases of $10.7 million of cash discounts related to REVLIMID®, $6.2 million related to OTEZLA® and $2.4 million related to POMALYST®, and a $1.6 million increase related to international cash discounts. These increases were partly offset by a $0.8 million decrease in discount provisions related to products with lower sales volumes.

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Government rebates provisions increased by $85.5 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily due to a $65.8 million increase in international government rebates, due to higher sales volumes and increased rebate rates, and a $15.7 million increase related to Medicaid rebates due to increased sales and Medicaid expansion and a $4.0 million increase in expense related to Medicare Part D Coverage Gap.

Chargebacks and distributor service fees provisions increased by $114.6 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014. Chargebacks increased by approximately $72.4 million and distributor service fees increased by approximately $42.2 million. The chargeback increases were primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates. The distributor service fee increase was primarily attributable to OTEZLA®, which launched in April 2014, resulting in service fees of $35.4 million for the nine-month period ended September 30, 2015.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2015 and 2014 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended September 30,		Increase (Decrease)	Percent Change
	2015	2014		
Cost of goods sold (excluding amortization of acquired intangible assets)	$314.7	$282.7	$32.0	11.3 %
Percent of net product sales	4.8 %	5.1 %		
Research and development	$2,920.5	$1,845.7	$1,074.8	58.2 %
Percent of total revenue	43.6 %	33.0 %		
Selling, general and administrative	$1,696.3	$1,483.5	$212.8	14.3 %
Percent of total revenue	25.3 %	26.6 %		
Amortization of acquired intangible assets	$190.9	$194.7	$(3.8)	(2.0)%
Acquisition related charges and restructuring, net	$215.9	$11.0	$204.9	1,862.7 %

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by $32.0 million to $314.7 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014. 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 4.8% for the nine-month period ended September 30, 2015 compared to 5.1% for the nine-month period ended September 30, 2014, 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 $1.075 billion to $2.921 billion for the nine-month period ended September 30, 2015, compared to the nine-month period ended September 30, 2014. The increase was primarily due to a $960.5 million increase in expenses related to collaboration arrangements as well as an increase in activity in support of our early- to mid-stage product pipeline activity.

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

	Nine-Month Periods Ended September 30,		Increase (Decrease)
	2015	2014	
Human pharmaceutical clinical programs	$716.3	$596.2	$120.1
Other pharmaceutical programs	518.9	591.5	(72.6)
Drug discovery and development	279.2	209.0	70.2

Collaboration arrangements	1,388.1	427.6	960.5
Cellular therapy	18.0	21.4	(3.4)
Total	$2,920.5	$1,845.7	$1,074.8

Selling, General and Administrative: Selling, general and administrative expenses increased by $212.8 million to $1.696 billion for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014. The increase

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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® and GED-0301, as well as increases in selling and marketing activities related to recently approved indications for OTEZLA®, POMALYST®/IMNOVID® and ABRAXANE®.

Amortization of Acquired Intangible Assets: Amortization of intangible assets acquired as a result of business combinations is summarized below for the nine-month periods ended September 30, 2015 and 2014 (in millions):

	Nine-Month Periods Ended September 30,	
Acquisitions	2015	2014
Abraxis	$113.9	$117.6
Avila	35.4	35.4
Gloucester	38.6	38.7
Pharmion	3.0	3.0
Total amortization	$190.9	$194.7

Acquisition Related Charges and Restructuring, net: Acquisition related charges and restructuring, net were a net expense of $215.9 million and $11.0 million for the nine-month periods ended September 30, 2015 and 2014, respectively. The $204.9 million increase in the current year nine-month period was primarily due to $231.6 million in costs related to the acquisition of Receptos in August 2015, a $45.7 million increase in expense in the current year nine-month period related to our contingent liabilities for the Nogra Pharma Limited (Nogra) acquisition, which was acquired in the second quarter of 2014, and a $21.2 million reduction in the benefit recorded in the current year nine-month period for our contingent liabilities related to the Avila acquisition compared to the prior year nine-month period. These increases in expense were partly offset by a $95.2 million reduction in expense in the current year nine-month period related to reductions in the fair value of our liability related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis.

Interest and Investment Income, Net: Interest and investment income, net increased by $5.8 million to $26.4 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014 primarily due to lower losses on the sale of marketable securities in 2015 compared to the prior year.

Interest (Expense): Interest (expense) increased by $61.6 million to $186.0 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014 primarily due to interest expense associated with the issuance of senior notes in August 2015 and May 2014. We anticipate an increase in interest expense for the remainder of 2015 due to our issuance of senior notes in August 2015. For more information related to our debt issuance, see Note 11 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

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Other Income (Expense), Net: Other income (expense), net and fluctuations in the components of Other income (expense), net is summarized below for the nine-month periods ended September 30, 2015 and 2014 (in millions):

	Nine-Month Periods Ended September 30,		
	2015	2014	Change
Foreign exchange gains (losses) including foreign exchange derivative instruments not designated as hedging instruments	$(4.7)	$(11.0)	$6.3
Premium paid on equity investment	—	(9.7)	9.7
Fair value adjustments of forward point amounts	35.5	(22.1)	57.6
Celgene puts sold	(9.9)	9.9	(19.8)
Milestones received	12.0	—	12.0
Impairment charges	(27.3)	(4.0)	(23.3)
Gain on sale of equity investment in Flexus Biosciences, Inc.	85.9	—	85.9
Other	(8.3)	(10.0)	1.7
Total other income (expense), net	$83.2	$(46.9)	$130.1

Other income (expense), net was a net income of $83.2 million for the nine-month period ended September 30, 2015 and a net expense of $46.9 million for the nine-month period ended September 30, 2014. The $130.1 million increase in income was primarily due to a gain on the sale of our equity investment in Flexus and currency fluctuations.

Income Tax Provision: The income tax provision increased by $6.4 million to $237.0 million for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014, primarily as a result of an increase in the effective tax rate, partially offset by a decrease in income before taxes. The estimated full year 2015 underlying effective tax rate of 19.3% reflects the impact of our global business footprint. The increase in the estimated underlying effective tax rate from the third quarter of 2014 reflects a projected increase in tax expense related to collaborations, primarily our collaborations with AstraZeneca and Juno, partially offset by a projected decrease in tax expense related to our acquisition of Receptos and a non-recurring tax expense from the launch of new products. The effective tax rate for the nine month period ended September 30, 2015 was reduced by 0.7 percentage points primarily as a result of certain tax benefits related to our 2014 income tax returns being more favorable than originally estimated. The income tax provision for the nine-month period ended September 30, 2014 included an estimated full year 2014 underlying effective tax rate of 14.4% (which subsequently decreased to 14.3% when the actual 2014 full year results were achieved). The effective tax rate for the nine month period ended September 30, 2014 was reduced by 0.1 percentage points primarily as a result of a net decrease in unrecognized tax benefits related to ongoing examinations and settlements of tax positions taken in prior years.

Liquidity and Capital Resources

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

	September 30, 2015	December 31, 2014	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$6,016.5	$4,121.6	$1,894.9
Marketable securities available for sale	1,489.1	3,425.1	(1,936.0)
Total financial assets	$7,505.6	$7,546.7	$(41.1)
Debt:			
Short-term borrowings and current portion of long-term debt	$1,199.7	$605.9	$593.8
Long-term debt, net of discount	14,297.9	6,265.7	8,032.2
Total debt	$15,497.6	$6,871.6	$8,626.0

Working capital[1]	$6,833.7	$7,617.2	$(783.5)

(1) Includes cash, cash equivalents and marketable securities available for sale, accounts receivable, net of allowances, inventory and other current assets, less short-term borrowings and current portion of long-term debt, accounts payable, accrued expenses, income taxes payable and other current liabilities.

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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 or pursue other strategic business initiatives for the foreseeable future.

Many of our operations are conducted outside the United States and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of September 30, 2015, we held approximately $6.820 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 and due to other reasons, such as repurchases of our common stock and business-development activities. 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 $6.820 billion of short-term funds in foreign tax jurisdictions, may not be required for use in offshore operations and may be available for use in the United States. These earnings are not treated as permanently reinvested and accordingly, our deferred tax liabilities as of September 30, 2015 and December 31, 2014 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: From April 2009 through September 2015, our Board of Directors approved purchases of up to $17.500 billion of our common stock. During the three-month period ended September 30, 2015 we used $576.8 million for purchases of our common stock, measured on a settlement date basis. As of September 30, 2015, we had a remaining purchase authorization of $4.297 billion.

Senior Notes: In August 2015, we issued an additional $8.000 billion principal amount of senior notes consisting of $1.000 billion aggregate principal amount of 2.125% Senior Notes due 2018 (the 2018 notes), $1.500 billion aggregate principal amount of 2.875% Senior Notes due 2020 (the 2020 notes), $1.000 billion aggregate principal amount of 3.550% Senior Notes due 2022 (the 2022 notes), $2.500 billion aggregate principal amount of 3.875% Senior Notes due 2025 (the 2025 notes) and $2.000 billion aggregate principal amount of 5.000% Senior Notes due 2045 (the 2045 notes and together with the 2018 notes, the 2020 notes, the 2022 notes, and the 2025 notes, referred to herein as the “2015 issued notes”). The 2015 issued notes were issued at 99.994%, 99.819%, 99.729%, 99.034%, and 99.691% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately $50.0 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the 2015 issued notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2016 and the principal on each 2015 issued note is due in full at their respective maturity dates. The 2015 issued notes may be redeemed at our option, in whole or in part; the 2018 notes, the 2020 notes, and the 2022 notes may be redeemed at any time, the 2025 notes and 2045 notes may be redeemed at three months and six months prior to the maturity dates, respectively. Early redemption would be at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the 2015 issued notes to be redeemed or the sum of the present values of the

remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2018 notes, 20 basis points in the case of the 2020 notes, 25 basis points in the case of the 2022 notes, 30 basis points in the case of the 2025 notes, and 35 basis points in the case of the 2045 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the 2015 issued notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

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

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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. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. The $41.1 million decrease in cash, cash equivalents and marketable securities available for sale at September 30, 2015 compared to December 31, 2014 was primarily due to a $7.579 billion payment for the acquisition of Receptos, net of cash acquired and $2.574 billion of payments under our share repurchase program partially offset by $7.913 billion in cash generated from the August 2015 debt issuance of an additional $8.000 billion principal amount of senior notes, $1.426 billion of net cash from operating activities, $600.1 million of net proceeds from commercial paper borrowing and other activity resulting in net cash proceeds of $177.3 million.

Marketable securities available for sale 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. For more information related to the fair value and valuation of our marketable securities, see Note 6 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Accounts Receivable, Net: Accounts receivable, net increased by $105.7 million to $1.272 billion at September 30, 2015 compared to December 31, 2014 primarily due to increased sales of REVLIMID®, POMALYST®/IMNOVID®, and OTEZLA®. 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 continue 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 $215.8 million at September 30, 2015 compared to $241.8 million at December 31, 2014. Approximately $36.3 million of the $215.8 million receivable balance at September 30, 2015 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 $27.8 million to $420.9 million at September 30, 2015 compared to December 31, 2014. The increase was primarily due to increased demand and an initiative to increase ABRAXANE® safety stock globally.

Other Current Assets: Other current assets increased by $109.5 million to $703.9 million at September 30, 2015 compared to December 31, 2014 primarily due to an $83.6 million increase in the fair value of derivative instruments and a $34.1 million

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increase in prepaid taxes and other prepaid accounts. The $34.1 million increase is primarily attributable to the acquisition of Receptos.

Commercial Paper: In September 2011, we entered into a commercial paper program (Program) under which we issue unsecured commercial paper notes (Commercial Paper) on a private placement basis, the proceeds of which are used for general corporate purposes. As of September 30, 2015, the maximum aggregate amount available under the Program was $1.750 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 are accounted for as short-term borrowings. As of September 30, 2015, $699.4 million of Commercial Paper was outstanding bearing an effective interest rate of 0.5%. In October, 2015, our Board of Directors authorized an increase in the size of our Commercial Paper program from $1.750 billion to $2.750 billion.

Credit Facility and Revolving Credit: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of $1.750 billion, which was increased from $1.500 billion in April 2015. Also in April 2015, the term of the Credit Facility was extended from April 18, 2018 to April 17, 2020. Subject to certain conditions, we have the right to increase the amount of the Credit Facility (but in no event more than one time per annum) up to a maximum aggregate amount of $2.000 billion. Amounts may be borrowed in U.S. dollars for general corporate purposes. In October 2015, we entered into a revolving credit agreement (Revolving Credit Agreement) with JPMorgan Chase Bank, N.A., under which we may borrow up to a maximum aggregate principal amount of $1.000 billion. The maturity date of any borrowings under the Revolving Credit Agreement and the expiration date of the agreement is December 31, 2015. The Credit Facility and Revolving Credit Agreement currently serve as backup liquidity for our Commercial Paper borrowings. At September 30, 2015, there was no outstanding borrowing against the Credit Facility or the Revolving Credit Agreement.

The Credit Facility contains affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2015. In July 2015, the debt covenants on our existing credit facility have been amended in order to accommodate additional borrowing related to our acquisition of Receptos. For more information related to our debt issuance, see Note 11 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by $398.4 million to $1.864 billion at September 30, 2015 compared to December 31, 2014. The increase was primarily due to increases of $275.4 million for accrued share repurchases, $93.3 million for sales adjustment accruals, $87.1 million for accrued expenses related to the Receptos acquisition, $49.5 million for accrued interest, and a net increase of $23.6 million from other activity. The increases were partly offset by a decrease of $130.5 million in deferred taxes.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by $43.1 million to $328.7 million at September 30, 2015 compared to December 31, 2014, primarily from the current provision for income taxes of $650.0 million and net deferred intercompany credits of $13.0 million, partially offset by income tax payments of $345.6 million, a tax benefit of stock options of $244.3 million, and a decrease in refundable income taxes of $30.0 million.

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Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2015 and 2014 were as follows (in millions):

	Nine-Month Periods Ended September 30,		
	2015	2014	Change
Net cash provided by operating activities	$1,425.8	$1,973.7	$(547.9)
Net cash used in investing activities	$(5,897.8)	$(1,365.1)	$(4,532.7)
Net cash provided by (used in) financing activities	$6,397.4	$(65.9)	$6,463.3

Operating Activities: Net cash provided by operating activities decreased by $547.9 million to $1.426 billion for the nine-month period ended September 30, 2015 compared to the nine-month period ended September 30, 2014. The decrease in net cash provided by operating activities was primarily attributable to a decrease in net income of $345.0 million in 2015 compared to 2014 and $164.5 million increase in deferred income taxes in 2015 compared to 2014.

Investing Activities: Net cash used in investing activities for the nine-month period ended September 30, 2015 amounted to $5.898 billion compared to net cash used in investing activity of $1.365 billion for the nine-month period ended September 30, 2014. The increase in net cash used in investing activities was primarily due to the $7.579 billion used for the acquisition of Receptos, net of cash acquired. This was partially offset by net proceeds of $1.962 billion from net sales of marketable securities available for sale during 2015 compared with $474.8 million of net purchases of marketable securities available for sale during 2014. In addition, $710.0 million was used for the acquisition of Nogra in 2014.

Financing Activities: Net cash provided by financing activities amounted to $6.397 billion for the nine-month period ended September 30, 2015, compared to net cash used in financing activities of $65.9 million for the nine-month period ended September 30, 2014. The $6.463 billion increase in net cash provided by financing activities was primarily attributable to the $5.443 billion increase in proceeds from issuance of long-term debt and the $1.045 billion increase in net proceeds from short-term borrowings.

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 2014 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2014 aside from those disclosed in Note 11 and 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 2014 Annual Report on Form 10-K. There have not been any material changes to such critical accounting estimates since December 31, 2014.

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 September 30, 2015, 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 September 30, 2015, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed (MBS) securities, non-U.S. government, agency and supranational securities, global corporate debt securities, asset backed securities and marketable equity securities. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. Government Sponsored Enterprises. U.S. government-sponsored agency MBS include mortgage backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and supranational securities consist of direct obligations of highly rated governments of nations other than the United States and obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. 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 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. In addition, our marketable securities available for sale includes equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration agreements. 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 September 30, 2015, 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	$67.5	$291.0	$17.7	$376.2
Fair value	$67.9	$291.9	$18.0	$377.8
Weighted average interest rate	2.0 %	1.4 %	2.4 %	1.5 %

Short-Term Borrowings and Current Portion of Long-Term Debt: The carrying value of short-term borrowings and current portion of long-term debt outstanding at September 30, 2015 and December 31, 2014 includes:

	September 30, 2015	December 31, 2014
Commercial paper	$699.4	$99.6
2.450% senior notes due 2015	500.3	506.3
Total	$1,199.7	$605.9

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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 September 30, 2015 are summarized below (in millions):

	Principal Amount	Carrying Value
1.900% senior notes due 2017	$500.0	$503.0
2.125% senior notes due 2018	1,000.0	999.9
2.300% senior notes due 2018	400.0	403.8
2.250% senior notes due 2019	500.0	511.3
2.875% senior notes due 2020	1,500.0	1,497.4
3.950% senior notes due 2020	500.0	514.6
3.250% senior notes due 2022	1,000.0	1,032.3
3.550% senior notes due 2022	1,000.0	997.3
4.000% senior notes due 2023	700.0	722.2
3.625% senior notes due 2024	1,000.0	1,003.4
3.875% senior notes due 2025	2,500.0	2,476.1
5.700% senior notes due 2040	250.0	249.6
5.250% senior notes due 2043	400.0	396.7
4.625% senior notes due 2044	1,000.0	996.5
5.000% senior notes due 2045	2,000.0	1,993.8
Total long-term debt	$14,250.0	$14,297.9

At September 30, 2015, the fair value of our senior notes outstanding was $14.847 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. 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 September 30, 2015 and December 31, 2014 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 transaction affects earnings. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Operations 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 September 30, 2015 and December 31, 2014:

	Notional Amount	
Foreign Currency	September 30, 2015	December 31, 2014
Australian Dollar	$38.6	$18.8
British Pound	332.6	304.8
Canadian Dollar	84.4	43.7
Euro	3,290.3	3,375.7
Japanese Yen	555.2	541.1
Total	$4,301.1	$4,284.1

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2015, 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 Operations in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2015 and December 31, 2014 were $831.8 million and $835.5 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2015 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately $508.5 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. 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 September 30, 2015 and December 31, 2014:

	Notional Amount[1]	
	September 30, 2015	December 31, 2014
Foreign currency option contracts designated as hedging activity:		
Purchased Put	$524.1	$152.6
Written Call	$562.4	$160.9

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

Assuming that the September 30, 2015 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately $42.3 million if the US Dollar were to strengthen and decrease by approximately $41.7 million if the US 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: In anticipation of issuing debt in 2015, we entered into forward starting swaps and treasury rate locks, that were designated as cash flow hedges, with aggregate notional value of $1.300 billion and $1.600 billion, respectively. All forward starting swaps and treasury rate locks 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 October 2015, we entered into forward starting swaps with effective dates in September 2017 and maturing in ten years.

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.

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes and also terminated the hedging relationship by settling certain of those swap contracts during 2014 and 2015. The settlement of swap contracts resulted in the receipt of net proceeds of $7.7 million and $15.3 million during the nine-month periods ended September 30, 2015 and 2014, respectively, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 for additional details related to reductions of current and future interest expense.

The following table summarizes the notional amounts of our outstanding swap contracts at September 30, 2015 and December 31, 2014:

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	Notional Amount	
	September 30, 2015	December 31, 2014
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
2.450% senior notes due 2015	$300.0	$300.0
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	750.0
4.000% senior notes due 2023	700.0	150.0
3.625% senior notes due 2024	100.0	—
Total	$3,600.0	$2,700.0

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 September 30, 2015 would have reduced the aggregate fair value of our net payable by $908.8 million. A one percentage point decrease at September 30, 2015 would have increased the aggregate fair value of our net payable by $1.067 billion.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

The following describes the 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.

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

Currently, our business is largely dependent on the commercial success of REVLIMID®, VIDAZA®, THALOMID®, ABRAXANE®, POMALYST®/IMNOVID® and OTEZLA®. 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 for 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.

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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®, 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® and POMALYST®/IMNOVID®, that receive accelerated approval can be subject to an expedited withdrawal if post-marketing restrictions are not adhered to or are shown to be inadequate to assure safe use, or if the drug is shown to be unsafe or ineffective under its conditions of use;
- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our approved products;
- Approved products, as well as their manufacturers, are subject to continuing and ongoing review by regulatory agencies, and the discovery of previously unknown problems with these products or the failure to comply with manufacturing or quality control requirements may result in restrictions on the manufacture, sale or use of a product or its withdrawal from the market; and
- Changes in regulatory agency policy or the adoption of new regulations or legislation could impose restrictions on the sale of our approved products.

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

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

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

- protection of the environment, privacy, healthcare reimbursement programs, and competition;

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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.

The FDA's Center for Biologics Evaluation and Research currently regulates human tissue or cells intended for transplantation, implantation, infusion or transfer to a human, requiring, among other things, cell and tissue establishments to screen and test donors, prepare and follow written procedures for the prevention of the spread of communicable disease and register with FDA. Through our Celgene Cellular Therapeutics (CCT) subsidiary, we are licensed in certain states to operate our allogeneic and private stem cell banking businesses. If we are unable to maintain those licenses or are unable to obtain licenses in other states that may adopt similar licensing requirements, those businesses could be adversely affected.

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 imposed upon 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 on March 23, 2010 and March 30, 2010, respectively, 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 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

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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 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 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, see "Legal Proceedings" contained elsewhere in this report.

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

Our intellectual property rights may be affected 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, new 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 Celgene's 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 Celgene's patent US 5,635,517. We cannot predict whether any other Celgene patents will ever become the subject of a post grant review. For more information with respect to the recently instituted IPRs, see Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report. A procedure similar to the IPR has existed in Europe for many years. Celgene has occasionally defended its European patents in such proceedings. For example, the validity of Celgene's patent EP 1 667 682 is currently the subject of an opposition proceeding before the EPO. 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" (the “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. While it is difficult to predict how the EMA will interpret and apply the Clinical Data Policy, any public disclosure of our trade secrets or other confidential and proprietary information may adversely impact our patent rights and our competitive advantage in the marketplace.

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Also, different countries have different procedures for obtaining patents and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. 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 United States Patent and Trademark Office 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 from 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, see "Legal Proceedings" contained elsewhere in this report.

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

Our business operates in an extremely competitive environment.

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

- Hematology and Oncology: AbbVie, Amgen, AstraZeneca, Bristol-Myers-Squibb, Eisai, Gilead, Johnson & Johnson, 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

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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. For more information relating to governmental investigations and other legal proceedings, see "Legal Proceedings" contained elsewhere in this report.

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.

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

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the process used to manufacture the product candidate;

- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

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.

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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 Receptos acquisition, 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;

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- 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.

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, payors, 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. Although we purchase product liability coverage from third-party carriers, it is increasingly difficult and costly to obtain. There can be no assurance that we will be able to recover under any insurance policy or that such coverage will be adequate to fully cover all risks or damage awards or settlements. 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.

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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 investment.

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;

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- 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 could subject us to liability 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.

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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.

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

(c) Issuer Purchases of Equity Securities

From April 2009 through September 2015, 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 September 30, 2015, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs
July 1 - July 31	1,280,427	$124.88	1,280,427	$4,952,353,338
August 1 - August 31	613,599	$118.19	613,599	$4,879,829,838
September 1 - September 30	5,205,100	$111.90	5,205,100	$4,297,382,026
Total	7,099,126	$114.79	7,099,126	

During the three-month period ended September 30, 2015, we purchased 7.1 million shares of common stock under the share repurchase program at a cost of $814.9 million, excluding commissions. As of September 30, 2015, we had a remaining purchase authorization of $4.297 billion.

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

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Item 6. Exhibits

3.1	Amendment to the By-Laws of Celgene Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 19, 2015).
3.2*	By-Laws of Celgene Corporation
10.1	Revolving Credit Agreement Between Celgene Corporation and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 19, 2015).
31.1*	Certification by the Company's Chief Executive Officer.
31.2*	Certification by the Company's Chief Financial Officer.
32.1*	Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2*	Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101*	The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) Notes to Unaudited Consolidated Financial Statements.

* Filed herewith.

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SIGNATURE

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

CELGENE CORPORATION

Date:	November 5, 2015	By:	/s/Peter N. Kellogg Peter N. Kellogg Executive Vice President and Chief Financial Officer (principal financial and accounting officer)