

CELGENE CORP /DE/  
Form 10-Q  
October 28, 2014  
Table of Contents

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

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended September 30, 2014

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

(State or other jurisdiction of incorporation or organization)

22-2711928

(I.R.S. Employer Identification Number)

86 Morris Avenue, Summit, NJ

(Address of principal executive offices)

07901

(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 21, 2014, 798,704,188 shares of Common Stock, par value \$.01 per share, were outstanding, reflecting the two-for-one Common Stock split effected in June 2014.

---

---

Table of Contents

CELGENE CORPORATION

FORM 10-Q TABLE OF CONTENTS

	Page No.
<u>PART I</u>	<u>FINANCIAL INFORMATION</u>
<u>Item 1</u>	<u>Financial Statements (unaudited)</u>
	<u>Consolidated Statements of Income - Three-Month and Nine-Month Periods Ended September 30, 2014 and 2013</u>
	<u>3</u>
	<u>Consolidated Statements of Comprehensive Income - Three-Month and Nine-Month Periods Ended September 30, 2014 and 2013</u>
	<u>4</u>
	<u>Consolidated Balance Sheets - As of September 30, 2014 and December 31, 2013</u>
	<u>5</u>
	<u>Consolidated Statements of Cash Flows - Nine-Month Periods Ended September 30, 2014 and 2013</u>
	<u>6</u>
	<u>Notes to Unaudited Consolidated Financial Statements</u>
	<u>8</u>
<u>Item 2</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	<u>32</u>
<u>Item 3</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	<u>51</u>
<u>Item 4</u>	<u>Controls and Procedures</u>
	<u>54</u>
<u>PART II</u>	<u>OTHER INFORMATION</u>
<u>Item 1</u>	<u>Legal Proceedings</u>
	<u>56</u>
<u>Item 1A</u>	<u>Risk Factors</u>
	<u>56</u>
<u>Item 2</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	<u>66</u>
<u>Item 6</u>	<u>Exhibits</u>
	<u>68</u>
<u>Signature</u>	<u>69</u>

Table of Contents

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited)

CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(In millions, except per share amounts)

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenue:				
Net product sales	\$1,956.8	\$1,644.0	\$5,508.9	\$4,637.4
Collaborative agreements and other revenue	2.2	2.2	6.8	12.4
Royalty revenue	23.2	28.2	69.2	88.2
Total revenue	1,982.2	1,674.4	5,584.9	4,738.0
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	97.7	86.2	282.7	247.6
Research and development	675.1	584.5	1,845.7	1,495.0
Selling, general and administrative	497.6	448.7	1,483.5	1,235.8
Amortization of acquired intangible assets	63.7	65.7	194.7	197.1
Acquisition related charges, net	1.5	33.7	11.0	79.4
Total costs and expenses	1,335.6	1,218.8	3,817.6	3,254.9
Operating income	646.6	455.6	1,767.3	1,483.1
Other income and (expense):				
Interest and investment income, net	6.9	5.3	20.6	14.6
Interest (expense)	(53.5)	) (24.0)	) (124.4)	) (61.5)
Other income (expense), net	(22.5)	) 5.1	(46.9)	) 12.0
Income before income taxes	577.5	442.0	1,616.6	1,448.2
Income tax provision	69.0	69.5	230.6	212.7
Net income	\$508.5	\$372.5	\$1,386.0	\$1,235.5
Net income per common share (Note1):				
Basic	\$0.64	\$0.45	\$1.72	\$1.49
Diluted	\$0.61	\$0.43	\$1.66	\$1.43
Weighted average shares (Note 1):				
Basic	799.6	824.5	803.5	829.5
Diluted	832.8	857.7	836.4	861.0

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(Dollars in millions)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
Net income	\$508.5	\$372.5	\$1,386.0	\$1,235.5
Other comprehensive income (loss):				
Foreign currency translation adjustments	(36.6 )	17.9	(32.5 )	22.0
Net unrealized gains (losses) related to cash flow hedges:				
Unrealized holding gains (losses)	382.8	(89.8 )	342.5	(3.2 )
Tax (expense) benefit	—	0.2	12.6	—
Unrealized holding gains (losses), net of tax	382.8	(89.6 )	355.1	(3.2 )
Reclassification adjustment for (gains) losses included in net income	(0.1 )	(11.1 )	4.8	(5.1 )
Tax expense (benefit)	(0.5 )	(0.3 )	(1.2 )	(6.5 )
Reclassification adjustment for (gains) losses included in net income, net of tax	(0.6 )	(11.4 )	3.6	(11.6 )
Net unrealized gains (losses) on marketable securities available for sale:				
Unrealized holding gains (losses)	64.6	163.1	196.9	216.0
Tax (expense) benefit	(22.2 )	(58.5 )	(67.3 )	(78.4 )
Unrealized holding gains (losses), net of tax	42.4	104.6	129.6	137.6
Reclassification adjustment for (gains) losses included in net income	1.2	3.0	4.2	6.2
Tax expense (benefit)	(0.4 )	(0.8 )	(1.5 )	(1.8 )
Reclassification adjustment for (gains) losses included in net income, net of tax	0.8	2.2	2.7	4.4
Total other comprehensive income (loss)	388.8	23.7	458.5	149.2
Comprehensive income	\$897.3	\$396.2	\$1,844.5	\$1,384.7

See accompanying Notes to Unaudited Consolidated Financial Statements

Table of Contents

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

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$3,742.5	\$3,234.4
Marketable securities available for sale	3,118.2	2,452.6
Accounts receivable, net of allowances of \$36.0 and \$40.0 at September 30, 2014 and December 31, 2013, respectively	1,068.1	1,061.4
Inventory	372.0	340.4
Deferred income taxes	25.9	25.3
Other current assets	509.4	436.4
Total current assets	8,836.1	7,550.5
Property, plant and equipment, net	623.6	593.4
Intangible assets, net	4,131.9	2,839.7
Goodwill	2,191.2	2,041.2
Other assets	620.5	353.4
Total assets	\$16,403.3	\$13,378.2
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings	\$100.0	\$544.8
Accounts payable	196.7	156.2
Accrued expenses	904.2	1,001.1
Income taxes payable	14.6	16.0
Current portion of deferred revenue	33.6	27.7
Other current liabilities	148.4	199.7
Total current liabilities	1,397.5	1,945.5
Deferred revenue, net of current portion	28.2	23.7
Income taxes payable	264.2	235.0
Deferred income taxes	615.1	804.9
Other non-current liabilities	1,592.6	582.7
Long-term debt, net of discount	6,737.3	4,196.5
Total liabilities	10,634.9	7,788.3
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding at September 30, 2014 and December 31, 2013, respectively	—	—
Common stock, \$.01 par value per share, 1,150.0 million shares authorized; issued 918.9 million and 906.5 million shares at September 30, 2014 and December 31, 2013, respectively (Note 1)	9.2	9.1
Common stock in treasury, at cost; 118.7 million and 101.5 million shares at September 30, 2014 and December 31, 2013, respectively (Note 1)	(10,091.7	) (7,662.1
Additional paid-in capital (Note 1)	9,439.9	8,676.4
Retained earnings	5,858.5	4,472.5
Accumulated other comprehensive income	552.5	94.0

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Total stockholders' equity	5,768.4	5,589.9
Total liabilities and stockholders' equity	\$16,403.3	\$13,378.2

See accompanying Notes to Unaudited Consolidated Financial Statements

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in millions)

	Nine-Month Periods Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net income	\$ 1,386.0	\$ 1,235.5
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	78.1	71.8
Amortization	203.3	205.0
Deferred income taxes	(248.6	) (161.5
Impairment charges	133.2	18.8
Change in value of contingent consideration	11.0	79.5
Share-based compensation expense	319.2	227.4
Share-based employee benefit plan expense	29.3	25.2
Reclassification adjustment for cash flow hedges included in net income	4.8	(5.1
Unrealized change in value of derivative instruments	(27.8	) 10.8
Other, net	0.7	14.4
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(46.0	) (138.7
Inventory	(33.6	) (62.6
Other operating assets	55.7	(49.7
Accounts payable and other operating liabilities	74.3	150.7
Income tax payable	27.7	22.0
Payment of contingent consideration	(5.0	) —
Deferred revenue	11.4	31.7
Net cash provided by operating activities	1,973.7	1,675.2
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	1,662.2	1,936.2
Purchases of marketable securities available for sale	(2,137.0	) (3,237.3
Payments for acquisition of business	(710.0	) —
Purchases of intellectual property and other assets	(21.0	) (19.4
Capital expenditures	(100.9	) (93.1
Purchases of investment securities	(58.4	) (27.9
Other investing activities	—	(1.9
Net cash used in investing activities	(1,365.1	) (1,443.4
Cash flows from financing activities:		
Payment for treasury shares	(2,433.8	) (2,068.0
Proceeds from short-term borrowing	2,436.9	3,761.0
Principal repayments on short-term borrowing	(2,881.9	) (3,665.9
Proceeds from issuance of long-term debt	2,470.6	1,479.6
Proceeds from sale of common equity put options	5.8	—
Payment of contingent consideration	(15.0	) —
Net proceeds from share-based compensation arrangements	205.1	458.0
Excess tax benefit from share-based compensation arrangements	146.4	139.0
Net cash (used in) provided by financing activities	(65.9	) 103.7
Effect of currency rate changes on cash and cash equivalents	(34.6	) (2.9



Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Net increase in cash and cash equivalents	508.1	332.6
Cash and cash equivalents at beginning of period	3,234.4	2,090.4
Cash and cash equivalents at end of period	\$3,742.5	\$2,423.0

See accompanying Notes to Unaudited Consolidated Financial Statements

6

---

Table of Contents

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

	Nine-Month Periods Ended September 30,	
	2014	2013
Supplemental schedule of non-cash investing and financing activity:		
Acquisition date fair value of contingent consideration issued in business combinations	\$ 1,060.0	\$—
Change in net unrealized (gain) loss on marketable securities available for sale	\$(196.9 )	\$(216.2 )
Investment in NantBioScience, Inc. preferred equity	\$90.0	\$—
Supplemental disclosure of cash flow information:		
Interest paid	\$ 126.2	\$ 67.4
Income taxes paid	\$ 275.0	\$ 226.2

See accompanying Notes to Unaudited Consolidated Financial Statements

Table of Contents

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 a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development designed to bring new therapies to market and are involved in research in several scientific areas designed to deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmune diseases and therapeutic application of cell therapies.

Our primary commercial stage products include REVLIMID<sup>®</sup>, ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, VIDAZA<sup>®</sup>, azacitidine for injection (generic version of VIDAZA<sup>®</sup>), THALOMID<sup>®</sup> (inclusive of Thalidomide Celgene<sup>™</sup>), OTEZLA<sup>®</sup> and ISTODAX<sup>®</sup>. OTEZLA<sup>®</sup> 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. We began recognizing revenue related to OTEZLA<sup>®</sup> during the second quarter of 2014.

Additional sources of revenue include royalties from Novartis Pharma AG (Novartis) on their sales of FOCALIN XR<sup>®</sup> and the entire RITALIN<sup>®</sup> family of drugs, the sale of products and services through our Celgene Cellular Therapeutics (CCT) subsidiary and other licensing agreements.

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.

In June 2014, our stockholders voted to approve an amendment to our Certificate of Incorporation that increased the number of shares of common stock that we are authorized to issue and effected a two-for-one stock split of outstanding shares (Stock Split). As a result, our total number of authorized shares of common stock increased from 575.0 million to 1.150 billion on June 18, 2014. Stockholders of record received one additional share of common stock for each share of common stock owned. All impacted share numbers and per share amounts presented in the accompanying consolidated financial statements and the accompanying notes to the financial statements have been restated to reflect the impact of the Stock Split. Common stock held in treasury was not adjusted for the Stock Split.

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, 2013 (2013 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.

8

---

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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 2017 using one of two prescribed transition methods. Early adoption is not permitted. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

## 3. Acquisition

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. A phase II trial of GED-0301 in patients with active Crohn's disease has been completed and we plan to initiate the phase III program for the use of GED-0301 in Crohn's disease before year-end 2014.

Under the terms of the agreement, which became effective on May 14, 2014 after receipt of certain governmental clearances and approvals, 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.

The development and application of the intellectual property covered under the license agreement will be managed by joint committees composed of members from each of Nogra and us. We have the tie-breaking vote on the joint steering committee and as such have ultimate decision-making authority for development, regulatory and commercialization decisions. The agreement also includes provisions for access to employees of Nogra, technical assistance, transfer of manufacturing agreements and transfer of Nogra know-how related to GED-0301. Based on the foregoing factors, for accounting purposes, we have concluded that the acquired assets meet the definition of a business and have accounted for the GED-0301 license as in-process research and development (IPR&D) acquired in a business combination. The acquisition method of accounting requires that (a) the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and (b) the fair value of IPR&D be classified as an indefinite-lived asset until the successful completion or abandonment of the associated research and development efforts. Pro-forma results of operations for this acquisition have not been presented because this acquisition is not material to our consolidated results of operations.

The fair value of consideration transferred to acquire the license amounted to:

	Fair Value at the Acquisition Date
Cash	\$710.0
Contingent consideration	1,060.0
Total fair value of consideration transferred	\$1,770.0

Our potential contingent consideration payments are classified as liabilities, which were measured at fair value as of the acquisition date, with \$5.0 million classified as current liabilities and \$1.055 billion classified as non-current liabilities. We estimated the fair value of potential contingent consideration using a probability-weighted income approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant inputs that are not observable in the market and thus represents a level three liability within the fair value hierarchy. The resulting probability weighted cash flows were discounted using a discount rate based on a market participant assumption.



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The purchase price allocation resulted in the following amounts being allocated to the assets acquired at the acquisition date based on their respective fair values:

	Fair Value at the Acquisition Date
In-process research and development product rights	\$1,620.0
Current deferred tax asset	1.3
Non-current deferred tax liability	(1.3
Total identifiable net assets	1,620.0
Goodwill	150.0
Total net assets acquired	\$1,770.0

The fair value of the acquired IPR&D asset was based on the present value of expected net cash flows from the GED-0301 product candidate. Net cash flows were determined by estimating future sales, net of the costs to complete development of GED-0301 into a commercially viable product. Estimated net cash flows were adjusted to reflect the probability of successfully developing a new drug from a product candidate that has completed a phase II trial. Additionally, the projections considered the relevant market sizes and growth factors and the nature and expected timing of a new product introduction. The resulting net cash flows from such potential products include our estimates of cost of sales, operating expenses, and income taxes. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the project and uncertainties in the economic estimates used in the projections described above. The acquired IPR&D asset is accounted for as an indefinite-lived intangible asset until regulatory approval in a major market or discontinuation.

The excess of purchase price over the fair value amounts assigned to the assets acquired represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is largely attributable to intangible assets that do not qualify for separate recognition. We expect this goodwill to be deductible for tax purposes.

The license agreement may be terminated (i) at our discretion upon 180 days' written notice to Nogra, provided that such termination will not become effective before May 14, 2017, and (ii) by either party upon material breach of the other party, subject to cure periods. Upon the expiration of our royalty payment obligations under the license agreement, on a country-by-country and licensed product-by-licensed product basis, the license granted under the license agreement will become fully paid-up, irrevocable, perpetual, and non-terminable with respect to such licensed product in such country.

## 4. Earnings Per Share (Note 1)

(Amounts in millions, except per share)	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
Net income	\$508.5	\$372.5	\$1,386.0	\$1,235.5
Weighted-average shares:				
Basic	799.6	824.5	803.5	829.5
Effect of dilutive securities:				
Options, restricted stock units and other incentives	33.2	33.2	32.9	31.5
Diluted	832.8	857.7	836.4	861.0
Net income per share:				
Basic	\$0.64	\$0.45	\$1.72	\$1.49

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Diluted	\$0.61	\$0.43	\$1.66	\$1.43
---------	--------	--------	--------	--------

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 13.7 million and 8.2 million shares for the three-month periods ended September 30, 2014 and 2013, respectively. The total number of potential shares of common stock excluded was 17.9 million and 10.2 million shares for the nine-month periods ended September 30, 2014 and 2013, respectively.



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Share Repurchase Program: In April 2014, 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 \$13.500 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 period ended September 30, 2014, we sold put options on \$200.0 million notional amount of shares of our common stock, which expired unexercised in September 2014, and recorded a gain from the premium of \$3.6 million, which was recorded on the Consolidated Statements of Income in other income (expense), net. During the nine-month period ended September 30, 2014, we recorded a net gain of \$9.9 million from selling put options on our common stock. At September 30, 2014, we had no outstanding put options.

We have purchased 2.8 million and 16.7 million shares of common stock under the share repurchase program from all sources at a total cost of \$251.6 million and \$2.388 billion during the three- and nine-month periods ended September 30, 2014, respectively. As of September 30, 2014, we had a remaining share repurchase authorization of \$3.680 billion.

## 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, 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
Balance December 31, 2012	\$(10.1 )	\$4.2	\$(16.0 )	\$(27.8)	\$(49.7 )
	—	137.6	(3.2)	22.0	156.4

Other comprehensive income (loss) before reclassifications					
Amounts reclassified from accumulated other comprehensive income	—	4.4	(11.6	) —	(7.2 )
Net current-period other comprehensive income (loss)	—	142.0	(14.8	) 22.0	149.2
Balance September 30, 2013	\$(10.1	) \$146.2	\$(30.8	) \$(5.8	) \$99.5

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Accumulated Other Comprehensive Income Components	Affected Line Item in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2014	2013	2014	2013
Gains (losses) from cash-flow hedges:					
Foreign exchange contracts	Net product sales	\$ 1.3	\$ 12.0	\$(1.7	) \$7.6
Treasury rate lock agreements	Interest (expense)	(0.9	) (0.9	) (2.6	) (2.5
	Income tax benefit (expense)	—	0.3	—	6.5
Interest rate swap agreements	Interest (expense)	(0.3	) —	(0.5	) —
	Income tax benefit (expense)	0.5	—	1.2	—
Gains (losses) from available-for-sale marketable securities:					
Realized income (loss) on sales of marketable securities	Interest and investment income, net	(1.2	) (3.0	) (4.2	) (6.2
	Income tax benefit (expense)	0.4	0.8	1.5	1.8
Total reclassification, net of tax		\$(0.2	) \$9.2	\$(6.3	) \$7.2

## 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, 2014 and the valuation techniques we utilized to determine such fair value. Fair values determined based on Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of marketable equity securities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Our Level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities (MBS), non-U.S. government, agency and Supranational securities, global corporate debt securities, asset backed securities, foreign currency forward contracts and interest rate swap contracts. Fair values determined based on 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 1 liability relates to our publicly traded contingent value rights (CVRs). See Note 18 of Notes to Consolidated Financial Statements included in our 2013 Annual Report on Form 10-K for a description of the CVRs. Our Level 2 liabilities relate to foreign currency forward contracts and interest rate swap contracts. Our Level 3 liabilities consist of contingent consideration related to undeveloped product rights resulting from the acquisition of Gloucester Pharmaceuticals, Inc. (Gloucester), contingent consideration related to the undeveloped product rights and the technology platform acquired from the Avila Therapeutics, Inc. (Avila) acquisition, and contingent consideration related to undeveloped product rights, regulatory and sales milestones as well as tiered royalties on sales of licensed products resulting from the acquisition of Nogra. 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 \$575.0 million, respectively, and \$1.865 billion plus amounts based on sales pursuant to the

license agreement with Nogra.

12

---

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

	Balance at September 30, 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	\$3,118.2	\$717.6	\$2,400.6	\$—
Forward currency contracts	369.2	—	369.2	—
Total assets	\$3,487.4	\$717.6	\$2,769.8	\$—
Liabilities:				
Contingent value rights	\$(146.7)	\$(146.7)	\$—	\$—
Interest rate swaps	(10.3)	—	(10.3)	—
Other acquisition related contingent consideration	(1,250.9)	—	—	(1,250.9)
Total liabilities	\$(1,407.9)	\$(146.7)	\$(10.3)	\$(1,250.9)

	Balance at December 31, 2013	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	\$2,452.6	\$433.1	\$2,019.5	\$—
Cash equivalents	20.0	—	20.0	—
Total assets	\$2,472.6	\$433.1	\$2,039.5	\$—
Liabilities:				
Forward currency contracts	\$(9.2)	\$—	\$(9.2)	\$—
Contingent value rights	(118.1)	(118.1)	—	—
Interest rate swaps	(49.6)	—	(49.6)	—
Other acquisition related contingent consideration	(228.5)	—	—	(228.5)
Total liabilities	\$(405.4)	\$(118.1)	\$(58.8)	\$(228.5)

There were no security transfers between Levels 1 and 2 during the nine-month periods ended September 30, 2014 and 2013. The following table represents a roll-forward of the fair value of Level 3 instruments:

	Nine-Month Periods Ended September 30,	
	2014	2013
Liabilities:		
Balance at beginning of period	\$ (228.5)	\$(198.1)
Amounts acquired or issued	(1,060.0)	—
Net change in fair value	17.6	(8.9)
Settlements	20.0	—
Transfers in and/or out of Level 3	—	—
Balance at end of period	\$ (1,250.9)	\$(207.0)

Level 3 liabilities outstanding as of September 30, 2014 primarily consisted of contingent consideration related to the acquisitions of Avila and Nogra. The \$1.022 billion net increase in the fair value of Level 3 liabilities in 2014 included \$1.060 billion from the May 2014 acquisition of Nogra, offset slightly by a \$20.0 million milestone payment related to our acquisition of Avila. The \$17.6 million net reduction in fair value of our Level 3 liabilities during the nine-month period ended September 30, 2014 included a \$58.0 million reduction in the fair value of our contingent consideration payable to the former shareholders of Avila due to an adjustment to the probability weighted forecasted cash flows related to CC-292 compared to prior estimates. Changes to the fair value of contingent consideration are recorded on the Consolidated Statements of Income as acquisition related charges, net. The adjustment to the probability weighted forecasted cash flows related to CC-292 also resulted in a reduction in the value of the IPR&D asset recorded in the purchase of Avila (see Note 10).

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

## 7. Derivative Instruments and Hedging Activities

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

## Foreign Currency Risk Management

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

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically within the next three years. 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 to 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, 2014 and December 31, 2013 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 (loss) (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. If a hedging relationship is terminated with respect to a foreign currency forward contract, accumulated gains or losses associated with the contract remain in OCI until the hedged forecasted transaction occurs and are reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in other income (expense), net. The forward point components of these foreign currency forward contracts are not designated as cash flow hedges and all fair value adjustments of forward point amounts are recorded to other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2014 and December 31, 2013:

Foreign Currency	Notional Amount	
	September 30, 2014	December 31, 2013
Australian Dollar	\$ 19.7	\$—

British Pound	360.8	279.4
Canadian Dollar	79.9	—
Euro	3,437.7	3,318.2
Japanese Yen	567.8	559.1
Total	\$4,465.9	\$4,156.7

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, 2014, credit risk did not materially change the fair value of our foreign currency forward contracts.



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

We also manage a portfolio of foreign currency contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies and, from time to time, we enter into foreign currency contracts to manage exposure related to translation of foreign earnings. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2014 and December 31, 2013 were \$897.2 million and \$878.5 million, respectively.

## 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:** In anticipation of issuing debt in 2014, we entered into an aggregate notional value of \$1.500 billion in forward starting swaps that were designated as cash flow hedges. In April 2014 we accelerated our planned debt issuance date, which resulted in hedge ineffectiveness in the forward starting swaps and a \$3.6 million charge to other income (expense), net due to differences between the effective date of the swaps and the accelerated debt issuance date. In addition, all forward starting swaps were settled upon the issuance of debt in May 2014 when the net fair value of the forward starting swaps in accumulated OCI was a loss position of \$25.9 million. The net loss of \$25.9 million will be recognized as interest expense over the life of the associated senior notes. There were no forward starting swaps outstanding as of September 30, 2014.

**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 2013 and 2014. The settlement of swap contracts resulted in the receipt of net proceeds of \$15.3 million and \$21.9 million during the nine-month periods ended September 30, 2014 and 2013, 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, 2014 and December 31, 2013:

Notional Amount

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

	September 30, 2014	December 31, 2013
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	350.0	—
3.950% senior notes due 2020	500.0	500.0
3.250% senior notes due 2022	850.0	850.0
4.000% senior notes due 2023	100.0	150.0
Total	\$2,600.0	\$2,300.0

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The following tables summarize the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of September 30, 2014 and December 31, 2013:

Instrument	September 30, 2014		Liability Derivatives	
	Asset Derivatives Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
	Other current assets	\$ 168.6	Other current assets	\$41.1
	Other current liabilities	—	Other current liabilities	0.2
Foreign exchange contracts*	Other non-current assets	213.6	Other non-current assets	8.4
	Other non-current liabilities	0.1	Other non-current liabilities	0.7
Interest rate swap agreements	Other current assets	15.8	Other current assets	—
	Other non-current liabilities	—	Other non-current liabilities	27.5
Derivatives not designated as hedging instruments:				
Foreign exchange contracts*	Other current assets	48.9	Other current assets	6.6
	Other current liabilities	1.4	Other current liabilities	6.4
Interest rate swap agreements	Other non-current assets	1.4	Other non-current assets	—
Total		\$449.8		\$90.9
Instrument	December 31, 2013		Liability Derivatives	
	Asset Derivatives Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
	Other current assets	\$63.6	Other current assets	\$24.9
	Other current liabilities	41.5	Other current liabilities	84.7
Foreign exchange contracts*	Other non-current assets	60.6	Other non-current assets	41.9
	Other non-current liabilities	4.3	Other non-current liabilities	25.6
Interest rate swap agreements	Other current assets	17.1	Other current assets	—
	Other non-current liabilities	—	Other non-current liabilities	68.3
Derivatives not designated as hedging instruments:				
Foreign exchange contracts*	Other current assets	11.3	Other current assets	0.7
	Other current liabilities	6.0	Other current liabilities	18.7
Interest rate swap agreements	Other current assets	0.1	Other current assets	—
	Other non-current assets	1.5	Other non-current assets	—
Total		\$206.0		\$264.8

\* 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.

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The following tables summarize the effect of derivative instruments designated as cash-flow hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2014 and 2013:

Instrument	Three-Month Period Ended September 30, 2014				
	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 (Ineffective Portion and Amount Excluded From Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)
Foreign exchange contracts	\$382.8	Net product sales	\$1.3	Other income, net	\$(16.4) (2)
Treasury rate lock agreements	\$—	Interest expense	\$(0.9)		
Interest rate swap agreements	\$—	Interest expense	\$(0.3)		

(1) Net gains of \$132.0 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) 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.

Instrument	Three-Month Period Ended September 30, 2013				
	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 (Ineffective Portion and Amount Excluded From Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)
	\$(89.8)	) Net product sales	\$11.9	Other income, net	\$5.1 (1)

Foreign  
exchange  
contracts

Treasury rate \$— Interest expense \$(0.9 )  
lock agreements

(1) The amount of net gains recognized in income represents \$5.3 million of gains related to amounts excluded from the assessment of hedge effectiveness and \$0.2 million of losses related to the ineffective portion of the hedging relationships.

Instrument	Nine-Month Period Ended September 30, 2014				
	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 (Ineffective Portion and Amount Excluded From Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)
Foreign exchange contracts	\$374.9	Net product sales	\$(1.7 )	Other income, net	\$(19.2 ) (2 )
Treasury rate lock agreements	\$—	Interest expense	\$(2.6 )		
Interest rate swap agreements	\$(32.4 )	Interest expense	\$(0.5 )	Other income, net	\$(3.6 ) (3)

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

(1) Net gains of \$132.0 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) 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.

(3) The amount of net loss recognized in income relates to the ineffective portion of the hedging relationships.

Nine-Month Period Ended September 30, 2013						
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative (Effective Portion)	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income (Effective Portion)	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income (Effective Portion)	Location of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)	
Foreign exchange contracts	\$ (3.2)	) Net product sales	\$ 7.6	Other income, net	\$ 9.0	(1 )
Treasury rate lock agreements	\$ —	Interest expense	\$ (2.5)	)		

(1) The amount of net gains recognized in income represents \$7.3 million of gains related to amounts excluded from the assessment of hedge effectiveness and \$1.7 million in gains related to the ineffective portion of the hedging relationships.

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2014 and 2013:

Instrument	Location of Gain (Loss) Recognized in Income on Derivative	Amount of Gain (Loss) Recognized in Income on Derivative			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2014	2013	2014	2013
Interest rate swap agreements	Interest expense	\$ 10.3	\$ 9.8	\$ 31.2	\$ 21.8

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2014 and 2013:

Amount of Gain (Loss) Recognized in Income on Derivative

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Instrument	Location of Gain (Loss) Recognized in Income on	Three-Month Periods		Nine-Month Periods	
		Ended September 30,		Ended September 30,	
	Derivative	2014	2013	2014	2013
Foreign exchange contracts	Other income (expense), net	\$55.4	\$(27.0 )	\$44.3	\$(42.2 )
Put options on our common stock	Other income (expense), net	\$3.6	\$—	\$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 Income in other income (expense), net for all periods presented. When we enter into foreign exchange contracts not designated as hedging instruments to mitigate the impact of exchange rate volatility in the translation of foreign earnings, gains and losses will generally be offset by fluctuations in the U.S. Dollar translated amounts of each Income Statement account in current and/or future periods.



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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

Money market funds of \$2.285 billion and \$1.697 billion at September 30, 2014 and December 31, 2013, 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, 2014 and December 31, 2013 were as follows:

September 30, 2014	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$1,012.8	\$0.4	\$(0.7)	) \$1,012.5
U.S. government-sponsored agency securities	195.5	0.2	(0.2)	) 195.5
U.S. government-sponsored agency MBS	556.4	0.7	(3.6)	) 553.5
Non-U.S. government, agency and Supranational securities	19.9	—	(0.1)	) 19.8
Corporate debt - global	438.8	1.1	(0.6)	) 439.3
Asset backed securities	180.2	—	(0.2)	) 180.0
Marketable equity securities	299.9	418.2	(0.5)	) 717.6
Total available-for-sale marketable securities	\$2,703.5	\$420.6	\$(5.9)	) \$3,118.2
December 31, 2013	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$795.2	\$0.3	\$(0.4)	) \$795.1
U.S. government-sponsored agency securities	208.9	0.2	(0.2)	) 208.9
U.S. government-sponsored agency MBS	450.8	0.1	(6.9)	) 444.0
Non-U.S. government, agency and Supranational securities	10.4	—	—	) 10.4
Corporate debt - global	379.2	1.1	(0.6)	) 379.7
Asset backed securities	181.6	—	(0.2)	) 181.4
Marketable equity securities	212.9	220.2	—	) 433.1
Total available-for-sale marketable securities	\$2,239.0	\$221.9	\$(8.3)	) \$2,452.6

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 equity securities that have become publicly traded. The increase in net unrealized gains in marketable equity securities during the nine-month period ended September 30, 2014 primarily reflects the increase in market value for certain equity investments subsequent to December 31, 2013.

Duration periods of available-for-sale debt securities at September 30, 2014 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	\$438.1	\$438.6
Duration of one through three years	1,760.3	1,758.7
Duration of three through five years	205.2	203.3
Total	\$2,403.6	\$2,400.6

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

## 9. Inventory

A summary of inventories by major category at September 30, 2014 and December 31, 2013 follows:

	September 30, 2014	December 31, 2013
Raw materials	\$ 174.0	\$ 147.4
Work in process	114.4	99.6
Finished goods	83.6	93.4
Total	\$ 372.0	\$ 340.4

## 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 Nogra and Gloucester acquisitions. The remaining weighted-average amortization period for finite-lived intangible assets not fully amortized is approximately 11.3 years.

The following summary of intangible assets by category includes intangibles currently being amortized and intangibles not yet subject to amortization:

September 30, 2014	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$3,405.9	\$(1,183.1)	) \$2,222.8
Technology	333.7	(123.2)	) 210.5
Licenses	66.2	(17.0)	) 49.2
Other	42.6	(21.9)	) 20.7
	3,848.4	(1,345.2)	) 2,503.2
Non-amortized intangible assets:			
Acquired IPR&D product rights	1,628.7	—	1,628.7
Total intangible assets	\$5,477.1	\$(1,345.2)	) \$4,131.9
December 31, 2013	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:			
Acquired developed product rights	\$3,405.9	\$(1,026.4)	) \$2,379.5
Technology	333.7	(87.4)	) 246.3
Licenses	66.2	(13.9)	) 52.3
Other	42.5	(18.8)	) 23.7
	3,848.3	(1,146.5)	) 2,701.8
Non-amortized intangible assets:			
Acquired IPR&D product rights	137.9	—	137.9
Total intangible assets	\$3,986.2	\$(1,146.5)	) \$2,839.7

The \$1.491 billion increase in the gross carrying value of intangible assets during the nine-month period ended September 30, 2014 was primarily due to the addition of \$1.620 billion of IPR&D from the Nogra acquisition, partly offset by a \$129.2 million impairment charge recorded as research and development expense to write down the

IPR&D asset recorded for the CC-292 program due to an adjustment to the probability weighted forecasted cash flows related to CC-292 compared to prior estimates. The adjustment to the probability weighted forecasted cash flows related to CC-292 also resulted in a \$58.0 million reduction in the fair value of our contingent consideration payable to the former shareholders of Avila (see Note 6).

Amortization expense related to intangible assets was \$65.0 million and \$67.5 million for the three-month periods ended September 30, 2014 and 2013, respectively, and \$198.8 million and \$201.6 million for the nine-month periods ended September 30,

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

2014 and 2013, respectively. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for years 2014 through 2018 is estimated to be in the range of approximately \$255.0 million to \$265.0 million annually.

Goodwill: At September 30, 2014, our goodwill related to the April 2014 Nogra acquisition (see Note 3), 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 \$150.0 million to \$2.191 billion as of September 30, 2014 compared to December 31, 2013 due to the Nogra acquisition.

## 11. Debt

Senior Notes: Summarized below are the carrying values of our senior notes at September 30, 2014 and December 31, 2013:

	September 30, 2014	December 31, 2013
2.450% senior notes due 2015	\$508.2	\$513.9
1.900% senior notes due 2017	500.3	499.9
2.300% senior notes due 2018	400.1	399.0
2.250% senior notes due 2019	498.8	—
3.950% senior notes due 2020	495.4	484.6
3.250% senior notes due 2022	991.1	956.6
4.000% senior notes due 2023	704.0	696.3
3.625% senior notes due 2024	996.7	—
5.700% senior notes due 2040	249.6	249.6
5.250% senior notes due 2043	396.6	396.6
4.625% senior notes due 2044	996.5	—
Total long-term debt	\$6,737.3	\$4,196.5

At September 30, 2014, the fair value of our outstanding Senior Notes was \$6.866 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

In May 2014, we issued an additional \$2.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.250% Senior Notes due 2019 (the 2019 notes), \$1.000 billion aggregate principal amount of 3.625% Senior Notes due 2024 (the 2024 notes) and \$1.000 billion aggregate principal amount of 4.625% Senior Notes due 2044 (the 2044 notes and together with the 2019 notes and 2024 notes, referred to herein as the “2014 issued notes”). The 2014 issued notes were issued at 99.751%, 99.659% and 99.646% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$21.2 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 2014 issued notes is payable semi-annually in arrears on May 15 and November 15 each year beginning November 15, 2014 and the principal on each 2014 issued note is due in full at their respective maturity dates. The 2014 issued notes may be redeemed at our option, in whole or in part, at any time at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the 2014 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 10 basis points in the case of the 2019 notes, 15 basis points in the case of the 2024 notes and 20 basis points in the case of the 2044 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 2014 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, 2014, a balance of \$53.3 million in losses remained in OCI related to these derivative instruments and will be recognized as interest expense over the life of the notes.

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

At September 30, 2014, 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, 2014 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, 2014, we had a balance of \$32.7 million of unamortized gains recorded as a component of our debt as a result of past swap contract settlements, including \$8.8 million related to the settlement of swap contracts during the nine months ended September 30, 2014. As of December 31, 2013, we had a balance of \$32.1 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, 2014 and December 31, 2013 was \$100.0 million and \$544.8 million, respectively, and approximated its fair value. The effective interest rate on our outstanding Commercial Paper at September 30, 2014 was 0.3%.

Senior Unsecured Credit Facility: In September 2011, we entered into a senior unsecured revolving credit facility (Credit Facility) providing for revolving credit. The Credit Facility is currently at an aggregate maximum amount of \$1.500 billion with an expiration date of April 18, 2018. 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 \$1.750 billion.

Amounts may be borrowed under the Credit Facility for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of September 30, 2014 and December 31, 2013 there were no outstanding borrowings under the Credit Facility.

The Credit Facility contains affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of September 30, 2014.

## 12. Share-Based Compensation

We have a stockholder-approved stock incentive plan, the 2008 Stock Incentive Plan (amended and restated as of April 17, 2013 and as further amended on April 17, 2014) (Plan) which provides for the granting of options, restricted stock awards (RSUs), stock appreciation rights, performance awards (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.

On June 18, 2014, our stockholders approved an amendment of the Plan, which included the following key modifications: adoption of an aggregate share reserve of 228.0 million shares of Common Stock (after giving effect to the Stock Split), which includes 18.0 million new post-split shares of Common Stock; and an extension of the term of the Plan through April 16, 2024.

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2014 and 2013:

	Three-Month Periods Ended September 30,	Nine-Month Periods Ended September 30,
--	--	---

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

	2014	2013	2014	2013
Cost of goods sold (excluding amortization of acquired intangible assets)	\$6.8	\$6.1	\$18.8	\$12.6
Research and development	48.4	41.7	141.2	100.5
Selling, general and administrative	56.2	44.2	159.2	114.3
Total share-based compensation expense	111.4	92.0	319.2	227.4
Tax benefit related to share-based compensation expense	31.4	29.9	92.4	66.1
Reduction in income	\$80.0	\$62.1	\$226.8	\$161.3



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

We utilize share-based compensation in the form of stock options, RSUs and PSUs. The following table summarizes the activity for stock options, RSUs and PSUs for the nine-month period ended September 30, 2014 (in millions unless otherwise noted):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units (in thousands)
Outstanding at December 31, 2013	79.2	10.2	115
Changes during the Year:			
Granted	10.6	1.8	48
Exercised / Released	(9.6	) (2.2	) (24
Forfeited	(1.3	) (0.3	) (6
Outstanding at September 30, 2014	78.9	9.5	133

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, 2014 were as follows (dollars in millions):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Unrecognized compensation cost	\$500.3	\$277.8	\$6.3
Expected weighted-average period in years of compensation cost to be recognized	2.1	1.3	1.8

## 13. Income Taxes

We regularly evaluate the likelihood of the realization of our deferred tax assets and reduce the carrying amount of those deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of our deferred tax assets, including recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, the carryforward periods available to us for tax reporting purposes and other relevant factors. Significant judgment is required in making this assessment.

Our tax returns are under routine examination in many taxing jurisdictions. The scope of these examinations includes, but is not limited to, the review of our taxable presence in a jurisdiction, our deduction of certain items, our claims for research and development credits, our compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from our tax returns as filed. Our U.S. federal income tax returns have been audited by the Internal Revenue Service (IRS) through the year ended December 31, 2008. Tax returns for the years ended December 31, 2009, 2010 and 2011 are currently under examination by the IRS. We are also subject to audits by various state and foreign taxing authorities, including, 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, 2014 gross unrecognized tax benefits increased by \$29.2 million, primarily from

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

unrecognized tax benefits related to current year operations of \$31.9 million and accrued interest of \$5.0 million, partially offset by a net decrease in unrecognized tax benefits related to ongoing examinations and settlements of tax positions taken in prior years of \$7.7 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. 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

From time to time, 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, option payments for the purchase or license of additional rights, development, regulatory and commercial performance milestone payments, cost sharing arrangements, royalty payments and profit sharing. 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. We do not consider any of the following arrangements to be material. See Note 17 of Notes to Consolidated Financial Statements included in our 2013 Annual Report on Form 10-K for a description of certain other collaboration agreements entered into prior to January 1, 2014. 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, 2014:

**Sutro Biopharma, Inc. (Sutro):** In December 2012, we entered into a collaboration and license agreement with Sutro for the development of an antibody drug conjugate (ADC) and a bispecific antibody construct (BAC). Sutro controls and conducts initial development activities. We have the right to select one ADC among a number of different sequence-payload combinations and positional variants, and one BAC. Sutro will provide adequate quantities of any selected ADC and selected BAC to allow us to conduct all necessary preclinical studies, including toxicology and pharmacokinetics studies.

Under the terms of the 2012 agreement, Sutro received payments totaling \$35.0 million, which included an equity investment and other rights. In addition, the 2012 collaboration and license agreement includes certain development and regulatory milestones that could total up to \$204.0 million for a selected ADC if approved in multiple indications, and up to \$279.0 million for a selected BAC if approved in multiple indications, as well as tiered royalties based on annual net sales of licensed products.

In September 2014, we entered into a second collaboration and license agreement with Sutro to jointly develop up to six prioritized anti-cancer BACs and/or ADCs directed primarily to immune-oncology targets. Sutro will control and conduct initial development activities. We have the right to advance any BAC and/or ADC to investigational new drug (IND)-enabling studies or to designate it as a development candidate, and in either case, we would then have the sole right and responsibility for development activities, although Sutro would still have certain limited manufacturing and supply obligations.

Under the terms of the 2014 agreement, Sutro received payments totaling \$95.0 million, which includes an equity investment that increases our ownership to approximately 15%, rights with respect to manufacturing and supply of BAC and ADC development candidates, and an option to acquire all of the outstanding equity of Sutro based on a pre-specified valuation procedure. The option is exercisable beginning September 2016 and expires upon the termination of the research term (as extended).

For a future one-time payment, we have the right to obtain access to Sutro's proprietary protein expression platform to use in conjunction with our intellectual property. Additionally, we have the right to have Sutro evaluate the performance of certain monospecific ADCs directed against up to five non-natural amino acid targets, and reengineer, express, and provide antibodies which incorporate a single non-natural amino acid sequence in a number of preferred locations.

The research term of the collaboration and license agreement is three years, with an extension available for an additional one-and-a-half years for a payment of an additional fee. We have worldwide commercialization rights for development candidates in which at least one binding domain is directed to a certain undisclosed target, plus the first development candidate which does not include at least one binding domain directed to that certain undisclosed target but which achieves IND clearance in the U.S. For all other development candidates, Sutro has U.S. rights, while we have all ex-U.S. rights.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Under the terms of the 2014 agreement, Sutro is eligible to receive research and manufacturing milestones of up to \$75.0 million, clinical development and regulatory approval milestones of up to \$275.0 million for each compound selected under the collaboration if approved in multiple indications, as well as tiered royalties based on annual net sales of licensed products.

The collaboration and license agreement may be terminated by us for convenience on a program-by-program basis upon one hundred twenty (120) days prior written notice, or by either party for material breach, intellectual property challenge, or bankruptcy by the other party. With certain exceptions, the collaboration and license agreement expires in its entirety upon the expiration of all applicable royalty terms under the Agreement.

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 through the end of phase I clinical trials to license any potential products that result from the Agios cancer metabolism research platform.

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 sales, and Agios may also participate in the development and commercialization of certain products in the United States. Our option to license a product will terminate on April 14, 2015.

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 harbor an IDH2 mutation with advanced hematologic malignancies, including acute myeloid leukemia (AML).

FORMA Therapeutics Holdings, LLC (FORMA): On April 19, 2013, we entered into a collaboration agreement with FORMA under which the parties will 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 will 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 will be 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.

Under the collaboration, the parties will 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 will enter into a pre-negotiated license

agreement and the collaboration will continue 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, would expire 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. On October 7, 2013, we entered into the first ex-US license with FORMA and paid the applicable upfront payment under such 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 licensed drug candidate, we have the obligation to pay designated amounts when certain development, regulatory and sales milestone events occur, with such amounts being variable and contingent on various factors. With respect to each licensed drug candidate, we will assume responsibility for all global development activities and costs after completion of phase I clinical trials. FORMA will retain U.S. rights to all such licensed assets, including responsibility for manufacturing and commercialization.

Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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.

NantBioScience, Inc. (NantBioScience): In January 2014, we entered into a collaboration agreement with NantBioScience, an entity controlled by Dr. Patrick Soon-Shiong in which Celgene contributed \$75 million of cash, the rights to the future royalty stream based on net sales of certain products of Active Biomaterials, LLC, another entity controlled by Dr. Patrick Soon-Shiong, and licenses to two nab<sup>®</sup> product candidates. In return, Celgene received a 14 percent preferred equity ownership in NantBioScience, an option to license a certain number of product candidates developed by NantBioScience, including the two nab<sup>®</sup> product candidates that Celgene is licensing to NantBioScience, and the parent company of NantBioScience assumed, and agreed to pay and satisfy when due, our obligation to pay The Chan Soon-Shiong Institute for Advanced Health (CSS Institute) \$50.0 million in contingent, matching contributions. The transaction became effective in March 2014. Unless Celgene terminates the collaboration earlier, in Celgene's sole discretion upon 30 days written notice, the collaboration will continue until the earliest to occur of: (a) Celgene licensing four NantBioScience product candidates; (b) NantBioScience presenting data packages for ten product candidates; and (c) the date which is ten years after the effective date. Regardless of any termination of the collaboration, the 14 percent preferred equity ownership in NantBioScience and the assumption of the \$50.0 million in contingent, matching contributions by the parent company of NantBioScience remain in effect. We performed a valuation of the components of the transaction and allocated the consideration transferred as follows: \$50.0 million for the collaboration agreement upfront expense; \$25.0 million related to the settlement of contingent matching contributions, and; \$90.0 million related to the equity ownership in NantBioScience.

In addition to the collaboration arrangements described above, we entered into new collaborative arrangements during the nine months ended September 30, 2014 that include the potential for future milestone payments of up to an aggregate of \$52.5 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<sup>1,2</sup>:

		Three-Month Periods Ended September 30,				
		Research and Development Expense				
		Upfront Fees	Milestones	Amortization of Prepaid R&D and Intangibles	Selling, General and Administrative Expense	Equity Investments Made During Period
Acceleron	2014	\$—	\$—	\$—	\$—	\$—
	2013	—	—	—	—	10.0
Acetylon	2014	—	—	4.3	—	—
	2013	50.0	—	0.6	—	10.0
Agiost	2014	—	—	—	—	—
	2013	—	—	—	—	12.8
bluebird	2014	—	—	0.1	—	—
	2013	—	—	—	—	—
Morphosys	2014	—	—	—	—	—
	2013	94.3	—	—	—	61.3
Sutro <sup>(3)</sup>	2014	72.6	—	0.1	—	11.9
	2013	—	—	0.5	—	—
	2014	6.0	6.8	0.4	—	27.0

Other Collaboration  
Arrangements

2013	27.0	—	0.8	—	—
------	------	---	-----	---	---



Table of Contents

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

		Nine-Month Periods Ended September 30, Research and Development Expense				
		Upfront Fees	Milestones	Amortization of Prepaid R&D and Intangibles	Selling, General and Administrative Expense	Equity Investments Made During Period
Acceleron <sup>(4)</sup>	2014	\$—	\$—	\$—	\$—	\$52.4
	2013	—	10.0	—	—	10.0
Acetylon	2014	—	—	11.4	—	—
	2013	50.0	—	0.6	—	10.0
Agios	2014	—	—	—	—	13.0
	2013	—	—	—	—	12.8
bluebird	2014	—	—	0.1	—	—
	2013	74.7	—	—	—	—
Epizyme	2014	—	—	—	—	9.9
	2013	—	—	—	—	1.0
FORMA	2014	225.0	—	0.1	—	—
	2013	23.8	—	—	—	—
Morphosys	2014	—	—	—	—	—
	2013	94.3	—	—	—	61.3
NantBioScience	2014	50.0	—	—	25.0	90.0
Sutro <sup>(3)</sup>	2014	72.6	—	0.2	—	11.9
	2013	—	—	1.6	—	—
Other Collaboration Arrangements	2014	54.0	7.3	6.9	—	47.9
	2013	106.0	1.0	1.7	—	8.9

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, 2014	\$—	\$139.5	14%
	December 31, 2013	—	127.2	11%
Acetylon	September 30, 2014	24.3	25.0	10%
	December 31, 2013	35.7	25.0	10%
Agios	September 30, 2014	—	307.6	14%
	December 31, 2013	—	113.0	15%
bluebird	September 30, 2014	0.1	—	N/A
	December 31, 2013	0.2	—	N/A
Epizyme	September 30, 2014	—	99.6	11%
	December 31, 2013	—	69.4	12%
FORMA	September 30, 2014	0.1	—	N/A
	December 31, 2013	0.2	—	N/A
Morphosys	September 30, 2014	—	78.2	3%
	December 31, 2013	—	61.4	3%
NantBioScience Sutro <sup>(3)</sup>	September 30, 2014	—	90.0	14%
	September 30, 2014	12.8	17.6	15%

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

	December 31, 2013	2.5	5.7	6%
Other Collaboration Arrangements	September 30, 2014	32.0	78.3	N/A
	December 31, 2013	23.1	49.5	N/A

Activity and balances are presented specifically for notable new collaborations and for those collaborations which we have described in detail in our 2013 Annual Report on Form 10-K if there has been new activity during the periods presented. Amounts related to collaborations that are not specifically described are presented in the aggregate as Other Collaboration Arrangements.

27

---

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

<sup>2</sup> 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.

<sup>3</sup> Based on our assessment of the fair value of the components of the September 2014 agreement with Sutro, our payments of \$95.0 million were allocated as \$72.6 million of upfront collaboration expense, \$11.9 million of equity investment asset, \$9.0 million of manufacturing rights asset and \$1.5 million of option to acquire asset.

<sup>4</sup> Our additional equity investment in Acceleron made in the second quarter of 2014 was transacted at a price per share that exceeded the market value of Acceleron publicly traded common stock on the transaction closing date, resulting in an expense for the premium of \$9.7 million that was recorded in the Consolidated Statements of Income as other income (expense), net in the second quarter of 2014.

### 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 our continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature and uncertainty of these arrangements and any future potential payments, no amounts have been recorded in our accompanying Consolidated Balance Sheets at September 30, 2014 and December 31, 2013. See Note 14 for additional details related to collaboration arrangements.

**Contingencies:** We believe we maintain insurance coverage adequate for our current needs. Our operations are subject to environmental laws and regulations, which impose limitations on the discharge of pollutants into the air and water and establish standards for the treatment, storage and disposal of solid and hazardous wastes. We review the effects of such laws and regulations on our operations and modify our operations as appropriate. We believe we are in substantial compliance with all applicable environmental laws and regulations.

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

### 16. Legal Proceedings

Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and others and we have been subject to claims and other actions related to our business activities. While the ultimate outcome of investigations, inquires, 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

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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 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. As a result of the filing of our actions, the FDA cannot grant final approval of Natco's ANDA until the earlier of (i) a decision of the court that each of the patents is not infringed, invalid or unenforceable, or (ii) December 12, 2014.

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. Fact discovery closed on August 4, 2014. On October 23, 2014, the court denied: (i) Natco's motion to limit the patent claims asserted by Celgene and (ii) Natco's motion to dismiss its inequitable-conduct claims and strike Celgene's unclean-hands defense. In addition, the court granted Celgene's motion to bifurcate and stay expert discovery pertaining to the REMS patents. All other expert discovery is ongoing. No trial date has been set.

We believe that Natco's defenses and counterclaims are unlikely to be sustained and we intend to vigorously assert our patent rights. Although there can be no assurance as to the ultimate outcome of this proceeding, we currently expect that it 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.

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. A scheduling order has yet to be issued.

ABRAXANE®: On December 14, 2011, Cephalon, Inc. and Acusphere, Inc. filed a complaint against us in the United States District Court for the District of Massachusetts, alleging, among other things, that the making, using, selling, offering to sell and importing of ABRAXANE® brand drug infringes claims of United States Patent No. RE40,493. The plaintiffs are seeking damages and injunctive relief. On December 3, 2013, the court issued an order construing certain claim terms. Based on that order, on March 18, 2014, the parties agreed to a judgment of noninfringement in Celgene's favor. On April 15, 2014, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit seeking a review of the lower court's construction of certain claim terms. On April 22, 2014 we filed a Notice of Cross-Appeal seeking review of certain terms defined in the lower court's order.

On May 23, 2014, the plaintiffs filed a motion to dismiss our cross-appeal, which motion was denied on June 30, 2014. On July 7, 2014, the plaintiffs filed an opening brief relating to the appeal. We filed our opening brief in August 18, 2014. Plaintiffs' reply brief is due on October 30, 2014 and our reply is due on November 6, 2014. Once briefing is complete, the Court will schedule a hearing on the appeal and cross-appeal.

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 November 25, 2013, we filed a motion to dismiss Andrulis’ complaint. Andrulis’ motion seeking leave to file an amended complaint was granted on December 30, 2013. We filed a motion to dismiss Andrulis’ amended complaint on January 30, 2014. 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. Fact discovery is set to close on June 16, 2015. A joint claim construction brief is due on March 30, 2015. A claim construction hearing is scheduled for April 30, 2015. Expert discovery is set to close on December 21, 2015. Trial is scheduled to begin on June 6, 2016. We do not expect the ultimate outcome of this lawsuit to have a material adverse effect on our financial condition or results of operations.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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., 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.

Fact discovery is set to close on August 7, 2015. A joint claim construction brief is due on August 7, 2015. A claim construction hearing is scheduled for September 3, 2015. Expert discovery is set to close on May 27, 2016. Trial is scheduled to begin on September 19, 2016.

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 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 September 12, 2014, Celgene and Astellas Pharma Inc., filed an infringement action in the United States District Court for the District of Delaware against InnoPharma. InnoPharma has not yet answered the complaint. 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.

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. Oral arguments on our motion to dismiss is scheduled for December 12, 2014. A scheduling order has not yet been issued in this case. 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 (Brown Action). The plaintiff filed an opposition to our motion to dismiss on May 23, 2014. The DOJ as well as several state Attorneys General also filed Statements of Interest opposing certain arguments made in our motion to dismiss. The judge issued an order on July 10, 2014 largely denying our motion to dismiss, but granting in part our motion with respect to certain state claims. We filed our answer to the complaint on August 28, 2014. We intend to vigorously defend against the remaining claims in the Brown Action.



Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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 has formed a Demand Investigation Committee of directors to consider the issues raised in the stockholders' letter, and the committee has retained independent counsel to assist it. 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. A scheduling conference was held on February 11, 2014 and the court ordered fact discovery to be completed by December 15, 2014. No trial date has as yet been set by the court. 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 identical causes of action with respect to REVLIMID® as those alleged by CMCC, and seeks unspecified damages and a declaration that the license agreement is still in effect. We intend to vigorously defend against CMCC's and CR Rev's claims. As of September 30, 2014, we consider the range of reasonably possible loss relating to this lawsuit to be between zero and \$72.4 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, 2014, 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, 2014.

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 is cooperating with the United States Attorney in connection with this subpoena.

In October 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 alleges that equity grants made to non-employee directors in 2012 and 2013 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. The complaint seeks equitable relief, disgorgement of the alleged excess compensation, modification of the Company's compensation process to limit the equity awards that may be granted to non-employee directors, and attorneys' fees and other costs. The Company is a nominal defendant in the case. Neither the Company nor the individual defendants have yet responded to the complaint.

Table of Contents

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

Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “aims,” “plans,” “could,” “will,” “will continue,” “seeks,” “should,” “predicts,” “potential,” “outlook,” “guidance,” “target,” “forecast,” “probable,” and the negative of such terms and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions and projections, which are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws. We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements and therefore you should not place too much reliance on them. These factors include, among others, those described in the sections “Forward-Looking Statements” and “Risk Factors” contained in our 2013 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 a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. 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<sup>®</sup>, ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, VIDAZA<sup>®</sup>, azacitidine for injection (generic version of VIDAZA<sup>®</sup>), THALOMID<sup>®</sup> (inclusive of Thalidomide Celgene<sup>™</sup>), OTEZLA<sup>®</sup> and ISTODAX<sup>®</sup>. OTEZLA<sup>®</sup> 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. We began recognizing revenue related to OTEZLA<sup>®</sup> during the second quarter of 2014. OTEZLA<sup>®</sup> is currently under review for plaque psoriasis and psoriatic arthritis in the European Union. Additional sources of revenue include royalties from Novartis Pharma AG (Novartis) on their sales of FOCALIN XR<sup>®</sup> and the entire RITALIN<sup>®</sup> family of drugs, the sale of products and services through our Celgene Cellular Therapeutics (CCT) subsidiary and other licensing agreements. 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.



Table of Contents

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
	- United States
Multiple myeloma (MM), in combination with dexamethasone, in patients who have received at least one prior therapy	- European Union - Japan - Other international markets
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

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 - Other international markets
NSCLC	- Japan - United States
Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, as first line treatment in combination with gemcitabine	- European Union - Other international markets
Gastric cancer	- Japan



Table of Contents

POMALYST®/IMNOVID®<sup>1</sup>(pomalidomide): POMALYST®/IMNOVID® is a proprietary, distinct, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST®/IMNOVID® received its first approvals from the FDA and the European Commission (EC) during 2013 for the treatment of patients as indicated below:

Disease	Geographic Approvals
Multiple myeloma for patients who have received at least two prior therapies, including lenalidomide and bortezomib 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

<sup>1</sup> We received FDA approval for pomalidomide under the trade name POMALYST®. We received EC approval for pomalidomide under the trade name IMNOVID®.

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 and has been granted orphan drug designation for the treatment of MDS and AML. 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 the fourth quarter of 2013. In 2013, we also contracted with Sandoz AG to sell a generic version of VIDAZA® in the United States, which we supply. Regulatory exclusivity for VIDAZA® is expected to continue in Europe through 2018. 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 - European Union
Intermediate-2 and high-risk MDS	- Other international markets
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

azacitidine for injection (generic version of VIDAZA®): We contracted with Sandoz AG to sell azacitidine for injection, which they launched after the introduction of a generic version of VIDAZA® in the United States by a competitor in September 2013. We recognize net product sales from our sales of azacitidine for injection to Sandoz AG.



Table of Contents

THALOMID® (thalidomide): THALOMID®, sold as Thalidomide Celgene™ outside 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
---	--

Otezla® (apremilast): Otezla® is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. Otezla® received approval from the FDA for active psoriatic arthritis in March 2014 and in September 2014 for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla® has been submitted for approval in the European Union for the treatment of plaque psoriasis and psoriatic arthritis. Otezla® is approved for the treatment of patients as indicated below:

Disease	Geographic Approvals
Adult patients with active psoriatic arthritis	- United States (Approved March 2014)
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- United States (Approved September 2014)

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

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 newly diagnosed multiple myeloma and maintenance, lymphomas, chronic lymphocytic leukemia (CLL) and MDS. POMALYST®/IMNOVID® was approved in the United States and the European Union for indications in multiple myeloma based on phase II and phase III results, respectively, and additional phase III trials are underway with POMALYST®/IMNOVID® in relapsed and refractory multiple myeloma. Phase III trials are also underway for VIDAZA® and CC-486 in MDS and AML and ISTODAX® in first-line 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 II/III programs for ankylosing spondylitis, Behçet's disease, atopic dermatitis and ulcerative colitis. Also in the inflammation and immunology therapeutic area, we have acquired a global development and commercialization license to GED-0301 and we plan to initiate the phase III program for the use of GED-0301 in Crohn's disease before year-end 2014.

Table of Contents

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 a combination of in-house developed compounds, compounds licensed from other companies and options to acquire compounds 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 following table summarizes total revenue and earnings for the three-month periods ended September 30, 2014 and 2013 (dollar amounts in millions, except per share data):

	Three-Month Periods Ended		Increase	Percent Change	
	September 30, 2014	September 30, 2013			
Total revenue	\$1,982.2	\$1,674.4	\$307.8	18.4	%
Net income	\$508.5	\$372.5	\$136.0	36.5	%
Diluted earnings per share	\$0.61	\$0.43	\$0.18	41.9	%

Revenue increased by \$307.8 million in the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily due to the continued growth in sales of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>, partially offset by a reduction in sales of VIDAZA<sup>®</sup> in the U.S. following the September 2013 launch in the U.S. of a generic version of VIDAZA<sup>®</sup>. POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> was approved by the FDA in February 2013 and by the EC in August 2013. The \$136.0 million increase in net income and \$0.18 increase in diluted earnings per share in the current year quarter were primarily due to a higher level of net product sales and a \$82.9 million decrease in collaboration arrangement related research and development expenses, partly offset by a \$129.2 million impairment charge related to an in-process research and development (IPR&D) intangible, expenses associated with our growing organization to support inflammation and immunology products and product candidates, and an increase in selling and marketing activities primarily related to launch activities in recently approved indications for OTEZLA<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>.

The following table summarizes total revenue and earnings for the nine-month periods ended September 30, 2014 and 2013 (dollar amounts in millions, except per share data):

	Nine-Month Periods Ended		Increase	Percent Change	
	September 30, 2014	September 30, 2013			
Total revenue	\$5,584.9	\$4,738.0	\$846.9	17.9	%
Net income	\$1,386.0	\$1,235.5	\$150.5	12.2	%
Diluted earnings per share	\$1.66	\$1.43	\$0.23	16.1	%

Revenue increased by \$846.9 million in the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to the continued growth in sales of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>, partially offset by a reduction in sales of VIDAZA<sup>®</sup> in the U.S. following the September 2013 launch in the U.S. of a generic version of VIDAZA<sup>®</sup>. The \$150.5 million increase in net income and \$0.23 increase in diluted earnings per share in the current nine-month period were primarily due to a higher level of net product sales partly offset by an increase in expenses, including the \$129.2 million impairment charge noted above, \$61.5 million increase in collaboration arrangement related research and development expenses, increase in drug discovery and development activities, expenses associated with our growing organization to support inflammation and immunology products and product candidates and an increase in selling and marketing activities primarily related to launch activities in recently approved indications for OTEZLA<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>.



Table of Contents

## Results of Operations

## Three-Month Periods Ended September 30, 2014 and 2013

Total Revenue: Total revenue and related percentage changes for the three-month periods ended September 30, 2014 and 2013 were as follows (dollar amounts in millions):

	Three-Month Periods Ended		Increase (Decrease)	Percent Change	
	September 30, 2014	2013			
Net product sales:					
REVLIMID®	\$1,300.0	\$1,089.8	\$210.2	19.3	%
ABRAXANE®	212.2	169.6	42.6	25.1	%
POMALYST®/IMNOVID®	181.1	89.5	91.6	102.3	%
VIDAZA®	157.8	220.4	(62.6)	(28.4)	)%
azacitidine for injection	19.9	—	19.9	N/M	
THALOMID®	51.9	60.0	(8.1)	(13.5)	)%
OTEZLA®	17.6	—	17.6	N/M	
ISTODAX®	15.7	14.0	1.7	12.1	%
Other	0.6	0.7	(0.1)	(14.3)	)%
Total net product sales	\$1,956.8	\$1,644.0	\$312.8	19.0	%
Collaborative agreements and other revenue	2.2	2.2	—	—	%
Royalty revenue	23.2	28.2	(5.0)	(17.7)	)%
Total revenue	\$1,982.2	\$1,674.4	\$307.8	18.4	%
N/M - Not meaningful					

Total revenue increased by \$307.8 million, or 18.4%, to \$1.982 billion for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, reflecting increases of \$147.9 million, or 14.8%, in the United States and \$159.9 million, or 23.7%, in international markets.

Net Product Sales: Total net product sales for the three-month period ended September 30, 2014 increased by \$312.8 million, or 19.0%, to \$1.957 billion compared to the three-month period ended September 30, 2013. The increase was comprised of net volume increases of \$249.5 million and net price increases of \$65.1 million, partially offset by a \$1.8 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity.

REVLIMID® net sales increased by \$210.2 million, or 19.3%, to \$1.300 billion for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, 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.

ABRAXANE® net sales increased by \$42.6 million, or 25.1%, to \$212.2 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily due to increased unit volumes in both the U.S. and international markets and price increases in the U.S. market. ABRAXANE® was approved for the treatment of metastatic adenocarcinoma of the pancreas in the United States in September 2013 and European Union in December 2013.

POMALYST®/IMNOVID® net sales increased by \$91.6 million, or 102.3%, to \$181.1 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily due to

increased unit volumes in both the U.S. and international markets. The respective net sales increases were \$41.3 million in the United States and \$50.3 million in international markets. IMNOVID<sup>®</sup> was approved by the EC in August 2013. Net sales of IMNOVID<sup>®</sup> for the 2013 three-month period were derived primarily from approved early access programs in Europe.

VIDAZA<sup>®</sup> net sales decreased by \$62.6 million, or 28.4%, to \$157.8 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily due to a \$67.8 million decrease in the U.S. market resulting from the September 2013 introduction of a generic version of VIDAZA<sup>®</sup> by a third party. The decrease in U.S. sales was partly offset by volume increases in international markets.

Table of Contents

Azacitidine for injection net sales were \$19.9 million for the three-month period ended September 30, 2014. Azacitidine for injection is a generic version of VIDAZA<sup>®</sup> supplied by Celgene to Sandoz AG (Sandoz) beginning in the fourth quarter of 2013.

THALOMID<sup>®</sup> net sales decreased by \$8.1 million, or 13.5%, to \$51.9 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily resulting from lower unit volumes in the U.S.

OTEZLA<sup>®</sup> net sales were \$17.6 million for the three-month period ended September 30, 2014. OTEZLA<sup>®</sup> 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<sup>®</sup> is under review for plaque psoriasis and psoriatic arthritis in the European Union. Launch activities for OTEZLA<sup>®</sup> commenced in March 2014 and we began recognizing revenue related to OTEZLA<sup>®</sup> during the second quarter of 2014.

ISTODAX<sup>®</sup> net sales increased by \$1.7 million, or 12.1%, to \$15.7 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily due to an increase in unit volume, partly offset by a decrease in price.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources was \$2.2 million for the three-month periods ended September 30, 2014 and 2013.

Royalty Revenue: Royalty revenue decreased by \$5.0 million to \$23.2 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013 due to decreased royalties earned from Novartis based on its sales of FOCALIN XR<sup>®</sup> and RITALIN<sup>®</sup>, which have both been negatively impacted by generic competition in certain markets. Generic competition entered the market in the United States for certain strengths of FOCALIN XR<sup>®</sup> in the fourth quarter of 2013.

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

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

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in

that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. As noted above, REVLIMID®, 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

Table of Contents

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 2013. 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, 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 a change in estimate of the ultimate obligation during the fourth quarter of 2013. 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 2013 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2014 and 2013 were as follows (in millions):

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



Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Balance at September 30, 2014	\$ 13.6	\$ 11.4	\$ 134.1	\$ 78.8	\$ 237.9
Balance at June 30, 2013	\$ 13.7	\$ 14.5	\$ 119.2	\$ 73.5	\$ 220.9
Allowances for sales during prior periods	—	—	0.4	(2.5	) (2.1 )
Allowances for sales during 2013	6.3	19.0	63.2	76.4	164.9
Credits/deductions issued for prior year sales	(1.0	) —	(2.7	) (0.2	) (3.9 )
Credits/deductions issued for sales during 2013	(1.1	) (19.2	) (45.3	) (66.6	) (132.2 )
Balance at September 30, 2013	\$ 17.9	\$ 14.3	\$ 134.8	\$ 80.6	\$ 247.6

Table of Contents

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2014 and 2013 follows:

Returns and allowances provisions decreased by \$4.4 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013 primarily due to a \$4.8 million increase in the returns allowance recorded in the third quarter of 2013 related to VIDAZA<sup>®</sup> inventory held by certain distributors at the end of September 2013 when a generic version of VIDAZA<sup>®</sup> was launched.

Discounts provisions increased by \$4.2 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, due to revenue increases in the U.S. and international markets, both of which offer discount programs.

Government rebate provisions increased by \$5.6 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013. The increase was primarily due to a \$6.4 million increase in Medicaid rebates and \$5.8 million increase in rebates in certain international markets, which were both due to increased sales volumes. The increase was partially offset by a \$6.6 million decrease in expense related to Medicare Part D Coverage Gap as a result of an adjustment to accrual rates that increased expense in the third quarter of 2013.

Chargebacks and distributor service fees provisions increased by a combined \$20.2 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013. Chargebacks increased by approximately \$17.3 million, including a \$2.2 million increase in the TRICARE program driven by higher volume and increased rebate rates, and distributor service fees increased by approximately \$2.9 million. The chargeback increases were primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended September 30, 2014 and 2013 were as follows (dollar amounts in millions):

	Three-Month Periods Ended		Increase (Decrease)	Percent Change	
	September 30, 2014	2013			
Cost of goods sold (excluding amortization of acquired intangible assets)	\$97.7	\$86.2	\$11.5	13.3	%
Percent of net product sales	5.0	% 5.2	%		
Research and development	\$675.1	\$584.5	\$90.6	15.5	%
Percent of total revenue	34.1	% 34.9	%		
Selling, general and administrative	\$497.6	\$448.7	\$48.9	10.9	%
Percent of total revenue	25.1	% 26.8	%		
Amortization of acquired intangible assets	\$63.7	\$65.7	\$(2.0)	(3.0)	)%
Acquisition related charges, net	\$1.5	\$33.7	\$(32.2)	(95.5)	)%

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$11.5 million to \$97.7 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.0% for the three-month period ended September 30, 2014 compared to 5.2% for the three-month period ended September 30, 2013. The increase in the dollar value of cost of goods sold was primarily due to the higher level of REVLIMID<sup>®</sup> and ABRAXANE<sup>®</sup> net product sales. The decrease in the percent of net product sales was primarily due to increased sales of lower cost REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>, partially offset by the introduction of azacitidine for injection in late 2013, which has a lower gross margin.

Research and Development: We make significant investments in research and development in support of multiple ongoing proprietary clinical development programs which support both our existing products and our pipeline of new drug candidates. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, supplies and upfront and milestone payments arising from collaboration arrangements.

Research and development expenses increased by \$90.6 million to \$675.1 million for the three-month period ended September 30, 2014, compared to the three-month period ended September 30, 2013. The increase was primarily due to a \$129.2 million

Table of Contents

impairment charge due to an adjustment in the probability weighted forecasted cash flows related to the CC-292 IPR&D intangible asset obtained in the acquisition of Avila Therapeutics, Inc. (Avila) and an increase in activity in support of our early- to mid-stage product pipeline, partly offset by a \$82.9 million decrease in expenses related to collaboration arrangements.

The following table provides a breakdown of research and development expenses for the three-month periods ended September 30, 2014 and 2013 (in millions):

	Three-Month Periods Ended		Increase (Decrease)
	September 30, 2014	2013	
Human pharmaceutical clinical programs	\$209.9	\$215.6	\$(5.7)
Other pharmaceutical programs	295.1	141.1	154.0
Drug discovery and development	72.6	47.6	25.0
Cellular therapy	7.2	7.0	0.2
Collaboration arrangements	90.3	173.2	\$(82.9)
Total	\$675.1	\$584.5	\$90.6

We do not collect costs on a project basis or for any category of projects for the majority of costs involved in carrying out research projects. While we do perform cost calculations to facilitate our internal evaluation of individual projects, these calculations include significant estimations and allocations that are not relevant to, or included in, our external financial reporting mechanisms. As a consequence, we do not report research and development costs at the project level.

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, 2014, 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
OTEZLA®	Behçet's
GED-0301	Crohn's disease <sup>1</sup>

## Regulatory approval requests in major markets

Product	Disease Indication	Major Market	Regulatory Agency	Date of Submission or Filing
POMALYST®	RRMM <sup>2</sup>	Japan	MHW <sup>3</sup>	Q3 2014 (Filed)

## Regulatory agency actions

Product	Disease Indication	Major Market	Regulatory Agency	Action
OTEZLA®	Plaque psoriasis	U.S.	FDA	Approval

<sup>1</sup> Planned future trial

<sup>2</sup> Relapsed and refractory multiple myeloma

<sup>3</sup> Ministry of Health and Welfare

Selling, General and Administrative: Selling, general and administrative expenses primarily include salary and benefit costs for employees included in our sales, marketing, finance, legal and administrative organizations, costs related to the launch of new products or those approved for new indications, outside legal and other professional services, donations to independent non-profit patient assistance organizations and facilities costs.

Table of Contents

Selling, general and administrative expenses increased by \$48.9 million to \$497.6 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013. The increase was primarily due to an increase in expenses associated with our growing organization to support inflammation and immunology products and product candidates, such as OTEZLA® 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, 2014 and 2013 (in millions):

	Three-Month Periods Ended September 30,	
	2014	2013
Acquisitions		
Abraxis	\$37.9	\$40.0
Avila	11.8	11.9
Gloucester	13.0	12.8
Pharmion	1.0	1.0
Total amortization	\$63.7	\$65.7

Acquisition Related Charges, net: Acquisition related charges, net were \$1.5 million and \$33.7 million for the three-month periods ended September 30, 2014 and 2013, respectively. The \$32.2 million decrease in the current year quarter was primarily due to a \$58.0 million reduction in the fair value of our contingent consideration payable to the former shareholders of Avila due to an adjustment to the probability weighted forecasted cash flows related to CC-292 compared to prior estimates, partly offset by a \$23.7 million expense in the current year quarter for accretion of our contingent liabilities related to the Nogra Pharma Limited (Nogra) acquisition.

Interest and Investment Income, Net: Interest and investment income, net increased by \$1.6 million to \$6.9 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013 primarily due to higher investment balances compared to the prior year quarter.

Interest (Expense): Interest (expense) increased by \$29.5 million to \$53.5 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013 primarily due to interest expense associated with the issuance of \$1.500 billion of senior notes in August 2013 and an additional \$2.500 billion of senior notes in May 2014.

Other Income (Expense), Net: Other income (expense), net is summarized below for the three-month periods ended September 30, 2014 and 2013 (in millions):

	Three-Month Periods Ended			
	September 30,		Change	
	2014	2013		
Foreign exchange gains (losses) including foreign exchange derivative instruments not designated as hedging instruments	\$(4.3	) \$0.3	\$(4.6	)
Fair value adjustments of forward point amounts	(18.6	) 5.3	(23.9	)
Celgene puts sold	3.6	—	3.6	
Impairment charges	(2.0	) —	(2.0	)
Other	(1.2	) (0.5	) (0.7	)
Total other income (expense), net	\$(22.5	) \$5.1	\$(27.6	)

Other income (expense), net was a net expense of \$22.5 million for the three-month period ended September 30, 2014 and a net income of \$5.1 million for the three-month period ended September 30, 2013. The \$27.6 million increase in

expense was primarily due to an unfavorable change in spreads between forward and spot rates during the three-month period ended September 30, 2014 compared to a favorable change in spreads between forward and spot rates in the 2013 period.

**Income Tax Provision:** The income tax provision decreased by \$0.5 million to \$69.0 million for the three-month period ended September 30, 2014 compared to the three-month period ended September 30, 2013, primarily as a result of a decrease in the effective tax rate for the quarter, partly offset by an increase in income before taxes. The estimated full year 2014 underlying effective tax rate of 14.4% reflects the impact of our global business footprint. The decrease in the estimated full year underlying effective tax rate from the third quarter of 2013 reflects a projected decrease in tax expense resulting from certain collaboration and acquisition-related items, including an IPR&D asset impairment charge of \$129.2 million and a non-taxable gain from an

Table of Contents

associated decrease in the fair value of a contingent liability of \$58.0 million, both related to the acquisition of Avila, partially offset by an increase in tax expense associated with the launch of new products. 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. The income tax provision for the three-month period ended September 30, 2013 included an estimated full year underlying effective tax rate of 15.0% (which subsequently decreased to 12.2% when the actual 2013 full year results were achieved). The effective tax rate for the third quarter of 2013 was increased by 0.2 percentage points as a result of a net increase in unrecognized tax benefits related to ongoing examinations of tax positions taken in prior years, partially offset by tax benefits related to the filing of our 2012 income tax returns with certain items being more favorable than originally estimated.

## Nine-Month Periods Ended September 30, 2014 and 2013

Total Revenue: Total revenue and related percentages for the nine-month periods ended September 30, 2014 and 2013 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended		Increase (Decrease)	Percent Change	
	September 30, 2014	2013			
Net product sales:					
REVLIMID <sup>®</sup>	\$3,657.5	\$3,144.1	\$513.4	16.3	%
ABRAXANE <sup>®</sup>	612.3	447.1	165.2	36.9	%
POMALYST <sup>®</sup> /IMNOVID <sup>®</sup>	477.6	184.2	293.4	159.3	%
VIDAZA <sup>®</sup>	458.2	635.8	(177.6)	(27.9)	)%
azacitidine for injection	62.7	—	62.7	N/M	
THALOMID <sup>®</sup>	164.2	183.6	(19.4)	(10.6)	)%
OTEZLA <sup>®</sup>	22.2	—	22.2	N/M	
ISTODAX <sup>®</sup>	48.9	40.4	8.5	21.0	%
Other	5.3	2.2	3.1	140.9	%
Total net product sales	\$5,508.9	\$4,637.4	\$871.5	18.8	%
Collaborative agreements and other revenue	6.8	12.4	(5.6)	(45.2)	)%
Royalty revenue	69.2	88.2	(19.0)	(21.5)	)%
Total revenue	\$5,584.9	\$4,738.0	\$846.9	17.9	%
N/M - Not meaningful					

Total revenue increased by \$846.9 million, or 17.9%, to \$5.585 billion for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, reflecting increases of \$404.6 million, or 14.4%, in the United States and \$442.3 million, or 23.0%, in international markets.

Net Product Sales: Total net product sales for the nine-month period ended September 30, 2014 increased by \$871.5 million, or 18.8%, to \$5.509 billion compared to the nine-month period ended September 30, 2013. The increase was comprised of net volume increases of \$698.5 million, net price increases of \$160.7 million and a \$12.3 million favorable foreign exchange impact, including the impact of foreign exchange hedging activity.

REVLIMID<sup>®</sup> net sales increased by \$513.4 million, or 16.3%, to \$3.658 billion for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, 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<sup>®</sup> 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.



ABRAXANE<sup>®</sup> net sales increased by \$165.2 million, or 36.9%, to \$612.3 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to increased unit volumes in both the U.S. and international markets. ABRAXANE<sup>®</sup> was approved for the treatment of metastatic adenocarcinoma of the pancreas in the United States in September 2013 and the European Union in December 2013.

POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> net sales increased by \$293.4 million, or 159.3%, to \$477.6 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, reflecting net sales of \$311.2 million in the

Table of Contents

United States and \$166.4 million in international markets. POMALYST® was approved by the FDA in February 2013 and IMNOVID® was approved by the EC in August 2013. The 2013 nine-month period included a partial period of sales in the U.S. and sales in Europe were derived primarily from approved early access programs.

VIDAZA® net sales decreased by \$177.6 million, or 27.9%, to \$458.2 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to a \$214.6 million decrease in the U.S. market resulting from the September 2013 introduction of a generic version of VIDAZA® by a third party. The decrease in U.S. sales was partly offset by volume increases in international markets.

Azacitidine for injection net sales were \$62.7 million for the nine-month period ended September 30, 2014. Azacitidine for injection is a generic version of VIDAZA® supplied by Celgene to Sandoz beginning in the fourth quarter of 2013.

THALOMID® net sales decreased by \$19.4 million, or 10.6%, to \$164.2 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily resulting from lower unit volumes in the U.S. and international markets, partly offset by U.S. price increases.

OTEZLA® net sales were \$22.2 million for the nine-month period ended September 30, 2014. 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® is under review for plaque psoriasis and psoriatic arthritis in the European Union. Launch activities for OTEZLA® commenced in March 2014 and we began recognizing revenue related to OTEZLA® during the second quarter of 2014.

ISTODAX® net sales increased by \$8.5 million, or 21.0%, to \$48.9 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to an increase in unit volume.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources decreased by \$5.6 million to \$6.8 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013 primarily due to a \$5.0 million milestone payment received in 2013 related to the approval of additional indications for ABRAXANE® in Japan. No milestone payments were received in 2014.

Royalty Revenue: Royalty revenue decreased by \$19.0 million to \$69.2 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013 due to decreased royalties earned from Novartis based on its sales of FOCALIN XR® and RITALIN®, which have both been negatively impacted by generic competition in certain markets. Generic competition entered the market in the United States for certain strengths of FOCALIN XR® in the fourth quarter of 2013.

Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2014 and 2013 were as follows (in millions):

	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
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
	(3.9)	(7.9)	(74.3)	(41.9)	(128.0)

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Credits/deductions issued for prior year sales						
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	
Balance at December 31, 2012	\$13.3	\$11.2	\$125.8	\$61.2	\$211.5	
Allowances for sales during prior periods	(1.1	) —	(6.5	) (2.0	) (9.6	)
Allowances for sales during 2013	11.6	57.5	193.4	206.2	468.7	
Credits/deductions issued for prior year sales	(3.4	) (5.2	) (52.8	) (41.9	) (103.3	)
Credits/deductions issued for sales during 2013	(2.5	) (49.2	) (125.1	) (142.9	) (319.7	)
Balance at September 30, 2013	\$17.9	\$14.3	\$134.8	\$80.6	\$247.6	

Table of Contents

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2014 and 2013 follows:

Returns and allowances provisions decreased by \$6.1 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to a \$7.9 million sales returns reserve for estimated returns related to the transition of THALOMID® distribution from retail to specialty pharmacies recorded during the first quarter of 2013 and a \$2.0 million decrease in the returns allowance related to VIDAZA® recorded in 2014 due to reductions in inventory held by distributors. These decreases were partially offset by a \$1.5 million increase in POMALYST® returns due to higher returns activity and a \$2.7 million reduction in the returns allowance recorded in 2013 related to VIDAZA® inventory levels held by distributors.

Discounts provisions increased by \$6.4 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to a \$6.9 million increase in cash discounts in the United States due to increased sales volume. International cash discounts decreased \$0.5 million as increased cash discounts due to increased sales volume were completely offset by the refinement of new product discount programs introduced into certain international markets.

Government rebates provisions increased by \$23.9 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily due to a \$14.0 million increase in expense related to Medicaid rebates, a \$6.9 million increase in international government rebates and a \$3.0 million increase in expense related to Medicare Part D Coverage Gap.

Chargebacks and distributor service fees provisions increased by \$59.6 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013. Chargebacks increased by approximately \$48.5 million, including \$5.3 million related to the TRICARE program driven by higher volume and increased rebate rates, and distributor service fees increased by approximately \$11.1 million. The chargeback increases were primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2014 and 2013 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended		Increase	Percent	
	September 30,	2013	(Decrease)	Change	
	2014				
Cost of goods sold (excluding amortization of acquired intangible assets)	\$282.7	\$247.6	\$35.1	14.2	%
Percent of net product sales	5.1	% 5.3	%		
Research and development	\$1,845.7	\$1,495.0	\$350.7	23.5	%
Percent of total revenue	33.0	% 31.6	%		
Selling, general and administrative	\$1,483.5	\$1,235.8	\$247.7	20.0	%
Percent of total revenue	26.6	% 26.1	%		
Amortization of acquired intangible assets	\$194.7	\$197.1	\$(2.4)	(1.2)	%
Acquisition related charges, net	\$11.0	\$79.4	\$(68.4)	(86.1)	%

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$35.1 million to \$282.7 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013. The increase was primarily due to the higher level of net product sales, partly offset by the elimination of royalty payments on sales of REVLIMID® which resulted from the expiration of our royalty obligations to Children's Medical Center Corporation (CMCC) at the end of February 2013. See Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in

this report for additional details of our royalty agreement and related litigation with CMCC. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.1% for the nine-month period ended September 30, 2014 compared to 5.3% for the nine-month period ended September 30, 2013, primarily due to the elimination of royalty payments to CMCC on our sales of REVLIMID® as noted above, partly offset by the introduction of azacitidine for injection in late 2013, which has a lower gross margin.

Research and Development: Research and development expenses increased by \$350.7 million to \$1.846 billion for the nine-month period ended September 30, 2014, compared to the nine-month period ended September 30, 2013. The increase was primarily due to a \$129.2 million impairment charge due to an adjustment in the probability weighted forecasted cash flows related to the CC-292

Table of Contents

IPR&D intangible asset obtained in the acquisition of Avila, a \$61.5 million increase in expenses related to collaboration arrangements, and an increase in activity in support of our early- to mid-stage product pipeline.

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

	Nine-Month Periods Ended		Increase
	September 30,		
	2014	2013	
Human pharmaceutical clinical programs	\$596.2	\$590.1	\$6.1
Other pharmaceutical programs	591.5	376.2	215.3
Drug discovery and development	209.0	144.1	64.9
Cellular therapy	21.4	18.5	2.9
Collaboration arrangements	427.6	366.1	61.5
Total	\$1,845.7	\$1,495.0	\$350.7

**Selling, General and Administrative:** Selling, general and administrative expenses increased by \$247.7 million to \$1.484 billion for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013. The increase was primarily due to an increase in expenses associated with our growing organization to support inflammation and immunology products and product candidates, such as OTEZLA<sup>®</sup> and GED-0301, as well as increases in selling and marketing activities related to recently approved indications for OTEZLA<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and ABRAXANE<sup>®</sup>. The increase also included \$25.0 million of expense related to the settlement of a contingent obligation to make matching contributions to The Chan Soon-Shiong Institute for Advanced Health.

**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, 2014 and 2013 (in millions):

	Nine-Month Periods Ended September 30,	
	2014	2013
Acquisitions		
Abraxis	\$117.6	\$120.0
Avila	35.4	35.5
Gloucester	38.7	38.6
Pharmion	3.0	3.0
Total amortization	\$194.7	\$197.1

**Acquisition Related Charges, net:** Acquisition related charges, net were \$11.0 million and \$79.4 million for the nine-month periods ended September 30, 2014 and 2013, respectively. The \$68.4 million decrease in the current year nine-month period was primarily due to a \$41.9 million reduction in expense from the change in fair value of our contingent liabilities related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis and a \$49.9 million net reduction in the fair value of our contingent consideration payable to the former shareholders of Avila, partly offset by a \$31.5 million expense in the current year period for accretion of our contingent liabilities related to the Nogra acquisition.

**Interest and Investment Income, Net:** Interest and investment income, net increased by \$6.0 million to \$20.6 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013 primarily due to higher investment balances compared to the prior year.

**Interest (Expense):** Interest (expense) increased by \$62.9 million to \$124.4 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013 primarily due to interest expense associated with the issuance of \$1.500 billion of senior notes in August 2013 and an additional \$2.500 billion of senior notes in May 2014.



Table of Contents

Other Income (Expense), Net: Other income (expense), net is summarized below for the nine-month periods ended September 30, 2014 and 2013 (in millions):

	Nine-Month Periods Ended September 30,		
	2014	2013	Change
Foreign exchange gains (losses) including foreign exchange derivative instruments not designated as hedging instruments	\$(11.0	) \$22.5	\$(33.5 )
Fair value adjustments of forward point amounts	(22.1	) 7.3	(29.4 )
Celgene puts sold	9.9	—	9.9
Premium paid on equity investment	(9.7	) —	(9.7 )
Impairment charges	(4.0	) (18.8	) 14.8
Other	(10.0	) 1.0	(11.0 )
Total other income (expense), net	\$(46.9	) \$12.0	\$(58.9 )

Other income (expense), net was a net expense of \$46.9 million for the nine-month period ended September 30, 2014 and a net income of \$12.0 million for the nine-month period ended September 30, 2013. The \$58.9 million increase in expense was primarily due to the impact of foreign exchange losses recorded in the 2014 period compared to gains recorded in the 2013 period. In addition, the 2014 period included an unfavorable change in spreads between forward and spot rates compared to a favorable change in spreads between forward and spot rates in the 2013 period. During the current year period, gains related to the sale of puts on our common stock and a decrease in impairment charges related to certain investments were partly offset by an expense related to a premium paid on an equity investment.

**Income Tax Provision:** The income tax provision increased by \$17.9 million to \$230.6 million for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013, primarily as a result of an increase in income before taxes partially offset by a decrease in the effective tax rate. The estimated full year 2014 underlying effective tax rate of 14.4% reflects the impact of our global business footprint. The decrease in the estimated underlying effective tax rate from the third quarter of 2013 reflects a projected decrease in tax expense resulting from certain collaboration and acquisition-related items, including an IPR&D asset impairment charge of \$129.2 million and a non-taxable gain from an associated decrease in the fair value of a contingent liability of \$58.0 million, both related to the acquisition of Avila, partially offset by an increase in tax expense associated with the launch of new products. 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. The income tax provision for the nine-month period ended September 30, 2013 included an estimated full year underlying effective tax rate of 15.0% (which subsequently decreased to 12.2% when the actual 2013 full year results were achieved). The effective tax rate for the nine-month period ended September 30, 2013 was reduced by 0.2 percentage points as a result of discrete items, including the retroactive reinstatement of the 2012 U.S. research and development tax credit, a net decrease in unrecognized tax benefits related to settlements and ongoing examinations of tax positions taken in prior years, and tax benefits related to the filing of our 2012 income tax returns with certain items being more favorable than originally estimated.

## Liquidity and Capital Resources

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

	September 30, 2014	December 31, 2013	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	\$3,742.5	\$3,234.4	\$508.1
Marketable securities available for sale	3,118.2	2,452.6	665.6
Total financial assets	\$6,860.7	\$5,687.0	\$1,173.7
Debt:			



Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

Short-term borrowings	\$100.0	\$544.8	\$(444.8 )
Long-term debt, net of discount	6,737.3	4,196.5	2,540.8
Total debt	\$6,837.3	\$4,741.3	\$2,096.0
Working capital <sup>(1)</sup>	\$7,446.3	\$5,607.4	\$1,838.9

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

Table of Contents

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, 2014, we held approximately \$6.103 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 purchases 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 \$6.103 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, 2014 and December 31, 2013 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 2014, our Board of Directors approved purchases of up to \$13.500 billion of our common stock, including \$4.000 billion approved by our Board of Directors in April 2014. During the nine-month period ended September 30, 2014 we used \$2.434 billion for purchases of our common stock, measured on a settlement date basis.

Senior Notes: In May 2014, we issued an additional \$2.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.250% Senior Notes due 2019 (the 2019 notes), \$1.000 billion aggregate principal amount of 3.625% Senior Notes due 2024 (the 2024 notes) and \$1.000 billion aggregate principal amount of 4.625% Senior Notes due 2044 (the 2044 notes and, together with the 2019 notes and 2024 notes, the “2014 issued notes”). The 2014 issued notes were issued at 99.751%, 99.659% and 99.646% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of \$21.2 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 2014 issued notes is payable semi-annually in arrears on May 15 and November 15 each year beginning November 15, 2014 and the principal on each note is due in full at their respective maturity dates. The 2014 issued notes may be redeemed at our option, in whole or in part, at any time at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 10 basis points in the case of the 2019 notes, 15 basis points in the case of the 2024 notes and 20 basis points in the case of the 2044 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 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.

In anticipation of issuing debt in 2014, we entered into an aggregate notional value of \$1.500 billion in forward starting swaps that were designated as cash flow hedges to hedge against changes in interest rates that could impact the issuance of debt. In April 2014 we accelerated our planned debt issuance date, which resulted in hedge ineffectiveness in the forward starting swaps and a \$3.6 million charge to other income (expense), net due to differences between the effective date of the swaps and the accelerated debt issuance date. In addition, all forward starting swaps were settled upon the issuance of debt in May 2014 when the net fair value of the forward starting swaps in accumulated other comprehensive income was a loss position of \$25.9 million. The net loss of \$25.9 million will be recognized as interest expense over the life of the associated senior notes. There were no forward starting swaps outstanding as of September 30, 2014.

Table of Contents

## 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 (MBS), non-U.S. government agency and Supranational securities, global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as marketable securities available for sale. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. The \$1.174 billion increase in cash, cash equivalents and marketable securities available for sale at September 30, 2014 compared to December 31, 2013 was primarily due to \$2.471 billion in cash generated from the May 2014 issuance of an additional \$2.500 billion principal amount of senior notes and \$1.974 billion in net cash provided by operating activities. These increases were partly offset by \$2.434 billion paid under our share repurchase program, \$710.0 million paid for the Nogra acquisition, and \$445.0 million of net repayments on short-term borrowings.

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 \$6.7 million to \$1.068 billion at September 30, 2014 compared to December 31, 2013 primarily due to an increased level of sales. 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 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 \$265.2 million at September 30, 2014 compared to \$348.4 million at December 31, 2013. Approximately \$47.8 million of the \$265.2 million receivable balance at September 30, 2014 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.

In determining the appropriate allowance for doubtful accounts for Spain, Italy and Portugal, we considered that the balance of past due receivables is 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 which would have a material adverse impact on our financial position or results of operations.

Inventory: Inventory balances increased by \$31.6 million to \$372.0 million at September 30, 2014 compared to December 31, 2013. The increase was primarily due to an increase in both ABRAXANE® and OTEZLA® inventory in anticipation of an increase

Table of Contents

in their future sales levels, partly offset by a decrease in VIDAZA® inventories which was negatively impacted by the introduction of generic versions in the U.S. market.

**Other Current Assets:** Other current assets increased by \$73.0 million to \$509.4 million at September 30, 2014 compared to December 31, 2013 primarily due to a \$119.1 million increase in the fair value of foreign currency forward contracts, partly offset by a \$12.8 million decrease in royalty receivables, \$18.3 million decrease in miscellaneous prepaid taxes and a net decrease in other receivable and prepaid accounts.

**Commercial Paper:** In September 2011, we entered into a commercial paper program (the 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. The maximum aggregate amount available under the Program is currently \$1.500 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, 2014, \$100.0 million of Commercial Paper was outstanding compared to \$544.8 million as of December 31, 2013, bearing an effective interest rate of 0.3%.

**Senior Unsecured Credit Facility:** In September 2011, we entered into a senior unsecured revolving credit facility (Credit Facility) providing for revolving credit. The Credit Facility has currently been established at an aggregate maximum amount of \$1.500 billion with an expiration date of April 18, 2018. 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 \$1.750 billion.

Amounts may be borrowed under the Credit Facility for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of September 30, 2014 there was no outstanding borrowing against the Credit Facility.

The Credit Facility contains affirmative and negative covenants including certain customary financial covenants. We were in compliance with all debt covenants as of September 30, 2014.

**Accounts Payable, Accrued Expenses and Other Current Liabilities:** Accounts payable, accrued expenses and other current liabilities decreased by \$107.7 million to \$1.249 billion at September 30, 2014 compared to December 31, 2013. The decrease was primarily due to a \$50.7 million decrease related to foreign exchange contracts, \$45.9 million decrease related to our common share repurchase program due to the timing of transaction settlements, a \$45.0 million decrease related to collaboration agreements and a net \$39.7 million decrease in contingent consideration primarily related to Avila, partly offset by a \$40.6 million increase in accounts payable and increases in other accrued expenses such as accrued interest and professional services.

**Income Taxes Payable (Current and Non-Current):** Income taxes payable increased by \$27.8 million to \$278.8 million at September 30, 2014 compared to December 31, 2013, primarily from the current provision for income taxes of \$479.2 million and net deferred inter-company credits of \$12.9 million, offset by income tax payments of \$275.0 million, a decrease in refundable income taxes of \$43.0 million and a tax benefit of stock options of \$147.1 million.

**Analysis of Cash Flows**

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2014 and 2013 were as follows (in millions):

Nine-Month Periods Ended  
September 30,

Edgar Filing: CELGENE CORP /DE/ - Form 10-Q

	2014	2013	Change
Net cash provided by operating activities	\$1,973.7	\$1,675.2	\$298.5
Net cash used in investing activities	\$(1,365.1 )	\$(1,443.4 )	\$78.3
Net cash (used in) provided by financing activities	\$(65.9 )	\$103.7	\$(169.6 )

Operating Activities: Net cash provided by operating activities increased by \$298.5 million to \$1.974 billion for the nine-month period ended September 30, 2014 compared to the nine-month period ended September 30, 2013. The increase in net cash provided by operating activities was primarily attributable to a an increase in net income of \$150.5 million, a \$91.8 million increase in the adjustment for share-based compensation expense and \$92.7 million from lower growth in accounts receivable in 2014 compared to the growth in 2013.

## Table of Contents

**Investing Activities:** Net cash used in investing activities for the nine-month period ended September 30, 2014 decreased to \$1.365 billion compared to \$1.443 billion for the nine-month period ended September 30, 2013. The decrease in net cash used in investing activities was primarily due to a year over year reduction of \$826.3 million in net purchases of marketable securities available for sale, partially offset by the \$710.0 million payment for the acquisition of Nogra.

**Financing Activities:** Net cash used in financing activities amounted to \$65.9 million for the nine-month period ended September 30, 2014, compared to net cash provided by financing activities of \$103.7 million for the nine-month period ended September 30, 2013. The \$169.6 million decrease in net cash provided by financing activities in the nine-month period ended September 30, 2014 was primarily attributable to \$445.0 net repayments of short-term borrowing in 2014 compared to net borrowing of \$95.1 million in 2013, \$365.8 million increase in cash used for purchases of common stock, and a \$252.9 million decrease in net proceeds from share-based compensation arrangements. These increases in cash uses were partially offset by an increase of \$991.0 million in proceeds from the issuance of long-term debt.

## 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 2013 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2013 aside from those disclosed in Note 3 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 2013 Annual Report on Form 10-K. There have not been any material changes to such critical accounting estimates since December 31, 2013.

## 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, 2014, 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, 2014, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored



agency 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.

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

Table of Contents

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, 2014, 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	\$435.0	\$1,740.3	\$197.4	\$2,372.7	
Fair value	\$438.6	\$1,758.7	\$203.3	\$2,400.6	
Weighted average interest rate	0.5	% 0.8	% 1.9	% 0.9	%

Long-Term Debt: We have issued an aggregate \$6.750 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, 2014 are summarized below (in millions):

	Principal Amount	Carrying Value
2.450% senior notes due 2015	\$500.0	\$508.2
1.900% senior notes due 2017	500.0	500.3
2.300% senior notes due 2018	400.0	400.1
2.250% senior notes due 2019	500.0	498.8
3.950% senior notes due 2020	500.0	495.4
3.250% senior notes due 2022	1,000.0	991.1
4.000% senior notes due 2023	700.0	704.0
3.625% senior notes due 2024	1,000.0	996.7
5.700% senior notes due 2040	250.0	249.6
5.250% senior notes due 2043	400.0	396.6
4.625% senior notes due 2044	1,000.0	996.5
Total long-term debt	\$6,750.0	\$6,737.3

At September 30, 2014, the fair value of our senior notes outstanding was \$6.866 billion.

Celgene 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. While such a purchase would be at a price above the then fair market value of our shares, it would be at a price that we feel is favorable in the overall context of our share repurchase program. At September 30, 2014, we had no outstanding put options.

**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.

#### 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.

Table of Contents

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 to 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, 2014 and December 31, 2013 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 (loss) (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. If a hedging relationship is terminated with respect to a foreign currency forward contract, accumulated gains or losses associated with the contract remain in OCI until the hedged forecasted transaction occurs and are reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in other income (expense), net. The forward point components of these foreign currency forward contracts are not designated as cash flow hedges and all fair value adjustments of forward point amounts are recorded to other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2014 and December 31, 2013 (in millions):

	Notional Amount	
	September 30, 2014	December 31, 2013
Foreign Currency		
Australian Dollar	\$ 19.7	\$—
British Pound	360.8	279.4
Canadian Dollar	79.9	—
Euro	3,437.7	3,318.2
Japanese Yen	567.8	559.1
Total	\$4,465.9	\$4,156.7

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, 2014, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also manage a portfolio of foreign currency contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies and, from time to time, we enter into foreign currency contracts to manage exposure related to translation of foreign earnings. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2014 and December 31, 2013 were \$897.2 million and \$878.5 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, 2014 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$529.3 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.

Table of Contents

## 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:** In anticipation of issuing debt in 2014, we entered into an aggregate notional value of \$1.500 billion in forward starting swaps that were designated as cash flow hedges. In April 2014 we accelerated our planned debt issuance date, which resulted in hedge ineffectiveness in the forward starting swaps and a \$3.6 million charge to other income (expense), net due to differences between the effective date of the swaps and the accelerated debt issuance date. In addition, all forward starting swaps were settled upon the issuance of debt in May 2014 when the net fair value of the forward starting swaps in accumulated other comprehensive income was a loss position of \$25.9 million. The net loss of \$25.9 million will be recognized as interest expense over the life of the associated senior notes. There were no forward starting swaps outstanding as of September 30, 2014.

**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 is 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 2013 and 2014. The settlement of swap contracts resulted in the receipt of net proceeds of \$15.3 million and \$21.9 million during the nine-month periods ended September 30, 2014 and 2013, respectively, which is accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report 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, 2014 and December 31, 2013 (in millions):

	Notional Amount	
	September 30, 2014	December 31, 2013
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	350.0	—
3.950% senior notes due 2020	500.0	500.0
3.250% senior notes due 2022	850.0	850.0
4.000% senior notes due 2023	100.0	150.0

Total	\$2,600.0	\$2,300.0
-------	-----------	-----------

A sensitivity analysis to measure potential changes in the market value of our fixed-rate senior notes and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at September 30, 2014 would have reduced the aggregate fair value of our net payable by \$388.2 million. A one percentage point decrease at September 30, 2014 would have increased the aggregate fair value of our net payable by \$461.6 million.

Table of Contents

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, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

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 are 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 and amortization of acquired intangibles and other acquisition related 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 option contracts 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<sup>®</sup>, VIDAZA<sup>®</sup>, THALOMID<sup>®</sup>, ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup>.

Currently, our business is largely dependent on the commercial success of REVLIMID<sup>®</sup>, VIDAZA<sup>®</sup>, THALOMID<sup>®</sup>, ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup>. 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 U.S. Food and Drug Administration (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 a requirement for 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.

## Table of Contents

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

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from the FDA and similar bodies in other countries. Certain of our pharmaceutical products, such as FOCALIN<sup>®</sup>, also require authorization by the U.S. Drug Enforcement Agency (DEA) of the U.S. Department of Justice. Our future growth would be negatively impacted if we fail to obtain timely, or at all, requisite regulatory approvals in the United States and internationally for products in development and approvals for our existing products for additional indications.

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

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

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

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

Even if a product is approved, the scope of the approval may significantly limit the indicated uses 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 other international regulatory agency may withdraw or modify an approval in a significant manner or request that we perform additional clinical trials or change the labeling of the product due to a number of reasons, including safety concerns, adverse events and side effects;

Products, such as REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, that are subject to 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<sup>®</sup> program), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and government regulations and policies. In addition, individual states, acting through their attorneys general, are increasingly seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. If we fail to comply with the laws and regulations regarding the promotion and sale of our products, appropriate distribution of our products under our restricted distribution systems, off-label promotion and the promotion of unapproved products, government agencies may bring enforcement actions against us that could inhibit our commercial capabilities and result in significant penalties.

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

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

parallel importation of prescription drugs from outside the United States at prices that are regulated by the governments

57

---

Table of Contents

of various foreign countries; and  
premature or mandated disclosures of clinical trial or other 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 is 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, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. 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 on 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 Celgene are required to pay. These changes also expanded the government's 340B drug discount program by expanding the category of entities qualified to participate in the program and benefit from its deeply discounted drug pricing. The Company has received inquiries from the Health Resources and Services Administration of the Department of Health & Human Services ("HRSA") regarding the Company's compliance with the 340B program. We have responded to these inquiries and believe that we have complied with applicable legal requirements. If, however, the Company is ultimately required to change its 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

58

---

Table of Contents

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, a court or patent authority ruling on such challenge will determine 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 the products or processes covered by the disputed rights, be subject to significant liabilities to such third party and/or be required to license technologies 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, which have not already been allowed, 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 includes a number of important changes to established practices, including transition to a first-to-file system, post-grant review for issued patents, and various procedural changes. The scope of these changes and the lack of experience with their practical implementation may result in uncertainty over the next few years.

On October 2, 2014, the European Medicines Agency ("EMA") adopted its clinical transparency policy, "Policy on Publication of Clinical Data for Medicinal Products for Human Use" (the “Clinical Data Policy”), which becomes 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 ultimately 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.

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 technology 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



## Table of Contents

these claims. 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 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: Amgen, AstraZeneca, Bristol-Myers-Squibb, Eisai, Gilead, Johnson & Johnson, Novartis, Pharmacylics, Roche/Genentech, Sanofi and Takeda.

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

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

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

Sales of our products are dependent, in large part, on third-party payers. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. For information about amounts receivable from the government-owned or -controlled hospitals in Spain, Italy and Portugal, see our discussion of accounts receivable from those countries in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this report.

In addition, due to tightened global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including

portions of our product manufacturing, clinical development of future collaboration products, conduct of clinical trials and supply of raw materials. If such third parties are unable to satisfy their commitments to us, our business could be adversely affected.

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

We may become subject to litigation or governmental investigations in the United States and foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we have from time to time received inquiries and subpoenas

## Table of Contents

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 Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

While the ultimate outcome 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 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 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; and

the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers.

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

61

---

## Table of Contents

by fire, contamination, natural disaster, terrorist attack, governmental action or military 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 distributors to distribute REVLIMID<sup>®</sup>, THALOMID<sup>®</sup>, VIDAZA<sup>®</sup>, ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, ISTODAX<sup>®</sup> and OTEZLA<sup>®</sup>. If our distributors fail to perform and we cannot secure a replacement distributor within a reasonable period of time, our revenue could be adversely affected.

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

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

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

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

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

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

- increased management, travel, infrastructure and legal compliance costs;
- longer payment and reimbursement cycles;
- difficulties in enforcing contracts and collecting accounts receivable;
- local marketing and promotional challenges;
- lack of consistency, and unexpected changes, in foreign regulatory requirements and practices;

- increased risk of governmental and regulatory scrutiny and investigations;
- increased exposure to fluctuations in currency exchange rates;
- the burdens of complying with a wide variety of foreign laws and legal standards;
- operating in locations with a higher incidence of corruption and fraudulent business practices;

## Table of Contents

difficulties in staffing and managing foreign sales and development operations;  
import and export requirements, tariffs, taxes and other trade barriers;  
weaker 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.

The integration of acquired businesses may present significant challenges to us.

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

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

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.

Table of Contents

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 attention, may harm our reputation and can impact the demand for our products.

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 option contracts, 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;

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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. Similarly, data privacy breaches by those who access our systems may pose a risk that sensitive data 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.

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, if any, of the CVRs;
- if the clinical approval milestones or net sales targets specified in the CVR Agreement are not achieved for any reason within the time periods specified therein, no payment will be made under the CVRs 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, if any, of the CVRs.



Table of Contents

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

## (c) Issuer Purchases of Equity Securities

In June 2014, our stockholders approved an amendment to our Certificate of Incorporation that increased the number of shares of common stock that we are authorized to issue and effected a two-for-one stock split. As a result, our total number of authorized shares of common stock increased from 575.0 million to 1.150 billion on June 18, 2014. Stockholders of record received one additional share of common stock for each share of common stock owned. All impacted share numbers and per share amounts presented in the consolidated financial statements and the accompanying notes to the financial statements in this report have been restated to reflect the impact of the stock split. Common stock held in treasury was not adjusted for the stock split.

From April 2009 through September 2014, our Board of Directors approved purchases of up to \$13.500 billion of our common stock, including \$4.000 billion approved by our Board of Directors in April 2014. Approved amounts exclude share purchase transaction fees.

The following table presents the number of shares purchased during the three-month period ended September 30, 2014, the average price paid per share, the number of shares that were purchased and the approximate 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	Approximate Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs
July 1 - July 31	319,676	\$87.86	319,676	\$3,903,578,976
August 1 - August 31	1,288,421	\$89.07	1,288,421	\$3,788,816,898
September 1 - September 30	1,182,319	\$91.94	1,182,319	\$3,680,117,889
Total	2,790,416	\$90.15	2,790,416	

During the three-month period ended September 30, 2014, we purchased 2.8 million shares of common stock under the share repurchase program at a total cost of \$251.5 million. As of September 30, 2014, we had a remaining purchase authorization of \$3.680 billion.

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

Table of Contents

Item 6. Exhibits

- 3.1 Certificate of Incorporation of the Company, as amended through June 18, 2014 (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2014).
- 3.2 Bylaws of the Company (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, dated September 16, 1996), as amended effective May 1, 2006 (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006), as further amended effective December 16, 2009 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 17, 2009), and as further amended effective February 17, 2010 (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009).
- 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, 2014, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) Notes to Unaudited Consolidated Financial Statements.

\* Filed herewith.

Table of Contents

SIGNATURE

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

CELGENE CORPORATION

Date: October 28, 2014

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