

CELGENE CORP /DE/
Form 10-Q
October 29, 2013
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, 2013

OR

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

Commission File Number 001-34912
CELGENE CORPORATION
(Exact name of registrant as specified in its charter)
Delaware 22-2711928
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification Number)

86 Morris Avenue, Summit, NJ 07901
(Address of principal executive offices) (Zip Code)
(908) 673-9000
(Registrant's telephone number, including area code)

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

Yes X No

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

Yes X No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer

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

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

At October 22, 2013, 412,069,519 shares of Common Stock, par value \$.01 per share, were outstanding.

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</u>
	<u>Consolidated Statements of Income - Three-Month and Nine-Month Periods Ended September 30, 2013 and 2012</u>
	<u>3</u>
	<u>Consolidated Statements of Comprehensive Income - Three-Month and Nine-Month Periods Ended September 30, 2013 and 2012</u>
	<u>4</u>
	<u>Consolidated Balance Sheets - As of September 30, 2013 and December 31, 2012</u>
	<u>5</u>
	<u>Consolidated Statements of Cash Flows - Nine-Month Periods Ended September 30, 2013 and 2012</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>29</u>
<u>Item 3</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	<u>47</u>
<u>Item 4</u>	<u>Controls and Procedures</u>
	<u>51</u>
<u>PART II</u>	<u>OTHER INFORMATION</u>
<u>Item 1</u>	<u>Legal Proceedings</u>
	<u>51</u>
<u>Item 1A</u>	<u>Risk Factors</u>
	<u>52</u>
<u>Item 2</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	<u>64</u>
<u>Item 6</u>	<u>Exhibits</u>
	<u>66</u>
<u>Signature</u>	<u>67</u>

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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,	
	2013	2012	2013	2012
Revenue:				
Net product sales	\$1,644.0	\$1,388.0	\$4,637.4	\$3,970.1
Collaborative agreements and other revenue	2.2	2.3	12.4	8.2
Royalty revenue	28.2	28.9	88.2	81.0
Total revenue	1,674.4	1,419.2	4,738.0	4,059.3
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	86.2	74.6	247.6	219.0
Research and development	584.5	441.5	1,495.0	1,250.7
Selling, general and administrative	448.7	354.6	1,235.8	1,003.4
Amortization of acquired intangible assets	65.7	46.2	197.1	132.1
Acquisition related charges and restructuring, net	33.7	0.7	79.4	28.9
Total costs and expenses	1,218.8	917.6	3,254.9	2,634.1
Operating income	455.6	501.6	1,483.1	1,425.2
Other income and (expense):				
Interest and investment income, net	5.3	2.8	14.6	9.6
Interest (expense)	(24.0) (17.9) (61.5) (40.7
Other income (expense), net	5.1	(10.0) 12.0	(2.9
Income before income taxes	442.0	476.5	1,448.2	1,391.2
Income tax provision	69.5	52.3	212.7	198.1
Net income	\$372.5	\$424.2	\$1,235.5	\$1,193.1
Net income per common share:				
Basic	\$0.90	\$0.99	\$2.98	\$2.75
Diluted	\$0.87	\$0.97	\$2.87	\$2.69
Weighted average shares:				
Basic	412.3	427.2	414.7	434.1
Diluted	428.8	436.3	430.5	443.4

See accompanying Notes to Unaudited Consolidated Financial Statements

Table of Contents

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

	Three-Month Periods		Nine-Month Periods	
	Ended September 30, 2013	2012	Ended September 30, 2013	2012
Net income	\$372.5	\$424.2	\$1,235.5	\$1,193.1
Other comprehensive income (loss):				
Foreign currency translation adjustments	17.9	4.7	22.0	6.8
Change in functional currency of a foreign subsidiary	—	—	—	13.1
Net unrealized gains (losses) related to cash flow hedges:				
Unrealized holding gains (losses), net of tax expense (benefit) of (\$0.2) and (\$1.3) for the three-months ended September 30, 2013 and 2012, respectively, and \$0 and (\$13.1) for the nine-months ended September 30, 2013 and 2012, respectively.	(89.6) (26.8) (3.2) 21.1
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$0.3 and \$0.6 for the three-months ended September 30, 2013 and 2012, respectively, and \$6.5 and (\$2.4) for the nine-months ended September 30, 2013 and 2012, respectively.	(11.4) (24.9) (11.6) (59.9
Net unrealized gains (losses) on marketable securities available for sale:				
Unrealized holding gains (losses), net of tax expense (benefit) of \$58.5 and \$0 for the three-months ended September 30, 2013 and 2012, respectively, and \$78.4 and (\$0.1) for the nine-months ended September 30, 2013 and 2012, respectively.	104.6	1.7	137.6	3.3
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$0.8 and \$0 for the three-months ended September 30, 2013 and 2012, respectively, and \$1.8 and \$0 for the nine-months ended September 30, 2013 and 2012, respectively.	2.2	0.4	4.4	0.1
Total other comprehensive income (loss)	23.7	(44.9) 149.2	(15.5
Comprehensive income	\$396.2	\$379.3	\$1,384.7	\$1,177.6

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, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$2,423.0	\$2,090.4
Marketable securities available for sale	3,424.3	1,809.9
Accounts receivable, net of allowances of \$44.0 and \$33.0 at September 30, 2013 and December 31, 2012, respectively	1,093.3	960.5
Inventory	313.3	259.5
Deferred income taxes	5.5	93.2
Other current assets	387.8	320.2
Total current assets	7,647.2	5,533.7
Property, plant and equipment, net	592.3	578.4
Intangible assets, net	2,908.2	3,100.4
Goodwill	2,042.1	2,042.8
Other assets	439.3	479.0
Total assets	\$13,629.1	\$11,734.3
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings	\$405.9	\$308.5
Accounts payable	139.6	145.6
Accrued expenses	870.1	775.7
Income taxes payable	9.9	11.8
Current portion of deferred revenue	44.8	17.3
Other current liabilities	471.0	431.3
Total current liabilities	1,941.3	1,690.2
Deferred revenue, net of current portion	20.8	16.2
Income taxes payable	209.6	188.2
Deferred income taxes	857.0	1,018.4
Other non-current liabilities	477.4	355.5
Long-term debt, net of discount	4,228.3	2,771.3
Total liabilities	7,734.4	6,039.8
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding at September 30, 2013 and December 31, 2012, respectively	—	—
Common stock, \$.01 par value per share, 575.0 million shares authorized; issued 509.5 million and 498.4 million shares at September 30, 2013 and December 31, 2012, respectively	5.1	5.0
Common stock in treasury, at cost; 96.9 million and 78.7 million shares at September 30, 2013 and December 31, 2012, respectively	(6,930.1) (4,823.2
Additional paid-in capital	8,462.1	7,539.8
Retained earnings	4,258.1	3,022.6
Accumulated other comprehensive income (loss)	99.5	(49.7

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

Total stockholders' equity	5,894.7	5,694.5
Total liabilities and stockholders' equity	\$13,629.1	\$11,734.3

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,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 1,235.5	\$ 1,193.1
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	71.8	59.9
Amortization	205.0	133.0
Provision for accounts receivable allowances	8.3	14.6
Deferred income taxes	(161.5) 143.6
Impairment charges	18.8	64.9
Change in value of contingent consideration	79.5	26.3
Share-based compensation expense	227.4	171.0
Share-based employee benefit plan expense	25.2	15.1
Reclassification adjustment for cash flow hedges included in net income	(5.1) (62.4
Unrealized change in value of derivative instruments	10.8	47.9
Realized losses on marketable securities available for sale	6.0	0.2
Other, net	0.1	1.3
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(138.7) (34.6
Inventory	(62.6) (46.3
Other operating assets	(49.7) 182.8
Assets held for sale, net	—	(1.2
Accounts payable and other operating liabilities	150.7	99.2
Income tax payable	22.0	(469.1
Deferred revenue	31.7	(0.3
Net cash provided by operating activities	1,675.2	1,539.0
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	1,936.2	1,188.7
Purchases of marketable securities available for sale	(3,237.3) (1,517.5
Payments for acquisition of business, net of cash acquired	—	(352.2
(Purchases) sales of intellectual property and other assets	(19.4) 15.8
Capital expenditures	(93.1) (81.9
Purchases of investment securities	(27.9) (30.0
Other investing activities	(1.9) (1.0
Net cash used in investing activities	(1,443.4) (778.1
Cash flows from financing activities:		
Payment for treasury shares	(2,068.0) (1,481.2
Proceeds from short-term borrowing	3,761.0	3,874.4
Principal repayments on short-term borrowing	(3,665.9) (4,075.4
Proceeds from the issuance of long-term debt	1,479.6	1,486.7
Net proceeds from exercise of common stock options and warrants	458.0	321.0
Excess tax benefit from share-based compensation arrangements	139.0	19.9
Net cash provided by financing activities	103.7	145.4

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

Effect of currency rate changes on cash and cash equivalents	(2.9) (50.3)
Net increase in cash and cash equivalents	332.6	856.0	
Cash and cash equivalents at beginning of period	2,090.4	1,859.5	
Cash and cash equivalents at end of period	\$2,423.0	\$2,715.5	
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,	
	2013	2012
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized (gain) loss on marketable securities available for sale	\$(216.2) \$(3.2
Matured shares tendered in connection with stock option exercises	\$(0.1) \$(0.2
Supplemental disclosure of cash flow information:		
Interest paid	\$67.4	\$25.0
Income taxes paid	\$226.2	\$369.6

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 that may 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[®], VIDAZA[®], ABRAXANE[®], POMALYST[®]/IMNOVID[®], THALOMID[®] (inclusive of Thalidomide Celgene[®]) and ISTODAX[®].

During the nine-months ended September 30, 2013, we received the following approvals in major markets for new products or additional approvals for existing products:

REVLIMID[®] was approved for an additional indication by the U.S. Food and Drug Administration (FDA) in June 2013 for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which must include bortezomib.

REVLIMID[®] was also approved by the European Commission (EC) in June 2013 for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

ABRAXANE[®] was approved for an additional indication by the FDA in September 2013 as a first-line treatment for patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

POMALYST[®] received its first approval from the FDA in February 2013 for the treatment of patients with multiple myeloma 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.

POMALYST[®] (sold in the European Union (EU) under the trade name IMNOVID[®]) was approved by the EC in August 2013, in combination with dexamethasone, for adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy.

Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR[®] and the entire RITALIN[®] family of drugs, the sale of services through our Celgene Cellular Therapeutics 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.

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 civil 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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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, 2012 (2012 Annual Report on Form 10-K). The following additional significant accounting policies also apply:

Investments in Other Entities: Investments in equity securities of companies that become publicly traded are accounted for as available-for-sale marketable securities prospectively from the date of such companies' initial public offering.

New Accounting Pronouncements: In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update "Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income" (ASU 2013-2). ASU 2013-2 requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. generally accepted accounting principles (GAAP) to be reclassified in its entirety to net income. The amendments require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. An entity shall provide this information together, in one location, either on the face of the statement where net income is presented or as a separate disclosure in the notes to the financial statements. The amendments are effective prospectively for reporting periods beginning after December 15, 2012. The adoption of ASU 2013-2 did not have a material impact on our financial position or results of operations.

In July 2013, the FASB issued Accounting Standards Update "Derivatives and Hedging (Topic 815): Inclusion of the Fed Funds Effective Swap Rate (or Overnight Index Swap Rate) as a Benchmark Interest Rate for Hedge Accounting Purposes" (ASU 2013-10). ASU 2013-10 permits the use of the Fed Funds Effective Swap Rate (also referred to as the Overnight Index Swap Rate), in addition to the U.S. government rate (UST) and London Interbank Offered Rate (LIBOR), as a U.S. benchmark interest rate for hedge accounting purposes. This update is effective prospectively for qualifying new or re-designated hedging relationships entered into on or after July 17, 2013. The adoption of ASU 2013-10 did not have a material impact on our financial position or results of operations.

In July 2013, the FASB issued Accounting Standards Update "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss (NOL) carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when (1) the uncertain tax position would reduce the NOL or other carryforward under the tax law of the applicable jurisdiction and (2) the entity intends to use the deferred tax asset for that purpose. ASU 2013-11 is effective prospectively for fiscal years and interim periods within those years, beginning after December 15, 2013 for public entities. Early adoption and retrospective application are permitted. We do not expect the adoption of ASU 2013-11 to have a material impact on our financial position or results of operations.

3. Acquisitions

Avila Acquisition

On March 7, 2012 (Acquisition Date) we acquired all of the outstanding common stock of Avila Therapeutics, Inc., which was subsequently renamed Celgene Avilomics Research (Avila). The acquisition resulted in Avila becoming our wholly-owned subsidiary. The results of operations for Avila are included in our consolidated financial statements from the Acquisition Date and the assets and liabilities of Avila have been recorded at their respective fair values on the Acquisition Date and consolidated with our other assets and liabilities.

We paid \$352.2 million in cash, net of cash acquired and we may make additional payments based on achievement of developmental and regulatory milestones. Our potential contingent milestone payments are classified as liabilities, which were measured at fair value as of the Acquisition Date. The range of potential milestone payments is from no payment if none of the milestones are achieved to an estimated maximum of \$595.0 million if all milestones are achieved. The potential milestones consist of the initiation of phase II and phase III studies, investigational new drug (IND) filings and other regulatory events related to certain potential products in various stages of development.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Contingent Value Rights

In connection with the acquisition of Abraxis BioScience, Inc. (Abraxis) on October 15, 2010, we issued Contingent Value Rights (CVRs). Each holder of a CVR is entitled to receive a pro rata portion, based on the number of CVRs then outstanding, of contingent cash payments.

In September 2013, the FDA approved ABRAXANE[®] for use in the treatment of pancreatic cancer, permitting us to market ABRAXANE[®] with a label that includes an overall survival claim. This approval resulted in the achievement of milestone #2 and the subsequent payment of the \$300 million milestone on October 4, 2013 in accordance with the CVR agreement. The fair value of our total liability related to the CVRs was \$347.9 million on September 30, 2013 and \$277.4 million on December 31, 2012. For more information, see Note 2 of Notes to Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K.

4. Earnings Per Share

(Amounts in millions, except per share)	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2013	2012	2013	2012
Net income	\$372.5	\$424.2	\$1,235.5	\$1,193.1
Weighted-average shares:				
Basic	412.3	427.2	414.7	434.1
Effect of dilutive securities:				
Options, restricted stock units, warrants and other incentives	16.5	9.1	15.8	9.3
Diluted	428.8	436.3	430.5	443.4
Net income per share:				
Basic	\$0.90	\$0.99	\$2.98	\$2.75
Diluted	\$0.87	\$0.97	\$2.87	\$2.69

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 4.1 million and 11.6 million shares for the three-month periods ended September 30, 2013 and 2012, respectively. The total number of potential shares of common stock excluded for the nine-month periods ended September 30, 2013 and 2012 was 5.1 million and 11.5 million, respectively.

During the period of April 2009 through September 2013, our Board of Directors has approved repurchases of up to an aggregate of \$9.500 billion of our common stock, including the June 2013 authorization to repurchase an additional \$3.000 billion of our common stock.

As part of the Board authorized share repurchase program, in February 2013 we entered into an Accelerated Share Repurchase (ASR) agreement with an investment bank to repurchase an aggregate of \$600.0 million of our common stock. The total number of shares repurchased under the ASR agreement was 5.2 million shares at a weighted average price of \$114.30 per share.

We have repurchased 1.5 million and 17.8 million shares of common stock under the program from all sources, including the ASR, during the three- and nine-month periods ended September 30, 2013, respectively. As of September 30, 2013, we had a remaining open-ended repurchase authorization of \$2.790 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, which includes changes in a subsidiary's functional currency.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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

	Pension Liability	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, 2012	\$(10.1)) \$4.2	\$(16.1)) \$(27.7)) \$(49.7)
Other comprehensive income (loss) before reclassifications	—	137.6	(3.2)) 22.0	156.4
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	\$(30.9)) \$(5.7)) \$99.5
Balance December 31, 2011	\$(5.4)) \$1.8	\$8.7) \$(67.4)) \$(62.3)
Other comprehensive income before reclassifications	—	3.3	21.1) 19.9	44.3
Amounts reclassified from accumulated other comprehensive income	—	0.1	(59.9)) —	(59.8)
Net current-period other comprehensive income (loss)	—	3.4	(38.8)) 19.9	(15.5)
Balance September 30, 2012	\$(5.4)) \$5.2	\$(30.1)) \$(47.5)) \$(77.8)

Accumulated Other Comprehensive Income Components	Affected Line Item in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2013	2012	2013	2012
Gains (losses) from cash-flow hedges:					
Foreign exchange contracts	Net product sales	\$12.0	\$24.8	\$7.6	\$62.8
Treasury rate lock agreements	Interest (expense)	(0.9)) (0.5)) (2.5)) (0.5)
	Income tax benefit (expense)	0.3	0.6	6.5	(2.4)
Gains (losses) from available-for-sale marketable securities:					
Realized income (loss) on sales of marketable securities	Interest and investment income, net	(3.0)) (0.4)) (6.2)) (0.1)
	Income tax benefit	0.8	—	1.8	—
		\$9.2	\$24.5	\$7.2	\$59.8

Total reclassification, net of
tax

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, 2013 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, non-U.S. government, agency and Supranational securities, global corporate debt securities, asset backed securities, foreign currency forward contracts, purchased foreign currency options and interest rate swap contracts. 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 CVRs. See Note 2 of Notes to Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K for a description of the CVRs. Our Level 2 liabilities relate to interest rate swap contracts, forward starting interest rate swap contracts and written foreign

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

currency options. Our Level 3 liabilities consist of contingent consideration related to undeveloped product rights resulting from the acquisition of Gloucester Pharmaceuticals, Inc. (Gloucester) and contingent consideration related to the undeveloped product rights and the technology platform acquired from the Avila acquisition. The maximum potential payments related to the contingent consideration from the acquisitions of Gloucester and Avila are estimated to be \$120.0 million and \$595.0 million, respectively.

	Balance at September 30, 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	\$3,424.3	\$422.3	\$3,002.0	\$—
Cash equivalents	52.0	—	52.0	—
Total assets	\$3,476.3	\$422.3	\$3,054.0	\$—
Liabilities:				
Forward currency contracts	\$(8.9) \$—	\$(8.9) \$—
Contingent value rights	(347.9) (347.9) —	—
Written currency options	(0.3) —	(0.3) —
Interest rate swaps	(31.5) —	(31.5) —
Other acquisition related contingent consideration	(207.0) —	—	(207.0
Total liabilities	\$(595.6) \$(347.9) \$(40.7) \$(207.0

	Balance at December 31, 2012	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	\$1,809.9	\$0.3	\$1,809.6	\$—
Cash equivalents	27.0	—	27.0	—
Interest rate swaps	1.7	—	1.7	—
Forward currency contracts	17.8	—	17.8	—
Purchased currency options	2.7	—	2.7	—
Total assets	\$1,859.1	\$0.3	\$1,858.8	\$—
Liabilities:				
Contingent value rights	\$(277.4) \$(277.4) \$—	\$—
Written currency options	(5.1) —	(5.1) —
Other acquisition related contingent consideration	(198.1) —	—	(198.1
Total liabilities	\$(480.6) \$(277.4) \$(5.1) \$(198.1

There were no security transfers between Levels 1 and 2 during the nine-month periods ended September 30, 2013 and 2012. The following table represents a roll-forward of the fair value of Level 3 instruments (significant unobservable inputs):

	Nine-Month Periods Ended September	
	30, 2013	2012
Liabilities:		
Balance at beginning of period	\$(198.1) \$(76.9
Amounts acquired or issued	—	(171.7
Net change in fair value	(8.9) 35.6
Settlements	—	—
Transfers in and/or out of Level 3	—	—
Balance at end of period	\$(207.0) \$(213.0

Level 3 liabilities issued during the nine-month period ended September 30, 2012 consisted of contingent consideration related to the acquisition of Avila.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

7. Derivative Instruments and Hedging Activities

Our revenue, 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 forward contracts, foreign currency option 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.

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

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

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at September 30, 2013 and December 31, 2012 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss) (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2013 and December 31, 2012:

	Notional Amount	
	September 30, 2013	December 31, 2012
Foreign Currency		
Australian Dollar	\$53.7	\$5.1
British Pound	313.8	77.9
Canadian Dollar	84.7	134.4
Euro	2,425.3	969.3
Japanese Yen	703.2	236.2
Total	\$3,580.7	\$1,422.9

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, 2013, 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, 2013 and December 31, 2012 were \$816.1 million and \$795.4 million, respectively.

Foreign Currency Option Contracts: We hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

denominated in euros. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and amounts but with different strike prices; this combination of transactions is generally referred to as a “collar”. The expiration dates and notional amounts correspond to the amount and timing of forecasted future foreign currency sales. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. dollar equivalent value of our anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the call option partially offsets the premium paid for the purchased put option, resulting in a net cost for the collars.

In order to fully offset the net cost of collars entered into to hedge sales, we sold local currency put options with a lower strike price and the same expiration dates and amounts as the option contracts included in the collars. These written put options introduced risk of loss if the U.S. dollar were to strengthen beyond the strike price of the written put options. We entered into purchased put options that were not designated as hedges in order to partially offset the risk of loss that would be incurred on the written put options if the US dollar were to strengthen beyond the strike price of the written put. Gains and losses associated with the non-hedge put options have been recorded on the income statement as other income (expense), net.

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2013 and December 31, 2012:

	Notional Amount*	
	September 30, 2013	December 31, 2012
Foreign Currency Option		
Designated as hedging activity:		
Purchased Put	\$24.3	\$228.8
Written Call	\$25.4	\$235.9
Not designated as hedging activity:		
Purchased Put	\$22.7	\$160.5
Written Put	\$(22.7) \$(216.0)

* U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied times the strike value of the foreign currency option. The local currency notional amounts of our purchased put and written call that are designated as hedging activity are equal to each other.

Interest Rate Risk Management

In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) or treasury rate lock agreements (treasury rate locks) that are designated as cash flow hedges to hedge against changes in interest rates that could impact expected future issuances of debt. To the extent these hedges of cash flows related to anticipated debt are effective, any realized or unrealized gains or losses on the treasury rate locks or forward starting swaps are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

Forward Starting Interest Rate Swaps: During September 2013 we entered into a forward starting swap, that was designated as a cash flow hedge, with a notional value of \$100.0 million, an effective date in November 2014 and a maturity of ten years to hedge against changes in interest rates that could impact an anticipated issuance of debt. During October 2013, we entered into additional forward starting swaps with an effective date in November 2014 and an aggregate notional value of \$150.0 million, consisting of \$100 million with a five year maturity and \$50 million

with a ten year maturity.

Treasury Rate Lock Agreements: During 2012, we entered into treasury rate locks in anticipation of issuing fixed-rate notes that were issued in August 2012. The treasury rate locks were settled during 2012, resulting in losses of \$35.3 million that were recorded to OCI. No material amounts were recorded in income during the nine-month periods ended September 30, 2013 or 2012 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. We have not entered into any treasury rate locks during the nine months ended September 30, 2013 and at September 30, 2013 we had no outstanding treasury rate locks.

Interest Rate Swap Contracts: From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in 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

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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. We may terminate the hedging relationship of certain swap contracts by settling the contracts or by entering into offsetting contracts. At the time a hedging relationship is terminated, accumulated gains or losses associated with the swap contract are measured and recorded as a reduction of current and future interest expense associated with the previously hedged notes.

During the nine-month period ended September 30, 2013, we entered into swap contracts that were designated as hedges of our fixed rate notes due in 2015, 2017, 2018, 2020, 2022 and 2023 and also terminated the hedging relationship by settling certain of those swap contracts during the nine-month period ended September 30, 2013. This resulted in net proceeds received of \$21.9 million which is accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 for additional details related to reductions of current and future interest expense.

At September 30, 2013, we were a party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. The following table summarizes the notional amounts of our outstanding swap contracts at September 30, 2013 and December 31, 2012:

	Notional Amount	
	September 30, 2013	December 31, 2012
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	\$—
1.900% senior notes due 2017	300.0	100.0
3.950% senior notes due 2020	500.0	—
3.250% senior notes due 2022	850.0	200.0
4.000% senior notes due 2023	50.0	—
Total	\$2,000.0	\$300.0

Derivatives not designated as hedging instruments:

Foreign exchange contracts*	Other current assets	45.8	Other current assets	36.3
	Other current liabilities	10.4	Other current liabilities	21.4
	Other current assets	0.6	Other current assets	—
Interest rate swap agreements	Other non-current assets	1.7	Other non-current assets	—
Total		\$133.5		\$116.4

* 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, 2013 and 2012:

Three-Month Period Ended September 30, 2013						
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative (1)	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative (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)	
	(Effective Portion)	(Effective Portion)	(Effective Portion)			
Foreign exchange contracts	\$ (89.8) Net product sales	\$ 11.9	Other income, net	\$ 5.1	(2)
Treasury rate lock agreements	\$ —	Interest expense	\$ (0.9)		

(1) Net losses of \$1.9 million are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) The amount of net gains recognized in income represents \$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.

Three-Month Period Ended September 30, 2012						
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative (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)	
	(Effective Portion)	(Effective Portion)	(Effective Portion)			
Foreign exchange contracts	\$ (24.5) Net product sales	\$ 24.8	Other income, net	\$ (1.7) (1)
	\$ (3.5) Interest expense	\$ (0.5)		

Treasury rate
lock agreements

(1) The amount of net losses recognized in income represents \$2.2 million in losses related to the ineffective portion of the hedging relationships and \$0.5 million of gains related to amounts excluded from the assessment of hedge effectiveness.

Nine-Month Period Ended September 30, 2013						
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative	
	(Effective Portion)	(Effective Portion)	(Effective Portion)	(Ineffective Portion and Amount Excluded From Effectiveness Testing)	(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 \$1.7 million in gains related to the ineffective portion of the hedging relationships and \$7.3 million of gains related to amounts excluded from the assessment of hedge effectiveness.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Instrument	Nine-Month Period Ended September 30, 2012				
	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
	(Effective Portion)	(Effective Portion)	(Effective Portion)	(Ineffective Portion and Amount Excluded From Effectiveness Testing)	(Ineffective Portion and Amount Excluded From Effectiveness Testing)
Foreign exchange contracts	\$43.3	Net product sales	\$62.8	Other income, net	\$(3.4) (1)
Treasury rate lock agreements	\$(35.3)) Interest expense	\$(0.5)))

(1) The amount of net losses recognized in income represents \$7.5 million in losses related to the ineffective portion of the hedging relationships and \$4.1 million of gains related to amounts excluded from the assessment of hedge effectiveness.

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, 2013 and 2012:

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,	
		2013	2012	2013	2012
Interest rate swap agreements	Interest expense	\$9.8	\$2.0	\$21.8	\$5.6

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, 2013 and 2012:

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,	
		2013	2012	2013	2012
Foreign exchange contracts	Other income, net	\$(27.0)	\$(11.5)	\$(42.2)	\$4.5
Treasury rate lock agreements	Other income, net	\$—	\$—	\$—	\$3.7

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 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.

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

Money market funds of \$860.4 million and \$1.160 billion at September 30, 2013 and December 31, 2012, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security at September 30, 2013 and December 31, 2012 were as follows:

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
September 30, 2013				
U.S. Treasury securities	\$1,017.2	\$0.7	\$—	\$1,017.9
U.S. government-sponsored agency securities	400.1	0.2	(0.9)) 399.4
U.S. government-sponsored agency MBS	587.1	0.5	(7.9)) 579.7
Non-U.S. government, agency and Supranational securities	74.2	—	(0.1)) 74.1
Corporate debt - global	701.8	0.9	(1.2)) 701.5
Asset backed securities	229.6	0.1	(0.3)) 229.4
Marketable equity securities	190.7	231.6	—	422.3
Total available-for-sale marketable securities	\$3,200.7	\$234.0	\$(10.4)) \$3,424.3
December 31, 2012				
U.S. Treasury securities	\$902.0	\$0.5	\$—	\$902.5
U.S. government-sponsored agency securities	303.5	0.3	—	303.8
U.S. government-sponsored agency MBS	387.2	1.6	(1.8)) 387.0
Non-U.S. government, agency and Supranational securities	7.1	—	—	7.1
Corporate debt - global	208.5	0.9	(0.2)) 209.2
Marketable equity securities	0.4	—	(0.1)) 0.3
Total available-for-sale marketable securities	\$1,808.7	\$3.3	\$(2.1)) \$1,809.9

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 mortgage-backed securities (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, 2013 primarily reflects the increase in market value for certain equity investments subsequent to their respective initial public offerings. Net unrealized losses in the marketable debt securities primarily reflect the impact of increased interest rates at September 30, 2013.

Duration periods of available-for-sale debt securities at September 30, 2013 were as follows:

Amortized Fair

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

	Cost	Value
Duration of one year or less	\$1,370.4	\$1,369.3
Duration of one through three years	1,419.0	1,415.7
Duration of three through five years	203.7	200.4
Duration of over five years	16.9	16.6
Total	\$3,010.0	\$3,002.0

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, 2013 and December 31, 2012 follows:

	September 30, 2013	December 31, 2012
Raw materials	\$ 125.7	\$ 79.2
Work in process	96.4	86.5
Finished goods	91.2	93.8
Total	\$ 313.3	\$ 259.5

10. Intangible Assets and Goodwill

Intangible Assets: Our intangible assets consist of developed product rights obtained primarily from the Pharmion, Gloucester and Abraxis acquisitions, in-process research and development (IPR&D) product rights from the Gloucester and Avila acquisitions and technology obtained primarily from the Avila acquisition. Also included are contract-based licenses and other miscellaneous intangibles. The amortization periods related to our finite-lived intangible assets range from one to 17 years. The following summary of intangible assets by category includes intangibles currently being amortized and intangibles not yet subject to amortization:

September 30, 2013	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
Amortizable intangible assets:				
Acquired developed product rights	\$ 3,405.9	\$ (973.4)	\$ 2,432.5	13.0
Technology	333.7	(75.5)	258.2	7.0
Licenses	66.2	(12.9)	53.3	16.5
Other	45.0	(18.7)	26.3	8.3
	3,850.8	(1,080.5)	2,770.3	12.5
Non-amortized intangible assets:				
Acquired IPR&D product rights	137.9	—	137.9	
Total intangible assets	\$ 3,988.7	\$ (1,080.5)	\$ 2,908.2	
December 31, 2012	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
Amortizable intangible assets:				
Acquired developed product rights	\$ 3,400.4	\$ (814.5)	\$ 2,585.9	13.0
Technology	333.3	(39.8)	293.5	7.0
Licenses	64.3	(10.0)	54.3	16.8
Other	43.4	(14.6)	28.8	8.5
	3,841.4	(878.9)	2,962.5	12.5
Non-amortized intangible assets:				
Acquired IPR&D product rights	137.9	—	137.9	
Total intangible assets	\$ 3,979.3	\$ (878.9)	\$ 3,100.4	

The gross carrying value of intangible assets increased by \$9.4 million at September 30, 2013 compared to December 31, 2012 primarily resulting from the acquisition of \$5.5 million in developed product rights and \$3.9

million from other miscellaneous agreements.

Amortization expense was \$67.5 million and \$46.4 million for the three-month periods ended September 30, 2013 and 2012, respectively, and \$201.6 million and \$133.0 million for the nine-month periods ended September 30, 2013 and 2012, respectively. The increases in amortization expense in the quarter and year-to-date periods ended September 30, 2013 were primarily due to the October 2012 approval of ABRAXANE® in the U.S. for the treatment of non-small cell lung cancer (NSCLC) which resulted in the commencement of amortization of the related intangible asset and an increase in amortization of technology related to the March 7, 2012 acquisition of Avila and its Avilomics™ platform. Assuming no changes in the gross carrying amount of intangible

20

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

assets, the amortization of intangible assets for years 2013 through 2017 is estimated to be in the range of approximately \$255.0 million to \$270.0 million annually.

Goodwill: At September 30, 2013, our goodwill related to 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 change in carrying value of goodwill is summarized as follows:

Balance at December 31, 2012	\$2,042.8
Tax benefit on the exercise of Pharmion converted stock options	(0.7)
Balance at September 30, 2013	\$2,042.1

11. Debt

Senior Notes: Summarized below are the carrying values of our senior notes at September 30, 2013 and December 31, 2012:

	September 30, 2013	December 31, 2012
2.450% senior notes due 2015	\$515.7	\$ 520.1
1.900% senior notes due 2017	500.8	500.6
2.300% senior notes due 2018	400.1	—
3.950% senior notes due 2020	492.4	499.0
3.250% senior notes due 2022	975.0	1,002.1
4.000% senior notes due 2023	698.1	—
5.700% senior notes due 2040	249.6	249.5
5.250% senior notes due 2043	396.6	—
Total long-term debt	\$4,228.3	\$ 2,771.3

At September 30, 2013, the fair value of our outstanding Senior Notes was \$4.252 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

In August 2013, we issued an additional \$1.500 billion principal amount of senior notes consisting of \$400.0 million aggregate principal amount of 2.300% Senior Notes due 2018 (the 2018 notes), \$700.0 million aggregate principal amount of 4.000% Senior Notes due 2023 (the 2023 notes) and \$400.0 million aggregate principal amount of 5.250% Senior Notes due 2043 (the 2043 notes) and, together with the 2018 notes and 2023 notes, referred to herein as the “2013 issued notes”. The 2013 issued notes were issued at 99.792%, 99.452% and 99.147% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$12.5 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 notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2014 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price defined in a make-whole clause 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 15 basis points in the case of the 2018 notes, 20 basis points in the case of the 2023 notes and 25 basis points in the case of the 2043 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.

During 2012, we entered into treasury rate locks in anticipation of issuing the fixed-rate notes that were issued in August 2012. As of September 30, 2013, a balance of \$31.4 million in losses remained in OCI related to treasury rate locks and will be recognized as interest expense over the life of the 2017 notes and the 2022 notes.

At September 30, 2013, 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, 2013 effectively convert the hedged

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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, 2013, we had a balance of \$33.8 million of gains recorded as a reduction of our debt as a result of past swap contract settlements, including \$14.7 million related to the settlement of swap contracts during the nine months ended September 30, 2013.

Commercial Paper: The maximum aggregate amount available under our Commercial Paper program was increased by \$500.0 million to \$1.500 billion in May 2013. The carrying value of Commercial Paper as of September 30, 2013 and December 31, 2012 was \$405.9 million and \$308.5 million, respectively, and approximated its fair value. The effective interest rate on our outstanding Commercial Paper at September 30, 2013 was 0.3%.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of \$1.500 billion, which was increased from \$1.000 billion in April 2013. During April 2013, the term of the Credit Facility was also extended from September 2, 2016 to 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 in U.S. dollars for working capital, capital expenditures and other corporate purposes. The Credit Facility currently serves as backup liquidity for our Commercial Paper borrowings. At September 30, 2013 and December 31, 2012, 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 financial covenants as of September 30, 2013.

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) (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 12, 2013, our stockholders approved an amendment and restatement of the Plan, which included the following key modifications: adoption of an aggregate share reserve of 104,981,641 shares of Common Stock, which includes 9,000,000 new shares of Common Stock; increase in the maximum payment to an eligible employee under a cash-based performance award from \$4.0 million to \$6.0 million; and extension of the term of the plan through April 17, 2023.

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, 2013 and 2012:

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Cost of goods sold (excluding amortization of acquired intangible assets)	\$6.1	\$3.3	\$12.6	\$9.2

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

Research and development	41.7	27.2	100.5	75.8
Selling, general and administrative	44.2	32.1	114.3	86.0
Total share-based compensation expense	92.0	62.6	227.4	171.0
Tax benefit related to share-based compensation expense	29.9	17.0	66.1	45.7
Reduction in income	\$62.1	\$45.6	\$161.3	\$125.3

Share-based compensation cost included in inventory was \$1.7 million and \$1.2 million at September 30, 2013 and December 31, 2012, respectively.

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, 2013 (in thousands):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Outstanding at December 31, 2012	42,592	4,463	26
Changes during the Year:			
Granted	6,639	1,517	45
Exercised / Released	(9,951) (832) (6
Forfeited	(863) (173) (8
Expired	(36) N/A	N/A
Outstanding at September 30, 2013	38,381	4,975	57

Total compensation cost related to nonvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at September 30, 2013 were as follows (dollars in millions):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Unrecognized compensation cost	\$369.7	\$243.6	\$4.4
Expected weighted-average period in years of compensation cost to be recognized	2.2	1.6	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.

We operate under an income tax holiday in Switzerland that exempts us from Swiss income taxes on most of our operations in Switzerland through the end of 2015. In September 2013, we entered into a new tax holiday agreement with the Swiss tax authorities which reflects the planned expansion of our Swiss operations and will result in substantially similar Swiss tax benefits through the end of 2024. The new tax holiday is not expected to have a material impact on our 2013 financial statements.

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 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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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, 2013 gross unrecognized tax benefits decreased by \$2.2 million, exclusive of interest, as a result of net settlements and ongoing examinations related to tax positions taken in prior years. Increases to the amount of unrecognized tax benefits since January 1, 2013 of approximately \$23.6 million relate primarily to current year operations. 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 significant decrease in our unrecognized tax benefits. 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 individual arrangement to be material. See Note 17 of Notes to Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K for a description of certain other collaboration agreements entered into prior to January 1, 2013. The following is a brief description of certain collaborations entered into during the nine months ended September 30, 2013:

bluebird bio, Inc.: On March 19, 2013, we entered into a collaboration agreement with bluebird bio, Inc. (bluebird) to discover, develop and commercialize novel disease-altering gene therapies in oncology. The collaboration focuses on applying gene therapy technology to modify a patient's own T-cells, known as chimeric antigen receptor (CAR) T-cells, to target and destroy cancer cells. The collaboration has the potential to lead to the development of multiple CAR T-cell products. Under the agreement, we have an option to license any products resulting from the collaboration after the completion of a phase I clinical study by bluebird for each such product.

The financial terms of the agreement include an upfront payment and up to \$225.0 million per product in aggregate potential option fees and clinical and regulatory milestones. bluebird also has the right to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and profit share in the United States in exchange for a reduction of milestone payments. Royalties would also be paid to bluebird in regions where there is no profit share, including in the United States if bluebird declines to exercise their co-development and profit sharing rights.

The agreement has a termination date of March 19, 2016 and we have the right to unilaterally extend the agreement until March 19, 2019 with the payment of extension fees. Further, we have the ability to terminate the collaboration at our discretion upon 90 days written notice to bluebird. If a product is optioned, the parties will enter into a pre-negotiated license agreement and potentially a co-development agreement should bluebird exercise its right to participate in the development and commercialization in the United States. The license agreement, if not terminated sooner, would expire upon the expiration of all applicable royalty terms under the agreement with respect to the particular product and the co-development agreement, if not terminated sooner, would expire when the product is no longer being developed or commercialized in the United States. Upon the expiration of a particular license agreement, we will have a fully paid-up, royalty-free license to use bluebird intellectual property to manufacture, market, use and sell such licensed product developed under the agreement.

FORMA Therapeutics Holdings, LLC: On April 19, 2013, we entered into a collaboration agreement with FORMA Therapeutics Holdings, LLC (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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

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.

MorphoSys AG: On June 26, 2013, we signed a collaboration, license and equity purchase agreement with MorphoSys AG (MorphoSys) to jointly develop MOR202 globally and to co-promote MOR202 in Europe. On August 10, 2013, the transaction became effective. MOR202 is a fully human monoclonal antibody targeting CD38 to treat patients with multiple myeloma and certain leukemias. MOR202 is currently being evaluated in a phase I/IIa trial in patients with relapsed/refractory multiple myeloma.

The financial terms of the transaction include an initial payment of EUR 117.0 million (approximately \$152.1 million) that includes an upfront payment and an equity investment for 797,150 new shares of MorphoSys. In addition, MorphoSys could receive up to EUR 511.0 million (approximately \$664.5 million) in development, regulatory and sales milestones and tiered royalties on net sales of MOR202 outside the co-promotion territory. In the co-promotion territory, MorphoSys retains a 50/50 profit sharing right on MOR202 in exchange for paying one third of the MOR202 development costs. Should MorphoSys choose to opt out of its co-promotion rights, MorphoSys would receive tiered royalties on net sales of MOR202 globally.

The agreement may be terminated at our discretion upon six months written notice to MorphoSys, or by either party upon material breach of the other party. Upon the expiration of the agreement, we will have a fully paid-up, irrevocable, perpetual, non-terminable license to use the intellectual property licensed from MorphoSys to research, develop, make, commercialize, use and sell MOR202.

Acetylon Pharmaceuticals, Inc.: On July 26, 2013, we entered into a strategic collaboration and option agreement with Acetylon Pharmaceuticals, Inc. (Acetylon). Under the agreement, the parties will support the development of Acetylon's portfolio of oral, selective HDAC inhibitors in oncology, hematology, immunology and neurologic disease

indications. In addition, we have rights to receive certain research and development services from Acetylon and an exclusive right to acquire Acetylon at a later date at a purchase price based upon future independent company valuations.

The collaboration focuses on the continued clinical advancement of Acetylon's lead candidate, ACY-1215, an HDAC6 inhibitor being developed for hematological malignancies, ACY-738 for neurological diseases, an HDAC1/2 inhibitor and a yet unnamed project, spanning cancer and non-cancer disease indications. Under the agreement, we made an upfront \$100.0 million cash payment to Acetylon, which payment included an upfront fee for entering into the collaboration, fees for the exclusive right to acquire Acetylon and the rights to receive certain research and development services from Acetylon. During the term of the agreement, Acetylon will retain control of its drug development programs. If we exercise our right to acquire Acetylon, in addition to the purchase price based upon independent company valuations to be paid at the time of the acquisition, Acetylon shareholders will be eligible to receive potential future milestone payments for either approvals of, or additional indications of, drugs developed by Acetylon and for accomplishing defined sales targets. If all the milestones are achieved, the aggregate amount of the milestone payments would be \$1.100 billion.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The agreement has an expiration date of December 31, 2015 and we have the right to unilaterally extend the agreement until either June 30, 2016 or December 31, 2016 with the payment of an extension fee. Further, we have the ability to terminate the agreement at our discretion upon written notice to Acetylon.

In addition to the collaboration arrangements described above, we entered into a number of collaborative arrangements during the nine months ended September 30, 2013 that resulted in \$12.0 million of assets for investments in equity or other assets. These additional collaboration arrangements include the potential for future milestone payments of up to an aggregate \$373.0 million related to the attainment of specified development and regulatory approval milestones over a period of several years. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs.

Upfront payments to all collaboration partners during the three- and nine-month periods ended September 30, 2013 resulted in research and development expenses of \$171.3 million and \$348.8 million, respectively.

15. Commitments and Contingencies

Other Commitments: In conjunction with a September 2013 equity investment, the parent company of NantHealth LLC assumed, and agreed to pay and satisfy when due, our obligation to pay The Chan Soon-Shiong Institute for Advanced Health (CSS Institute) a \$25.0 million contingent, milestone-based contribution.

Collaboration Arrangements: We have entered into certain research and development collaboration agreements with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature and uncertainty of these arrangements and any future potential payments, no amounts have been recorded in our accompanying Consolidated Balance Sheets at September 30, 2013 and December 31, 2012.

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

We and certain of our subsidiaries are involved in various patent, trademark, commercial and other claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of business. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and we have been subject to claims and other actions related to our business activities. While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters may result in, among other things, modification of our business

practices, product recalls, incurrence of costs and payment of significant penalties, 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 or enforceability of our patents relating to certain of our products or processes. Although we believe we have substantial defenses to these challenges with respect to all our material patents, there can be no assurance as to the outcome of these matters and a loss in any of these proceedings could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that product and could materially affect future results of operations.

Among the principal matters pending are the following:

In the fourth quarter of 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission (FTC). The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order for the FTC to evaluate whether there is reason to believe that we have

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 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.

In the first quarter of 2011, the United States Attorney's Office for the Central District of California informed us that they are investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In the third quarter of 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 are conducting related investigations. We are cooperating with these investigations.

On June 7, 2013, Children's Medical Center Corporation (CMCC) filed a lawsuit against us in the Superior Court of the Commonwealth of Massachusetts. CMCC alleges that our obligation under a license agreement relating to certain thalidomide analog patents entered into in December 2002 to pay a 1% royalty on REVLIMID® net sales revenue and a 2.5% royalty on POMALYST®/IMNOVID® net sales revenue extends beyond February 28, 2013 and that our failure to make royalty payments to CMCC with respect to REVLIMID® and POMALYST®/IMNOVID® subsequent to February 28, 2013 breached the license agreement. We disagree with CMCC's allegations. CMCC is seeking an unspecified amount of damages and a declaration that the license agreement remains in full force and effect. In July 2013, we removed these proceedings to the Federal District Court for the District of Massachusetts. We intend to vigorously defend against CMCC's claims. We do not believe that the ultimate outcome of this proceeding will have a material adverse impact on our financial condition.

REVLIMID®: We had previously announced that we received a Notice Letter dated August 30, 2010, from Natco Pharma Limited of India (Natco) notifying us of Natco's Abbreviated New Drug Application (ANDA), which contains 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). Under the Hatch-Waxman Act of 1984, a generic manufacturer may file an ANDA containing a certification (a "Paragraph IV certification") challenging the validity or infringement of a patent listed in the Orange Book. Natco's Notice letter alleges, among other things, that certain claims of United States Patent Nos. 5,635,517 (the "'517 patent"), 6,045,501 (the "'501 patent"), 6,315,720 (the "'720 patent"), 6,555,554 (the "'554 patent"), 6,561,976 (the "'976 patent"), 6,561,977 (the "'977 patent"), 6,755,784 (the "'784 patent"), 7,119,106 (the "'106 patent") and 7,465,800 (the "'800 patent") are invalid, unenforceable and/or not infringed. Natco's Notice Letter was sent in connection with its filing of an ANDA seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg REVLIMID® capsules.

On October 8, 2010, we filed an infringement action in the United States District Court of New Jersey against Natco in response to the Notice Letter with respect to the '517 patent, the '501 patent, United States Patent No. 6,281,230 (the "'230 patent"), the '720 patent, the '554 patent, the '976 patent, the '977 patent, the '784 patent, the '106 patent and the '800 patent.

Natco responded to our infringement action on November 18, 2010, with its Answer, Affirmative Defenses and Counterclaims. Natco has alleged (through Affirmative Defenses and Counterclaims) that the patents are invalid, unenforceable and/or not infringed by Natco's proposed generic products. After filing the infringement action, we learned the identity of Natco's U.S. partner, Arrow International Limited ("Arrow") and filed an amended complaint on January 7, 2011, adding Arrow as a defendant. On March 25, 2011, we filed a second amended complaint naming Natco, Arrow and Watson Laboratories, Inc. ("Watson", a wholly-owned subsidiary of Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.), which is Arrow's parent) as defendants. Those three entities remain the current

defendants in that action.

On June 12, 2012, we received a Second Notice Letter from Natco, notifying us of Natco's submission in its ANDA of new, additional Paragraph IV certifications against the '517 patent, the '230 patent and United States Patent Nos. 7,189,740 (the "'740 patent'"), 7,855,217 (the "'217 patent'") and 7,968,569 (the "'569 patent'"). On July 20, 2012, we filed a new infringement action in the United States District Court of New Jersey against Natco, Arrow and Watson in response to the Second Notice Letter with respect to the '517 patent, the '230 patent, the '740 patent and the '569 patent, as well as two non-Orange Book listed patents, United States Patent Nos. 7,977,357 (the "'357 patent'") and 8,193,219 (the "'219 patent'"). That action was consolidated with the original action. Natco filed its Answer and Counterclaims on September 28, 2012. Natco's counterclaims in the second action are similar to its counterclaims in the first action. In the second action, Natco added counterclaims against United States Patent No. 8,204,763 (the "'763 patent'"), which we have not asserted against Natco. We moved to dismiss those counterclaims related to the '763 patent for lack of subject matter jurisdiction and Natco withdrew its counterclaims after the Court ordered jurisdictional discovery.

On March 14, 2013, we received a Third Notice Letter from Natco notifying us of Natco's submission in its ANDA of new, additional Paragraph IV certifications against United States Patent Nos. 8,288,415 (the "'415 patent'") and 8,315,886 (the "'886'")

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

patent). On March 22, 2013, we filed a Third Amended Complaint in the original action in the United States District Court of New Jersey against Natco, Arrow and Watson in response to the Third Notice Letter regarding the '415 and '886 patent. Natco filed its Answer and Counterclaims on April 8, 2013. Natco's counterclaims in response to the Third Amended Complaint are similar to its counterclaims in the two previous actions.

On April 16, 2013, we filed a Fourth Amended Complaint in the original action, in the United States District Court of New Jersey, which asserts another recently issued patent, United States Patent No. 8,404,717, against Natco, Arrow and Watson. Natco filed its Answer and Counterclaims on May 2, 2013. Natco's counterclaims in response to the Fourth Amended Complaint are similar to its counterclaims in the three previous actions. On May 6, 2013, we filed a Fifth Amended Complaint in the original action in the United States District Court of New Jersey, which asserts another recently issued patent, United States Patent No. 8,431,598, against Natco, Arrow and Watson. Natco filed its Answer and Counterclaims on May 23, 2013. Natco's counterclaims in response to the Fifth Amended Complaint are similar to its counterclaims in the four previous actions.

A revised Scheduling Order was entered by the Court on May 7, 2013, setting the close of fact discovery for January 20, 2014. Claim construction is currently expected to be fully briefed by the end of December 2013. Dates for a claim construction hearing and trial have yet to be set.

We believe that Natco's defenses and counterclaims are unlikely to be sustained and we intend to vigorously defend our patent rights. We believe it unlikely that (i) Natco will prevail on each and every patent and patent claim subject to the lawsuits and (ii) all of the patent claims will be deemed to be invalid, unenforceable and/or not infringed. Accordingly, the ultimate outcome is not expected to have a material adverse effect on our financial condition or results of operations.

However, if Natco is successful in challenging our patents and the FDA were to approve Natco's ANDA with a comprehensive education and risk management program for a generic version of lenalidomide and a generic product were to be introduced, sales of REVLIMID® could be significantly reduced in the United States, which would have a material adverse effect on our results of operations, cash flows and financial condition.

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. Plaintiffs are seeking damages and injunctive relief. Pursuant to the agreement of the parties, discovery will proceed only with respect to claim construction. A hearing regarding the disputed claims of the patent occurred on August 29, 2013. The court has not yet ruled on the disputed claims. After the Court's ruling on the disputed claims, discovery on all other issues will proceed. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties and may have to license rights from plaintiffs. However, we believe that (a) it is unlikely that the plaintiffs in this matter will prevail and (b) the ultimate outcome will not have a material adverse effect on our financial condition or results of operations.

VIDAZA®: On September 28, 2012, we were named as a defendant in a complaint filed by Ivax LLC (formerly Ivax Corporation) ("Ivax") in the United States District Court for the Southern District of Florida. Ivax LLC alleges that we have infringed the claims of United States Patent No. 7,759,481 (the "'481 patent") by making, using and selling VIDAZA® brand drug in the United States. On October 19, 2012, we filed an answer to this complaint and filed a counterclaim asserting that the '481 patent was invalid and unenforceable. We filed a motion for judgment on the pleadings on November 15, 2012, to which Ivax LLC filed an opposition on December 7, 2012. On March 7, 2013

the Court granted in part and denied in part our motion for judgment on the pleadings. Specifically, the Court dismissed Ivax's complaint without prejudice and ordered Ivax to (i) either file an amended complaint with all necessary factual allegations or (ii) file dismissal papers by March 15, 2013. The Court denied our motion for judgment on the pleadings with respect to our counterclaim.

On March 13, 2013, Ivax filed an amended complaint. On March 28, 2013 we filed an answer and invalidity counterclaim in response to Ivax's amended complaint. A trial date of July 14, 2014 is currently scheduled. At Celgene's request, the Court has ordered that discovery shall be phased to focus on a threshold issue relating to the potential invalidity of the patent. Pursuant to the Court's Order, on or before September 16, 2013, Ivax was required to complete its evaluation of the discovery from the initial phase and report to the Court whether it will continue with the case. On September 16, 2013, Ivax filed a case status report with the Court stating that the parties had reached an agreement in principle on a resolution of this case. In the interim, all discovery as to other issues is stayed. If final agreement is not reached, the case will continue, in which event we intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages and/or ongoing royalties to the plaintiff. However, we believe (a) that it is unlikely that the plaintiff in this matter will prevail and (b) that the ultimate outcome will not 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)

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”) entitled “Treatment of Cancer with Thalidomide Alone or in Combination with Other Anti-Cancer Agents.” Andrulis alleges that we directly infringed, induced infringement of and/or contributed to infringement of one or more claims of the ‘346 patent, by making, using and selling THALOMID® and 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 with respect to the claimed combination. We disagree with Andrulis’ allegations and intend to vigorously defend against this infringement suit. We are required to respond to the complaint on or before November 25, 2013. We believe that the ultimate outcome of this lawsuit will not have a material adverse effect on our financial condition or results of operations.

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 2012 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 (collectively with its subsidiaries, “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 that may 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. Celgene was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID[®], VIDAZA[®], ABRAXANE[®], POMALYST[®]/IMNOVID[®], THALOMID[®] (inclusive of Thalidomide Celgene[®]) and ISTODAX[®].

REVLIMID[®] is an oral immunomodulatory drug marketed in the United States and many international markets for the treatment of patients as indicated below:

29

Table of Contents

Disease Indication	Geographic Approvals
Multiple myeloma (MM), in combination with dexamethasone, in patients who have received at least one prior therapy.	* United States * European Union * Japan * Other international markets
Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities.	* United States * European Union when other therapeutic options are insufficient or inadequate (Approved June 2013) * Japan * Other international markets
Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.	* United States (Approved June 2013)

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 is marketed in the United States for the treatment of all subtypes of MDS. The U.S. regulatory exclusivity for VIDAZA® expired in May 2011. A generic version of VIDAZA® was launched in the United States by a competitor in September 2013 and we expect to experience a significant reduction in our U.S. sales of VIDAZA® beginning in the fourth quarter of 2013. In 2013, we also entered into an agreement to allow Sandoz AG to sell a generic version of VIDAZA®, which we supply. In Europe, VIDAZA® is marketed for the treatment of intermediate-2 and high-risk MDS, as well as acute myeloid leukemia (AML) with 30% blasts and has been granted orphan drug designation for the treatment of MDS and AML. Regulatory exclusivity is expected to continue in Europe through 2018 and in Japan through 2019.

ABRAXANE® is a solvent-free chemotherapy treatment option for approved disease indications 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 Indication	Geographic Approvals
Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy.	* United States * European Union * Japan * Other international markets
Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.	* United States * Japan * Other international markets
Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, in combination with gemcitabine	* United States (Approved September 2013)
Gastric cancer	* Japan

POMALYST®/IMNOVID®¹ (pomalidomide) 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 U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) during 2013 for the treatment of patients as indicated below:

Table of Contents

Disease Indication	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 (Approved February 2013)
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 (Approved August 2013)

¹ We received FDA approval for pomalidomide under the trade name POMALYST®. We received EMA approval for pomalidomide under the trade name IMNOVID®.

POMALYST®/IMNOVID® is also being evaluated in multiple trials in various phases for expanded usage in multiple myeloma and in a phase II trial for systemic sclerosis.

THALOMID®, in combination with dexamethasone, is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) an inflammatory complication of leprosy and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.

ISTODAX® is approved in the United States for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy and for the treatment of peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy. ISTODAX® has received orphan drug designation for the treatment of non-Hodgkin’s T-cell lymphomas, which includes CTCL and PTCL.

Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Celgene Cellular Therapeutics subsidiary and other licensing agreements.

We continue to invest substantially in research and development in support of multiple ongoing clinical proprietary 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. Phase III trials with POMALYST®/IMNOVID® in relapsed refractory multiple myeloma, in addition to VIDAZA® for AML, CC-486 for MDS and AML and ISTODAX for first-line PTCL are also underway. In solid tumors, we are evaluating ABRAXANE® in phase III trials for metastatic melanoma and additional geographies for pancreatic cancer. Our lead product candidate in inflammation & immunology, apremilast, is being evaluated in a broad phase III program for psoriatic arthritis, psoriasis and ankylosing spondylitis.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies intended to address significant unmet medical needs. For more information relating to our pipeline of potential therapies, see “Item 1 – Business – Celgene Leading Product Candidates” in our 2012 Annual Report on Form 10-K.

We believe that continued acceptance 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.

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

The following table summarizes total revenue and earnings for the three-month periods ended September 30, 2013 and 2012 (dollar amounts in millions, except per share data):

	Three-Month Periods Ended		Increase	Percent	
	September 30,	September 30,			
	2013	2012	(Decrease)	Change	
Total revenue	\$1,674.4	\$1,419.2	\$255.2	18.0	%
Net income	\$372.5	\$424.2	\$(51.7)	(12.2))%
Diluted earnings per share	\$0.87	\$0.97	\$(0.10)	(10.3))%

Table of Contents

Revenue increased \$255.2 million in the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to the continued growth in sales of REVLIMID® and ABRAXANE® as well as sales of POMALYST®/IMNOVID® which was approved by the FDA in February 2013 and by the EMA in August 2013. The \$51.7 million decrease in net income and \$0.10 decrease in diluted earnings per share in the current year quarter was primarily due to a \$116.3 million increase in expenses for upfront payments to enter into collaboration arrangements, an increase of \$33.0 million in expenses for the change in contingent consideration from business acquisitions, increased spending in support of both our currently marketed products and those that we plan to launch, as well as increased amortization expense related to the October 2012 approval of ABRAXANE® in the United States for the treatment of NSCLC and increased share-based compensation expense associated with our increased stock price and changes in forfeiture rate estimates, partly offset by a higher level of net product sales.

The following table summarizes total revenue and earnings for the nine-month periods ended September 30, 2013 and 2012 (dollar amounts in millions, except per share data):

	Nine-Month Periods Ended			Percent	
	September 30,		Increase	Change	
	2013	2012			
Total revenue	\$4,738.0	\$4,059.3	\$678.7	16.7	%
Net income	\$1,235.5	\$1,193.1	\$42.4	3.6	%
Diluted earnings per share	\$2.87	\$2.69	\$0.18	6.7	%

Revenue increased \$678.7 million in the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to the continued growth in sales of REVLIMID® and ABRAXANE® as well as the FDA approval of POMALYST®. The \$42.4 million increase in net income and \$0.18 increase in diluted earnings per share in the current year nine-month period was primarily due to the higher level of net product sales, partly offset by a \$229.9 million increase in expenses related to research and development collaboration arrangements, increased spending in support of both our currently marketed products and those that we plan to launch, as well as increased amortization expense related to ABRAXANE® and share-based compensation expense as noted above.

Results of Operations

Three-Month Periods Ended September 30, 2013 and 2012

Total Revenue: Total revenue and related percentages for the three-month periods ended September 30, 2013 and 2012 were as follows (dollar amounts in millions):

	Three-Month Periods Ended		Increase	Percent	
	September 30,			Change	
	2013	2012	(Decrease)		
Net product sales:					
REVLIMID®	\$1,089.8	\$970.1	\$119.7	12.3	%
VIDAZA®	220.4	219.6	0.8	0.4	%
ABRAXANE®	169.6	106.3	63.3	59.5	%
POMALYST®/IMNOVID®	89.5	3.4	86.1	N/M	
THALOMID®	60.0	75.3	(15.3)	(20.3))%
ISTODAX®	14.0	12.6	1.4	11.1	%
Other	0.7	0.7	—	—	%
Total net product sales	\$1,644.0	\$1,388.0	\$256.0	18.4	%
Collaborative agreements and other revenue	2.2	2.3	(0.1)	(4.3))%
Royalty revenue	28.2	28.9	(0.7)	(2.4))%

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

Total revenue	\$1,674.4	\$1,419.2	\$255.2	18.0	%
N/M - Not meaningful					

Total revenue increased by \$255.2 million, or 18.0%, to \$1.674 billion for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, reflecting increases of \$197.4 million, or 24.6%, in the United States and \$57.8 million, or 9.4%, in international markets.

Net Product Sales: Total net product sales for the three-month period ended September 30, 2013 increased by \$256.0 million, or 18.4%, to \$1.644 billion compared to the three-month period ended September 30, 2012. The increase was comprised of net

Table of Contents

volume increases of \$267.3 million and net price increases of \$4.8 million, partially offset by a \$16.1 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity.

REVLIMID® net sales increased by \$119.7 million, or 12.3%, to \$1.090 billion for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to increased unit sales in both U.S. and international markets in addition to 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 United States unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains. These increases were partially offset by unfavorable changes in price and unfavorable foreign exchange impacts, including the impact of foreign exchange hedging activity.

VIDAZA® net sales increased by \$0.8 million, or 0.4%, to \$220.4 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily reflecting volume increases in international markets which were mostly offset by decreases in international pricing, volume reductions in the United States and unfavorable foreign exchange impacts. A generic version of VIDAZA® was launched in the United States by a competitor in September 2013 and we expect to experience a significant reduction in our U.S. sales of VIDAZA® beginning in the fourth quarter of 2013. In 2013, we also entered into an agreement to allow Sandoz AG to sell a generic version of VIDAZA®, which we supply.

ABRAXANE® net sales increased by \$63.3 million, or 59.5%, to \$169.6 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to increased unit volumes in both U.S. and international markets, reflecting increased acceptance of ABRAXANE® in the treatment of metastatic breast cancer and the October 2012 FDA approval for NSCLC.

POMALYST® was approved by the FDA in February 2013 for patients with multiple myeloma 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. IMNOVID® in combination with dexamethasone was approved by the European Agency for the Evaluation of Medicinal Products in August 2013 for adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy. Net sales of POMALYST®/IMNOVID® totaled \$89.5 million for the three-month period ended September 30, 2013, reflecting net sales of \$77.0 million in the United States and \$12.5 million in international markets.

THALOMID® net sales decreased by \$15.3 million, or 20.3%, to \$60.0 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to lower unit volumes in the U.S. and international markets. The reductions in volume were partially offset by price increases in the United States.

ISTODAX® net sales increased by \$1.4 million, or 11.1%, to \$14.0 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to increases in price and unit sales.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources decreased by \$0.1 million to \$2.2 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012.

Royalty Revenue: Royalty revenue decreased by \$0.7 million to \$28.2 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012 due to decreased royalties earned from Novartis for its sales of FOCALIN XR®.

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

REVLIMID® and POMALYST® are distributed in the United States primarily through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS®) and POMALYST® REMS® programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID® and POMALYST®. Internationally, REVLIMID® and IMNOVID® are distributed under mandatory risk-management distribution programs tailored to meet local competent 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.

Table of Contents

THALOMID[®] is distributed in the United States under our proprietary “System for Thalidomide Education and Prescribing Safety” (S.T.E.P.[®]), program which is a comprehensive education and risk-management distribution program with the objective of providing for the safe and appropriate distribution and use of THALOMID[®]. During 2013, we are integrating the THALOMID[®] distribution program with the REMS[®] programs described above for REVLIMID[®] and POMALYST[®]. Internationally, THALOMID[®] is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities’ specifications to provide for the safe and appropriate distribution and use of THALOMID[®]. These programs vary by country. VIDAZA[®], ABRAXANE[®] and ISTODAX[®] are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID[®], POMALYST[®]/IMNOVID[®] and THALOMID[®].

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[®] and POMALYST[®] are distributed primarily through hospitals and contracted pharmacies, which are typically subject to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity.

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

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We have also analyzed actual billings received from certain 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, or collectively the 2010 U.S. Health Care Reform Law, certain states have only recently begun submitting partial Medicaid Managed Care Organization bills. Our accruals for these Medicaid Managed Care Organization costs remain at an elevated level as we expect more complete invoices from certain states. 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 addition, certain international markets have government-sponsored programs that 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 provide 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 based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

See Critical Accounting Estimates and Significant Accounting Policies in our 2012 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

Table of Contents

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2013 and 2012 were as follows (in millions):

	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
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
Balance at June 30, 2012	\$4.3	\$10.8	\$136.3	\$66.0	\$217.4
Allowances for sales during prior periods	—	—	(9.4)	(2.7)	(12.1)
Allowances for sales during 2012	2.1	16.8	42.5	50.9	112.3
Credits/deductions issued for prior year sales	(0.1)	—	(0.5)	—	(0.6)
Credits/deductions issued for sales during 2012	(1.8)	(14.6)	(31.3)	(47.6)	(95.3)
Balance at September 30, 2012	\$4.5	\$13.0	\$137.6	\$66.6	\$221.7

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2013 and 2012 follows:

Returns and allowances increased by \$4.2 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to a \$4.8 million increase in the returns allowance related to VIDAZA® inventory held by distributors at September 30, 2013 given the launch of a generic version of VIDAZA® in September 2013.

Discounts increased by \$2.2 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to sales increases in the United States.

Government rebates increased by \$30.5 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012, primarily due to a net increase of approximately \$19.4 million in rebates in international markets and an increase of approximately \$11.1 million in rebates related to various U.S. government agencies. The \$19.4 million increase in international markets was primarily driven by a reduction in rebates recorded during 2012 for an amendment to a price/volume agreement for VIDAZA® in a specific European country that resulted in a reduction in government rebates of approximately \$11.5 million for the three-month period ended September 30, 2012. The \$11.1 million increase in the United States was primarily attributable to volume increases and an adjustment to accrual rates for the Medicare Part D Coverage Gap.

Chargebacks and distributor service fees increased by \$25.7 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012. Chargebacks and distributor service fees increased by approximately \$15.6 million and \$6.0 million, respectively, primarily due to higher sales volumes. Increases in rebates related to the TRICARE program and other discounts accounted for the remainder of the increases.

Table of Contents

Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended September 30, 2013 and 2012 were as follows (dollar amounts in millions):

	Three-Month Periods Ended			Percent	
	September 30, 2013	2012	Increase	Change	
Cost of goods sold (excluding amortization of acquired intangible assets)	\$86.2	\$74.6	\$11.6	15.5	%
Percent of net product sales	5.2	% 5.4	%		
Research and development	\$584.5	\$441.5	\$143.0	32.4	%
Percent of total revenue	34.9	% 31.1	%		
Selling, general and administrative	\$448.7	\$354.6	\$94.1	26.5	%
Percent of total revenue	26.8	% 25.0	%		
Amortization of acquired intangible assets	\$65.7	\$46.2	\$19.5	42.2	%
Acquisition related (gains) charges and restructuring, net	\$33.7	\$0.7	\$33.0	N/M	

N/M - Not meaningful

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$11.6 million to \$86.2 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012. The increase was primarily due to the higher level of sales activity, especially the increase in ABRAXANE[®], partly offset by the elimination of royalty payments on sales of REVLIMID[®] resulting 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 related to our royalty agreement with CMCC. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.2% for the three-month period ended September 30, 2013 compared to 5.4% for the three-month period ended September 30, 2012, primarily due to the increase in lower cost REVLIMID[®] sales and the elimination of royalty payments to CMCC on our sales of REVLIMID[®] as noted above.

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 \$143.0 million to \$584.5 million for the three-month period ended September 30, 2013, compared to the three-month period ended September 30, 2012. The increase was primarily due to a \$116.3 million increase in payments related to research and development collaboration arrangements as well as an increase in research activity and clinical study related costs, partly offset by a \$31.2 million in-process research and development (IPR&D) impairment charge recorded in the 2012 three-month period related to the approval of ISTODAX[®] for PTCL in Europe and no IPR&D asset impairment charges recorded in the 2013 three-month period.

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

	Three-Month Periods Ended		Increase (Decrease)
	September 30, 2013	2012	
Human pharmaceutical clinical programs	\$215.6	\$195.8	\$19.8
Other pharmaceutical programs	141.1	112.1	29.0
Drug discovery and development	49.5	40.2	9.3

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

Cellular therapy	7.0	7.3	(0.3)
Collaboration arrangements	171.3	55.0	116.3	
IPR&D impairment	—	31.1	(31.1)
Total	\$584.5	\$441.5	\$143.0	

36

Table of Contents

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, 2013, 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
REVLIMID®	Relapsed and refractory indolent lymphoma

Regulatory approval requests in major markets

Product	Disease Indication	Major Market	Regulatory Agency	Date Targeted for Filing
Apremilast	Psoriasis	U.S.	FDA	Q4-13
Apremilast	Psoriasis and Psoriatic arthritis	E.U.	EMA	Q4-13

Regulatory agency actions

Product	Disease Indication	Major Market	Regulatory Agency	Action
ABRAXANE®	Pancreatic cancer	U.S.	FDA	Approval
IMNOVID®	RRMM ¹	E.U.	EMA	Approval

¹ Relapsed and refractory multiple myeloma

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 professional services, donations to independent non-profit organizations and facilities costs.

Selling, general and administrative expenses increased by \$94.1 million to \$448.7 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012 partly due to a \$25.5 million increase in donations to independent non-profit organizations in the United States, an increase in headcount related costs and marketing activities primarily related to the launch of POMALYST®, pre-launch expenses for ABRAXANE® in pancreatic cancer, headcount increases to prepare for a future launch of apremilast, a \$3.6 million increase in service fees attributable to Latin American operations, an increase in incentive accruals and continued support of our currently marketed products.

Table of Contents

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, 2013 and 2012 (in millions):

	Three-Month Periods Ended		Increase
	September 30,		
	2013	2012	(Decrease)
Acquisitions			
Abraxis	\$40.0	\$20.5	\$19.5
Avila	11.9	11.8	0.1
Gloucester	12.8	12.9	(0.1)
Pharmion	1.0	1.0	—
Total amortization	\$65.7	\$46.2	\$19.5

Amortization of acquired intangible assets increased by \$19.5 million to \$65.7 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012 primarily due to \$19.5 million from the October 2012 approval of ABRAXANE® in the United States for the treatment of NSCLC which resulted in the commencement of amortization of the related intangible asset.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition related (gains) charges and restructuring, net was a net charge of \$33.7 million and \$0.7 million for the three-month periods ended September 30, 2013 and 2012, respectively. The \$33.0 million increase in net charges in the current year quarter was primarily due to a change in the fair value of our liability related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis.

Interest and Investment Income, Net: Interest and investment income, net increased by \$2.5 million to \$5.3 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012 primarily due to higher investment balances compared to the prior year quarter.

Interest (Expense): Interest (expense) increased by \$6.1 million to \$24.0 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012 primarily due to interest and fees associated with the issuance of \$1.500 billion in senior notes in August 2012 and the issuance of an additional \$1.500 billion in senior notes in August 2013.

Other Income (Expense), Net: Other income (expense), net was a net income of \$5.1 million for the three-month period ended September 30, 2013 and an expense of \$10.0 million for the three-month periods ended September 30, 2012. The \$15.1 million favorable variance was primarily due to \$11.5 million in impairment losses related to our investments in certain cost basis equity securities included in the 2012 three-month period and the 2013 favorable impact from forward point amortization on foreign exchange forward contracts.

Income Tax Provision: The income tax provision increased by \$17.2 million to \$69.5 million for the three-month period ended September 30, 2013 compared to the three-month period ended September 30, 2012. The estimated full year 2013 underlying effective tax rate of 15.0% reflects the impact of our global business footprint. The increase in the estimated underlying effective tax rate from the third quarter of 2012 reflects a projected decrease in tax benefits from certain collaboration and acquisition-related items. The effective tax rate for the third quarter of 2013 was increased by 0.2 percentage points as a result of a net increases in unrecognized tax benefits related to ongoing examinations of tax positions taken in prior years, offset by tax benefits related to the filing of our 2012 income tax returns with certain items being more favorable than originally estimated. The income tax provision for the three-month period ended September 30, 2012 included an estimated full year underlying effective tax rate of 14.4% (which subsequently decreased to 13.5% when the actual 2012 full year results were achieved). The effective tax rate for the third quarter of 2012 was increased by 0.5 percentage points as a result of a discrete item related to the filing of our 2011 income tax returns with certain items being less favorable than originally estimated.

Table of Contents

Nine-Month Periods Ended September 30, 2013 and 2012

Total Revenue: Total revenue and related percentages for the nine-month periods ended September 30, 2013 and 2012 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended		Increase (Decrease)	Percent Change	
	September 30, 2013	2012			
Net product sales:					
REVLIMID®	\$3,144.1	\$2,765.0	\$379.1	13.7	%
VIDAZA®	635.8	607.1	28.7	4.7	%
ABRAXANE®	447.1	320.3	126.8	39.6	%
POMALYST®/IMNOVID®	184.2	6.6	177.6	N/M	
THALOMID®	183.6	229.6	(46.0)	(20.0))%
ISTODAX®	40.4	36.5	3.9	10.7	%
Other	2.2	5.0	(2.8)	(56.0))%
Total net product sales	\$4,637.4	\$3,970.1	\$667.3	16.8	%
Collaborative agreements and other revenue	12.4	8.2	4.2	51.2	%
Royalty revenue	88.2	81.0	7.2	8.9	%
Total revenue	\$4,738.0	\$4,059.3	\$678.7	16.7	%

Total revenue increased by \$678.7 million, or 16.7%, to \$4.738 billion for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, reflecting increases of \$495.8 million, or 21.3%, in the United States and \$182.9 million, or 10.6%, in international markets.

Net Product Sales: Total net product sales for the nine-month period ended September 30, 2013 increased by \$667.3 million, or 16.8%, to \$4.637 billion compared to the nine-month period ended September 30, 2012. The increase was comprised of net volume increases of \$657.9 million and net price increases of \$84.0 million, partially offset by a \$74.6 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity. The increases in volume and net product sales for the nine-month period ended September 30, 2013 were primarily attributable to growth in sales of REVLIMID®, POMALYST®/IMNOVID® and ABRAXANE®, all of which have received approval for additional disease indications, or initial approvals in the case of POMALYST®/IMNOVID®, in the United States or EU subsequent to the nine-month period ended September 30, 2012.

REVLIMID® net sales increased by \$379.1 million, or 13.7%, to \$3.144 billion for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to increased unit sales in both international and U.S. markets in addition to price increases in the U.S. market. These increases were partially offset by unfavorable changes in price and unfavorable foreign exchange impacts, including the impact of foreign exchange hedging activity. Increases in market penetration and treatment duration of patients using REVLIMID® in multiple myeloma contributed to the increase in United States unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains.

VIDAZA® net sales increased by \$28.7 million, or 4.7%, to \$635.8 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, reflecting volume increases in international markets and price increases in the U.S. market, partially offset by unfavorable foreign exchange impacts. A generic version of VIDAZA® was launched in the United States by a competitor in September 2013 and we expect to experience a significant reduction in our U.S. sales of VIDAZA® beginning in the fourth quarter of 2013. In 2013, we also entered into an agreement to allow Sandoz AG to sell a generic version of VIDAZA®, which we supply.

ABRAXANE[®] net sales increased by \$126.8 million, or 39.6%, to \$447.1 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to increased unit volumes in both U.S. and international markets, reflecting increased acceptance of the product in the treatment of metastatic breast cancer and the October 2012 FDA approval for NSCLC.

Net sales of POMALYST[®]/IMNOVID[®] totaled \$184.2 million for the nine-month period ended September 30, 2013, reflecting net sales of \$156.5 million in the United States and \$27.7 million in international markets.

Table of Contents

THALOMID® net sales decreased by \$46.0 million, or 20.0%, to \$183.6 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to lower unit volumes in the U.S. and international markets and an increase in estimated returns related to the transition of THALOMID® distribution from retail to specialty pharmacies. The reductions in volume were partially offset by price increases in the United States.

ISTODAX® net sales increased by \$3.9 million, or 10.7%, to \$40.4 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to increases in price and unit sales for the treatment of CTCL and PTCL.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources increased by \$4.2 million to \$12.4 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012. The increase was due to receipt of a \$5.0 million milestone payment related to approval of additional indications for ABRAXANE® in Japan.

Royalty Revenue: Royalty revenue increased by \$7.2 million to \$88.2 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012 due to increased royalties earned from Novartis for its sales of RITALIN® and FOCALIN XR®.

Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2013 and 2012 were as follows (in millions):

	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
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
Balance at December 31, 2011	\$9.0	\$8.7	\$137.0	\$64.3	\$219.0
Allowances for sales during prior periods	(7.5)	—	(8.6)	(2.4)	(18.5)
Allowances for sales during 2012	4.4	49.9	158.8	153.5	366.6
Credits/deductions issued for prior year sales	1.7	(4.3)	(58.9)	(42.4)	(103.9)
Credits/deductions issued for sales during 2012	(3.1)	(41.3)	(90.7)	(106.4)	(241.5)
Balance at September 30, 2012	\$4.5	\$13.0	\$137.6	\$66.6	\$221.7

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2013 and 2012 follows:

Returns and allowances increased by \$13.6 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, partly due to a first quarter 2012 reversal of approximately \$7.5 million in reserves established for certain products with quality issues which were resolved in 2012. In addition,

during the nine-month period of 2013 we recorded a sales returns reserve of \$7.9 million for estimated returns related to the transition of THALOMID[®] distribution from retail to specialty pharmacies. The increases were partly offset by a \$2.9 million net reduction in the VIDAZA[®] returns provision, which included a \$7.5 million reduction in the returns allowance related to inventory levels held by distributors in early 2013 and was partly offset by the \$4.8 million increase in the returns allowance related to inventory held by distributors at September 30, 2013 given the launch of a generic version of VIDAZA[®] in September 2013.

Discounts increased by \$7.6 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, primarily due to sales increases in the United States.

Government rebates increased by \$36.7 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012, partly due to an increase of approximately \$23.9 million in government rebates related to U.S.

Table of Contents

governmental agencies, primarily attributable to volume increases and higher accrual rates for the Medicare Part D Coverage Gap. Rebates related to international markets increased by approximately \$12.8 million, primarily due to a reduction in rebates recorded during 2012 for an amendment to a price/volume agreement for VIDAZA® in a specific European country that resulted in a reduction in government rebates of approximately \$10.9 million for the nine-month period ended September 30, 2012.

Chargebacks and distributor service fees increased by \$53.1 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012. Chargebacks and distributor service fees increased by approximately \$29.5 million and \$19.5 million, respectively, primarily due to higher sales volumes. Rebates related to the TRICARE program increased by \$4.1 million due to higher sales volume.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2013 and 2012 were as follows (dollar amounts in millions):

	Nine-Month Periods Ended			Percent	
	September 30,		Increase	Change	
	2013	2012			
Cost of goods sold (excluding amortization of acquired intangible assets)	\$247.6	\$219.0	\$28.6	13.1	%
Percent of net product sales	5.3	% 5.5	%		
Research and development	\$1,495.0	\$1,250.7	\$244.3	19.5	%
Percent of total revenue	31.6	% 30.8	%		
Selling, general and administrative	\$1,235.8	\$1,003.4	\$232.4	23.2	%
Percent of total revenue	26.1	% 24.7	%		
Amortization of acquired intangible assets	\$197.1	\$132.1	\$65.0	49.2	%
Acquisition related (gains) charges and restructuring, net	\$79.4	\$28.9	\$50.5	174.7	%

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$28.6 million to \$247.6 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012. The increase was primarily due to the higher level of sales activity, especially the increase in ABRAXANE®, partly offset by the elimination of royalty payments on sales of REVLIMID® resulting from the expiration of our royalty obligations to CMCC at the end of February 2013. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.3% for the nine-month period ended September 30, 2013 compared to 5.5% for the nine-month period ended September 30, 2012 primarily due to the increase in lower cost REVLIMID® sales and the elimination of royalty payments to CMCC on our sales of REVLIMID® as noted above. See Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for additional details related to our royalty agreement with CMCC.

Research and Development: Research and development expenses increased by \$244.3 million to \$1.495 billion for the nine-month period ended September 30, 2013, compared to the nine-month period ended September 30, 2012. The increase was primarily due to a \$229.9 million increase in payments made related to research and development collaboration arrangements as well as an increase in general research activity, partly offset by a \$53.4 million IPR&D asset impairment charge related to the approval of ISTODAX® for PTCL in Europe recorded in the 2012 nine-month period and no IPR&D asset impairment charges recorded in the 2013 nine-month period.

Table of Contents

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

	Nine-Month Periods Ended		Increase (Decrease)
	September 30,		
	2013	2012	
Human pharmaceutical clinical programs	\$590.1	\$590.1	\$—
Other pharmaceutical programs	376.2	327.0	49.2
Drug discovery and development	148.0	124.8	23.2
Cellular therapy	18.5	23.1	(4.6)
Collaboration arrangements	362.2	132.3	229.9
IPR&D impairments	—	53.4	(53.4)
Total	\$1,495.0	\$1,250.7	\$244.3

Selling, General and Administrative: Selling, general and administrative expenses increased by \$232.4 million to \$1.236 billion for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012 partly due to an increase in headcount related costs and marketing activities primarily related to the launch of POMALYST®, pre-launch expenses for ABRAXANE® in pancreatic cancer, headcount increases to prepare for the future launch of apremilast, a \$22.7 million increase in service fees attributable to Latin American operations, a \$12.4 million increase in donations to independent non-profit organizations in the United States, an increase in incentive accruals and continued support of our currently marketed products.

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, 2013 and 2012 (in millions):

	Nine-Month Periods Ended		Increase
	September 30,		
	2013	2012	
Acquisitions			
Abraxis	\$120.0	\$62.9	\$57.1
Avila	35.5	27.6	7.9
Gloucester	38.6	38.6	—
Pharmion	3.0	3.0	—
Total amortization	\$197.1	\$132.1	\$65.0

Amortization of acquired intangible assets increased by \$65.0 million to \$197.1 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012 primarily due to \$58.6 million from the October 2012 approval of ABRAXANE® in the United States for the treatment of NSCLC which resulted in the commencement of amortization of the related intangible asset, partly offset by certain Abraxis related intangibles becoming fully amortized in the beginning of 2012 and a \$7.9 million increase in amortization related to intangible assets obtained in the March 2012 acquisition of Avila.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition related (gains) charges and restructuring, net was a net charge of \$79.4 million and \$28.9 million for the nine-month periods ended September 30, 2013 and 2012, respectively. The \$50.5 million increase in net charges in the current year nine-month period was primarily due to changes in the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis.

Interest and Investment Income, Net: Interest and investment income, net increased by \$5.0 million to \$14.6 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012 primarily due to higher investment balances compared to the prior year nine-month period.

Interest (Expense): Interest (expense) increased by \$20.8 million to \$61.5 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012 primarily due to interest and fees associated with the issuance of \$1.500 billion in senior notes in August 2012 and the issuance of an additional \$1.500 billion in senior notes in August 2013.

Other Income (Expense), Net: Other income (expense), net was a net income of \$12.0 million for the nine-month period ended September 30, 2013 and a net expense of \$2.9 million for the nine-month period ended September 30, 2012. The \$14.9 million favorable variance in the 2013 nine-month period was primarily due to an increase in gains related to foreign exchange contracts not designated as hedging instruments which were intended to mitigate the impact of exchange rate volatility in the translation of

Table of Contents

foreign earnings, partly offset by a \$7.3 million increase in impairment losses related to certain cost basis equity securities and the 2012 inclusion of a \$7.4 million gain related to the sale of equity securities and \$3.7 million in net gains related to the short period in June 2012 when certain treasury rate lock agreements were not designated as hedges.

Income Tax Provision: The income tax provision increased by \$14.6 million to \$212.7 million for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012. The estimated full year 2013 underlying effective tax rate of 15.0% reflects the impact of our global business footprint. The increase in the estimated underlying effective tax rate from the nine-month period ending September 30, 2012 reflects a projected decrease in tax benefits from certain collaboration and acquisition-related items. The effective tax rate 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 related to 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. The U.S. research and development tax credit expired on December 31, 2011 and was retroactively reinstated in the first quarter of 2013. The income tax provision for the nine-month period ended September 30, 2012 included an estimated full year underlying effective tax rate of 14.4% (which subsequently decreased to 13.5% when the actual 2012 full year results were achieved). The effective tax rate for the nine-month period ended September 30, 2012 was reduced by 0.3 percentage points as a result of discrete items, including tax benefits related to the settlement of tax examinations and expirations of statutes of limitations offset by an increase in deferred tax liabilities recorded on certain unremitted foreign earnings previously treated as permanently reinvested in such foreign jurisdictions and tax expense related to the filing of our 2011 income tax returns with certain items being less favorable than originally estimated.

Liquidity and Capital Resources

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

	September 30, 2013	December 31, 2012	Increase
Financial assets:			
Cash and cash equivalents	\$2,423.0	\$2,090.4	\$332.6
Marketable securities available for sale	3,424.3	1,809.9	1,614.4
Total financial assets	\$5,847.3	\$3,900.3	\$1,947.0
Debt:			
Short-term borrowings	\$405.9	\$308.5	\$97.4
Long-term debt, net of discount	4,228.3	2,771.3	1,457.0
Total debt	\$4,634.2	\$3,079.8	\$1,554.4
Working capital (1)	\$5,745.2	\$3,767.5	\$1,977.7

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

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 repurchase 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, 2013, we held approximately \$4.457 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business and due to other reasons, such as repurchases of our common stock and business-development activities. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the United States, no accrual for U.S. taxes is provided. Approximately \$900.0 million of our foreign earnings, included in the \$4.457 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

Table of Contents

reinvested and accordingly, our deferred tax liabilities as of September 30, 2013 and December 31, 2012 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: During the period of April 2009 through September 2013, our Board of Directors had authorized an aggregate of \$9.5 billion for stock repurchases. During the three-month period ended September 30, 2013 we used \$210.7 million for repurchases of our common stock. See Part II Item 2 of this report for more information concerning our share repurchase program.

Debt Issuance: In August 2013, we issued an additional \$1.500 billion principal amount of senior notes consisting of \$400.0 million aggregate principal amount of 2.300% Senior Notes due 2018 (the 2018 notes), \$700.0 million aggregate principal amount of 4.000% Senior Notes due 2023 (the 2023 notes) and \$400.0 million aggregate principal amount of 5.250% Senior Notes due 2043 (the 2043 notes) and, together with the 2018 notes and 2023 notes, referred to herein as the “2013 issued notes”. The 2013 issued notes were issued at 99.792%, 99.452% and 99.147% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$12.5 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 notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2014 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price defined in a make-whole clause 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 15 basis points in the case of the 2018 notes, 20 basis points in the case of the 2023 notes and 25 basis points in the case of the 2043 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.

Forward Starting Interest Rate Swaps: During September 2013 we entered into a forward starting interest rate swap (forward starting swap), that was designated as a cash flow hedge, with a notional value of \$100.0 million, an effective date in November 2014 and a maturity of ten years to hedge against changes in interest rates that could impact an anticipated issuance of debt. During October 2013, we entered into additional forward starting swaps with an effective date in November 2014 and an aggregate notional value of \$150.0 million, consisting of \$100 million with a five year maturity and \$50 million with a ten year maturity.

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 \$1.947 billion increase in cash, cash equivalents and marketable securities available for sale at September 30, 2013

compared to December 31, 2012 was primarily due to \$1.675 billion cash generated from operations, \$1.480 billion in cash generated from the August 2013 issuance of an additional \$1.500 billion principal amount of senior notes, \$458.0 million cash provided by stock option exercises and \$335.1 million of cost method investments that are now classified as marketable securities due to certain of our equity investments becoming publicly traded. These increases were partially offset by \$2.068 billion paid under our share repurchase program.

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.

Table of Contents

Accounts Receivable, Net: Accounts receivable, net increased by \$132.8 million to \$1.093 billion at September 30, 2013 compared to December 31, 2012 primarily due to increased U.S. and international sales of REVLIMID[®], ABRAXANE[®] and POMALYST[®]/IMNOVID[®]. 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 \$356.4 million at September 30, 2013 compared to \$324.2 million at December 31, 2012. Approximately \$76.4 million of the \$356.4 million receivable at the end of September 30, 2013 was greater than one year past due. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of receivables in Greece. We maintain timely and direct communication with hospital customers in Spain, Italy and Portugal regarding both the current and past due receivable balances. We continue to receive payments from these countries and closely monitor the plans for payment at the regional government level. Payments from customers in these countries are not received on regular intervals and several months could elapse between significant payments. We have the option to pursue legal action against certain of our customers. In view of the protracted time-line associated with collecting the outstanding balances through legal action and the current direct communication with our customers, in many instances, we do not believe pursuing legal action to be the best approach for any of the parties involved.

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 \$53.8 million to \$313.3 million at September 30, 2013 compared to December 31, 2012. The increase was primarily due to an increase in ABRAXANE[®] inventory in anticipation of an increase in future sales levels.

Other Current Assets: Other current assets increased by \$67.6 million to \$387.8 million at September 30, 2013 compared to December 31, 2012 primarily due to a \$30.4 million increase in the fair value of foreign currency forward contracts, \$17.0 million increase in receivables related to exercises of employee stock options, \$7.2 million increase in interest receivable from our investments in marketable securities available for sale and net increases 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 will be 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, 2013, \$405.9 million of Commercial Paper was outstanding compared to \$308.5 million as of December 31, 2012, 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 in the aggregate amount of \$1.000 billion, which was increased to \$1.500 billion in April 2013. The

Table of Contents

term of the Credit Facility was also extended from September 2, 2016 to 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, 2013 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, 2013.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by \$128.1 million to \$1.481 billion at September 30, 2013 compared to December 31, 2012. The increase was primarily due to a \$56.3 million net increase in compensation-related accruals, \$33.0 million increase in sales adjustments, \$24.0 million increase in the fair value of foreign currency forward contracts, a \$22.6 million increase in the current portion of contingent consideration liabilities related to the Abraxis acquisition and a \$10.9 million increase in clinical trial accruals. These increases were partly offset by a \$20.4 million decrease in accrued amounts related to our common share repurchase program due to the timing of transaction settlements and a \$11.6 million decrease in accrued royalty and licensing payments.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by \$19.5 million to \$219.5 million at September 30, 2013 compared to December 31, 2012, primarily from the current provision for income taxes of \$374.2 million and net deferred inter-company credits of \$13.0 million, offset by income tax payments of \$226.2 million and a tax benefit of stock options of \$140.3 million.

Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2013 and 2012 were as follows (in millions):

	Nine-Month Periods Ended		
	September 30,		
	2013	2012	Change
Net cash provided by operating activities	\$1,675.2	\$1,539.0	\$136.2
Net cash used in investing activities	\$(1,443.4)	\$(778.1)	\$(665.3)
Net cash provided by financing activities	\$103.7	\$145.4	\$(41.7)

Operating Activities: Net cash provided by operating activities increased by \$136.2 million to \$1.675 billion for the nine-month period ended September 30, 2013 compared to the nine-month period ended September 30, 2012. The increase in net cash provided by operating activities was primarily attributable to an expansion of our operations and related increase in net earnings.

Investing Activities: Net cash used in investing activities for the nine-month period ended September 30, 2013 increased to a net usage of \$1.433 billion compared to a net usage of \$778.1 million for the nine-month period ended September 30, 2012. The increase in net cash used in investing activities was principally related to \$1.301 billion used for net purchases of marketable securities available for sale during the nine-month period ended September 30, 2013 compared to net purchases of \$328.8 million in the nine-month period ended September 30, 2012. This increase was partially offset by the cash use of \$352.2 million related to the acquisition of Avila in March 2012.

Financing Activities: Net cash provided in financing activities for the nine-month period ended September 2013 was \$103.7 million compared to net cash provided of \$145.4 million in the nine-month period ended September 2012. The

\$41.7 million decrease in net cash provided in financing activities in the nine-month period ended September 30, 2013 was primarily attributable to \$2.068 billion for repurchases of our common stock as compared to \$1.481 billion for repurchases in the nine-month period ended September 30, 2012. This decrease was partially offset by \$95.1 million in net proceeds from short-term borrowings in 2013 as compared to \$201.0 million of net repayments on short-term borrowings in the nine-month period ended September 30, 2012. Proceeds from issuances of common stock under our employee stock plans plus the excess tax benefit from share-based compensation arrangements provided an aggregate \$597.0 million during the nine-month period ended September 30, 2013, which is an increase of \$256.1 million from the nine-month period ended September 30, 2012.

Table of Contents

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 2012 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2012 aside from those disclosed in Note 14 and Note 17 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 2012 Annual Report on Form 10-K. There have not been any material changes to such critical accounting estimates since December 31, 2012.

Investments in Other Entities: During the nine-month period ended September 30, 2013, certain of our investments in equity securities became publicly traded. Our investments in publicly traded equity securities are accounted for as available-for-sale marketable securities. Our significant accounting policies, including a description of our accounting for available-for-sale marketable securities and for securities under the equity method, are described in Note 1 of Notes to Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K as noted above.

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, 2013, our market risk sensitive instruments consisted of marketable securities available for sale, our long-term debt and certain foreign exchange contracts.

Marketable Securities Available for Sale: At September 30, 2013, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency MBS, non-U.S. government, agency and Supranational securities, global corporate debt securities, asset backed securities 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, 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 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.

Table of Contents

As of September 30, 2013, 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				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	Over 5 Years	
Principal amount	\$1,362.7	\$1,395.7	\$193.5	\$16.3	\$2,968.2
Fair value	\$1,369.3	\$1,415.7	\$200.4	\$16.6	\$3,002.0
Weighted average interest rate	0.4	% 0.8	% 2.0	% 2.4	% 0.7

Long-Term Debt: We have issued an aggregate \$4.250 billion principal amount of senior notes at varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of are summarized below as of September 30, 2013 (in millions):

	Principal Amount	Carrying Value
2.450% senior notes due 2015	\$500.0	\$515.7
1.900% senior notes due 2017	500.0	500.8
2.300% senior notes due 2018	400.0	400.1
3.950% senior notes due 2020	500.0	492.4
3.250% senior notes due 2022	1,000.0	975.0
4.000% senior notes due 2023	700.0	698.1
5.700% senior notes due 2040	250.0	249.6
5.250% senior notes due 2043	400.0	396.6
Total long-term debt	\$4,250.0	\$4,228.3

At September 30, 2013, the fair value of our senior notes outstanding was \$4.252 billion.

MARKET RISK MANAGEMENT

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We actively manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts.

Foreign Currency Risk Management

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

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

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

currencies.

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at September 30, 2013 and December 31, 2012 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss) (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any

48

Table of Contents

ineffectiveness on these foreign currency forward contracts is reported in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2013 and December 31, 2012:

	Notional Amount	
	September 30, 2013	December 31, 2012
Foreign Currency		
Australian Dollar	\$53.7	\$5.1
British Pound	313.8	77.9
Canadian Dollar	84.7	134.4
Euro	2,425.3	969.3
Japanese Yen	703.2	236.2
Total	\$3,580.7	\$1,422.9

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, 2013, 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, 2013 and December 31, 2012 were \$816.1 million and \$795.4 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, 2013 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$419.8 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.

Foreign Currency Option Contracts: We hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in euros. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and amounts but with different strike prices; this combination of transactions is generally referred to as a "collar". The expiration dates and notional amounts correspond to the amount and timing of forecasted future foreign currency sales. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. dollar equivalent value of our anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the call option partially offsets the premium paid for the purchased put option, resulting in a net cost for the collars.

In order to fully offset the net cost of the collars, we also sold local currency put options with a lower strike price and the same expiration dates and amounts as the option contracts that were used to hedge sales. These written put options

introduced risk of loss if the U.S. dollar were to strengthen beyond the strike price of the written put options. We entered into purchased put options that are not designated as hedges in order to partially offset the risk of loss that would be incurred on the written put options if the US dollar were to strengthen beyond the strike price of the written put. Gains and losses associated with the non-hedge put options have been recorded on the income statement as other income (expense), net.

Table of Contents

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2013 and December 31, 2012:

	Notional Amount*	
	September 30, 2013	December 31, 2012
Foreign Currency Option		
Designated as hedging activity:		
Purchased Put	\$24.3	\$228.8
Written Call	\$25.4	\$235.9
Not designated as hedging activity:		
Purchased Put	\$22.7	\$160.5
Written Put	\$(22.7) \$(216.0

* U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied times the strike value of the foreign currency option. The local currency notional amounts of our purchased put and written call that are designated as hedging activity are equal to each other.

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, 2013 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts that are designated as hedges would change by approximately \$2.7 million. However, since the foreign currency option contracts designated as hedges hedge specific forecasted intercompany transactions denominated in foreign 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. The foreign currency option contracts that are not designated as hedges completely offset each other and at September 30, 2013 had no net value. A hypothetical 10% change in the September 30, 2013 exchange rates would not change the net fair value of the foreign currency option contracts that are not designated as hedges.

Interest Rate Risk Management

In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) that are designated as cash flow hedges or treasury rate lock agreements (treasury rate locks). To the extent these cash flow hedges of 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: During September 2013 we entered into a forward starting swap, that was designated as a cash flow hedge, with a notional value of \$100.0 million, an effective date in November 2014 and a maturity of ten years to hedge against changes in interest rates that could impact expected future issuances of long-term bonds. The fair value of our forward starting swap at September 30, 2013 and the results of a sensitivity analysis to measure potential changes in the market value of our forward starting swap contract from a one percentage point change in interest rates were not material.

Treasury Rate Lock Agreements: During 2012, we entered into treasury rate locks in anticipation of issuing fixed-rate notes that were issued in August 2012. The treasury rate locks were settled during 2012, resulting in losses of \$35.3 million that were recorded to OCI. No material amounts were recorded in income during the nine-month periods ended September 30, 2013 or 2012 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. We have not entered into any treasury rate locks during the nine-month period ended September 30, 2013 and at September 30, 2013 we had no outstanding treasury rate locks.

Interest Rate Swap Contracts: From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amounts of the swaps are intended to match those of the debt being hedged, they are assumed to be highly effective hedges and all changes in fair value of the swaps 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. We may terminate the hedging relationship of certain swap contracts by settling the contracts or by entering into offsetting contracts. At the time a hedging relationship is terminated, accumulated gains or losses associated with the swap contract are measured and recorded as a reduction of current and future interest expense associated with the previously hedged notes.

Table of Contents

During the nine-month period ended September 30, 2013, we entered into swap contracts that were designated as hedges of our fixed rate notes due in 2015, 2017, 2018, 2020, 2022 and 2023 and also terminated the hedging relationship by settling certain of those swap contracts during the nine-month period ended September 30, 2013. This resulted in net proceeds received of \$21.9 million 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.

At September 30, 2013, we were a party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. The following table summarizes the notional amounts of our outstanding swap contracts at September 30, 2013 and December 31, 2012:

	Notional Amount	
	September 30, 2013	December 31, 2012
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	\$—
1.900% senior notes due 2017	300.0	100.0
3.950% senior notes due 2020	500.0	—
3.250% senior notes due 2022	850.0	200.0
4.000% senior notes due 2023	50.0	—
Total	\$2,000.0	\$300.0

Since our interest rate swap contracts are entered into as fair value hedges of our fixed-rate senior notes, we measure the net sensitivity of our fixed-rate senior notes and interest rate swap contracts together. 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, 2013 would have reduced the aggregate fair value of our net payable by \$177.0 million. A one percentage point decrease at September 30, 2013 would have increased the aggregate fair value of our net payable by \$206.0 million.

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, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

The information called for by this item is incorporated herein by reference to Note 16 included in Part I, Item 1, Financial Statements - Notes to Unaudited Consolidated Financial Statements.

Table of Contents

Item 1A. Risk Factors

The following statements describe 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 price of our common stock 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 our business, financial results and operations.

We may experience significant fluctuations in our quarterly operating results which could cause our financial results to be below expectations and cause our stock price to be volatile.

We have historically experienced and may continue to experience, significant fluctuations in our quarterly operating results. These fluctuations are due to a number of factors, many of which are outside our control and may result in volatility of our stock price. Future operating results will depend on many factors, including:

- demand or lack of demand for our products, including demand that adversely affects our ability to optimize the use of our manufacturing facilities;

- the introduction and pricing of products competitive with ours, including generic competition;

- developments regarding the safety or efficacy of our products;

- regulatory approvals for our products and pricing determinations with respect to our products;

- regulatory approvals for our manufacturing facilities and those of our suppliers;

- timing and levels of spending for research and development, sales and marketing;

- timing and levels of reimbursement from third-party payers for our products;

- development or expansion of business infrastructure in new clinical and geographic markets;

- the acquisition of new products and companies;

- tax rates in the jurisdictions in which we operate;

- timing and recognition of certain research and development milestones and license fees;

- ability to control our costs;

- fluctuations in foreign currency exchange rates; and

- economic and market instability.

We are dependent on the continued commercial success of our primary products REVLIMID[®], VIDAZA[®], THALOMID[®], ABRAXANE[®] and POMALYST[®]/IMNOVID[®] and a significant decline in demand for or use of these products or our other commercially available products could materially and adversely affect our operating results.

During the next several years, the growth of our business will be largely dependent on the commercial success of REVLIMID[®], VIDAZA[®], THALOMID[®], ABRAXANE[®] and POMALYST[®]/IMNOVID[®]. We cannot predict the extent to which these or our other existing or new products will be accepted by regulators, physicians, patients and other key opinion leaders as effective drugs with certain advantages over existing or future therapies. We continue to introduce our products in additional international markets and to obtain approvals for additional indications both in the United States and internationally. A delay in gaining the requisite regulatory approvals for these markets or indications could negatively impact our growth plans and the value of our stock.

Further, if unexpected adverse experiences are reported in connection with the use of any of our products, physician and patient comfort with the product could be undermined, the commercial success of such product could be adversely affected and the

Table of Contents

acceptance of our other products could be negatively impacted. We are subject to adverse event reporting regulations that require us to report to the FDA or similar bodies in other countries if our products are associated with a death or serious injury. These adverse events, among others, could result in additional regulatory controls, such as the performance of costly post-approval clinical studies or revisions to our approved labeling, which could limit the indications or patient population for our products or could even lead to the withdrawal of a product from the market. Similarly, the occurrence of serious adverse events known or suspected to be related to the products could negatively impact product sales. For example, THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities in the baby. REVLIMID® and POMALYST®/IMNOVID® are also considered fetal toxic and there are warnings against use of VIDAZA® in pregnant women as well. While we have restricted distribution systems for both THALOMID®, REVLIMID® and POMALYST®/IMNOVID®, we 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 have a material adverse effect on our business.

It is necessary that our primary products achieve and maintain market acceptance. A number of factors may adversely impact the degree of market acceptance of our products, including the products' efficacy, safety, price and benefits, if any, over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans, patent disputes and claims about adverse side effects.

If we do not gain or maintain regulatory approval of our products we will be unable to sell our current products and products in development.

Changes in law, government regulations or policies can have a significant impact on our results of operations. The discovery, preclinical development, clinical trials, manufacturing, risk evaluation and mitigation strategies (such as our S.T.E.P.S.® and RevAssist® programs), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and regulations, including, without limitation, the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, Medicare Modernization Act, Food and Drug Administration Amendments Act, and other federal and state statutes, as well as similar laws in foreign jurisdictions. Changes in laws, government regulations or policies can have a significant adverse impact on our ability to continue to commercialize our products or introduce new products to the market, which would adversely affect our results of operations.

If we or our agents, contractors or collaborators are delayed in receiving, or are unable to obtain all, necessary governmental approvals, we will be unable to effectively market our products.

The testing, marketing and manufacturing of our products requires regulatory approval, including approval from the FDA and, in some cases, from the Environmental Protection Agency (EPA) or governmental authorities outside of the United States that perform roles similar to those of the FDA and EPA, including the EMA, European Commission, the Japanese Pharmaceuticals and Medical Devices Agency, the Swissmedic, the Australian Therapeutic Goods Administration and Health Canada. Certain of our pharmaceutical products, such as FOCALIN®, fall under the Controlled Substances Act of 1970 that requires authorization by the U.S. Drug Enforcement Agency (DEA) of the U.S. Department of Justice in order to handle and distribute these products.

The regulatory approval process presents a number of risks to us, principally:

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 can be susceptible to varying interpretation that could delay, limit or prevent regulatory approval;

-

Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first or receives approval of other labeled indications;

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

The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and reimbursed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the drug;

Table of Contents

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

Regulatory authorities and agencies of the United States or foreign governments may promulgate additional regulations restricting the sale of our existing and proposed products, including specifically tailored risk evaluation and mitigation strategies;

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

Once a product receives marketing approval, we cannot market that product for broader or different applications and the FDA might not grant us approval with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing approvals in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products. The FDA may also request that we perform additional clinical trials or change the labeling of our existing or proposed products if we or others identify side effects after our products are on the market;

Products, such as REVLIMID® and POMALYST®, that are subject to accelerated approval can be subject to an expedited withdrawal if the post-marketing restrictions are not adhered to or are shown to be inadequate to assure the safe use of the drug, or evidence demonstrates that the drug is not shown to be safe and effective under its conditions of use. Additionally, promotional materials for such products are subject to enhanced surveillance, including pre-approval review of all promotional materials used within 120 days following marketing approval and a requirement for the submissions 30 days prior to initial dissemination of all promotional materials disseminated after 120 days following marketing approval; and

Our risk evaluation and mitigation strategies, labeling and promotional activities relating to our products as well as our post-marketing activities are regulated by the FDA, the Federal Trade Commission, the United States Department of Justice, the DEA, state regulatory agencies and foreign regulatory agencies and are subject to associated risks. In addition, individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. If we fail to comply with 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, such agencies may bring enforcement actions against us that could inhibit our commercial capabilities as well as result in significant penalties.

Other matters that may be the subject of governmental or regulatory action which could adversely affect our business include:

• changes in laws and regulations, including without limitation, patent, environmental, privacy, health care and competition laws;

• parallel importation of prescription drugs from outside the United States at prices that are regulated by the governments of various foreign countries;

• additional restrictions on interactions with healthcare professionals;

• premature or mandated disclosures of clinical trial or other data; and

privacy restrictions that may limit our ability to share data from foreign jurisdictions.

We collect placentas and umbilical cord blood for our unrelated allogeneic and private stem cell banking businesses. 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 recipient under 21 CFR Parts 1270 and 1271. Part 1271 requires cell and tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease and to register the establishment with FDA. This part also provides for inspection by the FDA of cell and tissue establishments. Currently, we are required to be, and are, licensed to operate in New York, New Jersey, Maryland and California. If other states adopt similar licensing requirements, we would need to obtain such licenses to continue operating any stem cell banking businesses if we are

Table of Contents

deemed to be operating in those states. If we are delayed in receiving, or are unable to obtain at all, necessary licenses, we will be unable to provide services in those states and this could have a negative effect on our revenue.

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 products will depend, in part, on the extent to which the costs of our products will be paid 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 healthcare costs of patients. These health care management organizations and third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the 2010 U.S. Health Care Reform Law, which became effective in January 2011, has provided sweeping health care reform in the United States, which may impact access to and reimbursement for our products. In addition to the federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs and adoption of more restrictive policies in jurisdictions with existing controls and measures, including the impact of the 2010 U.S. Health Care Reform Law, could adversely impact our business and future results. If these organizations and third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations (GPOs). Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of that contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We encounter similar regulatory and legislative issues in most countries outside the United States. International operations are generally subject to extensive governmental price controls and other market regulations and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on access to and reimbursement for our products. Although we cannot predict the extent to which our business may be affected by future cost-containment measures or other potential legislative or regulatory developments, additional price controls or other changes in pricing regulation could restrict access to and reimbursement for our current and future products, which could adversely affect our revenue and results of operations.

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 including those related to our risk evaluation and mitigation strategies

(such as our S.T.E.P.S.[®] and RevAssist[®] programs). In addition, the coverage sought in a patent application can be significantly reduced before the patent is issued.

Consequently, 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 any patents are issued, whether they will be dominated by third-party patent rights, whether they will provide significant proprietary protection or commercial advantage or whether they will be circumvented, opposed, invalidated, rendered unenforceable or infringed by others. Further, we are aware of third-party U.S. patents that relate to, for example, the use of certain technologies and cannot be certain as to any impact to our potential products, or whether our patents or pending applications will not be involved in, or be defeated as a result of, opposition proceedings before a foreign patent office or any interference proceedings before the United States Patent & Trademark Office (PTO) or U.S. or foreign courts.

Table of Contents

With respect to patents and patent applications we have licensed-in, there can be no assurance that additional patents will be issued to any of the third parties from whom we have licensed patent rights, or that, if any new patents are issued, such patents will not be opposed, challenged, invalidated, infringed or dominated or provide us with significant proprietary protection or commercial advantage. Moreover, there can be no assurance that any of the existing licensed patents will provide us with proprietary protection or commercial advantage. Nor can we guarantee that these licensed patents will not be either infringed, invalidated or circumvented by others, or that the relevant agreements will not be terminated. A termination of material licenses granted to us could have a material adverse effect on our business, financial condition and results of operations.

Because (1) patent applications filed in the United States on or before November 28, 2000 are maintained in secrecy until patents issue, (2) patent applications filed in the United States on or after November 29, 2000 are not published until approximately 18 months after their earliest claimed priority date, (3) United States patent applications that are not filed outside the United States may not publish at all until issued and (4) publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we, or our licensors, were the first to make the inventions covered by each of the issued patents or pending patent applications or that we, or our licensors, were the first to file patent applications for such inventions. In the event a third party has also filed a patent for any of our inventions, we, or our licensors, may have to participate in interference proceedings before the PTO to determine priority of invention, which could result in the loss of a U.S. patent or loss of any opportunity to secure U.S. patent protection for the invention. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us.

Our intellectual property rights will further be affected in ways that are difficult to anticipate at this time by the provisions of the America Invents Act, signed into law on September 16, 2011. This law is the first major overhaul of the U.S. patent system since 1952 and includes a number of changes to established practices. The most significant changes include the transition to a first-to-file system, the availability of new post-grant review for issued patents, various procedural changes, including the submission of prior art and the availability of derivation proceedings and supplemental examination and an expanded prior commercial user rights defense to a claim of patent infringement. The scope of these changes and the lack of experience with their practical implementation, suggest a transitional period with some uncertainty over the next few years. Several provisions of the new law will likely be tested in courts over time.

The changes in the U.S. patent law will have an impact on our intellectual property rights and how business is conducted in general. For example, the first-to-file system places a premium on filing as early as possible and appears to increase what is available as prior art, by changing the applicable definitions. In the future, in addition to patents and printed publications, we may be required to deal with unfamiliar prior art categories such as art that is “otherwise available to the public.” For patent applications filed on or after March 16, 2013, we may expect post-grant review challenges initiated up to nine months after the corresponding patent issues.

While the changes in the patent law were intended to make the resolution of intellectual property disputes easier and less expensive, we may in the future have to prove that we are not infringing patents or we may be required to obtain licenses to such patents. However, we do not know whether such licenses will be available on commercially reasonable terms, or at all. Prosecution of patent applications, post-grant opposition proceedings and litigation to establish the validity and scope of patents, to assert patent infringement claims against others and to defend against patent infringement claims by others can be expensive and time-consuming. There can be no assurance that, in the event that claims of any of our owned or licensed patents are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation or post-grant proceeding could cause us to lose exclusivity relating to the subject matter delineated by such patent claims and may have a material adverse effect on our business. 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. 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, therefore, 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 the judicial interpretation given to a corresponding patent issued in another country. Competitors have chosen and in the future may choose to file oppositions to patent applications, which have been deemed allowable by foreign patent examiners. Furthermore, even if our owned or licensed patents are determined to be valid and enforceable, there can be no assurance that competitors will not be able to challenge the validity or our patent claims in post-grant proceedings, or to design around such patents and compete with us using the resulting alternative technology. Additionally, for these same reasons, we cannot be sure that patents of a broader scope than ours may be issued and thereby create freedom to operate issues. If this occurs we may need

Table of Contents

to reevaluate pursuing such technology, which is dominated by others' patent rights, or alternatively, seek a license to practice our own invention, whether or not patented.

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. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach or that our trade secrets, proprietary know-how and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology or that such technology will not be found to be non-proprietary or not a trade secret.

Our products may face competition from lower cost generic or follow-on products and providers of these products may be able to sell them at a substantially lower cost than us.

Generic drug manufacturers are seeking to compete with our drugs and present an important challenge to us. Even if our patent applications, or those we have licensed-in, are issued, innovative and generic drug manufacturers and other competitors may challenge the scope, validity or enforceability of such patents in court, requiring us to engage in complex, lengthy and costly litigation. Alternatively, innovative and generic drug manufacturers and other competitors may be able to design around our owned or licensed patents and compete with us using the resulting alternative technology. If any of our issued or licensed patents are infringed or challenged, we may not be successful in enforcing or defending our or our licensor's intellectual property rights and subsequently may not be able to develop or market the applicable product exclusively.

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

The FDA approval process allows for the approval of an Abbreviated New Drug Application (ANDA) or 505(b)(2) application for a generic version of our approved products upon the expiration, through passage of time or successful legal challenge, of relevant patent or non-patent exclusivity protection. Generic manufacturers pursuing ANDA approvals are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative companies who have incurred substantial expenses associated with the research and development of the drug product. Accordingly, while our products currently may retain certain regulatory and/or patent exclusivity, our products are or will be subject to ANDA applications to the FDA in light of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. The ANDA procedure includes provisions allowing generic manufacturers to challenge the effectiveness of the innovator's patent protection prior to the generic manufacturer actually commercializing their products—the so-called "Paragraph IV" certification procedure. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the Orange Book-listed patents on a wide array of innovative pharmaceuticals and we expect this trend to continue. During the exclusivity periods, the FDA is generally prevented from granting effective approval of an ANDA. Upon the expiration of the applicable exclusivities, through passage of time or successful legal challenge, the FDA may grant effective approval of an ANDA for a generic drug, or may accept reference to a previously protected NDA in a 505(b)(2) application. Further, upon such expiration event, the FDA may require a generic competitor to participate in some form of risk management system which could include our participation as well. Depending upon the scope of the applicable exclusivities, any such approval could be limited to certain formulations and/or indications/claims.

If an ANDA filer or a 505(b)(2) applicant were to receive approval to sell a generic or follow-on version of one of our products, that product would become subject to increased competition and our revenues for that product would be adversely affected.

We received four Paragraph IV Certification Letters dated August 30, 2010, June 12, 2012, September 28, 2012 and March 14, 2013, respectively, advising us that Natco Pharma Limited of Hyderabad, India (Natco) submitted an ANDA to the FDA with respect to REVLIMID®. See Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report for further information.

If we are not able to effectively compete our business will be adversely affected.

Table of Contents

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, Roche/Genentech, Sanofi and Takeda.

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

Many of these companies have considerably greater financial, technical and marketing resources than we do. This enables them, among other things, to make greater research and development investments and spread their research and development costs, as well as their marketing and promotion costs, over a broader revenue base. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. We also experience competition from universities and other research institutions, and in some instances, 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 in the field are made and become more widely known. The development of products, including generics, or processes by our competitors with significant advantages over those that we are seeking to develop could cause the marketability of our products to stagnate or decline.

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

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, U.S. federal and state health authorities may reduce Medicare and Medicaid reimbursements and private insurers may limit access to and reimbursement for our products. A reduction in the availability or extent of reimbursement could negatively affect our product sales, revenue and cash flows.

See our discussion of accounts receivable from Spain, Italy and Portugal in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this report for details related to amounts receivable from the government owned or controlled hospitals in Spain, Italy and Portugal.

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, royalty revenue, clinical development of future collaboration products, conduct of clinical trials and 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 losses due to litigation or governmental investigations.

From time to time, we may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, Qui Tam, privacy, anti-kickback, anti-bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and we have been subject to claims and other actions related to our business activities.

We are also subject to significant product liability risks as a result of the testing of our products in human clinical trials and for products that we sell after regulatory approval. Although we have insurance coverage with respect to potential product liability claims, there can be no guarantee that insurance coverage will be adequate or continue to be available at sufficient levels to fully cover claims that may arise in the future.

In the fourth quarter of 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission (FTC). The FTC requested documents and other information relating to requests by generic companies to purchase our patented

Table of Contents

REVLIMID® and THALOMID® brand drugs in order for the FTC to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, we received a second CID from the FTC relating to this matter. We continue to cooperate with the FTC and the State of Connecticut investigations.

In the first quarter of 2011, the United States Attorney's Office for the Central District of California informed us that they are investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In the third quarter of 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 are conducting related investigations. We are cooperating with these investigations.

While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters may have a material adverse effect on our results of operations, cash flows or financial condition and result in, among other things:

rulings that are materially unfavorable to us, including significant damage awards, fines or penalties and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that prevent us from operating our business in a certain manner;

changes to our business operations to avoid perceived risks associated with such litigation or investigations;

modification of our business practices;

product recalls;

reputational damage and decreased demand for our products; and

expenditure of significant time and resources, which may divert the attention of our management and interfere with the pursuit of our strategic objectives.

While we maintain insurance for certain risks, the amount of our insurance coverage may not be adequate to cover the total amount of all such claims and liabilities. It also is not possible to obtain insurance to protect against all potential risks and liabilities. If any litigation or governmental investigation were to have a material adverse result, there could be a material adverse effect on our results of operations, cash flows or financial condition. See Note 16 of Notes to Unaudited Consolidated Financial Statements contained elsewhere in this report.

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

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process involves a high degree of risk and takes many years. Our product development efforts with respect to a product candidate may fail for many reasons, including the failure of the product candidate in preclinical studies; adverse patient reactions to the product candidate or indications or 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; or 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 desirable. Moreover, our commercially available products may require additional studies with respect to approved indications as well as new indications pending approval.

The stem cell products that we are developing through our Celgene Cellular Therapeutics (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.

Table of Contents

Due to the inherent uncertainty involved in conducting clinical studies, we can give no assurances that our studies will have a positive result or that we will receive regulatory approvals for our new products or new indications.

Manufacturing and distribution risks including a disruption at certain of our manufacturing and distribution sites, would significantly interrupt our production capabilities, which could result in significant product delays and adversely affect our results.

We have our own manufacturing facilities for many of our products and we have contracted with third-party manufacturers and distributors to provide active pharmaceutical ingredient (API) encapsulation, finishing services, packaging and distribution services. These operations expose us to risks that include the possibility that our or our suppliers' manufacturing processes and distribution channels could be partially or completely disrupted by a fire, contamination, natural disaster, terrorist attack, governmental action or military action. In the case of a disruption, we may need to establish alternative manufacturing sources for these products. This would likely lead to substantial production delays as we build or locate replacement facilities and seek and obtain the necessary regulatory approvals. If this occurs and our finished goods inventories are insufficient to meet demand, we may be unable to satisfy customer orders on a timely basis, if at all. Further, our business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the uncovered cost of any disruption. For these reasons, a significant disruptive event affecting these manufacturing facilities or sites could materially and adversely affect our business and results of operations. In addition, if we inaccurately predict market demand for our products, we may be unable to sufficiently increase production capacity to satisfy demand or may incur costs associated with excess inventory that we manufacture.

In all the countries where we sell our products, governmental regulations define standards for manufacturing, packaging, labeling, distribution and storing. All of our suppliers of raw materials, contract manufacturers and distributors must comply with these regulations, as applicable. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current Good Manufacturing Practice regulations and guidelines. Our failure to comply, or failure of our third-party manufacturers 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, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

If our outside manufacturers do not meet our requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, our ability to continue supplying such products at a level that meets demand could be adversely affected.

We have contracted with distributors, to distribute REVLIMID®, THALOMID®, VIDAZA®, ABRAXANE®, POMALYST®/IMNOVID® and ISTODAX®. If our distributors fail to perform and we cannot secure a replacement distributor within a reasonable period of time, we may experience adverse effects to our business and results of operations.

We are continuing to establish marketing and distribution capabilities in international markets with respect to our products. At the same time, we are in the process of obtaining necessary governmental and regulatory approvals to sell our products in certain countries. If we have not successfully completed and implemented adequate marketing and distribution support services upon our receipt of such approvals, our ability to effectively launch our products in

these countries would be severely restricted.

The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of the 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 reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

60

Table of Contents

Risks from the improper conduct of employees, agents or 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 would violate the laws or regulations of the jurisdictions in which we operate, including without limitation, employment, foreign corrupt practices, environmental, competition and privacy laws. Such improper actions could subject us to civil or criminal investigations, monetary and injunctive penalties and could adversely impact our ability to conduct business, our results of operations and our reputation.

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

We may face significant challenges in effectively integrating entities and businesses that we may 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, but not limited to:

- demands on management related to the increase in our size after the acquisition;

- the diversion of management's attention from the management of daily operations to the integration of operations;

- higher integration costs than anticipated;

- 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 required by the Sarbanes-Oxley Act of 2002 and related procedures and policies.

If we cannot successfully integrate acquired businesses we may experience material negative consequences to our business, financial condition or results of operations. Successful integration of acquired businesses will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by product offerings and expanded geographic market coverage and, to some degree, to eliminate redundant and excess costs.

An inability to continue to attract and retain key leadership, managerial, commercial and scientific talent would adversely affect our business.

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and commercial personnel, (ii) successfully integrate large numbers of new employees into our corporate culture and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Among other benefits, we use share-based compensation to attract and retain personnel. Share-based compensation accounting rules require us to recognize all share-based compensation costs as expenses. These or other factors could reduce the number of share-based compensation awards we grant under our incentive plan. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships, or that the costs of retaining such personnel or maintaining such relationships 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 general business activities. While we believe we are currently in substantial compliance with the federal, state and local laws and regulations governing the use of these materials,

Table of Contents

we cannot be certain that accidental injury or contamination will not occur. If an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. This could result in substantial liabilities 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.

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, but are not limited to, 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 jurisdictions, 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 may be significant and could have an impact on our results of operations.

Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and could 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 exposures 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 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.

The price of our common stock may fluctuate significantly and you may lose some or all of your investment in us.

The market for our shares of common stock may be subject to conditions that cause prices to fluctuate significantly. The following key factors may have an adverse impact on the market price of our common stock:

• results of our clinical trials or adverse events associated with our marketed products;

fluctuations in our commercial and operating results;

announcements of technical or product developments by us or our competitors;

market conditions for pharmaceutical and biotechnology stocks in particular;

stock market conditions generally;

changes in governmental regulations and laws, including, without limitation, changes in tax laws, health care legislation, environmental laws, competition laws and patent laws;

62

Table of Contents

- 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 or processes related to production and formulation of those products or uses of those products;
- other litigation or governmental investigations;
- regulatory actions that may impact our products or potential products;
- disruptions in our manufacturing processes or supply chain;
- competition; and
- investor reaction to announcements regarding business or product acquisitions.

In addition, our operations may be materially impacted by conditions affecting the global markets generally. Global markets may be adversely affected by many factors beyond our control, including global, regional and industrial economic instability and market volatility, sovereign debt issues, rising interest rates or inflation, terrorism or political uncertainty. 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 obligations under our incurred indebtedness.

We have incurred various forms of indebtedness including senior notes, commercial paper and a senior unsecured credit facility. Our ability to pay interest, principal amounts when due at maturity, to comply with debt covenants or to 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, without limitation, 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 incurred indebtedness, we may be forced to take 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 obligations under our indebtedness. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms, if at all.

A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy breaches by employees and others who access our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to protect our data and information technology

Table of Contents

systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect 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 and in connection with our acquisition, CVRs, were issued under a CVR Agreement entered into between us and American Stock Transfer & Trust Company, LLC, as trustee. Pursuant to the CVR Agreement, each holder of a CVR is entitled to receive a pro rata portion, based on the number of CVRs then outstanding, of certain milestone and net sales payments if certain specified conditions are satisfied. For more information, see Part II, Item 8, Note 2 of Notes to Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K.

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 resale price, if any, of the CVRs;

in the absence of an active public market for the CVRs, the market price and trading volume of the CVRs may be volatile;

if the clinical approval milestones specified in the CVR Agreement are not achieved for any reason within the time periods specified therein and if net sales do not exceed the thresholds set forth in the CVR Agreement 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 any CVR payment could be treated as ordinary income and required to be included in income 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 to achieve each of the CVR milestones and 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.

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

(c) Issuer Purchases of Equity Securities

During the period of April 2009 through September 2013, our Board of Directors has approved repurchases of up to an aggregate of \$9.500 billion of our common stock, including the June 2013 authorization to repurchase an additional \$3.000 billion of our common stock. Approved amounts exclude share repurchase transaction fees.

As part of the Board authorized share repurchase program, in February 2013 we entered into an Accelerated Share Repurchase (ASR) agreement with an investment bank to repurchase an aggregate of \$600.0 million of our common stock. The total number of shares repurchased under the ASR agreement was 5,249,137 shares at a weighted average price of \$114.30 per share.

Table of Contents

The following table presents the total number of shares purchased during the three-month period ended September 30, 2013, 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	—	\$—	—	\$3,000,188,990
August 1 - August 31	455,350	\$139.28	455,350	\$2,936,768,595
September 1 - September 30	995,000	\$147.95	995,000	\$2,789,555,193
Total	1,450,350	\$145.23	1,450,350	

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.

- 4.1 Indenture, dated as of August 6, 2013, relating to the 2.300% Senior Notes due 2018, the 4.000% Senior Notes due 2023 and the 5.250% Senior Notes due 2043 between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 6, 2013).
- 4.2 Form of 2.300% Senior Notes due 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 6, 2013).
- 4.3 Form of 4.000% Senior Notes due 2023 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on August 6, 2013).
- 4.4 Form of 5.250% Senior Note due 2043 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on August 6, 2013).
- 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, 2013, 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.

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 29, 2013

By: /s/Jacquelyn A. Fouse
Jacquelyn A. Fouse, Ph.D.
Executive Vice President and
Chief Financial Officer
(principal financial and accounting officer)