

CELGENE CORP /DE/
Form 10-Q
April 30, 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 March 31, 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
(State or other jurisdiction of incorporation
or organization)

86 Morris Avenue, Summit, NJ
(Address of principal executive offices)

22-2711928
(I.R.S. Employer Identification
Number)

07901
(Zip Code)

Table of Contents

CELGENE CORPORATION

FORM 10-Q TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1</u>	
<u>Financial Statements</u>	
<u>Consolidated Statements of Income -</u> <u>Three-Month Periods Ended March 31, 2013 and 2012</u>	2
<u>Consolidated Statements of Comprehensive Income -</u> <u>Three-Month Periods Ended March 31, 2013 and 2012</u>	3
<u>Consolidated Balance Sheets -</u> <u>As of March 31, 2013 and December 31, 2012</u>	4
<u>Consolidated Statements of Cash Flows -</u> <u>Three-Month Periods Ended March 31, 2013 and 2012</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	7
<u>Item 2</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
<u>Item 3</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	44
<u>Item 4</u>	
<u>Controls and Procedures</u>	49
<u>PART II</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1</u>	
<u>Legal Proceedings</u>	49
<u>Item 1A</u>	
<u>Risk Factors</u>	49
<u>Item 2</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	66
<u>Item 6</u>	
<u>Exhibits</u>	67
<u>Signature</u>	68

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	
	March 31,	
	2013	2012
Revenue:		
Net product sales	\$ 1,429.3	\$ 1,245.5
Collaborative agreements and other revenue	7.1	2.6
Royalty revenue	28.2	25.2
Total revenue	1,464.6	1,273.3
Expenses:		
Cost of goods sold (excluding amortization of acquired intangible assets)	80.5	72.5
Research and development	452.4	362.0
Selling, general and administrative	369.0	325.8
Amortization of acquired intangible assets	65.7	41.8
Acquisition related (gains) charges and restructuring, net	33.2	(11.1)
Total costs and expenses	1,000.8	791.0
Operating income	463.8	482.3
Other income and (expense):		
Interest and investment income, net	4.8	3.7
Interest (expense)	(17.9)	(11.4)
Other income (expense), net	(2.3)	(0.6)
Income before income taxes	448.4	474.0
Income tax provision	63.5	72.5
Net income	\$ 384.9	\$ 401.5
Net income per common share:		
Basic	\$ 0.92	\$ 0.92
Diluted	\$ 0.89	\$ 0.90
Weighted average shares:		
Basic	417.9	438.3
Diluted	432.2	448.6

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

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 Ended	
	2013	2012
Net income	\$ 384.9	\$ 401.5
Other comprehensive income (loss):		
Foreign currency translation adjustments	(5.9)	18.4
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 for the three-months ended March 31, 2013, and 2012, respectively	74.9	23.3
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$3.4 and (\$2.6) for the three-months ended March 31, 2013 and 2012, respectively	3.8	(16.4)
Net unrealized gains (losses) on marketable securities available for sale:		
Unrealized holding gains (losses), net of tax expense (benefit) of \$0 for the three-months ended March 31, 2013 and 2012, respectively	(1.9)	2.5
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$0 for the three-months ended March 31, 2013 and 2012, respectively	0.8	(0.4)
Total other comprehensive income (loss)	71.7	40.5
Comprehensive income	\$ 456.6	\$ 442.0

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)

	March 31, 2013		December 31, 2012
Assets			
Current assets:			
Cash and cash equivalents	\$ 1,495.6	\$	2,090.4
Marketable securities available for sale	2,024.9		1,809.9
Accounts receivable, net of allowances of \$36.6 and \$33.0 at March 31, 2013 and December 31, 2012, respectively	1,028.7		960.5
Inventory	275.4		259.5
Deferred income taxes	92.3		93.2
Other current assets	385.0		320.2
Total current assets	5,301.9		5,533.7
Property, plant and equipment, net	578.2		578.4
Intangible assets, net	3,034.1		3,100.4
Goodwill	2,042.3		2,042.8
Other assets	496.1		479.0
Total assets	\$ 11,452.6	\$	11,734.3
Liabilities and Stockholders' Equity			
Current liabilities:			
Short-term borrowings	\$ 362.0	\$	308.5
Accounts payable	116.8		145.6
Accrued expenses	675.2		775.7
Income taxes payable	12.1		11.8
Current portion of deferred revenue	16.5		17.3
Other current liabilities	391.6		431.3
Total current liabilities	1,574.2		1,690.2
Deferred revenue, net of current portion	17.0		16.2
Income taxes payable	194.7		188.2
Deferred income taxes	968.8		1,018.4
Other non-current liabilities	379.4		355.5
Long-term debt, net of discount	2,764.1		2,771.3
Total liabilities	5,898.2		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 March 31, 2013 and December 31, 2012, respectively	-		-
Common stock, \$.01 par value per share, 575.0 million shares authorized; issued 504.0 million and 498.4 million shares at March 31, 2013 and December 31, 2012, respectively	5.0		5.0
Common stock in treasury, at cost; 85.9 million and 78.7 million shares at March 31, 2013 and December 31, 2012, respectively	(5,528.7)		(4,823.2)
Additional paid-in capital	7,648.6		7,539.8
Retained earnings	3,407.5		3,022.6
Accumulated other comprehensive income (loss)	22.0		(49.7)
Total stockholders' equity	5,554.4		5,694.5

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

Total liabilities and stockholders' equity	\$	11,452.6	\$	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)

	Three-Month Periods Ended	
	March 31,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 384.9	\$ 401.5
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	23.2	18.6
Amortization	67.7	42.0
Provision for accounts receivable allowances	1.9	2.7
Deferred income taxes	(53.1)	(166.5)
Impairment charges	9.3	22.1
Change in value of contingent consideration	33.2	(12.4)
Share-based compensation expense	65.6	57.2
Share-based employee benefit plan expense	7.6	3.8
Reclassification adjustment for cash flow hedges included in net income	7.2	(19.1)
Unrealized change in value of derivative instruments	(33.8)	9.2
Realized (gains) losses on marketable securities available for sale	0.9	(0.4)
Other, net	3.0	(4.5)
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(87.0)	(79.3)
Inventory	(25.8)	(25.5)
Other operating assets	35.7	101.0
Assets held for sale, net	-	(0.1)
Accounts payable and other operating liabilities	(82.3)	(40.7)
Income tax payable	7.7	30.5
Deferred revenue	1.4	4.3
Net cash provided by operating activities	367.3	344.4
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	896.0	485.5
Purchases of marketable securities available for sale	(1,115.5)	(105.8)
Payments for acquisition of business, net of cash acquired	-	(352.2)
Purchases of intellectual property and other assets	(0.7)	-
Capital expenditures	(25.4)	(28.1)
(Purchases) refunds of investment securities	(5.5)	(5.0)
Other investing activities	(0.4)	(0.8)
Net cash (used in) provided by investing activities	(251.5)	(6.4)
Cash flows from financing activities:		
Payment for treasury shares	(1,043.7)	(202.7)
Proceeds from short-term borrowing	1,422.9	1,045.9
Principal repayments on short-term borrowing	(1,369.6)	(1,421.3)
Net proceeds from exercise of common stock options and warrants	266.4	215.5
Excess tax benefit from share-based compensation arrangements	36.6	18.6
Net cash (used in) provided by financing activities	(687.4)	(344.0)
Effect of currency rate changes on cash and cash equivalents	(23.2)	7.6
Net (decrease) increase in cash and cash equivalents	(594.8)	1.6

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

Cash and cash equivalents at beginning of period	2,090.4	1,859.5
Cash and cash equivalents at end of period	\$ 1,495.6	\$ 1,861.1

See accompanying Notes to Unaudited Consolidated Financial Statements

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS - (Continued)

(Unaudited)

(Dollars in millions)

	Three-Month Periods Ended	
	March 31,	
	2013	2012
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized (gain) loss on marketable securities available for sale	\$ 2.0	\$ (2.4)
Matured shares tendered in connection with stock option exercises	\$ (0.1)	\$ (0.2)
Supplemental disclosure of cash flow information:		
Interest paid	\$ 22.3	\$ 1.0
Income taxes paid	\$ 76.6	\$ 85.4

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 which is 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®, THALOMID® (inclusive of Thalidomide Celgene®), ISTODAX® and POMALYST®. POMALYST® was approved by the U.S. Food and Drug Administration (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. Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, other licensing royalties, and the sale of services through our Celgene Cellular Therapeutics subsidiary.

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. We record net income (loss) attributable to non-controlling interest, if any, in our Consolidated Statements of Income equal to the percentage of ownership interest retained in the respective operations by the non-controlling parties. 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 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.

2. Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 of the Notes to the 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).

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 2013-02). ASU 2013-02 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

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

in the notes to the financial statements. The amendments are effective prospectively for reporting periods beginning after December 15, 2012. The adoption of ASU 2013-02 did not have a material impact on our financial position or results of operations.

3. Acquisitions and Divestitures**Avila Acquisition**

On March 7, 2012 (Acquisition Date) we acquired all of the outstanding common stock of Avila Therapeutics, Inc., subsequently renamed Celgene Avilomics Research, herein referred to as 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.

4. Earnings Per Share

<i>(Amounts in millions, except per share)</i>	Three-Month Periods Ended	
	2013	March 31, 2012
Net income	\$ 384.9	\$ 401.5
Weighted-average shares:		
Basic	417.9	438.3
Effect of dilutive securities:		
Options, restricted stock units, warrants and other incentives	14.3	10.3
Diluted	432.2	448.6
Net income per share:		

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

Basic	\$	0.92	\$	0.92
Diluted	\$	0.89	\$	0.90

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 2.0 million and 5.2 million shares for the three-month periods ended March 31, 2013 and 2012, respectively.

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.500 billion of our common stock. As part of the existing 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. As part of the ASR agreement we received an initial delivery of 3.0 million shares, which is included in Common stock in treasury in the accompanying Consolidated Balance Sheet as of March 31, 2013, with a fair market value of \$300.0 million. The initial delivery of 3.0 million shares reduced our outstanding shares used to determine our weighted average shares outstanding for purposes of calculating basic and diluted earnings per share. The remaining \$300.0 million

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

was included in Additional paid-in capital as of March 31, 2013. The total number of shares that will ultimately be repurchased under the ASR agreement will be determined upon final settlement in May 2013 and will be based on a discount to the volume-weighted average price of our common stock during the ASR period. We have evaluated the ASR agreement for its potential dilution of earnings per share and determined that the additional shares to be received upon final settlement would have had an anti-dilutive effect and as a result, these shares were not included in our weighted average diluted earnings per share calculation.

As of March 31, 2013, an aggregate of 81.6 million shares of common stock have been repurchased under the program, including 7.2 million shares of common stock repurchased from all sources, including the ASR, during the three-month period ended March 31, 2013. As of March 31, 2013, we had a remaining open-ended repurchase authorization of \$834.2 million after deducting the full \$600.0 million paid under the ASR.

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 and net asset transfers of common control subsidiaries.

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 before reclassifications	-	(1.9)	74.9	(5.9)	67.1
Amounts reclassified from accumulated other comprehensive income	-	0.8	3.8	-	4.6
Net current-period other comprehensive income	-	(1.1)	78.7	(5.9)	71.7
Balance March 31, 2013	\$ (10.1)	\$ 3.1	\$ 62.6	\$ (33.6)	\$ 22.0
Balance December 31, 2011	\$ (5.4)	\$ 1.8	\$ 8.7	\$ (67.4)	\$ (62.3)

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

Other comprehensive income before reclassifications	-	2.5	23.3	31.5	57.3
Amounts reclassified from accumulated other comprehensive income	-	(0.4)	(16.4)	-	(16.8)
Net current-period other comprehensive income	-	2.1	6.9	31.5	40.5
Balance March 31, 2012	\$ (5.4)	\$ 3.9	\$ 15.6	\$ (35.9)	\$ (21.8)

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Accumulated Other Comprehensive Income Components	Affected Line Item in the Consolidated Statements of Income	Gains (Losses) Reclassified Out of Accumulated Other Comprehensive Income Three-Month Periods Ended March 31,	
		2013	2012
Gains (losses) from cash-flow hedges:			
Foreign exchange contracts	Net product sales	\$ (6.4)	\$ 19.0
Treasury rate lock agreements	Interest (expense)	(0.8)	-
	Income tax expense	3.4	(2.6)
Gains (losses) from available-for-sale marketable securities:			
Realized gain (loss) on sales of marketable securities	Interest and investment income, net	(0.8)	0.4
	Income tax expense	-	-
Total reclassification, net of tax		\$ (4.6)	\$ 16.8

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 March 31, 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 Contingent Value Rights (CVRs). See Note 2 of the Notes to the Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K for a description of the CVRs. Our Level 2 liability relates to written foreign 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.

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	Balance at March 31, 2013	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities	\$ 2,024.9	\$ 0.2	\$ 2,024.7	\$ -
Forward currency contracts	117.9	-	117.9	-
Purchased currency options	3.3	-	3.3	-
Total assets	\$ 2,146.1	\$ 0.2	\$ 2,145.9	\$ -
Liabilities:				
Contingent value rights	\$ (307.2)	\$ (307.2)	\$ -	\$ -
Written currency options	(1.2)	-	(1.2)	-
Interest rate swaps	(1.9)	-	(1.9)	-
Other acquisition related contingent consideration	(201.5)	-	-	(201.5)
Total liabilities	\$ (511.8)	\$ (307.2)	\$ (3.1)	\$ (201.5)

	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 three-month periods ended March 31, 2013 and 2012. The following table represents a roll-forward of the fair value of Level 3 instruments (significant unobservable inputs):

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	Three-Month Periods Ended March 31,	
	2013	2012
Liabilities:		
Balance at beginning of period	\$ (198.1)	\$ (76.9)
Amounts acquired or issued	-	(179.1)
Net change in fair value	(3.4)	36.2
Settlements	-	-
Transfers in and/or out of Level 3	-	-
Balance at end of period	\$ (201.5)	\$ (219.8)

Level 3 liabilities issued during the three-month period ended March 31, 2012 consisted of contingent consideration related to the acquisition of Avila.

7. Derivative Instruments and Hedging Activities

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We 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 have established revenue hedging and balance sheet risk management programs to mitigate volatility in future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

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.

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

Foreign Currency Forward Contracts: We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies and to reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We enter into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at March 31, 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 March 31, 2013 and December 31, 2012:

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Foreign Currency	Notional Amount	
	March 31, 2013	December 31, 2012
Australian Dollar	\$ 6.2	\$ 5.1
British Pound	87.7	77.9
Canadian Dollar	105.2	134.4
Euro	1,322.4	969.3
Japanese Yen	393.5	236.2
Total	\$ 1,915.0	\$ 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 March 31, 2013, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also enter into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at March 31, 2013 and December 31, 2012 were \$971.2 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 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.

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

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

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Foreign Currency Option	Notional Amount*	
	March 31, 2013	December 31, 2012
Designated as hedging activity:		
Purchased Put	\$ 139.0	\$ 228.8
Written Call	\$ 144.6	\$ 235.9
Not designated as hedging activity:		
Purchased Put	\$ 131.0	\$ 160.5
Written Put	\$ (131.0)	\$ (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

Treasury Rate Lock Agreements: In anticipation of issuing fixed-rate debt, we may use treasury rate lock agreements (treasury rate locks) that we designate as cash-flow hedges. To the extent treasury rate locks are effective cash-flow hedges, any realized or unrealized gains or losses on the treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

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 three-month periods ended March 31, 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 three months ended March 31, 2013 and at March 31, 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 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.

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

During the three-month period ended March 31, 2013, we entered into \$400.0 million notional amount of swap contracts that were designated as hedges of our 3.95% fixed rate notes due in 2020 and also during the three-month period ended March 31, 2013 terminated the hedging relationship by settling the contracts. This resulted in net proceeds received of \$2.8 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 March 31, 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 March 31, 2013:

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Notional Amount	
	March 31,	December 31,
	2013	2012
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
2.450% senior notes due in 2015	\$ 400.0	\$ -
1.900% senior notes due in 2017 (1)	500.0	100.0
3.250% senior notes due in 2022 (2)	1,000.0	200.0
Total	\$ 1,900.0	\$ 300.0

(1) \$400.0 million was settled in April 2013 resulting in net proceeds received of \$1.7 million, which is accounted for as a reduction of past and future interest expense associated with these notes.

(2) \$400.0 million was settled in April 2013 resulting in net proceeds received of \$4.5 million, which is accounted for as a reduction of past and future interest expense associated with these notes.

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of March 31, 2013 and December 31, 2012:

Instrument	March 31, 2013			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<i>Derivatives designated as hedging instruments:</i>				
	Other current assets	\$ 107.3	Other current assets	\$ 51.7
	Other current liabilities	-	Other current liabilities	0.4
Foreign exchange contracts*	Other non-current assets	56.9	Other non-current assets	16.8
	Other non-current liabilities	4.2	Other non-current liabilities	6.9
	Other current assets	4.4	Other current assets	-
	Other non-current assets	0.5	Other non-current assets	2.2
Interest rate swap agreements	Other non-current liabilities	-	Other non-current liabilities	6.9
<i>Derivatives not designated as hedging instruments:</i>				
Foreign exchange contracts*	Other current assets	70.9	Other current assets	36.4
	Other current liabilities	4.7	Other current liabilities	12.1
Interest rate swap agreements	Other non-current assets	2.3	Other non-current assets	-
Total		\$ 251.2		\$ 133.4
December 31, 2012				
Instrument	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
	<i>Derivatives designated as hedging instruments:</i>			
	Other current assets	\$ 35.2	Other current assets	\$ 12.7
	Other current liabilities	9.1	Other current liabilities	31.4
Foreign exchange contracts*	Other non-current assets	30.5	Other non-current assets	13.8
	Other current assets	0.1	Other current assets	-
	Other non-current assets	0.1	Other non-current assets	0.2
Interest rate swap agreements	Other non-current liabilities	-	Other non-current liabilities	0.6
<i>Derivatives not designated as hedging instruments:</i>				
Foreign exchange contracts*	Other current assets	45.8	Other current assets	36.3
	Other current liabilities	10.4	Other current liabilities	21.4
Interest rate swap agreements	Other current assets	0.6	Other current assets	-
	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-month periods ended March 31, 2013 and 2012:

Instrument	Three-Month Period Ended March 31, 2013				
	Amount of Gain/(Loss) Recognized in OCI on Derivative (1)	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>
Foreign exchange contracts	\$ 75.0	Net product sales	\$ (6.4)	Other income, net	\$ 3.5(2)
Treasury rate lock agreements	\$ -	Interest Expense	\$ (0.8)		

(1) Net gains of \$16.0 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 \$2.0 million in gains related to the ineffective portion of the hedging relationships and \$1.5 million of gains related to amounts excluded from the assessment of hedge effectiveness.

Instrument	Three-Month Period Ended March 31, 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
	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>
Foreign exchange	\$ 23.5	Net product sales	\$ 19.1	Other income, net	\$ (1.9)(1)

contracts

(1) The amount of net losses recognized in income represents \$4.4 million in losses related to the ineffective portion of the hedging relationships and \$2.5 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)**

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the three-month periods ended March 31, 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 March 31,	
		2013	2012
Interest Rate Swaps	Interest expense	\$ 6.9	\$ 1.8

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the three-month periods ended March 31, 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 March 31,	
		2013	2012
Foreign exchange contracts	Other income, net	\$ 38.7	\$ (7.9)

The impact of gains and losses on foreign exchange contracts not designated as hedging instruments are generally offset by net foreign exchange gains and losses, which are also included in other income (expense), net for all periods presented.

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

Money market funds of \$643.1 million and \$1.160 billion at March 31, 2013 and December 31, 2012, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

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

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

March 31, 2013	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 848.6	\$ 0.6	\$ -	\$ 849.2
U.S. government-sponsored agency securities	232.9	0.3	-	233.2
U.S. government-sponsored agency MBS	558.2	1.7	(2.9)	557.0
Non-U.S. government, agency and Supranational securities	10.4	-	-	10.4
Corporate debt - global	336.3	1.0	(0.5)	336.8
Asset backed securities	38.1	-	-	38.1
Marketable equity securities	0.4	-	(0.2)	0.2
Total available-for-sale marketable securities	\$ 2,024.9	\$ 3.6	\$ (3.6)	\$ 2,024.9

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2012	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
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. Net unrealized gains in the marketable debt securities primarily reflect the impact of decreased interest rates at March 31, 2013.

Duration periods of available-for-sale debt securities at March 31, 2013 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	\$ 278.2	\$ 277.6
Duration of one through three years	1,458.0	1,458.6
Duration of three through five years	264.5	264.9
Duration of over five years	23.8	23.6
Total	\$ 2,024.5	\$ 2,024.7

9. Inventory

A summary of inventories by major category at March 31, 2013 and December 31, 2012 follows:

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

	March 31, 2013	December 31, 2012
Raw materials	\$ 95.0	\$ 79.2
Work in process	86.1	86.5
Finished goods	94.3	93.8
Total	\$ 275.4	\$ 259.5

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
March 31, 2013				
Amortizable intangible assets:				
Acquired developed product rights	\$ 3,400.4	\$ (867.3)	\$ 2,533.1	13.0
Technology	333.6	(51.7)	281.9	7.0
Licenses	64.3	(10.9)	53.4	16.8
Other	43.7	(15.9)	27.8	8.4
	3,842.0	(945.8)	2,896.2	12.5
Non-amortized intangible assets:				
Acquired IPR&D product rights	137.9	-	137.9	
Total intangible assets	\$ 3,979.9	\$ (945.8)	\$ 3,034.1	
December 31, 2012				
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 \$0.6 million at March 31, 2013 compared to December 31, 2012 primarily resulting from two miscellaneous agreements.

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

Amortization expense was \$66.9 million and \$42.0 million for the three-month periods ended March 31, 2013 and 2012, respectively. The \$24.9 million increase in amortization expense in the 2013 quarter included \$19.5 million from 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 a \$5.9 million increase in amortization of technology related to the acquisition of Avila and its Avilomics™ platform as that was acquired on March 7, 2012. Assuming no changes in the gross carrying amount of intangible 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.

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Goodwill: At March 31, 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		(0.5)
Balance at March 31, 2013	\$	2,042.3

11. Debt

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

	March 31, 2013	December 31, 2012
2.450% senior notes due 2015	\$ 518.4	\$ 520.1
1.900% senior notes due 2017	501.1	500.6
3.950% senior notes due 2020	501.5	499.0
3.250% senior notes due 2022	993.6	1,002.1
5.700% senior notes due 2040	249.5	249.5
Total long-term debt	\$ 2,764.1	\$ 2,771.3

At March 31, 2013, the fair value of our outstanding Senior Notes was \$2.868 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

During the year ended December 31, 2012, we entered into treasury rate locks in anticipation of issuing the fixed-rate notes that were issued in August 2012. As of March 2013, a balance of \$33.1 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.

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

At March 31, 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 March 31, 2013 effectively convert the hedged portion of our fixed-rate notes to floating rates. From time to time we terminate the hedging relationship on certain of our swap contracts by settling the contracts or by entering into offsetting contracts. Any net proceeds received or paid in these settlements are accounted for as a reduction or increase of current and future interest expense associated with the previously hedged notes. As of March 31, 2013, we had a balance of \$26.0 million of gains recorded as a reduction of our debt as a result of past swap contract settlements, including \$2.5 million related to the settlement of \$400.0 million of swap contracts during the three months ended March 31, 2013 that had previously been designated as a hedge of our 3.950% senior notes due 2020. In April 2013, an additional \$800.0 million in swap contracts were settled with combined gains of \$3.8 million accounted for as a reduction of future interest expense associated with these notes.

Commercial Paper: The carrying value of Commercial Paper as of March 31, 2013 and December 31, 2012 was \$362.0 million and \$308.5 million, respectively, and approximated its fair value. The effective interest rate on the outstanding Commercial Paper balance at March 31, 2013 was 0.4%.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of \$1.000 billion, which was increased to

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$1.500 billion in 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 serves as backup liquidity for our Commercial Paper borrowings. At March 31, 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 March 31, 2013.

12. Share-Based Compensation

We have a stockholder-approved stock incentive plan, the 2008 Stock Incentive Plan as amended and restated (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.

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three-month periods ended March 31, 2013 and 2012:

	Three-Month Periods Ended	
	2013	2012
Cost of goods sold	\$ 2.8	\$ 2.9
Research and development	27.0	25.0
Selling, general and administrative	35.8	26.8
Total share-based compensation expense	65.6	54.7
Tax benefit related to share-based compensation expense	17.9	14.6
Reduction in income	\$ 47.7	\$ 40.1

Share-based compensation cost included in inventory was \$1.3 million and \$1.2 million at March 31, 2013 and December 31, 2012, respectively.

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

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 three-month period ended March 31, 2013 (in thousands):

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	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	2,072	78	-
Exercised / Released	(5,166)	(97)	(6)
Forfeited	(299)	(35)	(8)
Expired	(8)	N/A	N/A
Outstanding at March 31, 2013	39,191	4,409	12

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 March 31, 2013 were as follows (dollars in millions):

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Unrecognized compensation cost	\$ 291.2	\$ 152.1	\$ 0.4
Expected weighted-average period in years of compensation cost to be recognized	2.3	1.5	1.3

13. Income Taxes

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

Our tax returns are under routine examination in many taxing jurisdictions. The scope of these examinations includes, but is not limited to, the review of our taxable presence in a jurisdiction, our deduction of certain items, our claims for research and development credits, our compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from our tax returns as filed. Our U.S. federal income tax

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

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

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

methodologies in making these estimates and assumptions, which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as our industry experience. These evaluations are based on estimates and assumptions that have been deemed reasonable by management. However, if management's estimates are not representative of actual outcomes, our results of operations could be materially impacted.

Unrecognized tax benefits, generally represented by liabilities on the consolidated balance sheet and all subject to tax examinations, arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. These unrecognized tax benefits relate primarily to issues common among multinational corporations. Virtually all of these unrecognized tax benefits, if recognized, would impact the effective income tax rate. We account for interest and potential penalties related to uncertain tax positions as part of our provision for income taxes. Increases to the amount of unrecognized tax benefits since January 1, 2013 of approximately \$6.5 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. 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 the Notes to the 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 three months ended March 31, 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.

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

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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

In addition to the collaboration arrangements described above, we entered into a number of collaborative arrangements during the three months ended March 31, 2013 that resulted in \$5.3 million of assets for investments in equity or other assets. These additional arrangements include the potential for future milestone payments of up to an aggregate \$45.0 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 months ended March 31, 2013 resulted in research and development expenses of \$95.7 million.

15. Commitments and Contingencies

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

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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 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 Attorney's 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.

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), 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 970 patent, the 977 patent, the 784 patent, the 106 patent and the 800 patent.

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

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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

A revised Scheduling Order was entered by the Court on November 9, 2012, setting the close for fact discovery on August 14, 2013. A Markman hearing is currently expected to be fully briefed by the end of July 2013. Dates for a Markman hearing and trial have yet to be set.

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 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 has not yet filed a responsive pleading.

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 Natco will prevail on each and every patent and patent claim subject to the lawsuits, and that 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.

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

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. 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.

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. 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.

17. Subsequent Events

Credit Facility: In April 2013, we increased the borrowing limit on our Credit Facility, described in Note 11, from \$1.000 billion to \$1.500 billion. The term of the Credit Facility was also extended from September 2, 2016 to April 18, 2018. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. 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.

Collaboration Agreements: Subsequent to the quarter end, we entered into two collaborative arrangements that resulted in research and development expenses of approximately \$56.0 million as well as approximately \$3.0 million of assets for investments in equity or other assets. These collaborative arrangements include the potential to enter into additional arrangements and for future licensing and milestone payments with total possible cash payments of up to an aggregate of \$5.400 billion related to the attainment of specified development, regulatory, and commercial milestones over a period of several years, such payment being based off of broad regulatory approval of over 10 new drugs. We do not have an obligation to fund these efforts unless we continue our involvement in the programs through exercise, at our discretion, of certain option and development rights and/or the lack of any adverse events which could cause the discontinuance of the programs. The activities under these collaboration arrangements are performed with no guarantee of either technological or commercial success. We do not consider any individual arrangement to be material.

Table of Contents

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

Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words expects, anticipates, believes, intends, estimates, aims, plans, may, could, will, will continue, seeks, should, predicts, potential, outlook, guidance, possible or 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®, THALOMID® (inclusive of Thalidomide Celgene®), POMALYST® (pomalidomide) and ISTODAX®. POMALYST® was approved by the U.S. Food and Drug Administration (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.

- REVLIMID® is an oral immunomodulatory drug marketed in the United States and many international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy. It is also marketed in the United States and certain international markets for the treatment of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

Table of Contents

- 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. If a generic version of VIDAZA® is successfully launched, we may quickly lose a significant portion of our sales for this product in the United States. 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. European regulatory exclusivity is expected to continue through 2018.
- ABRAXANE® is a solvent-free chemotherapy treatment option for metastatic breast cancer and non-small cell lung cancer which was developed using our proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. It is approved for the treatment of metastatic breast cancer in the United States and many international markets and, in the United States for the treatment of metastatic non-small cell lung cancer. In January 2013, we announced the results from a phase III trial for ABRAXANE® in combination with gemcitabine in treatment-naïve patients with metastatic pancreatic cancer. The ABRAXANE® combination demonstrated a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone. Based on these results, we have submitted dossiers for registration in the United States and Europe in March and April 2013, respectively, and plan submissions in other countries and regions during the second half of 2013. ABRAXANE® is currently in various stages of investigation for the treatment of the following cancers: pancreatic; expanded applications for metastatic breast; malignant melanoma; and bladder and ovarian.
- 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.
- POMALYST® (pomalidomide) 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, and is under review by the European Medicines Agency (EMA) for use in Europe. POMALYST® is a proprietary, distinct, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST® 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.
- 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.

Table of Contents

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® in relapsed refractory multiple myeloma, in addition to VIDAZA for AML, and CC-486 for MDS and AML are also underway. In solid tumors, we are evaluating ABRAXANE in a phase III trial for metastatic melanoma. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in a broad phase III program for psoriatic arthritis, psoriasis, ankylosing spondylitis, and Behçet's disease.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies intended to address significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORK inhibitor), CC-115 (dual TORK/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-220 and CC-11050 (anti-inflammatory), PDA-001 and PDA-002 (cellular therapies), in addition to partnered molecules ACE-011 (ActR fusion protein), ACE-536 (GDF trap), and EPZ-5676 (DOT1L inhibitor). 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.

The following table summarizes total revenue and earnings for the three-month periods ended March 31, 2013 and 2012 (dollar amounts in millions, except per share data):

	Three-Month Periods Ended			Increase (Decrease)	Percent Change		
	2013	March 31,	2012				
Total revenue	\$	1,464.6	\$	1,273.3	\$	191.3	15.0%
Net income	\$	384.9	\$	401.5	\$	(16.6)	(4.1%)
Diluted earnings per share	\$	0.89	\$	0.90	\$	(0.01)	(1.1%)

Revenue increased \$191.3 million in the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to the continued growth in sales of REVLIMID® and the FDA approval of POMALYST® 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. Sales of VIDAZA® and ABRAXANE® in both U.S. and international markets also contributed to the growth in revenue. The \$16.6 million decrease in net income and \$0.01 decrease in diluted earnings per share in the current year quarter was primarily due to \$105.7 million in payments made related to research and development collaboration arrangements, partly offset by the higher level of net product sales.

Table of Contents**Results of Operations:****Three-Month Periods Ended March 31, 2013 and 2012**

Total Revenue: Total revenue and related percentages for the three-month periods ended March 31, 2013 and 2012 were as follows (dollar amounts in millions):

	Three-Month Periods Ended		Increase (Decrease)	Percent Change
	2013	March 31, 2012		
Net product sales:				
REVLIMID®	\$ 1,002.8	\$ 861.0	\$ 141.8	16.5%
VIDAZA®	204.1	186.2	17.9	9.6%
ABRAXANE®	122.7	104.3	18.4	17.6%
THALOMID®	57.4	77.9	(20.5)	(26.3%)
POMALYST®	28.5	1.0	27.5	N/A
ISTODAX®	12.9	11.8	1.1	9.3%
Other	0.9	3.3	(2.4)	(72.7%)
Total net product sales	\$ 1,429.3	\$ 1,245.5	\$ 183.8	14.8%
Collaborative agreements and other revenue	7.1	2.6	4.5	173.1%
Royalty revenue	28.2	25.2	3.0	11.9%
Total revenue	\$ 1,464.6	\$ 1,273.3	\$ 191.3	15.0%

Total revenue increased by \$191.3 million, or 15.0%, to \$1.465 billion for the three-month period ended March 31, 2013, compared to the three-month period ended March 31, 2012, reflecting increases of \$122.4 million, or 16.7%, in the United States, and \$68.9 million, or 12.7%, in international markets.

Net Product Sales: Total net product sales for the three-month period ended March 31, 2013 increased by \$183.8 million, or 14.8%, to \$1.429 billion compared to the three-month period ended March 31, 2012. The increase was comprised of net volume increases of \$181.1 million which included a \$27.5 million increase from sales of POMALYST® and price increases of \$29.8 million, partially offset by a \$27.1 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity. We expect quarterly and full year revenue comparisons of 2013 periods to prior year periods to continue to be negatively impacted by net foreign exchange and foreign exchange hedging activity.

REVLIMID® net sales increased by \$141.8 million, or 16.5%, to \$1.003 billion for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to increased unit sales in both U.S. and international markets as well as price increases in the U.S. market. Increases in market penetration and treatment duration of patients using REVLIMID® in multiple myeloma contributed to the increase in U.S. unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains. These increases were partially offset by modest losses recognized on foreign exchange hedging activity, compared with gains on foreign exchange hedges during the three-month period ended March 31, 2012, primarily due to significant Euro depreciation from 2011 into 2012.

VIDAZA® net sales increased by \$17.9 million, or 9.6%, to \$204.1 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, reflecting volume and price increases in both U.S. and international markets.

ABRAXANE® net sales increased by \$18.4 million, or 17.6%, to \$122.7 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to increased

Table of Contents

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 approval for non-small cell lung cancer (NSCLC).

THALOMID® net sales decreased by \$20.5 million, or 26.3%, to \$57.4 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to lower unit volumes in the United States 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.

POMALYST® was approved by the FDA in February 2013 and net sales totaled \$28.5 million for the three-month period ended March 31, 2013. POMALYST® sales included \$6.7 million associated with approved early access programs in Europe.

ISTODAX® net sales increased by \$1.1 million, or 9.3%, to \$12.9 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to increased unit sales in the treatment of CTCL and PTCL.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources increased by \$4.5 million to \$7.1 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. The increase was due to a \$5.0 million milestone payment related to approval of additional indications for ABRIXANE® in Japan.

Royalty Revenue: Royalty revenue increased by \$3.0 million to \$28.2 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012 due to increased royalties earned from Novartis based upon 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, and 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® is 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.

THALOMID® is distributed in the United States under our proprietary *System for Thalidomide Education and Prescribing Safety* (S.T.E.P.S.)®, 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 plan to integrate 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

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

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® 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

Table of Contents

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 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 March 31, 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	0.6	-	(6.4)	0.2	(5.6)
Allowances for sales during 2013	2.8	19.4	66.8	55.7	144.7
Credits/deductions issued for prior year sales	(0.9)	(5.2)	(16.6)	(35.9)	(58.6)
Credits/deductions issued for sales during 2013	(0.8)	(11.3)	(11.8)	(22.5)	(46.4)
Balance at March 31, 2013	\$ 15.0	\$ 14.1	\$ 157.8	\$ 58.7	\$ 245.6
Balance at December 31, 2011	\$ 9.0	\$ 8.7	\$ 137.0	\$ 64.3	\$ 219.0
Allowances for sales during prior periods	(7.5)	-	1.2	0.3	(6.0)
Allowances for sales during 2012	1.3	15.7	60.0	47.2	124.2
Credits/deductions issued for prior year sales	2.2	(4.3)	(27.5)	(28.8)	(58.4)
Credits/deductions issued for sales during 2012	(0.7)	(10.0)	(1.6)	(15.5)	(27.8)
Balance at March 31, 2012	\$ 4.3	\$ 10.1	\$ 169.1	\$ 67.5	\$ 251.0

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended March 31, 2013 and 2012 follows:

Returns and allowances increased by \$9.6 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to the reversal during the first quarter of 2012 of approximately \$7.5 million in reserves established for certain products with quality issues which were resolved in 2012. In addition, during the first quarter 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 increase was partially offset by a \$5.7 million reduction in the returns allowance related to VIDAZA® inventory levels held by distributors, which decreased during the three months ended March 31, 2013.

Discounts increased by \$3.7 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to revenue increases in the U.S. and international markets, both of which offer different discount programs, and expansion into new international markets.

Government rebates decreased by \$0.8 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012, primarily due to a decrease of approximately \$5.0 million in government rebates related to international markets primarily driven by the refinement of select government programs. The decrease was partially offset by a \$4.2 million increase related to various U.S. programs. The U.S. programs increase was primarily attributable to volume increases and the refinement of accrual rates for Medicaid Managed Care Organizations and Medicare Part D Coverage Gap.

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

Chargebacks and distributor service fees increased by \$8.4 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. Chargebacks and distributor service fees increased by approximately \$4.0 million and \$4.3 million, respectively, primarily due to higher sales volumes.

Table of Contents

Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended March 31, 2013 and 2012 were as follows (dollar amounts in millions):

	Three-Month Periods Ended			Increase	Percent Change
	2013	March 31, 2012			
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 80.5	\$ 72.5	\$ 8.0	11.0%	
Percent of net product sales	5.6%	5.8%			
Research and development	\$ 452.4	\$ 362.0	\$ 90.4	25.0%	
Percent of total revenue	30.9%	28.4%			
Selling, general and administrative	\$ 369.0	\$ 325.8	\$ 43.2	13.3%	
Percent of total revenue	25.2%	25.6%			
Amortization of acquired intangible assets	\$ 65.7	\$ 41.8	\$ 23.9	57.2%	
Acquisition related (gains) charges and restructuring, net	\$ 33.2	\$ (11.1)	\$ 44.3	399.1%	

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$8.0 million to \$80.5 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. The increase was primarily due to the higher level of sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.6% for the three-month period ended March 31, 2013 compared to 5.8% for the three-month period ended March 31, 2012. The cost of goods sold ratio in 2013 was favorably impacted by lower cost products, such as REVLIMID®, comprising a larger portion of total net sales.

Research and Development: Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, supplies and upfront and milestone payments arising from collaboration arrangements.

Research and development expenses increased by \$90.4 million to \$452.4 million for the three-month period ended March 31, 2013, compared to the three-month period ended March 31, 2012. The increase was primarily due to \$105.7 million in payments made related to research and development collaboration arrangements in the current year quarter. The three-month period ended March 31, 2012 included a \$22.2 million in-process research and development (IPR&D) asset impairment charge related to ISTODAX® for PTCL in Europe and no IPR&D asset impairment charges were recorded in the period ended March 31, 2013.

Table of Contents

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

	Three-Month Periods Ended		Increase (Decrease)
	2013	March 31, 2012	
Human pharmaceutical clinical programs	\$ 176.5	\$ 189.4	\$ (12.9)
Other pharmaceutical programs	119.1	102.0	17.1
Drug discovery and development	45.1	40.6	4.5
Cellular therapy	6.0	7.8	(1.8)
Collaboration arrangements	105.7	-	105.7
IPR&D impairments	-	22.2	(22.2)
Total	\$ 452.4	\$ 362.0	\$ 90.4

We make significant investments in research and development in support of multiple ongoing proprietary clinical development programs which support both 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, CLL, and non-deletion 5q MDS. Phase III trials for POMALYST® in relapsed refractory multiple myeloma, in addition to VIDAZA® in AML, and CC-486 for MDS and AML are also underway. In solid tumors, we continue to evaluate ABRAXANE® in a phase III trial for metastatic melanoma and have recently completed a phase III trial for ABRAXANE® in pancreatic cancer. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in broad phase III programs for psoriatic arthritis, psoriasis, and ankylosing spondylitis.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies addressing significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORK inhibitor), CC-115 (dual TORK/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-220 and CC-11050 (anti-inflammatory), PDA-001 and PDA-002 (cellular therapies), in addition to partnered molecules ACE-011 (ActR fusion protein), ACE-536 (GDF trap) and EPZ-5676 (DOT1L inhibitor).

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.

Table of Contents

The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended March 31, 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
ISTODAX®	Front line PTCL

Regulatory approval requests in major markets

Product	Disease Indication	Major Market	Regulatory Agency	Date of Submission
ABRAXANE®	Pancreatic cancer	U.S.	FDA	Mar-13
ABRAXANE®	Pancreatic cancer	E.U.	CHMP1	Apr-13
Apremilast	Psoriatic arthritis	U.S.	FDA	Mar-13

Regulatory agency actions

Product	Disease Indication	Major Market	Regulatory Agency	Action
REVLIMID®	Del 5q MDS2	E.U.	CHMP1	Positive Opinion
REVLIMID®	RRMM3	China	SFDA4	Approval
POMALYST®	RRMM3	U.S.	FDA	Approval
ISTODAX®	PTCL	E.U.	EMA	Adopted CHMP1 recommended denial

1 European Medicines Agency s Committee for Medicinal Products for Human Use

2 Deletion 5q myelodysplastic syndromes

3 Relapsed/refractory multiple myeloma

4 China State Food and Drug Administration

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 \$43.2 million to \$369.0 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012 partly due to a \$14.1 million increase in service fees attributable to Latin American operations, a \$15.1 million increase related to headcount and marketing activities primarily related to the launch of POMALYST® and increases in other personnel related costs and marketing activities in support of our products. The increase was partly offset by a \$32.5 million decrease in donations to independent non-profit organizations in the United States.

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 March 31, 2013 and 2012 (in millions):

Acquisitions	Three-Month Periods Ended		Increase
	2013	March 31, 2012	
Abraxis	\$ 40.0	\$ 21.9	\$ 18.1
Avila	11.8	6.0	5.8
Gloucester	12.9	12.9	-
Pharmion	1.0	1.0	-
Total amortization	\$ 65.7	\$ 41.8	\$ 23.9

Amortization of acquired intangible assets increased by \$23.9 million to \$65.7 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012 primarily due to \$19.5 million from the October 2012 approval of ABRAXANE® in the U.S. for the treatment of NSCLC which resulted in the commencement of amortization of the related intangible asset and a \$5.9 million increase in amortization related to intangible assets obtained in the March 2012 acquisition of Avila. The increases were partly offset by an intangible asset becoming fully amortized during 2012.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition related (gains) charges and restructuring, net was a net charge of \$33.2 million for the three-month period ended March 31, 2013 compared to a net gain of \$11.1 million for the three-month period ended March 31, 2012. The three-month period ended March 31, 2012 included a \$37.0 million favorable adjustment to the accretion of a contingent liability related to the acquisition of Gloucester. In addition, an increase 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 increased the Abraxis-related expense by \$6.1 million to \$29.9 million for the three-month period ended March 31, 2013.

Interest and Investment Income, Net: Interest and investment income, net increased by \$1.1 million to \$4.8 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. The increase was primarily due to a \$3.8 million increase in interest income generated from higher investment balances compared to the prior year quarter, partly offset by a net increase in the cost of amortization of discounts and premiums related to investments and a decrease in gains on the sale of investments.

Interest (Expense): Interest (expense) increased by \$6.5 million to \$17.9 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012 primarily due to interest and fees associated with the issuance of an additional \$1.500 billion in senior notes in August 2012.

Other Income (Expense), Net: Other income (expense), net was a net expense of \$2.3 million and \$0.6 million for the three-month periods ended March 31, 2013 and 2012, respectively. The expense for the three-month period ended March 31, 2013 primarily included a \$9.3 million impairment charge related to a certain investment, partly offset by net foreign exchange gains and the favorable impact from forward point amortization on foreign exchange forward contracts.

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

Income Tax Provision: The income tax provision decreased by \$9.0 million to \$63.5 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. The estimated full year 2013 underlying effective tax rate of 14.4% reflects the impact of our global business footprint. The decrease in the estimated underlying effective tax rate from the first quarter of 2012 reflects a

Table of Contents

projected increase in tax benefits from certain acquisition-related items. The effective tax rate for the first quarter of 2013 was reduced by 0.2 percentage points as a result of a discrete item related to the retroactive reinstatement of the 2012 U.S. research and development tax credit. 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 three-month period ended March 31, 2012 included an estimated full year underlying effective tax rate of 16.1% (which subsequently decreased to 13.5% when the actual 2012 full year results were achieved). The effective tax rate for the first quarter of 2012 was reduced by 0.8 percentage points as a result of a decrease in unrecognized tax benefits related to the expirations of statutes of limitations.

Liquidity and Capital Resources

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

	March 31, 2013	December 31, 2012	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	\$ 1,495.6	\$ 2,090.4	\$ (594.8)
Marketable securities available for sale	2,024.9	1,809.9	215.0
Total financial assets	\$ 3,520.5	\$ 3,900.3	\$ (379.8)
Debt:			
Short-term borrowings	\$ 362.0	\$ 308.5	\$ 53.5
Long-term debt, net of discount	2,764.1	2,771.3	(7.2)
Total debt	\$ 3,126.1	\$ 3,079.8	\$ 46.3
Working capital (1)	\$ 3,652.0	\$ 3,767.5	\$ (115.5)

(1) Includes cash, cash equivalents and marketable securities available for sale, accounts receivable, net of allowances, inventory and other current assets, less short-term borrowings, 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 March 31, 2013, we held approximately \$3.200 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

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

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 U.S., no accrual for U.S. taxes is provided. Approximately \$900.0 million of our foreign earnings may not be required for use in offshore operations and may be available for use in the United States. These

Table of Contents

earnings are not treated as permanently reinvested, and accordingly, our deferred tax liabilities as of March 31, 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 U.S. We do not rely on these earnings as a source of funds for our domestic business as we expect to have sufficient current cash resources combined with future cash flows in the United States to fund our U.S. operational and strategic needs.

Share Repurchase Program: Our Board of Directors has approved an aggregate \$6.500 billion stock repurchase program of which we have approximately \$834.2 million remaining for future share repurchases, after deducting \$600.0 million paid in February 2013 pursuant to an accelerated share repurchase (ASR) agreement. During the three-month period ended March 31, 2013, we used \$1.044 billion for repurchases of our common stock, including the \$600.0 million paid for the ASR for which we have received a partial delivery of shares.

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 \$379.8 million decrease in cash, cash equivalents and marketable securities available for sale at March 31, 2013 compared to December 31, 2012 was primarily due to \$1.044 billion paid under our share repurchase program, \$133.0 million in payments related to research and development collaboration arrangements, and purchases of marketable securities, partly offset by cash generated from operations.

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 to the Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Accounts Receivable, Net: Accounts receivable, net increased by \$68.2 million to \$1.029 billion at March 31, 2013 compared to December 31, 2012. The impact of increased U.S. and international sales of REVLIMID®, VIDAZA® and ABRAXANE® was partly offset by increased collections in certain markets. 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

Table of Contents

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 \$325.3 million at March 31, 2013 compared to \$324.2 million at December 31, 2012. Approximately \$53.1 million of the \$325.3 million receivable at the end of March 31, 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 timeline 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 \$15.9 million to \$275.4 million at March 31, 2013 compared to December 31, 2012. The increase was primarily due to an expected increase in future sales levels of our major products.

Other Current Assets: Other current assets increased by \$64.8 million to \$385.0 million at March 31, 2013 compared to December 31, 2012 primarily due to a \$61.9 million increase in the fair value of foreign currency forward contracts and a \$16.0 million increase in receivables related to exercises of employee stock options, partly offset by a \$19.8 million decrease in other prepaid taxes and decreases in other 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 up to a maximum aggregate amount outstanding at any time of \$1.000 billion, the proceeds of which will be used for general corporate purposes. 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 March 31, 2013, \$362.0 million of Commercial Paper was outstanding compared to \$308.5 million as of December 31, 2012, bearing an effective interest rate of 0.4%.

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

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

Table of Contents

increased to \$1.500 billion in April 2013. The term of the Credit Facility was also extended to September 2, 2016 from 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 March 31, 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 March 31, 2013.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities decreased by \$169.1 million to \$1.184 billion at March 31, 2013 compared to December 31, 2012. The decrease was primarily due to a \$54.4 million decrease in compensation-related accruals, \$41.0 million decrease in amounts owed related to our common share repurchase program due to the timing of transaction settlements, \$31.9 million decrease in other taxes payable, \$25.6 million decrease in the fair value of foreign currency forward derivative contracts and \$8.6 million decrease in clinical trial accruals, partly offset by a \$31.2 million increase in sales adjustments.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by \$6.8 million to \$206.8 million at March 31, 2013 compared to December 31, 2012, primarily from the current provision for income taxes of \$116.6 million and net deferred intercompany credits of \$4.3 million, offset by income tax payments of \$76.6 million and a tax benefit of stock options of \$37.2 million.

Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the three-month periods ended March 31, 2013 and 2012 were as follows (in millions):

	Three-Month Periods Ended			Change		
	2013	March 31,	2012			
Net cash provided by operating activities	\$	367.3	\$	344.4	\$	22.9
Net cash provided by (used in) investing activities	\$	(251.5)	\$	(6.4)	\$	(245.1)
Net cash provided by (used in) financing activities	\$	(687.4)	\$	(344.0)	\$	(343.4)

Operating Activities: Net cash provided by operating activities increased by \$22.9 million to \$367.3 million for the three-month period ended March 31, 2013 compared to the three-month period ended March 31, 2012. The increase in net cash provided by operating activities was primarily attributable to an expansion of our operations.

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

Investing Activities: Net cash used in investing activities for the three-month period ended March 31, 2013 increased to a net usage of \$251.5 million compared to a net usage of \$6.4 million for the three-month period ended March 31, 2012. The increase in net cash used in investing activities was principally related to \$219.5 million used for net purchases of marketable securities available for sale during the three-month period ended March 31, 2013 compared to net sales of \$379.7 million in the three-month period ended March 31, 2012. This 2012 source of cash was substantially offset by the cash use of \$352.2 million related to the acquisition of Avila in March 2012.

Table of Contents

Financing Activities: Net cash used in financing activities for the three-month period ended 2013 was \$687.4 million compared to net cash used of \$344.0 million in the three-month period ended 2012. The \$343.4 million increase in net cash used in financing activities in the three-month period ended March 31, 2013 was primarily attributable to \$1.044 billion for repurchases of our common stock, including \$600.0 million paid under the ASR agreement, as compared to \$202.7 million for repurchases in the three-month period ended March 31, 2012. This increase was partially offset by \$53.3 million in net proceeds from short-term borrowings in 2013 as compared to \$375.4 million of net repayments on short-term borrowings in the three-month period ended March 31, 2012.

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 of the 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 significant accounting policies are more fully described in Note 1 of the Notes to the Consolidated Financial Statements included in our 2012 Annual Report on Form 10-K. 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 significant accounting policies and critical accounting estimates since December 31, 2012.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

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

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At March 31, 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 March 31, 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

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

securities, global corporate debt securities, asset backed securities and a marketable equity security. 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

Table of Contents

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.

As of March 31, 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	\$ 275.2	\$ 1,430.9	\$ 250.5	\$ 23.0	\$ 1,979.6
Fair value	\$ 277.6	\$ 1,458.6	\$ 264.9	\$ 23.6	\$ 2,024.7
Weighted average interest rate	0.3%	0.6%	1.5%	1.4%	0.7%

Long-Term Debt: In August 2012 and October 2010, we issued an aggregate \$2.750 billion principal amount of senior notes at varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of are summarized below as of March 31, 2013 (in millions):

	Principal Amount	Carrying Value
2.450% senior notes due 2015	\$ 500.0	\$ 518.4
1.900% senior notes due 2017	500.0	501.1
3.950% senior notes due 2020	500.0	501.5
3.250% senior notes due 2022	1,000.0	993.6
5.700% senior notes due 2040	250.0	249.5
Total long-term debt	\$ 2,750.0	\$ 2,764.1

At March 31, 2013, the fair value of our senior notes outstanding was \$2.868 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 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 options, foreign currency forward contracts, treasury

rate lock agreements and interest rate swap contracts.

Foreign Currency Risk Management

We have established revenue hedging and balance sheet risk management programs to mitigate volatility in future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

Table of Contents

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

Foreign Currency Forward Contracts: We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies and to reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We enter into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at March 31, 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 March 31, 2013 and December 31, 2012 (in millions):

Foreign Currency	Notional Amount	
	March 31, 2013	December 31, 2012
Australian Dollar	\$ 6.2	\$ 5.1
British Pound	87.7	77.9
Canadian Dollar	105.2	134.4
Euro	1,322.4	969.3
Japanese Yen	393.5	236.2
Total	\$ 1,915.0	\$ 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 March 31, 2013, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also enter into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at March 31, 2013 and December 31, 2012 were \$971.2 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 March 31, 2013 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$291.4 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the

underlying asset or liability

Table of Contents

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.

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at March 31, 2013 and December 31, 2012 (in millions):

Foreign Currency Option	Notional Amount*	
	March 31, 2013	December 31, 2012
Designated as hedging activity:		
Purchased Put	\$ 139.0	\$ 228.8
Written Call	\$ 144.6	\$ 235.9
Not designated as hedging activity:		
Purchased Put	\$ 131.0	\$ 160.5
Written Put	\$ (131.0)	\$ (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 March 31, 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 \$12.9 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. Assuming that the March 31, 2013 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts that are not designated as hedges would change by approximately \$1.6 million. This impact would be recorded to income during the period during which the change in currency rates occurred.

Interest Rate Risk Management

Treasury Rate Lock Agreements: In anticipation of issuing fixed-rate debt, we may use treasury rate lock agreements (treasury rate locks) that we designate as cash-flow hedges. To the extent treasury rate locks are

Table of Contents

effective cash-flow hedges, any realized or unrealized gains or losses on the treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

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 three-month periods ended March 31, 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 three months ended March 31, 2013 and at March 31, 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 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 three-month period ended March 31, 2013, we entered into \$400.0 million notional amount of swap contracts that were designated as hedges of our 3.95% fixed rate notes due in 2020 and also during the three-month period ended March 31, 2013 terminated the hedging relationship by settling the contracts. This resulted in net proceeds received of \$2.8 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 March 31, 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 March 31, 2013 (in millions):

	Notional Amount	
	March 31, 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 in 2015	\$ 400.0	\$ -
1.900% senior notes due in 2017 (1)	500.0	100.0
3.250% senior notes due in 2022 (2)	1,000.0	200.0
Total	\$ 1,900.0	\$ 300.0

(1) \$400.0 million was settled in April 2013 resulting in net proceeds received of \$1.7 million, which is accounted for as a reduction of past and future interest expense associated with these notes.

(2) \$400.0 million was settled in April 2013 resulting in net proceeds received of \$4.5 million, which is accounted for as a reduction of past and future interest expense associated with these notes.

Table of Contents

A sensitivity analysis to measure potential changes in the market value of our debt and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at March 31, 2013 would have reduced the aggregate fair value of our net payable by \$68.3 million. A one percentage point decrease at March 31, 2013 would have increased the aggregate fair value of our net payable by \$78.6 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 March 31, 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.

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:

Table of Contents

- 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® 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®. 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 are continuing 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 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

Table of Contents

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® is 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® and REVLIMID® and 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;

Table of Contents

- 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;
- 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 may not market that product for broader or different applications, and the FDA may 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:

Table of Contents

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

Table of Contents

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 foreign 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 stem cell technologies and cannot be certain as to any impact to our potential products, or guarantee that 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).

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

Table of Contents

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. The new patent 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 in the new law 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. For example, while some provisions of the new patent law have already taken effect, others will take effect up to 18 months from enactment. The U.S. PTO is still in the process of publishing regulations concerning the implementation of the law. Several provisions of the new law will likely be tested in courts over time.

The changes in the new 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 new patent law was 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 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.

Table of Contents

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 applicability of 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, i.e., those not covered by any outstanding exclusivities.

Table of Contents

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 three Paragraph IV Certification Letters dated August 30, 2010, June 12, 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.

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:

- Takeda and Johnson & Johnson, which compete with REVLIMID® and THALOMID® in the treatment of multiple myeloma and in clinical trials with our compounds;
- Eisai, SuperGen and Johnson & Johnson, which compete or may potentially compete with VIDAZA®, in addition Eisai potentially competes with ABRAXANE®, and in other oncology products in general;
- Amgen, which potentially competes with our TNF- and kinase inhibitors;
- AstraZeneca, which potentially competes in clinical trials with our compounds and TNF- inhibitors;
- Biogen Idec is generally developing drugs that address the oncology and immunology markets;
- Bristol Myers Squibb, which potentially competes with ABRAXANE®, and in clinical trials with our compounds and TNF-inhibitors, in addition to other oncology products in general;
- F. Hoffman-La Roche, which potentially competes in clinical trials with our ®TNF- inhibitors, in addition to other oncology products in general;

- Johnson & Johnson, Pfizer, and Abbott Laboratories also compete with our oral anti-inflammatory programs;
- Novartis, which potentially competes with our compounds and kinase programs;
- Pfizer, which potentially competes in clinical trials with our kinase inhibitors; and
- Sanofi, which competes with ABRAXANE®, in addition to other oncology products in general.

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

Table of Contents

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 could 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 Discussion and Analysis 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.

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

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 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.

Table of Contents

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 insured 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 impact 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.

Table of Contents

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.

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 to meet our needs. 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, 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 exist to 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.

Table of Contents

We have contracted with distributors, to distribute REVLIMID®, THALOMID®, VIDAZA®, ABRAXANE® 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.

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;

Table of Contents

- 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 could 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.

We could be subject to significant liability as a result of risks associated with using hazardous materials in our business.

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, 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

Table of Contents

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, but not to engage in currency speculation. We use these derivative instruments to hedge certain forecasted transactions and balance sheet exposures denominated in foreign currencies. The use of these derivative instruments is intended to mitigate the exposure of these risks with the intent to reduce our risk or cost, but may 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;
- new accounting pronouncements or regulatory rulings;

Table of Contents

- 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;
- 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 could 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.

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

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.

Table of Contents

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 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;

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

- 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

Table of Contents

- 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

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.500 billion of our common stock. Approved amounts exclude share repurchase transaction fees.

As part of the existing Board authorized share repurchase program, in February 2013 we entered into an ASR agreement with an investment bank to repurchase an aggregate of \$600.0 million of our common stock.

The following table presents the total number of shares purchased during the three-month period ended March 31, 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 publicly announced repurchase program:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Approximate Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs (1)
January 1 - January 31	2,980,000	\$ 93.98	2,980,000	\$ 1,556,832,514
February 1 - February 28	4,036,263	\$ 98.83	4,036,263	\$ 853,060,964
March 1 - March 31	166,614	\$ 113.00	166,614	\$ 834,233,515
Total	7,182,877	\$ 95.97	7,182,877	

(1) As part of the ASR agreement we received an initial delivery of 2,986,263 shares with a fair market value of \$300.0 million. The initial delivery of 2,986,263 shares reduced our outstanding shares used to determine our weighted average shares outstanding for purposes of calculating basic and diluted earnings per share. The total number of shares that will ultimately be repurchased under the ASR agreement will be determined upon final settlement in May 2013 and will be based on a discount to the volume-weighted average price of our common stock during the ASR period.

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

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

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.

- 10.1 Letter agreement with Mark J. Alles
- 10.2 Letter agreement with Thomas O. Daniel, M.D.
- 10.3 Letter agreement with Perry A. Karsen
- 31.1 Certification by the Company's Chief Executive Officer.
- 31.2 Certification by the Company's Chief Financial Officer.
- 32.1 Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
- 32.2 Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
- 101 The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 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: April 30, 2013

By: /s/Jacquelyn A. Fouse
Jacquelyn A. Fouse, Ph.D.
Executive Vice President

Chief Financial Officer
(principal financial and accounting officer)