

CELGENE CORP /DE/  
Form 10-Q  
October 29, 2012

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2012**

**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)

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

(908) 673-9000

(Registrant's telephone number, including area code)

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

Yes    X        No

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

Yes    X        No

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

Large accelerated filer                              X            Accelerated filer

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes                              No        X

At October 19, 2012, 422,987,284 shares of Common Stock, par value \$.01 per share, were outstanding.

CELGENE CORPORATION

FORM 10-Q TABLE OF CONTENTS

	<u>Page No.</u>	
<b><u>PART I</u></b>	<b><u>FINANCIAL INFORMATION</u></b>	
<u>Item 1</u>	<u>Financial Statements</u>	
	<u>Consolidated Statements of Income -</u> <u>Three-Month and Nine-Month Periods Ended September 30, 2012 and 2011</u>	2
	<u>Consolidated Statements of Comprehensive Income -</u> <u>Three-Month and Nine-Month Periods Ended September 30, 2012 and 2011</u>	3
	<u>Consolidated Balance Sheets -</u> <u>As of September 30, 2012 and December 31, 2011</u>	4
	<u>Consolidated Statements of Cash Flows -</u> <u>Nine-Month Periods Ended September 30, 2012 and 2011</u>	5
	<u>Notes to Unaudited Consolidated Financial Statements</u>	7
<u>Item 2</u>	<u>Management's Discussion and Analysis of Financial</u> <u>Condition and Results of Operations</u>	30
<u>Item 3</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	52
<u>Item 4</u>	<u>Controls and Procedures</u>	56
<b><u>PART II</u></b>	<b><u>OTHER INFORMATION</u></b>	
<u>Item 1</u>	<u>Legal Proceedings</u>	57
<u>Item 1A</u>	<u>Risk Factors</u>	57
<u>Item 2</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	73
<u>Item 6</u>	<u>Exhibits</u>	74
<u>Signature</u>		75

**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****CELGENE CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME**

(Unaudited)

(In thousands, except per share amounts)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Revenue:				
Net product sales	\$ 1,388,013	\$ 1,219,118	\$ 3,970,102	\$ 3,457,055
Collaborative agreements and other revenue	2,362	3,766	8,223	16,468
Royalty revenue	28,876	26,853	80,978	84,650
Total revenue	1,419,251	1,249,737	4,059,303	3,558,173
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	74,622	94,645	218,994	348,356
Research and development	441,595	356,839	1,250,737	1,163,837
Selling, general and administrative	354,644	303,303	1,003,449	911,207
Amortization of acquired intangible assets	46,157	75,044	132,065	214,181
Acquisition related (gains) charges and restructuring, net	649	(11,209)	28,864	(117,430)
Total costs and expenses	917,667	818,622	2,634,109	2,520,151
Operating income	501,584	431,115	1,425,194	1,038,022
Other income and expense:				
Interest and investment income, net	2,745	8,481	9,561	18,948
Interest (expense)	(17,793)	(10,292)	(40,652)	(31,460)
Other income (expense), net	(10,034)	(16,663)	(2,915)	(7,650)
Income before income taxes	476,502	412,641	1,391,188	1,017,860
Income tax provision	52,347	39,657	198,123	110,582
Net income	424,155	372,984	1,193,065	907,278
Net loss attributable to non-controlling interest	-	-	-	694
Net income attributable to Celgene	\$ 424,155	\$ 372,984	\$ 1,193,065	\$ 907,972
Net income per share attributable to Celgene:				
Basic	\$ 0.99	\$ 0.83	\$ 2.75	\$ 1.97
Diluted	\$ 0.97	\$ 0.81	\$ 2.69	\$ 1.94
Weighted average shares:				
Basic	427,209	452,019	434,062	460,161
Diluted	436,272	459,530	443,432	467,052

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

See accompanying Notes to Unaudited Consolidated Financial Statements

## CELGENE CORPORATION AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(In thousands)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Net income	\$ 424,155	\$ 372,984	\$ 1,193,065	\$ 907,278
Other comprehensive income (loss):				
Foreign currency translation adjustments	4,664	(12,713)	6,746	6,108
Change in functional currency of a foreign subsidiary	-	-	13,144	-
Net unrealized gains (losses) related to cash flow hedges:				
Unrealized holding gains (losses), net of tax expense (benefit) of (\$1,263) and \$84 for the three-months ended September 30, 2012 and 2011, respectively, and (\$13,144) and \$79 for the nine-months ended September 30, 2012 and 2011, respectively	(26,728)	47,902	21,148	(9,269)
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$552 and (\$514) for the three-months ended September 30, 2012 and 2011, respectively, and (\$2,470) and (\$1,631) for the nine-months ended September 30, 2012 and 2011, respectively	(24,880)	5,316	(59,893)	9,464
Net unrealized gains (losses) on marketable securities available for sale:				
Unrealized holding gains (losses), net of tax expense (benefit) of \$22 and (\$92) for the three-months ended September 30, 2012 and 2011, respectively, and (\$72) and \$1,418 for the nine-months ended September 30, 2012 and 2011, respectively	1,647	(301)	3,281	3,637
Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$5 and \$4 for the three-months ended September 30, 2012 and 2011, respectively, and \$50 and \$260 for the nine-months ended September 30, 2012 and 2011, respectively	412	(3,076)	108	(2,043)
Total other comprehensive income (loss)	(44,885)	37,128	(15,466)	7,897
Comprehensive income	379,270	410,112	1,177,599	915,175
Comprehensive loss attributable to non-controlling interest	-	-	-	694
Comprehensive income attributable to Celgene	\$ 379,270	\$ 410,112	\$ 1,177,599	\$ 915,869

See accompanying Notes to Unaudited Consolidated Financial Statements

## CELGENE CORPORATION AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(Unaudited)

(Dollars in thousands, except per share amounts)

	September 30, 2012	December 31, 2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,715,534	\$ 1,859,464
Marketable securities available for sale	1,117,402	788,690
Accounts receivable, net of allowances of \$36,485 and \$18,855 at September 30, 2012 and December 31, 2011, respectively	957,453	945,531
Inventory	235,866	189,573
Deferred income taxes	134,920	116,751
Other current assets	224,494	395,094
Assets held for sale	-	58,122
Total current assets	5,385,669	4,353,225
Property, plant and equipment, net	547,396	506,042
Intangible assets, net	3,188,303	2,844,698
Goodwill	2,042,837	1,887,220
Other assets	444,622	414,725
Total assets	\$ 11,608,827	\$ 10,005,910
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Short-term borrowings	\$ 324,895	\$ 526,684
Accounts payable	110,394	121,525
Accrued expenses	744,065	701,707
Income taxes payable	2,006	30,042
Current portion of deferred revenue	12,100	14,346
Other current liabilities	157,849	138,424
Liabilities of disposal group	-	7,244
Total current liabilities	1,351,309	1,539,972
Deferred revenue, net of current portion	15,388	12,623
Income taxes payable	178,369	616,465
Deferred income taxes	1,083,197	775,022
Other non-current liabilities	482,541	273,516
Long-term debt, net of discount	2,769,313	1,275,585
Total liabilities	5,880,117	4,493,183
<b>Commitments and Contingencies (Note 15)</b>		
<b>Stockholders Equity:</b>		
Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none outstanding at September 30, 2012 and December 31, 2011	-	-
Common stock, \$.01 par value per share, 575,000,000 shares authorized; issued 495,171,932 and 487,381,255 shares at September 30, 2012 and December 31, 2011, respectively	4,952	4,874
Common stock in treasury, at cost; 71,201,387 and 49,889,078 shares at September 30, 2012 and December 31, 2011, respectively	(4,241,425)	(2,760,705)
Additional paid-in capital	7,283,505	6,764,479
Retained earnings	2,759,481	1,566,416
Accumulated other comprehensive income (loss)	(77,803)	(62,337)
Total stockholders equity	5,728,710	5,512,727

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

Total liabilities and stockholders' equity	\$	11,608,827	\$	10,005,910
--	----	------------	----	------------

See accompanying Notes to Unaudited Consolidated Financial Statements



## CELGENE CORPORATION AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in thousands)

	Nine-Month Periods Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income	\$ 1,193,065	\$ 907,278
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	59,853	53,051
Amortization	133,022	215,961
Allocation of prepaid royalties	1,370	16,214
Provision for accounts receivable allowances	14,626	3,375
Deferred income taxes	143,565	(101,510)
Impairment charges	64,866	118,000
Change in value of contingent consideration	26,287	(122,547)
Share-based compensation expense	171,041	162,958
Share-based employee benefit plan expense	15,125	14,567
Reclassification adjustment for cash flow hedges included in net income	(62,363)	7,833
Unrealized change in value of derivative instruments	47,903	(37,837)
Realized (gains) losses on marketable securities available for sale	158	(1,616)
Other, net	(93)	(994)
Change in current assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(34,558)	(188,503)
Inventory	(46,298)	73,776
Other operating assets	182,806	48,113
Assets held for sale, net	(1,176)	2,647
Accounts payable and other operating liabilities	88,359	90,344
Income tax payable	(469,129)	80,119
Deferred revenue	(267)	(2,756)
Net cash provided by operating activities	1,528,162	1,338,473
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	1,188,657	1,814,974
Purchases of marketable securities available for sale	(1,517,460)	(1,327,244)
Payments for acquisition of business, net of cash acquired	(352,245)	(180,000)
Proceeds from the sale of assets, net	15,782	93,185
Capital expenditures	(81,883)	(90,559)
(Purchases) refunds of investment securities	(29,988)	6,597
Other investing activities	(1,010)	(4,949)
Net cash provided by (used in) investing activities	(778,147)	312,004
Cash flows from financing activities:		
Payment for treasury shares	(1,470,365)	(1,574,415)
Proceeds from short-term borrowing	3,874,416	404,843
Principal repayments on short-term borrowing	(4,075,374)	(135,750)
Proceeds from the issuance of long-term debt	1,486,682	-
Net proceeds from exercise of common stock options and warrants	321,064	92,258
Excess tax benefit from share-based compensation arrangements	19,867	15,734
Net cash provided by (used in) financing activities	156,290	(1,197,330)
Effect of currency rate changes on cash and cash equivalents	(50,235)	(9,348)
Net increase in cash and cash equivalents	856,070	443,799
Cash and cash equivalents at beginning of period	1,859,464	1,351,128

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

Cash and cash equivalents at end of period	\$	2,715,534	\$	1,794,927
--	----	-----------	----	-----------

See accompanying Notes to Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS - (Continued)

(Unaudited)

(Dollars in thousands)

	Nine-Month Periods Ended September 30,	
	2012	2011
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized (gain) loss on marketable securities available for sale	\$ (3,209)	\$ (4,928)
Matured shares tendered in connection with stock option exercises	\$ (156)	\$ (16)
Supplemental disclosure of cash flow information:		
Interest paid	\$ 25,001	\$ 26,179
Income taxes paid	\$ 369,619	\$ 79,159

See accompanying Notes to Unaudited Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**(In all accompanying tables, amounts of dollars expressed in thousands,  
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 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® and ISTODAX®. Additional sources of revenue include a licensing agreement with Novartis, which entitles us to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Cellular Therapeutics subsidiary and other licensing agreements.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Investments in limited partnerships and interests where we have an equity interest of 50% or less and do not otherwise have a controlling financial interest are accounted for by either the equity or cost method. 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.

The preparation of these unaudited 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, 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**

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

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, 2011, or the 2011 Annual Report on Form 10-K.

**New Accounting Pronouncements:** In July 2012, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2012-02, Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment, or ASU 2012-02. ASU 2012-02 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. Under that option, a company would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the company determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. ASU 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for periods beginning after September 15, 2012. Early adoption is permitted and we intend to adopt this standard in the fourth quarter of 2012. The adoption of ASU 2012-02 is not expected to have a material impact on our financial position or results of operations.

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. Acquisitions and Divestitures**

**Avila Acquisition**

On March 7, 2012, or the 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. Avila's results of operations prior to the Acquisition Date were determined to be immaterial to us; therefore, *pro forma* financial statements are not required to be presented.

We paid \$352.2 million in cash, net of cash acquired, and may make additional payments of up to an estimated maximum of \$595.0 million in contingent developmental and regulatory milestone payments.

Avila is a clinical-stage biotechnology company focused on the design and development of targeted covalent drugs to achieve best-in class outcomes. Avila's product pipeline has been created using its proprietary Avilomics platform for developing targeted covalent drugs that treat diseases through protein silencing. Avila's most advanced product candidate, CC-292, formerly AVL-292, a potential treatment for cancer and autoimmune diseases, is currently in phase I clinical testing. We acquired Avila to enhance our portfolio of potential therapies for patients with life-threatening illnesses worldwide.

Our potential contingent consideration 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 developmental and regulatory achievements, including milestones for the initiation of phase II and phase III studies, investigational new drug, or IND, filings, and other regulatory events.

We estimated the fair value of potential contingent consideration using a probability-weighted income approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant input not observable in the market and thus represents a Level 3 liability within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a discount rate based on a market participant assumption.

Subsequent to the acquisition date, we measure the contingent consideration arrangements at fair value each period with changes in fair value recognized in operating earnings unless changes pertain to facts and circumstances that existed as of the Acquisition Date, in which case changes are recognized as adjustments to goodwill. Changes in fair value reflect new information about the in-process research and development, or IPR&D, assets and the passage of time. In the absence of new information, changes in fair value only reflect the passage of time as development

work towards the achievement of the milestones progresses and are accrued based on an accretion schedule.

Fair value amounts allocated to contingent consideration and certain assets have been adjusted during the three-month period ended September 30, 2012 based on analysis of facts and circumstances that existed as of the Acquisition Date. These measurement period adjustments were not significant and did not have a significant impact on our financial condition, results of operations or cash flows in any interim period in 2012 and, therefore, we did not retrospectively adjust our interim financial statements for prior periods.

The acquisition has been accounted for using the acquisition method of accounting which requires that most assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date and

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

requires the fair value of acquired IPR&D to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

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

	Fair Value at the Acquisition Date
Cash	\$ 363,405
Contingent consideration	171,654
Total fair value of consideration transferred	\$ 535,059

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

	Amounts Recognized as of Acquisition Date
Working capital (1)	\$ 11,987
Property, plant and equipment	2,559
Platform technology intangible asset (2)	330,800
In-process research and development product rights	198,400
Net deferred tax liability (3)	(164,993)
Total identifiable net assets	378,753
Goodwill	156,306
Net assets acquired	\$ 535,059

(1) Includes cash and cash equivalents, accounts receivable, other current assets, accounts payable and other current liabilities.

(2) Platform technology related to the Avilomics discovery platform which is being amortized over a useful life of seven years based on the estimated useful life of the platform.

(3) Includes current deferred income tax asset of \$14.7 million and non-current deferred tax liability of \$179.7 million.

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



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

The fair value of the platform technology intangible asset was based primarily on expected cash flows from future product candidates to be developed from the Avilomics platform and the fair value assigned to acquired IPR&D was primarily based on expected cash flows from the CC-292 product candidate which is in phase I testing. The values assigned to the platform technology intangible asset and the IPR&D asset were determined by estimating the costs to develop CC-292 and future product candidates into commercially viable products, estimating the resulting revenue from the potential products, and discounting the net cash flows to present value. The revenue and cost projections used were reduced based on the probability of developing new drugs. Additionally, the projections considered the relevant market sizes, growth factors and the nature and expected timing of new product introductions. The resulting net cash flows from such potential products are based on our estimates of cost of sales, operating expenses, and income taxes. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections described above. Acquired IPR&D will be accounted for as an indefinite-lived intangible asset until regulatory approval in specified markets or discontinuation of CC-292.

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is largely attributable to full ownership rights to the Avilomics platform. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

Prior to the acquisition, Avila had a number of collaboration agreements in place which we are now party to. These agreements entitle us to receive potential milestone payments and reimbursement of expenses for research and development expenses incurred under the collaborations and our collaboration partners may receive intellectual property rights or options to purchase such rights related to products developed under the collaborations. We do not consider these collaboration arrangements to be significant.

**Sale of Facilities**

Two manufacturing and research facilities located in Melrose Park, Illinois, and the equipment associated with operations at those facilities, were sold in June 2012 to APP Pharmaceuticals, Inc. (now known as Fresenius Kabi USA, LLC), or APP, a subsidiary of Fresenius Kabi AG. APP manufactures ABRAXANE® at one of the facilities. In exchange for the facilities, we received rights to free and reduced cost manufacturing of specified quantities of ABRAXANE®, which we recorded as current or non-current assets based on anticipated timing of delivery, a five-year rent-free lease of a portion of one of the facilities, and a net cash payment of \$1.8 million. The transaction did not result in any gain or loss.

**4. Earnings Per Share**

<i>(Amounts in thousands, except per share)</i>	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Net income attributable to Celgene	\$ 424,155	\$ 372,984	\$ 1,193,065	\$ 907,972
Weighted-average shares:				
Basic	427,209	452,019	434,062	460,161
Effect of dilutive securities:				
Options, restricted stock units, warrants and other incentives	9,063	7,511	9,370	6,891
Diluted	436,272	459,530	443,432	467,052
Net income per share:				
Basic	\$ 0.99	\$ 0.83	\$ 2.75	\$ 1.97
Diluted	\$ 0.97	\$ 0.81	\$ 2.69	\$ 1.94

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

The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 11,588,987 and 21,682,141 shares for the three-month periods ended September 30, 2012 and 2011, respectively. The total number of potential common shares excluded for the nine-month periods ended September 30, 2012 and 2011 was 11,462,879 and 26,846,063, respectively.

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.5 billion of our common stock, including \$2.5 billion approved by our Board of Directors during their June 2012 meeting. As of September 30, 2012, an aggregate of 67,008,026 shares of common stock were repurchased under the program, including 10,766,077 shares of common stock repurchased during the three-month period

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ended September 30, 2012. As of September 30, 2012, we had a remaining open-ended repurchase authorization of \$2.417 billion.

### 5. Accumulated Other Comprehensive Income (Loss)

The components of other comprehensive income (loss) consist of changes in pension liability, changes in net unrealized gains (losses) on marketable securities classified as available-for-sale, net unrealized gains (losses) related to cash flow hedges and changes in foreign currency translation adjustments, which includes changes in a subsidiary's functional currency 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, 2011	\$ (5,382)	\$ 4,707	\$ 5,713	\$ (67,375)	\$ (62,337)
Other comprehensive income (loss)	-	3,389	(38,745)	19,890	(15,466)
Balance September 30, 2012	\$ (5,382)	\$ 8,096	\$ (33,032)	\$ (47,485)	\$ (77,803)
Balance December 31, 2010	\$ (3,836)	\$ 3,102	\$ (15,556)	\$ (57,477)	\$ (73,767)
Other comprehensive income (loss)	-	3,145	(1,356)	6,108	7,897
Balance September 30, 2011	\$ (3,836)	\$ 6,247	\$ (16,912)	\$ (51,369)	\$ (65,870)

### 6. Financial Instruments and Fair Value Measurement

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2012 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, 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, or CVRs. Our Level 2 liability relates to written foreign currency options. The Level 3 liability consists of contingent consideration related to undeveloped product rights resulting from the acquisition of Gloucester Pharmaceuticals, Inc., or Gloucester, and contingent consideration related to the undeveloped product rights and the technology platform acquired from the Avila acquisition. The estimated maximum potential payments related to the contingent consideration from the acquisitions of Gloucester and Avila are \$120.0 million and \$595.0 million, respectively.



## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Balance at September 30, 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	\$ 1,117,402	\$ 485	\$ 1,116,917	\$ -
Cash equivalents	83,098	-	83,098	-
Interest rate swaps	639	-	639	-
Forward currency contracts	8,626	-	8,626	-
Purchased currency options	6,274	-	6,274	-
Total assets	\$ 1,216,039	\$ 485	\$ 1,215,554	\$ -
Liabilities:				
Contingent value rights	\$ (122,465)	\$ (122,465)	\$ -	\$ -
Written currency options	(6,388)	-	(6,388)	-
Other acquisition related contingent consideration	(212,950)	-	-	(212,950)
Total liabilities	\$ (341,803)	\$ (122,465)	\$ (6,388)	\$ (212,950)

	Balance at December 31, 2011	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	\$ 788,690	\$ 560	\$ 788,130	\$ -
Forward currency contracts	48,561	-	48,561	-
Total assets	\$ 837,251	\$ 560	\$ 836,691	\$ -
Liabilities:				
Contingent value rights	\$ (60,583)	\$ (60,583)	\$ -	\$ -
Other acquisition related contingent consideration	(76,890)	-	-	(76,890)
Total liabilities	\$ (137,473)	\$ (60,583)	\$ -	\$ (76,890)

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

	Nine-Month Periods Ended September 30,	
	2012	2011
Assets:		
Balance at beginning of period	\$ -	\$ 23,372
Amounts acquired or issued	-	-
Net realized and unrealized gains	-	1,182
Settlements	-	(22,477)
Transfers in and/or out of Level 3	-	-
Balance at end of period	\$ -	\$ 2,077



## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Settlements of \$22.5 million during the nine-month period ended September 30, 2011 consisted of Level 3 instruments that were considered non-core assets acquired in the acquisition of Abraxis BioScience, Inc., or Abraxis, and were included in the sale of the non-core assets in April 2011.

	Nine-Month Periods Ended September 30,	
	2012	2011
Liabilities:		
Balance at beginning of period	\$ (76,890)	\$ (252,895)
Amounts acquired or issued	(171,654)	-
Net change in fair value	35,594	(14,198)
Settlements	-	-
Transfers in and/or out of Level 3	-	180,000
Balance at end of period	\$ (212,950)	\$ (87,093)

Level 3 liabilities issued during the nine-month period ended September 30, 2012 consist of contingent consideration related to the acquisition of Avila. Transfers out of Level 3 during the nine-month period ended September 30, 2011 consisted of a \$180.0 million milestone that was part of the contingent consideration in the Gloucester acquisition. This milestone was valued based on the contractually defined amount of the milestone and paid in July 2011.

## 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.



*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 September 30, 2012 and December 31, 2011 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), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

affect operations. Any ineffectiveness on these foreign currency forward contracts is reported in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2012 and December 31, 2011:

Foreign Currency	Notional Amount	
	September 30, 2012	December 31, 2011
Australian Dollar	\$ 11,483	\$ 17,169
British Pound	94,407	53,764
Canadian Dollar	163,078	67,281
Euro	389,452	714,446
Japanese Yen	504,668	606,538
Swiss Franc	337	49,182
Total	\$ 1,163,425	\$ 1,508,380

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2012, 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 September 30, 2012 and December 31, 2011 were \$947.9 million and \$916.9 million, respectively.

*Foreign Currency Option Contracts:* During the three-month period ended September 30, 2012, we hedged 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. At the same time, in order to offset the upfront cost of this collar, a local currency put option is sold with a lower strike price and the same expiration dates and amounts as the option contracts that are used to hedge sales. The written put is not designated as a hedging instrument and gains and losses associated with the written put option are recorded on the income statement as other income (expense), net. If the U.S. dollar strengthens relative to the currency of the hedged foreign currency sales to levels that reduce the exchange rate of the foreign currency below the strike price of this written put option, the put option would increase in value, resulting in losses to us equal to the difference between the strike price and the actual exchange rate multiplied by the notional amount of the hedged foreign currency sales.



## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2012 and December 31, 2011:

Foreign Currency Option	Notional Amount*	
	September 30, 2012	December 31, 2011
Designated as hedging activity:		
Purchased Put	\$ 228,779	\$ -
Written Call	\$ 235,920	\$ -
Not designated as hedging activity:		
Written Put	\$ 215,952	\$ -

\* 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, written call, and written put options are equal to each other.

**Interest Rate Risk Management**

*Treasury Rate Lock Agreements:* During the nine-month period ended September 30, 2012, we entered into treasury rate lock agreements, or treasury rate locks, in anticipation of issuing fixed-rate notes that were issued in August 2012. With the exception of a short period in June when certain outstanding treasury rate locks were not designated as hedges, our treasury rate locks were designated as cash flow hedges and, to the extent effective, any realized or unrealized gains or losses on them were reported in OCI and will be recognized in income over the life of the anticipated fixed-rate notes. Treasury rate locks were settled during the nine-month period ended September 30, 2012 which resulted in losses of \$35.3 million that were recorded to OCI. During the short period in June when we had outstanding treasury rate locks that were not considered hedging instruments, we recorded the change in fair value of \$3.7 million in other income (expense), net. No material amounts were recorded in income during the nine-month periods ended September 30, 2012 or 2011 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. At September 30, 2012 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 is recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense.

At September 30, 2012, we were party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts matched the amount of the hedged fixed-rate notes. Our swap contracts outstanding at September 30, 2012 will mature in 2022, with an aggregate notional amount of \$200.0 million, which effectively converts a portion of our \$1.0 billion, 3.25% fixed-rate notes due in 2022 to a floating rate. In August 2011, we settled outstanding interest rate swap contracts we entered into with respect to our \$500.0 million, 2.45% fixed-rate notes due in 2015 resulting in the receipt of \$34.3 million. The proceeds from the settlements are being accounted for as a reduction of current and future interest expense associated with these notes.



## 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 September 30, 2012 and December 31, 2011:

Instrument	Asset Derivatives		September 30, 2012		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<i>Derivatives designated as hedging instruments:</i>						
Foreign exchange contracts*	Other current assets	\$ 25,278	Other current assets	\$ 14,199		
	Other current liabilities	16,689	Other current liabilities	24,628		
	Other non-current assets	5,375	Other non-current assets	3,249		
	Other non-current liabilities	3,859	Other non-current liabilities	6,221		
Interest rate swap agreements	Other current assets	151	Other current assets	-		
	Other non-current assets	489	Other non-current assets	-		
<i>Derivatives not designated as hedging instruments:</i>						
Foreign exchange contracts*	Other current assets	52,015	Other current assets	39,713		
	Other current liabilities	796	Other current liabilities	8,166		
	Other non-current assets	10,857	Other non-current assets	9,790		
	Other non-current liabilities	-	Other non-current assets	392		
Total	\$ 115,509		\$ 106,358			

Instrument	Asset Derivatives		December 31, 2011		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<i>Derivatives designated as hedging instruments:</i>						
Foreign exchange contracts*	Other current assets	\$ 68,889	Other current assets	\$ 32,430		
	Other current liabilities	129	Other current liabilities	3,940		
	Other non-current liabilities	-	Other non-current liabilities	24,832		
<i>Derivatives not designated as hedging instruments:</i>						
Foreign exchange contracts*	Other current assets	66,639	Other current assets	10,395		
	Other current liabilities	2,462	Other current liabilities	22,289		

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

	Other non-current assets	36,684	Other non-current assets	32,356
Total		\$ 174,803		\$ 126,242

\* 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.

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following tables summarize the effect of derivative instruments designated as cash flow hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2012 and 2011, respectively:

Instrument	Three-Month-Period Ended September 30, 2012				
	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	\$ (24,500)	Net product sales	\$ 24,784	Other income, net	\$ (1,681)(2)
Treasury rate lock agreements	\$ (3,492)	Interest expense	\$ (457)		

(1) Net gains of \$1,983 are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) The amount of net losses recognized in income represents \$2,230 in losses related to the ineffective portion of the hedging relationships and \$549 of gains related to amounts excluded from the assessment of hedge effectiveness.

Instrument	Three-Month-Period Ended September 30, 2011				
	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)</i>	<i>(Ineffective Portion and Amount Excluded)</i>



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

					<i>From Effectiveness Testing)</i>		<i>From Effectiveness Testing)</i>
Foreign exchange contracts	\$	47,987	Net product sales	\$	(4,802)	Other income, net	\$ (6,256)(1)

(1) The amount of net losses recognized in income represents \$2,125 in gains related to the ineffective portion of the hedging relationships and \$8,381 of losses related to amounts excluded from the assessment of hedge effectiveness.

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Nine-Month Period Ended September 30, 2012					
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative (1) <i>(Effective Portion)</i>	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i>	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i>	Location of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>	Amount of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>
Foreign exchange contracts	\$ 43,258	Net product sales	\$ 62,820	Other income, net	\$ (3,422)(2)
Treasury rate lock agreements	\$ (35,255)	Interest Expense	\$ (457)		

(1) Net gains of \$1,983 are expected to be reclassified from Accumulated OCI into income in the next 12 months.

(2) The amount of net losses recognized in income represents \$7,472 in losses related to the ineffective portion of the hedging relationships and \$4,050 of gains related to amounts excluded from the assessment of hedge effectiveness.

Nine-Month Period Ended September 30, 2011					
Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative <i>(Effective Portion)</i>	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i>	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i>	Location of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>	Amount of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>
Foreign exchange contracts	\$ (9,190)	Net product sales	\$ (7,833)	Other income, net	\$ (6,021)(1)

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

(1) The amount of net losses recognized in income represents \$566 in losses related to the ineffective portion of the hedging relationships and \$5,455 of losses related to amounts excluded from the assessment of hedge effectiveness.

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2012 and 2011:

Instrument	Location of Gain (Loss) Recognized in Income on Derivative	Amount of Gain (Loss) Recognized in Income on Derivative			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2012	2011	2012	2011
Interest rate swaps	Interest Expense	\$ 1,959	\$ 2,620	\$ 5,561	\$ 6,356

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2012 and 2011:

Instrument	Location of Gain (Loss) Recognized in Income on Derivative	Amount of Gain (Loss) Recognized in Income on Derivative			
		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2012	2011	2012	2011
Foreign exchange contracts	Other income, net	\$ (11,457)	\$ (46,586)	\$ 4,470	\$ (11,666)
Treasury rate lock agreements	Other income, net	\$ -	\$ -	\$ 3,718	\$ -

The impact of gains and losses on derivatives 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 \$1.445 billion and \$738.7 million at September 30, 2012 and December 31, 2011, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security at September 30, 2012 and December 31, 2011 were as follows:

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
September 30, 2012				
U.S. Treasury securities	\$ 452,083	\$ 374	\$ (8)	\$ 452,449

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

U.S. government-sponsored agency securities	239,470	247	(19)	239,698
U.S. government-sponsored agency MBS	261,620	1,884	(1,067)	262,437
Non-U.S. government, agency and Supranational securities	5,535	25	-	5,560
Corporate debt - global	155,756	1,025	(8)	156,773
Marketable equity securities	407	78	-	485
Total available-for-sale marketable securities	\$ 1,114,871	\$ 3,633	\$ (1,102)	\$ 1,117,402

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2011	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 228,996	\$ 58	\$ (38)	\$ 229,016
U.S. government-sponsored agency securities	196,833	81	(69)	196,845
U.S. government-sponsored agency MBS	256,440	600	(1,901)	255,139
Non-U.S. government, agency and Supranational securities	2,666	19	-	2,685
Corporate debt - global	104,181	497	(233)	104,445
Marketable equity securities	407	153	-	560
Total available-for-sale marketable securities	\$ 789,523	\$ 1,408	\$ (2,241)	\$ 788,690

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, or 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. Net unrealized gains in the marketable debt securities primarily reflect the impact of decreased interest rates at September 30, 2012.

Duration periods of available-for-sale debt securities at September 30, 2012 were as follows:

	Amortized Cost	Fair Value
Duration of one year or less	\$ 449,266	\$ 450,044
Duration of one through three years	600,905	602,095
Duration of three through five years	64,293	64,778
Total	\$ 1,114,464	\$ 1,116,917

## 9. Inventory

A summary of inventories by major category at September 30, 2012 and December 31, 2011 follows:

September 30,                      December 31,

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

	2012	2011
Raw materials	\$ 67,767	\$ 50,533
Work in process	105,680	115,170
Finished goods	62,419	23,870
Total	\$ 235,866	\$ 189,573

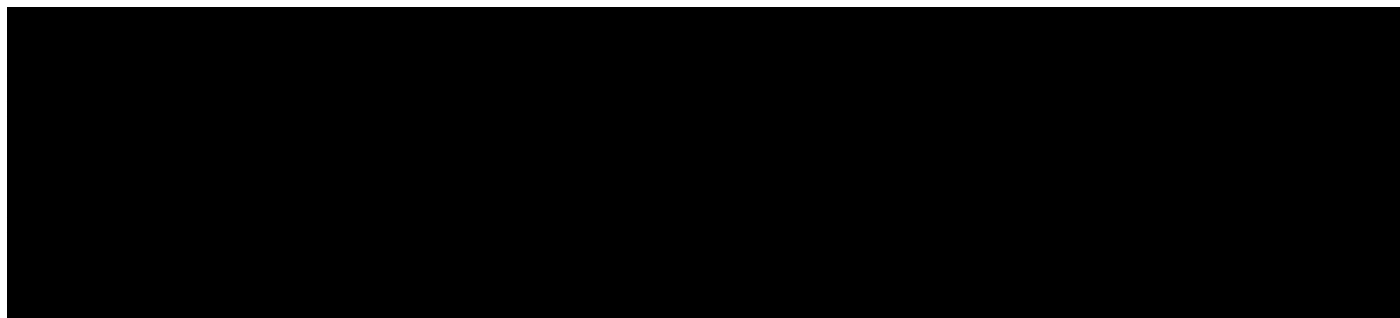
CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

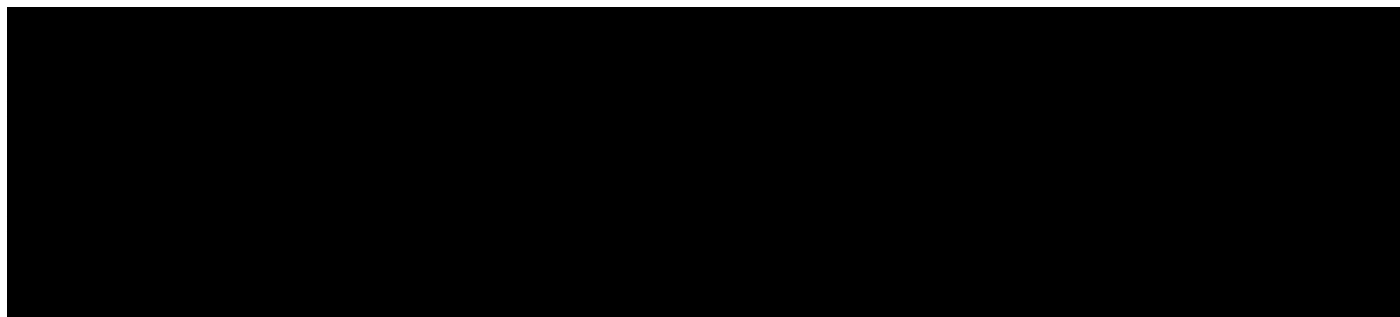
10. Intangible Assets and Goodwill

**Intangible Assets:** Our intangible assets consist of developed product rights from the Pharmion, Gloucester and Abraxis acquisitions, IPR&D product rights from the Gloucester, Abraxis and Avila acquisitions, technology obtained primarily from the Avila acquisition, contract-based licenses and other miscellaneous intangibles. The amortization periods related to non-IPR&D 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)
September 30, 2012				



	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
December 31, 2011				



The increase in gross carrying value of intangible assets at September 30, 2012 compared to December 31, 2011 was primarily due to the acquisition of Avila, which resulted in increases of \$330.8 million in technology and \$198.4 million in IPR&D product rights. The net change in the gross carrying value of acquired IPR&D product rights also included an aggregate \$53.3 million of impairment charges, including \$31.2 million in the three-month period ended September 30, 2012, related to the IPR&D product right for ISTODAX® for peripheral T-cell lymphoma, or PTCL, in Europe. The initial charge reflected a negative opinion issued by the European Medicines Agency's Committee for



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

Medicinal Products for Human Use, or CHMP, for a similar product. The subsequent charge was recorded to reflect the negative opinion issued by CHMP regarding the Marketing Authorization Application submitted for ISTODAX® for the treatment of PTCL. In addition, the contingent consideration liability from the acquisition of Gloucester relating to the approval of ISTODAX® for PTCL in Europe was reduced by \$46.5 million and \$59.9 million during the three- and nine-month periods ended September 30, 2012, respectively, resulting in the recognition of gains of those amounts in the respective periods.

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Amortization expense was \$46.4 million and \$75.3 million for the three-month periods ended September 30, 2012 and 2011, respectively. Amortization expense was \$133.0 million and \$214.9 million for the nine-month periods ended September 30, 2012 and 2011, respectively. Amortization expense was higher during the three- and nine-month periods ended September 30, 2011 than during the corresponding periods in 2012 primarily due to the inclusion of amortization expense related to Vidaza in the U.S., which became fully amortized during the third quarter of 2011. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for years 2012 through 2016 is estimated to be in the range of approximately \$205.0 million to \$303.0 million annually.

**Goodwill:** At September 30, 2012, 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, 2011	\$ 1,887,220
Acquisition of Avila (see Note 3)	156,306
Tax benefit on the exercise of Pharmion converted stock options	(689)
Balance at September 30, 2012	\$ 2,042,837

**11. Debt**

**Senior Notes:** Summarized below are the carrying values of our senior notes at September 30, 2012 and December 31, 2011:

	September 30, 2012	December 31, 2011
2.450% senior notes due 2015	\$ 521,889	\$ 527,191
1.900% senior notes due 2017	498,958	-
3.950% senior notes due 2020	498,937	498,854
3.250% senior notes due 2022	999,984	-
5.700% senior notes due 2040	249,545	249,540
Total long-term debt	\$ 2,769,313	\$ 1,275,585

At September 30, 2012, the fair value of our outstanding Senior Notes was \$2.866 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

In August 2012, we issued an additional \$1.5 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, or the 2017 notes, and \$1.0 billion aggregate principal amount of 3.25% Senior Notes due 2022 (the 2022 notes

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

and, together with the 2017 notes, referred to herein as the 2012 issued notes ). The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

During the nine-month period ended September 30, 2012, we entered into treasury rate lock agreements, or treasury rate locks, in anticipation of issuing the fixed-rate notes that were issued in August 2012. Losses related to these treasury rate locks of \$35.3 million have been recognized in OCI during the nine-month period ended September 30, 2012 and will be recognized as interest expense over the life of the 2017 notes and the 2022 notes.

At September 30, 2012, we were a party to four 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 four interest rate swap contracts outstanding as of September 30, 2012, mature in 2022, with an aggregate notional amount of \$200.0 million, which effectively converted a portion the Company's \$1.0 billion, 3.25% fixed-rate notes due in 2022 to a floating rate. Additional interest rate swap contracts with an aggregate notional amount of \$300.0 million were entered into in October 2012 as fair value hedges of our \$0.5 billion, 1.90% fixed-rate notes due in 2017.

**Commercial Paper:** The carrying value of Commercial Paper as of September 30, 2012 and December 31, 2011 was \$324.9 million and \$401.4 million, respectively, and approximated its fair value. The effective interest rate on the outstanding Commercial Paper balance at September 30, 2012 was 0.5%.

**Senior Unsecured Credit Facility:** We maintain a senior unsecured revolving credit facility, or the Credit Facility, that provides revolving credit in the aggregate amount of \$1.0 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. As of September 30, 2012 and December 31, 2011, 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 debt covenants as of September 30, 2012.

**Credit Facility:** In November 2011, we entered into an uncommitted facility, or the Facility, not exceeding an aggregate \$125.0 million. As of December 31, 2011, \$125.0 million was outstanding under the Facility and accounted for as short-term borrowings. The outstanding balance was repaid in January 2012 and there was no outstanding borrowing under the Facility as of September 30, 2012.

**12. Share-Based Compensation**

We have a stockholder-approved stock incentive plan, the 2008 Stock Incentive Plan as amended and restated in 2009, and further amended in 2011 and 2012, or the Plan, that provides for the granting of options, restricted stock awards, stock appreciation rights, performance awards and other share-based awards to our employees and officers. The Management Compensation and Development Committee of the Board of Directors, or the Compensation Committee, may determine the type, amount and terms, including vesting, of any awards made under the Plan.

On June 13, 2012, our stockholders approved an amendment of the Plan, which included the following key modifications: adoption of an aggregate share reserve of 95,981,641 shares of Common Stock, which includes an increase in the share reserve by 14,000,000 shares; extension of the term of the plan through April 18, 2022; a change in the weighting of full-value awards such as restricted stock and restricted stock units such that the weighting of grants of full-value awards will be increased from 1.6 shares for every share granted to 2.1 shares for every share granted for purposes of determining usage of the aggregate share reserve.

## CELGENE CORPORATION AND SUBSIDIARIES

## NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2012 and 2011:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Cost of goods sold	\$ 3,315	\$ 2,627	\$ 9,174	\$ 7,054
Research and development	27,274	24,527	75,858	79,998
Selling, general and administrative	32,118	27,198	86,009	75,906
Total share-based compensation expense	62,707	54,352	171,041	162,958
Tax benefit related to share-based compensation expense	17,025	13,728	45,761	41,598
Reduction in income	\$ 45,682	\$ 40,624	\$ 125,280	\$ 121,360

Share-based compensation cost included in inventory was \$1.1 million and \$2.0 million at September 30, 2012 and December 31, 2011, respectively.

We utilize share-based compensation in the form of stock options, restricted stock units, or RSUs, and performance-based restricted stock units, or PSUs. The following table summarizes the activity for stock options, RSUs and PSUs for the nine-month period ended September 30, 2012:

	Stock Options	Restricted Stock Units	Performance- Based Restricted Stock Units
Outstanding at December 31, 2011	44,526,748	3,019,943	28,500
Changes during the Year:			
Granted	6,904,411	1,669,856	-
Exercised / Released	(7,080,447)	(405,586)	-
Forfeited	(1,049,012)	(145,927)	(3,000)
Expired	(77,932)	N/A	N/A
Outstanding at September 30, 2012	43,223,768	4,138,286	25,500

Total compensation cost related to nonvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at September 30, 2012 were as follows (dollars in thousands):

Stock	Restricted Stock	Performance- Based Restricted
-------	---------------------	----------------------------------

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

	Options	Units	Stock Units
Unrecognized compensation cost	\$ 284,519	\$ 165,240	\$ 832
Expected weighted-average period in years of compensation cost to be recognized	2.3	1.8	1.3

24

---

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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. During the three months ended June 30, 2012, we settled an examination with the U.S. Internal Revenue Service, or the IRS, for the years ended December 31, 2006, 2007 and 2008. Our U.S. federal income tax returns have now been audited by the IRS through the year ended December 31, 2008. Tax returns for the years ended December 31, 2009, 2010, and 2011 are currently under examination by the IRS. We are also subject to audits by various state and foreign taxing authorities, including, but not limited to, most U.S. states and major European and Asian countries where we have operations.

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

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.

During the second quarter of 2012, we settled examinations with various taxing authorities related to tax positions taken in prior years. The settlements resulted in a decrease in our gross unrecognized tax benefits of \$450.6 million, exclusive of interest, and a reduction to income tax expense of \$318.6 million. The decrease in unrecognized tax benefits and the reduction to income tax expense reflect the impact of the settlements on tax returns filed in various taxing jurisdictions for the years examined as well as certain adjustments to unrecognized tax benefits for years subsequent to the examination period. Increases to the amount of unrecognized tax benefits since January 1, 2012 of approximately \$41.2 million relate primarily to current year operations. The liability for unrecognized tax benefits is expected to increase in the next 12



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

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

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

We do not provide for U.S. federal or state income taxes on unremitted earnings of foreign subsidiaries that are indefinitely invested outside the United States. During the second quarter of 2012, we concluded that approximately \$900.0 million of our foreign earnings may not be required for use in offshore operations, and are no longer treated as permanently reinvested. Accordingly, we recorded a deferred tax liability of \$316.5 million for the estimated U.S. federal and state income taxes that may be incurred should those earnings be repatriated. In drawing this conclusion, we considered our future sources of funds as well as our global operating and strategic liquidity needs.

**14. Collaboration Agreements**

We have entered into a number of collaborations in the ordinary course of business, as is customary in our industry. See Note 19 of the Notes to the Consolidated Financial Statements included in our 2011 Annual Report on Form 10-K for a more comprehensive description of existing collaboration agreements entered into prior to January 1, 2012.

*Epizyme:* On April 2, 2012, we entered into a collaboration and license agreement with Epizyme, Inc., or Epizyme, to discover, develop and commercialize novel therapeutic compounds by inhibiting histone methyltransferases (HMTs), an important epigenetic target class.

Under the terms of the agreement, we made an upfront payment of \$65.0 million to Epizyme and also made a \$25.0 million equity investment in Epizyme Series C Preferred Stock. Epizyme could receive up to \$165.0 million in milestone payments associated with each Epizyme compound developed to inhibit each distinct HMT target under the collaboration plus royalties on sales. Under this agreement, we have the exclusive option to license rights to HMT targets outside the United States and each Epizyme compound associated with such target during the option term. Epizyme will have the sole responsibility to develop and commercialize compounds in the United States.

The option term expires on either July 9, 2015, or July 9, 2016 if we unilaterally extend the option term for a fourth year and pay an option extension fee. Further, if an HMT target or targets are selected then the agreement shall expire upon the expiration of all applicable royalty terms under the agreement with respect to all licensed Epizyme compounds. Upon the expiration of the agreement, we will have a fully paid-up, royalty-free license to use Epizyme intellectual property to manufacture, market, use and sell such licensed Epizyme compounds developed under the agreement outside the United States.

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Other Collaboration Arrangements in 2012:* In addition to the collaboration agreement described above, we entered into other collaborative arrangements during 2012 that resulted in research and development expenses of \$65.0 million, of which \$55.0 million were made during the three-month period ended September 30, 2012. We also became party to a number of collaboration agreements as a result of our acquisition of Avila during 2012. We do not consider these collaboration arrangements to be significant.

**15. Commitments and Contingencies**

**Collaboration Arrangements:** We have entered into certain research and development collaboration agreements, as identified in Note 14, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded in our accompanying Consolidated Balance Sheets at September 30, 2012 and December 31, 2011.

**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. These legal proceedings and other matters are complex in nature and have outcomes that are difficult to predict and could have a material adverse effect on us.

Patent proceedings include challenges to scope, validity or enforceability of our patents relating to our various 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 cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that drug and could materially affect future results of operations.

Among the principal matters pending to which we are party to are the following:

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

In the fourth quarter of 2009, we received a Civil Investigative Demand, or CID, from the U.S. Federal Trade Commission, or the 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 respond to requests for information.

In the first quarter of 2011, the United States Attorney for the Central District of California informed us that we were under investigation relating to our promotion of the drugs THALOMID® and REVLIMID® regarding alleged off-label marketing and improper payments to physicians.

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 in connection with these investigations.

**REVLIMID®:** We have publicly announced that we received a Notice Letter dated August 30, 2010, sent from Natco Pharma Limited of India (Natco) notifying us of Natco's Abbreviated New Drug Application, or ANDA, which contains Paragraph IV certifications against certain of Celgene's patents that are listed in the U.S. Federal Drug Administration's, or FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book) for REVLIMID® (lenalidomide). Under the Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA containing a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the Orange Book. Natco's Notice letter alleges, among other things, that certain claims of United States Patent Nos. 5,635,517 (the 517 patent), 6,045,501 (the 501 patent), 6,315,720 (the 720 patent), 6,555,554 (the 554 patent), 6,561,976 (the 976 patent), 6,561,977 (the 977 patent), 6,755,784 (the 784 patent), 7,119,106 (the 106 patent) and 7,465,800 (the 800 patent) are invalid, unenforceable, and/or not infringed. Natco's Notice Letter was sent pursuant to Natco having filed an ANDA seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg REVLIMID® capsules.

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

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

On June 12, 2012, we received a Second Notice Letter from Natco, notifying us of Natco's submission in its ANDA of new, additional Paragraph IV certifications against the 517 patent, the 230 patent and United States Patent Nos. 7,189,740 (the 740 patent), 7,855,217 (the 217 patent) and 7,968,569 (the 569 patent). On July 20, 2012, we filed a new infringement action in the United States District Court of New Jersey against Natco, Arrow, Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. 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). Natco filed its Answer and Counterclaims on September 28, 2012. A revised Scheduling Order has not yet been entered by the Court.

If Natco is successful in challenging our patents in either litigation, and the FDA were to approve Natco's ANDA with a comprehensive education and risk management program for a generic version of lenalidomide, sales of REVLIMID® could be significantly reduced in the United States by the entrance of a generic lenalidomide product, potentially reducing our revenue.

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

We believe that Natco's counterclaims in the first action, and any claim that it raises in the second action, are unlikely to be sustainable 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 would be deemed to be invalid, unenforceable and/or not infringed. Accordingly, we believe that the

**CELGENE CORPORATION AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

ultimate outcome is not expected to have a material adverse effect on our financial condition or results of operations.

**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 (a) that it is unlikely that the plaintiffs 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. We filed motions to dismiss on February 20, 2012.

**VIDAZA®:** On September 28, 2012, we were named as a defendant in a complaint filed by Ivax LLC (formerly Ivax Corporation) 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 by making, using, and selling VIDAZA® brand drug in the United States. We filed an answer to this complaint on October 19, 2012. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties or license rights from the plaintiff. However, we believe that (a) it is unlikely that the plaintiff 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.

**17. Subsequent Event**

In October 2012, the FDA approved ABRAXANE® for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. The FDA approval was based on tumor response rates and did not result in the use of a marketing label that includes a progression-free survival claim, and accordingly, the CVR milestone payment #1, as described in Note 2 to Notes to Consolidated Financial Statements contained in our 2011 Annual Report on Form 10-K, has not been achieved. This approval will result in the related \$1.172 billion intangible asset obtained from the Abraxis acquisition being reclassified in October 2012 from an acquired IPR&D intangible to an acquired developed product rights intangible asset and amortization will commence in October 2012.

## 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 2011 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or the SEC, and in this report and our other public reports filed with the SEC. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

### Executive Summary

Celgene Corporation, together with its subsidiaries (collectively we, our, us, Celgene or the Company), is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development which is designed to bring new therapies to market, and we 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® and ISTODAX®.

- 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, or MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

- 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, or 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 metastatic 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 specific international markets and for the treatment of metastatic non-small cell lung cancer in the United States. ABRAXANE® is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast, non-small cell lung, malignant melanoma, pancreatic, bladder and ovarian. In October, 2012, the U.S. Food and Drug Administration, or FDA, approved ABRAXANE® for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. The FDA approval was based on tumor response rates and did not result in the use of a marketing label that includes a progression-free survival claim, and accordingly, the CVR milestone payment #1, as described in Note 2 to Notes to Consolidated Financial Statements contained in our 2011 Annual Report on Form 10-K, has not been achieved.

- THALOMID® 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, or ENL, an inflammatory complication of leprosy and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.

- ISTODAX® is approved in the United States for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy. Additionally, in June 2011, ISTODAX® received U.S. approval for the treatment of peripheral T-cell lymphoma, or 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. The European Medicines Agency, or EMA, has granted orphan drug designation for ISTODAX® for the treatment of both CTCL and PTCL. In July 2012, the European Medicines Agency's Committee for Medicinal Products for Human Use, or CHMP, issued a negative opinion regarding the Marketing Authorization Application submitted for ISTODAX® for the treatment of relapsed or refractory PTCL. We remain convinced of the favorable benefit/risk profile of ISTODAX®, which has the potential to offer an important new treatment option in this area of high unmet medical need in the European Union, or EU, where no agents are currently approved. We will therefore, in accordance with European regulations, request a re-examination of the CHMP opinion.

Additional sources of revenue include a licensing agreement with Novartis, which entitles us to royalties on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Cellular Therapeutics subsidiary and other licensing agreements.

We continue to invest substantially in research and development, and the drug candidates in our pipeline are at various stages of preclinical and clinical development. These candidates include: pomalidomide, our leading oral anti-myeloma agent; apremilast, our PDE 4 inhibitor that inhibits multiple proinflammatory mediators; PDA-001, our leading cellular therapy; CC-292 for cancer and autoimmune diseases; CC-486 (oral azacitidine), CC-223 and CC-115 for hematological and solid tumor malignancies; CC-122, our anti-cancer pleiotropic pathway modifier; and ACE-011 and ACE-536 biological products for anemia in several clinical settings of unmet need. We believe that continued acceptance of our primary commercial stage products, participation in research and development collaboration arrangements, depth of our product pipeline, regulatory approvals of new products and expanded use of existing products will provide the catalysts for future growth.



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

The following table summarizes total revenue and earnings for the three-month periods ended September 30, 2012 and 2011:

<i>(In thousands \$, except earnings per share)</i>	Three-Month Periods Ended			Increase	Percent Change
	2012	September 30,	2011		
Total revenue	\$ 1,419,251		\$ 1,249,737	\$ 169,514	13.6%
Net income attributable to Celgene	\$ 424,155		\$ 372,984	\$ 51,171	13.7%
Diluted earnings per share attributable to Celgene	\$ 0.97		\$ 0.81	\$ 0.16	19.8%

The increase in revenue for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011 was primarily due to the continued growth in sales of REVLIMID® and VIDAZA® in both U.S. and international markets. Net income and diluted earnings per share for the three-month period ended September 30, 2012 were favorably impacted by the following: higher level of revenue; decrease in cost of goods sold, partly due to lower royalties and manufacturing costs; and reduced amortization of acquired intangible assets due to certain intangible assets becoming fully amortized at the end of 2011. These items were partly offset by an increase in research and development costs, which included an increase in upfront payments related to collaboration agreements.

<i>(In thousands \$, except earnings per share)</i>	Nine-Month Periods Ended			Increase	Percent Change
	2012	September 30,	2011		
Total revenue	\$ 4,059,303		\$ 3,558,173	\$ 501,130	14.1%
Net income attributable to Celgene	\$ 1,193,065		\$ 907,972	\$ 285,093	31.4%
Diluted earnings per share attributable to Celgene	\$ 2.69		\$ 1.94	\$ 0.75	38.7%

The increase in revenue for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011 was primarily due to the continued growth in sales of REVLIMID® and VIDAZA® in both U.S. and international markets. Net income and diluted earnings per share for the nine-month period ended September 30, 2012 were favorably impacted by the following: higher level of revenue; decrease in cost of goods sold, partly due to lower royalties; and reduced amortization of acquired intangible assets due to certain intangible assets becoming fully amortized at the end of 2011. Other favorable earnings items included the 2011 divestment of Abraxis non-core activities and the 2011 inclusion of \$90.3 million in inventory step-up amortization for sales of ABRAXANE®. These items were partly offset by an increase in research and development costs, which included an increase in upfront payments related to collaboration agreements and an increase in acquisition related charges.

**Results of Operations:****Three-month periods ended September 30, 2012 and 2011**

*Total Revenue:* Total revenue and related percentages for the three-month periods ended September 30, 2012 and 2011 were as follows:

<i>(In thousands \$)</i>	Three-Month Periods Ended		Increase (Decrease)	Percent Change
	2012	September 30, 2011		
Net product sales:				
REVLIMID®	\$ 970,117	\$ 820,019	\$ 150,098	18.3%
VIDAZA®	219,617	191,162	28,455	14.9%
ABRAXANE®	106,344	113,549	(7,205)	(6.3%)
THALOMID®	75,253	83,305	(8,052)	(9.7%)
ISTODAX®	12,640	8,252	4,388	53.2%
Other	4,042	2,831	1,211	42.8%
Total net product sales	\$ 1,388,013	\$ 1,219,118	\$ 168,895	13.9%
Collaborative agreements and other revenue	2,362	3,766	(1,404)	(37.3%)
Royalty revenue	28,876	26,853	2,023	7.5%
Total revenue	\$ 1,419,251	\$ 1,249,737	\$ 169,514	13.6%

Total revenue increased by \$169.5 million, or 13.6%, to \$1.419 billion for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, reflecting increases of \$75.3 million, or 10.4%, in the United States, and \$94.2 million, or 18.0%, in international markets.

*Net Product Sales:*

Total net product sales for the three-month period ended September 30, 2012 increased by \$168.9 million, or 13.9%, to \$1.388 billion compared to the three-month period ended September 30, 2011. The increase was comprised of net volume increases of \$123.3 million, price increases of \$67.8 million and the unfavorable impact from foreign exchange of \$22.2 million. The increase in price was primarily due to price increases on REVLIMID® and VIDAZA® in the U.S. market, partly offset by reductions in other markets, mainly in Europe.

REVLIMID® net sales increased by \$150.1 million, or 18.3%, to \$970.1 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, primarily due to increased unit sales in both U.S. and international markets. Increased market penetration, increase in treatment duration of patients using REVLIMID® in multiple myeloma and an increase in price contributed to U.S. growth. The growth in international markets was primarily the result of volume increases, mainly driven by increased duration of use and market share gains.

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

VIDAZA® net sales increased by \$28.5 million, or 14.9%, to \$219.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, reflecting increases in both U.S. and international markets. The U.S. growth reflects increases in volume and price, in addition to lower gross to net adjustments. The growth in international markets was partly due to the increase in treatment duration of patients using VIDAZA® and launches of VIDAZA® in new markets, including the United Kingdom and Japan. VIDAZA® retains orphan drug exclusivity in Europe through 2018 and in Japan until January 2021.

ABRAXANE® net sales decreased by \$7.2 million, or 6.3%, to \$106.3 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The decrease was primarily due to lower U.S. unit volumes. Sales for the three-month period ended September 30, 2011 were favorably impacted by a temporary shortage of a competing generic product. The U.S. sales decrease was partly offset by an increase in international markets.

THALOMID® net sales decreased by \$8.1 million, or 9.7%, to \$75.3 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The decrease was primarily due to lower unit volumes in the United States, partly offset by an increase in price.

ISTODAX® net sales increased by \$4.4 million, or 53.2%, to \$12.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The increase was primarily due to increased unit sales in the treatment of CTCL and also PTCL in patients who have received at least one prior therapy.

*Collaborative Agreements and Other Revenue:* Revenues from collaborative agreements and other sources decreased by \$1.4 million to \$2.4 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011.

*Royalty Revenue:* Royalty revenue increased by \$2.0 million to \$28.9 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The increase was primarily due to higher royalties from Novartis based upon its sales of FOCALIN XR®, partly offset by a decrease in royalties from sales of RITALIN® which were negatively impacted by generic competition.

*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® is distributed in the United States primarily through contracted pharmacies under the RevAssist® program, which is a proprietary risk-management distribution program tailored specifically to help ensure the safe and appropriate distribution and use of REVLIMID®. Internationally, REVLIMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to help ensure 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*, or 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®. Internationally, THALOMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to help ensure the safe and appropriate distribution and use of THALOMID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA®, ABRAXANE® 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® and THALOMID®.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization





initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. As noted above, REVLIMID® is distributed primarily through hospitals and contracted pharmacies, lending itself to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity. THALOMID® is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product.

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 not yet submitted actual Medicaid Managed Care Organization bills, resulting in an increase in the accrual balance. 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 Note 1 of the Notes to the Consolidated Financial Statements included in our 2011 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

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

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2012 and 2011 were as follows (in thousands):

2012	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at June 30, 2012	\$ 4,345	\$ 10,798	\$ 136,269	\$ 66,009	\$ 217,421
Allowances for sales during prior periods	-	-	(9,444)	(2,753)	(12,197)
Allowances for sales during 2012	2,072	16,827	42,456	50,945	112,300
Credits/deductions issued for prior year sales	(86)	(7)	(416)	-	(509)
Credits/deductions issued for sales during 2012	(1,805)	(14,665)	(31,216)	(47,648)	(95,334)
Balance at September 30, 2012	\$ 4,526	\$ 12,953	\$ 137,649	\$ 66,553	\$ 221,681

2011	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at June 30, 2011	\$ 4,008	\$ 14,642	\$ 120,188	\$ 48,834	\$ 187,672
Allowances for sales during 2011	1,599	19,261	42,651	48,984	112,495
Credits/deductions issued for prior year sales	(1,577)	(681)	(2,763)	(2,902)	(7,923)
Credits/deductions issued for sales during 2011	(408)	(15,611)	(33,635)	(44,893)	(94,547)
Balance at September 30, 2011	\$ 3,622	\$ 17,611	\$ 126,441	\$ 50,023	\$ 197,697

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2012 and 2011 follows:

Returns and allowances increased by \$0.5 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011.

Discounts decreased by \$2.4 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, primarily due to rebates related to VIDAZA® sales in the Japanese market being included in the chargebacks and distributor service fees category in 2012, partly offset by revenue increases in the United States and international markets, both of which offer different discount programs, and expansion into new international markets.

Government rebates decreased by \$9.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, primarily due a \$17.6 million decrease in rebates in certain international markets, partly offset by an increase of approximately \$8.0 million in rebates related to various U.S. programs. The decrease in governmental rebates of \$17.6 million in international markets was primarily driven by an amendment to a price/volume agreement for VIDAZA® in a specific European country that resulted in a

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

reduction in government rebates of approximately \$11.5 million for the three-month period ended September 30, 2012. The U.S. increase was primarily attributable to the non-recurrence of a \$5.9 million refinement of accrual rates for Medicare Part D Coverage Gap recorded in 2011.

Chargebacks and distributor service fees decreased by \$0.8 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. Chargebacks decreased by \$1.0 million primarily due to product mix. Distributor service fees increased by \$0.2 million, primarily due to higher specialty pharma fees from higher REVLIMID® sales volume.

*Operating Costs and Expenses:* Operating costs, expenses and related percentages for the three-month periods ended September 30, 2012 and 2011 were as follows (dollar amounts in thousands):

	Three-Month Periods Ended		Increase (Decrease)	Percent Change
	2012	September 30, 2011		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 74,622	\$ 94,645	\$ (20,023)	(21.2%)
Percent of net product sales	5.4%	7.8%		
Research and development	\$ 441,595	\$ 356,839	\$ 84,756	23.8%
Percent of total revenue	31.1%	28.6%		
Selling, general and administrative	\$ 354,644	\$ 303,303	\$ 51,341	16.9%
Percent of total revenue	25.0%	24.3%		
Amortization of acquired intangible assets	\$ 46,157	\$ 75,044	\$ (28,887)	(38.5%)
Acquisition related (gains) charges and restructuring, net	\$ 649	\$ (11,209)	\$ 11,858	105.8%

*Cost of goods sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) decreased by \$20.0 million to \$74.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The decrease was partly due to a \$2.9 million decrease in royalties related to a certain product to be divested. In addition, the three-month period ended September 30, 2011 included a \$6.9 million inventory step-up amortization adjustment related to sales of ABRAXANE® and approximately \$6.0 million in charges related to a certain manufacturing agreement and a product specific inventory adjustment not repeated in the 2012 quarter. These items were partly offset by an increase in 2012 material costs resulting from a higher level of sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.4% in the three-month period ended September 30, 2012 compared to 7.8% for the three-month period ended September 30, 2011. Excluding the inventory step-up amortization for ABRAXANE®, the cost of goods sold ratio for the three-month period ended September 30, 2011 was 7.2%. The cost of goods sold ratio for 2012 was also favorably impacted by product mix, as lower cost products made up a larger portion of total net sales.

*Research and Development:* Research and development expenses increased by \$84.8 million to \$441.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The increase was primarily due to a \$22.5 million increase in payments related to research and development collaboration arrangements, a \$31.2 million in-process research and development, or IPR&D, asset impairment charge related to the approval of ISTODAX® for PTCL in Europe, the inclusion of \$20.9 million in Avila expenses subsequent to the March 2012 acquisition date and an increase in 2012 research and development project spending in support of multiple programs across a broad range of diseases.

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

	Three-Month Periods Ended			Increase		
	2012	September 30,	2011			
Human pharmaceutical clinical programs	\$	195,752	\$	185,768	\$	9,984
Other pharmaceutical programs		112,061		98,493		13,568
Drug discovery and development		40,274		34,371		5,903
Cellular therapy		7,307		5,707		1,600
Collaboration arrangements		55,000		32,500		22,500
IPR&D impairment		31,201		-		31,201
Total	\$	441,595	\$	356,839	\$	84,756

Research and development expenditures support multiple ongoing clinical proprietary development programs for: REVLIMID® in multiple myeloma, or MM, mantle cell lymphoma, follicular lymphoma, diffuse large B-cell lymphoma, MDS, AML, chronic lymphocytic leukemia; VIDAZA® for treatment of AML and MDS; ABRAXANE® in breast, melanoma, non-small cell lung and pancreatic cancers; ISTODAX® for the treatment of CTCL and PTCL; apremilast, our PDE 4 inhibitor that inhibits multiple proinflammatory mediators and which is currently being evaluated in phase III clinical trials for the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis and in phase II for treatment of rheumatoid arthritis; pomalidomide, which is currently being evaluated in phase II and III clinical trials in MM and myelofibrosis; CC-486 (oral azacitidine), which is currently being evaluated in phase I and II clinical trials for hematological and solid tumor malignancies; sotatercept, currently in phase II in renal anemia, Blackfan Diamond anemia and beta-thalassemia; CC-11050, which has a phase II clinical trial in progress in lupus; CC-223, 115 and 122 in solid tumors, non-hodgkins lymphoma and MM; as well as our cellular therapy programs in early development in rheumatoid arthritis, multiple sclerosis, Crohn's disease and sarcoidosis.

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

The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended September 30, 2012, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

**New phase III trials**

<b>Product</b>	<b>Disease Indication</b>
Apremilast	Psoriatic Arthritis

**Regulatory agency actions**

<b>Product</b>	<b>Disease Indication</b>	<b>Major Market</b>	<b>Regulatory Agency</b>	<b>Action</b>
ISTODAX®	PTCL <sup>1</sup>	E.U.	CHMP <sup>2</sup>	Negative opinion
ABRAXANE®	NSCLC <sup>3</sup>	U.S.	FDA	Approval

1 Peripheral T-Cell Lymphoma

2 European Medicines Agency's Committee for Medicinal Products for Human Use

3 Non Small Cell Lung Cancer

**REVLIMID®:** In June 2012 we withdrew the new indication submission to CHMP for REVLIMID® (lenalidomide), which was intended for the maintenance treatment of newly diagnosed multiple myeloma patients who have not progressed following initial treatment with melphalan, prednisone and REVLIMID®, or maintenance therapy following autologous stem cell transplantation. We continue to evaluate data and plan to resubmit the new indication submission based on more mature data.

**ISTODAX®:** In July 2012, CHMP issued a negative opinion regarding the Marketing Authorization Application submitted for ISTODAX® (romidepsin) for the treatment of relapsed or refractory PTCL. We remain convinced of the favorable benefit/risk profile of romidepsin, which has the potential to offer an important new treatment option in this area of high unmet medical need in the EU, where no agents are currently approved. We will therefore, in accordance with European regulations, request a re-examination of the CHMP opinion.

**Selling, General and Administrative:** Selling, general and administrative expenses increased by \$51.3 million to \$354.6 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011, partly due to a \$21.5 million increase in donations to non-profit foundations, a \$7.8 million increase in bad debt reserves principally related to our European operations and increased marketing activities for ABRAXANE® and REVLIMID®, in addition to pomalidomide prelaunch activities.

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

*Amortization of Acquired Intangible Assets:* Amortization of acquired intangible assets is summarized below for the three-month periods ended September 30, 2012 and 2011(in thousands):

Acquisitions	Three-Month Periods Ended September 30,		Increase (Decrease)
	2012	2011	
Avila	\$ 11,815	\$ -	\$ 11,815
Abraxis	20,467	22,232	(1,765)
Gloucester	12,875	12,875	-
Pharmion	1,000	39,937	(38,937)
Total amortization	\$ 46,157	\$ 75,044	\$ (28,887)

Amortization of acquired intangible assets decreased by \$28.9 million to \$46.2 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011 primarily due to certain Pharmion intangible assets becoming fully amortized at the end of 2011. The decrease was partly offset by the addition of intangible assets resulting from the March 2012 acquisition of Avila.

In October 2012, the FDA approved ABRAXANE® for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. This approval will result in the related \$1.172 billion intangible asset obtained from the Abraxis acquisition being reclassified in October 2012 from an acquired IPR&D intangible asset to an acquired developed product rights intangible asset and amortization will commence in October 2012. The amortization of this intangible asset is expected to result in annual amortization expense of approximately \$100.0 million.

*Acquisition Related (Gains) Charges and Restructuring, net:* Acquisition related (gains) charges and restructuring, net was a net charge of \$0.6 million for the three-month period ended September 30, 2012 and a net gain of \$11.2 million for the three-month period ended September 30, 2011. The three-month period ended September 30, 2012 included a \$46.5 million reduction to the contingent consideration liability related to the approval of ISTODAX® for PTCL in Europe, a \$44.5 million increase to the fair value of our liability related to publicly traded contingent value rights, or CVRs, that were issued as part of the acquisition of Abraxis and \$2.6 million in the accretion of charges related to the acquisition of Avila. The three-month period ended September 30, 2011 included a \$13.4 million reduction to the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis, partly offset by \$2.0 million in accretion of contingent consideration liabilities related to the acquisition of Gloucester and \$0.2 million in restructuring charges related to the acquisition of Abraxis.

*Interest and Investment Income, Net:* Interest and investment income, net decreased by \$5.7 million to \$2.7 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The decrease was primarily due to a \$1.1 million reduction in interest income due to lower overall interest rates, \$3.5 million reduction in net gains on sales of marketable securities and a \$1.2 million net increase in the cost of amortization of discounts and premiums related to marketable securities.

*Interest (Expense):* Interest (expense) increased by \$7.5 million to \$17.8 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011 primarily due to interest and fees associated with the issuance of an additional \$1.5 billion in senior notes and an increase in interest on Commercial Paper borrowings.





*Other Income (Expense), Net:* Other income (expense), net was a net expense of \$10.0 million and \$16.7 million for the three-month periods ended September 30, 2012 and 2011, respectively. The expense for the three-month period ended September 30, 2012 included \$11.5 million in impairment losses related to cost method investments and net foreign exchange losses/forward point amortization of \$2.3 million, partly offset by a \$3.7 million economic development grant from the State of New Jersey. The three-month period ended September 30, 2011 primarily included \$15.6 million in net foreign exchange losses/forward point amortization.

*Income Tax Provision:* The income tax provision increased by \$12.7 million to \$52.3 million for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011. The full year estimated 2012 underlying effective tax rate of 14.4% reflects the impact of our global business footprint. The increase in the underlying effective tax rate from 2011 reflects a projected decrease in tax benefits from certain acquisition-related items. The effective tax rate for the three-month period ended September 30, 2012 was increased by 0.5 percentage points as a result of a discrete item related to the filing of our 2011 income tax returns with certain items being less favorable than originally estimated. The income tax provision for the three-month period ended September 30, 2011 included a full year underlying effective tax rate of 12.3%. The underlying effective tax rate reflected benefits related to a non-taxable gain from a decrease in the fair value of our liability under the CVR Agreement related to the acquisition of Abraxis and a benefit from an IPR&D asset impairment charge. The effective tax rate for the three-month period ended September 30, 2011 was reduced by 5.5 percentage points as a result of discrete items, including tax benefits related to a foreign tax credit and the filing of our 2010 income tax returns with certain items being more favorable than originally estimated.

#### Nine-month periods ended September 30, 2012 and 2011

*Total Revenue:* Total revenue and related percentages for the nine-month periods ended September 30, 2012 and 2011 were as follows:

<i>(In thousands \$)</i>	Nine-Month Periods Ended		Increase (Decrease)	Percent Change
	2012	September 30, 2011		
Net product sales:				
REVLIMID ®	\$ 2,764,980	\$ 2,353,334	\$ 411,646	17.5%
VIDAZA ®	607,128	516,142	90,986	17.6%
ABRAXANE ®	320,376	282,206	38,170	13.5%
THALOMID ®	229,553	256,894	(27,341)	(10.6%)
ISTODAX ®	36,597	20,957	15,640	74.6%
Other	11,468	27,522	(16,054)	(58.3%)
Total net product sales	\$ 3,970,102	\$ 3,457,055	\$ 513,047	14.8%
Collaborative agreements and other revenue	8,223	16,468	(8,245)	(50.1%)
Royalty revenue	80,978	84,650	(3,672)	(4.3%)
Total revenue	\$ 4,059,303	\$ 3,558,173	\$ 501,130	14.1%

Total revenue increased by \$501.1 million, or 14.1%, to \$4.059 billion for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, reflecting increases of \$239.3 million, or 11.4%, in the United States, and \$261.8 million, or 17.9%, in international markets.

*Net Product Sales:*

Total net product sales for the nine-month period ended September 30, 2012 increased by \$513.0 million, or 14.8%, to \$3.970 billion compared to the nine-month period ended September 30, 2011. The increase was

comprised of net volume increases of \$414.7 million, price increases of \$129.6 million and the unfavorable impact from foreign exchange of 31.3 million. The increase in price was primarily due to price increases on REVLIMID®, VIDAZA® and THALOMID® in the U.S. market, partly offset by reductions in other markets, mainly in Europe.

REVLIMID® net sales increased by \$411.6 million, or 17.5%, to \$2.765 billion for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, primarily due to increased unit sales in both U.S. and international markets. Increases in market penetration, treatment duration of patients using REVLIMID® in multiple myeloma and price contributed to U.S. growth. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains.

VIDAZA® net sales increased by \$91.0 million, or 17.6%, to \$607.1 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, reflecting increases in both the U.S. and international markets. The U.S. growth reflects an increase in volume and price. The growth in international markets was partly due to the increase in treatment duration of patients using VIDAZA® and launches of VIDAZA® in new markets, including the United Kingdom and Japan. VIDAZA® retains orphan drug exclusivity in Europe through the end of 2018 and in Japan until January 2021.

ABRAXANE® net sales increased by \$38.2 million, or 13.5%, to \$320.4 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The increase was primarily due to increased unit volumes in both U.S. and international markets.

THALOMID® net sales decreased by \$27.3 million, or 10.6%, to \$229.6 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, primarily due to lower unit volumes in the United States, partially offset by an increase in price and lower gross to net adjustments.

ISTODAX® net sales increased by \$15.6 million, or 74.6%, to \$36.6 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The increase was primarily due to increased unit sales in the treatment of CTCL and the June 2011 FDA approval of ISTODAX® for the treatment of PTCL in patients who have received at least one prior therapy.

The other net product sales category decreased by \$16.1 million, or 58.3%, to \$11.5 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The decrease was primarily due to elimination of Abraxis non-core product sales resulting from the April 2011 sale of Abraxis non-core assets. Sales of Abraxis non-core products totaled \$21.3 million in the 2011 nine-month period.

*Collaborative Agreements and Other Revenue:* Revenues from collaborative agreements and other sources decreased by \$8.2 million to \$8.2 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The nine-month period ended September 30, 2011 included a \$6.3 million milestone payment related to the VIDAZA® launch by our distribution partner in Japan.

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

*Royalty Revenue:* Royalty revenue decreased by \$3.7 million to \$81.0 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The decrease was primarily due to reduced royalties from Novartis based upon its sales of RITALIN® due to generic competition, partly offset by an increase in royalties from sales of FOCALIN XR®.

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

Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2012 and 2011 were as follows (in thousands):

2012	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at December 31, 2011	\$ 8,974	\$ 8,724	\$ 137,039	\$ 64,309	\$ 219,046
Allowances for sales during prior periods	(7,489)	-	(8,598)	(2,467)	(18,554)
Allowances for sales during 2012	4,381	49,900	158,754	153,522	366,557
Credits/deductions issued for prior year sales	1,747	(4,280)	(58,893)	(42,447)	(103,873)
Credits/deductions issued for sales during 2012	(3,087)	(41,391)	(90,653)	(106,364)	(241,495)
Balance at September 30, 2012	\$ 4,526	\$ 12,953	\$ 137,649	\$ 66,553	\$ 221,681

2011	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at December 31, 2010	\$ 4,779	\$ 8,272	\$ 84,964	\$ 47,367	\$ 145,382
Allowances for sales during prior periods	-	-	(4,277)	2,084	(2,193)
Allowances for sales during 2011	5,188	54,443	159,371	131,473	350,475
Credits/deductions issued for prior year sales	(4,228)	(7,444)	(34,225)	(34,927)	(80,824)
Credits/deductions issued for sales during 2011	(2,117)	(37,660)	(79,392)	(95,974)	(215,143)
Balance at September 30, 2011	\$ 3,622	\$ 17,611	\$ 126,441	\$ 50,023	\$ 197,697

A comparison of provisions for allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2012 and 2011 follows:

Returns and allowances decreased by \$8.3 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, primarily due to the reversal of approximately \$7.5 million in reserves established for certain products with quality issues which have now been resolved and lower returns experience on THALOMID®.

Discounts decreased by \$4.5 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, primarily due to rebates related to VIDAZA® sales in the Japanese market being included in the chargebacks and distributor service fees category in 2012, partly offset by 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 \$4.9 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, primarily due to a \$16.5 million decrease in rebates in certain international markets, partly offset by an increase of approximately \$11.6 million in rebates related to various U.S. programs offset. The decrease in the governmental rebates of \$16.5 million in international markets was primarily driven by an amendment to a price/volume agreement for VIDAZA® in a European country that resulted in

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

a reduction in government rebates of approximately \$10.9 million for the nine-month period ended September 30, 2012. The U.S. program increase was primarily attributable to volume increases and the refinement of accrual rates for Medicaid Managed Care Organizations and Medicare Part D Coverage Gap.

Chargebacks and distributor service fees increased by \$17.5 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. Chargebacks increased by approximately \$1.3 million primarily due to higher sales volumes. Distributor service fees increased by

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

approximately \$16.2 million, primarily due to \$6.2 million in service fees associated with higher sales of ABRAXANE® and \$9.7 million of rebates related to VIDAZA® sales in the Japanese market which were included within discounts during the 2011 period.

*Operating Costs and Expenses:* Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2012 and 2011 were as follows (dollar amounts in thousands):

	Nine-Month Periods Ended		Increase (Decrease)	Percent Change
	2012	September 30, 2011		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 218,994	\$ 348,356	\$ (129,362)	(37.1%)
Percent of net product sales	5.5%	10.1%		
Research and development	\$ 1,250,737	\$ 1,163,837	\$ 86,900	7.5%
Percent of total revenue	30.8%	32.7%		
Selling, general and administrative	\$ 1,003,449	\$ 911,207	\$ 92,242	10.1%
Percent of total revenue	24.7%	25.6%		
Amortization of acquired intangible assets	\$ 132,065	\$ 214,181	\$ (82,116)	(38.3%)
Acquisition related (gains) charges and restructuring, net	\$ 28,864	\$ (117,430)	\$ 146,294	124.6%

*Cost of goods sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) decreased by \$129.4 million to \$219.0 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The decrease was primarily due to the 2011 nine-month period inclusion of a \$90.3 million inventory step-up amortization adjustment related to sales of ABRAXANE®, an aggregate \$13.2 million in costs related to the sale of non-core Abraxis products which were divested in April 2011 and a \$14.8 million higher allocation of prepaid royalties related to sales of VIDAZA®. These items were partly offset by an increase in 2012 material costs resulting from a higher level of sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.5% in the nine-month period ended September 30, 2012 compared to 10.1% for the nine-month period ended September 30, 2011. Excluding the inventory step-up amortization for ABRAXANE®, the cost of goods sold ratio for the nine-month period ended September 30, 2011 was 7.5%. The cost of goods sold ratio for the nine-month period ended September 30, 2012 was favorably impacted by 0.4% from a reduction in royalties due to the expiration of U.S. patents for VIDAZA® and lower cost products comprising a larger portion of total net sales.

*Research and Development:* Research and development expenses increased by \$86.9 million to \$1.251 billion for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The increase was primarily due to a \$51.8 million increase in payments related to research and development collaboration arrangements, the inclusion of \$66.2 million in Avila expenses subsequent to the March 2012 acquisition date and increase in 2012 research and development project spending in support of multiple programs across a broad range of diseases. These expense increases were partly offset by a \$64.6 million decrease in IPR&D asset impairment charges.





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

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

	Nine-Month Periods Ended		Increase (Decrease)
	2012	September 30, 2011	
Human pharmaceutical clinical programs	\$ 590,075	\$ 542,736	\$ 47,339
Other pharmaceutical programs	327,102	296,787	30,315
Drug discovery and development	124,828	111,127	13,701
Cellular therapy	23,129	14,705	8,424
Collaboration arrangements	132,250	80,482	51,768
IPR&D impairment	53,353	118,000	(64,647)
Total	\$ 1,250,737	\$ 1,163,837	\$ 86,900

Research and development expenditures support multiple ongoing clinical proprietary development programs for: REVLIMID® in multiple myeloma, or MM, mantle cell lymphoma, follicular lymphoma, diffuse large B-cell lymphoma, MDS, AML, chronic lymphocytic leukemia; VIDAZA® for treatment of AML and MDS; ABRAXANE® in melanoma, non-small cell lung and pancreatic cancers; ISTODAX® for treatment of CTCL and PTCL; apremilast, our PDE 4 inhibitor that inhibits multiple proinflammatory mediators and which is currently being evaluated in phase III clinical trials for the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis and in phase II for treatment of rheumatoid arthritis; pomalidomide, which is currently being evaluated in phase II and III clinical trials in MM and myelofibrosis; CC-486 (oral azacitidine), which is currently being evaluated in phase I and II clinical trials for hematological and solid tumor malignancies; sotatercept, currently in phase II in renal anemia; CC-11050, which has a phase II clinical trial in progress in lupus; CC-223, 115 and 122 in solid tumors, non-hodgkins lymphoma and MM; as well as our cellular therapy programs in early development in rheumatoid arthritis, multiple sclerosis, Crohn's disease and sarcoidosis.

*Selling, General and Administrative:* Selling, general and administrative expenses increased by \$92.2 million to \$1.003 billion for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011, partly due to a \$34.0 million increase in donations to non-profit foundations, a \$11.9 million increase in bad debt reserves related to our European operations and increased marketing activities for ABRAXANE® and REVLIMID®, in addition to pomalidomide prelaunch activities.

*Amortization of Acquired Intangible Assets:* Amortization of acquired intangible assets is summarized below for the nine-month periods ended September 30, 2012 and 2011 (in thousands):

Acquisitions	Nine-Month Periods Ended		Increase (Decrease)
	2012	September 30, 2011	
Avila	\$ 27,567	\$ -	\$ 27,567
Abraxis	62,873	67,027	(4,154)
Gloucester	38,625	27,342	11,283
Pharmion	3,000	119,812	(116,812)
Total amortization	\$ 132,065	\$ 214,181	\$ (82,116)

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

Amortization of acquired intangible assets decreased by \$82.1 million to \$132.1 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011 primarily

due to certain Pharmion intangible assets becoming fully amortized at the end of 2011. The decrease was partly offset by the addition of intangible assets resulting from the March 2012 acquisition of Avila and the June 2011 FDA approval of ISTODAX® for treatment of PTCL in patients who have received at least one prior therapy, which resulted in the commencement of amortization of the related PTCL intangible asset.

The approval of ABRAXANE® in the U.S. for the treatment of non-small cell lung cancer in October 2012 is expected to result in annual amortization expense of approximately \$100.0 million over the estimated useful life of the associated intangible asset.

*Acquisition Related (Gains) Charges and Restructuring, net:* Acquisition related (gains) charges and restructuring, net was a net charge of \$28.9 million for the nine-month period ended September 30, 2012 and a net gain of \$117.4 million for the nine-month period ended September 30, 2011. The nine-month period ended September 30, 2012 primarily included a \$61.9 million increase to the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis and \$24.3 million in accretion of the contingent consideration liability related to our acquisition of Avila, partly offset by a \$59.9 million reduction in the contingent consideration liability related to the approval of ISTODAX® for PTCL in Europe. The nine-month period ended September 30, 2011 primarily included a \$136.7 million reduction to the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis, partly offset by \$14.2 million in accretion of contingent consideration liabilities related to the acquisition of Gloucester and \$5.5 million in restructuring charges related to the acquisition of Abraxis.

*Interest and Investment Income, Net:* Interest and investment income, net decreased by \$9.4 million to \$9.6 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The decrease was primarily due to a \$6.4 million reduction in interest income due to lower overall interest rates, \$1.9 million net decrease in gains on sales of marketable securities and a \$0.8 million net increase in the cost of amortization of discounts and premiums related to marketable securities.

*Interest (Expense):* Interest (expense) increased by \$9.2 million to \$40.7 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011 primarily due to interest and fees associated with the issuance of an additional \$1.5 billion in senior notes and an increase in interest on Commercial Paper borrowings.

*Other Income (Expense), Net:* Other income (expense), net was a net expense of \$2.9 million and \$7.7 million for the nine-month periods ended September 30, 2012 and 2011, respectively. The nine-month period ended September 30, 2012 primarily included \$11.5 million in impairment losses related to cost method investments and net foreign exchange losses/forward point amortization of \$7.6 million, partly offset by a \$7.4 million gain on the sale of equity securities, net gains of \$3.7 million related to the short period in June 2012 when certain treasury rate lock agreements were not designated as hedges and a \$3.7 million economic development grant from the State of New Jersey. The nine-month period ended September 30, 2011 primarily included net foreign exchange losses/forward point amortization of \$13.6, partly offset by a \$2.9 million gain on the sale of non-core assets and \$3.6 million in economic development grant proceeds received from the State of New Jersey.

*Income Tax Provision:* The income tax provision increased by \$87.5 million to \$198.1 million for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011. The full year estimated 2012 underlying effective tax rate of 14.4% reflects the impact of our global business footprint. The increase in the underlying effective tax rate from 2011 reflects a projected decrease in tax benefits from certain acquisition-related items. The effective tax rate for the nine-month period ended September 30, 2012 was reduced by 0.3 percentage points as a result of discrete items, including tax benefits related to the settlement of tax examinations and expirations of statutes of limitations offset by an increase in deferred tax liabilities recorded on certain unremitted foreign earnings previously treated as permanently reinvested in such foreign jurisdictions and tax expense related to the filing of our 2011 income tax returns



with certain items being less favorable than originally estimated. The income tax provision for the nine-month period ended September 30, 2011 included a full year underlying effective tax rate of 12.3%. The underlying effective tax rate reflected benefits from acquisition-related charges, including an IPR&D asset impairment charge of \$118.0 million and a non-taxable gain from a decrease in the fair value of our liability under the CVR Agreement related to the acquisition of Abraxis of \$136.7 million. The effective tax rate for the nine-month period ended September 30, 2011 was reduced by 1.4 percentage points as a result of discrete items, including tax benefits related to a foreign tax credit and the filing of our 2010 income tax returns with certain items being more favorable than originally estimated, offset by tax expense related to a change in state tax law.

## Financial Condition, Liquidity and Capital Resources

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

	September 30, 2012	December 31, 2011	Increase (Decrease)
Financial assets:			
Cash, cash equivalents	\$ 2,715,534	\$ 1,859,464	\$ 856,070
Marketable securities available for sale	1,117,402	788,690	328,712
Total financial assets	\$ 3,832,936	\$ 2,648,154	\$ 1,184,782
Debt:			
Short-term borrowings	\$ 324,895	\$ 526,684	\$ (201,789)
Long-term debt	2,769,313	1,275,585	1,493,728
Total debt	\$ 3,094,208	\$ 1,802,269	\$ 1,291,939
Working capital (1)	\$ 3,911,540	\$ 2,659,970	\$ 1,251,570

- (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 U.S., and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of September 30, 2012, we held approximately \$2.6 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business and due to other reasons, such as repurchases of our common stock and business-development activities. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the U.S., no accrual for U.S. taxes is provided. During the second quarter of 2012, we concluded that approximately \$900 million of our foreign earnings may not be required for use in offshore operations and are no longer treated as permanently reinvested. Accordingly, we recorded a deferred tax liability of \$316.5 million for the estimated U.S. federal



and state income taxes that may be incurred should those 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 unremitted 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 \$6.5 billion stock repurchase program of which we have approximately \$2.417 billion remaining for future share repurchases. During the three-month period ended September 30, 2012, we used \$743.7 million for repurchases of our common stock.

#### Components of Working Capital

*Cash, Cash Equivalents and Marketable Securities Available for Sale:* We invest our excess cash primarily in money market funds, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government agency and Supranational securities and global corporate debt securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as marketable securities available for sale. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. The \$1.185 billion increase in cash, cash equivalents and marketable securities available for sale at September 30, 2012 compared to December 31, 2011 was primarily due to the issuance of \$1.5 billion in senior notes in August 2012 and by cash generated from operations, partly offset by a net repayment of \$201.0 million in short-term borrowings, \$352.2 million paid for the acquisition of Avila and \$1.470 billion paid under our share repurchase program.

Marketable securities available for sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges, is included in interest and investment income, net. For more information related to the fair value and valuation of our marketable securities, see Note 6 to the Notes to the Consolidated Financial Statements included elsewhere in this report.

*Accounts Receivable, Net:* Accounts receivable, net increased by \$11.9 million to \$957.5 million as of September 30, 2012 compared to December 31, 2011. 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, who in turn directly deliver critical care to patients. Our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.





The credit and economic conditions within Spain, Italy, Portugal and Greece, as well as increasing sales levels in those countries have resulted in, and may continue to result in, an increase in the average length of time it takes to collect accounts receivable. Our total net receivables in Spain, Italy and Portugal are composed almost entirely of amounts receivable from government-owned or controlled hospitals and the public sector and amounted to \$328.7 million at September 30, 2012 compared to \$396.1 million at December 31, 2011. Approximately \$52.5 million of the \$328.7 million receivable at September 30, 2012 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. This payment pattern was recently observed in Spain, where a significant portion of aged receivables were paid in late June and early July 2012. We also regularly request and receive positive confirmation of the validity of our receivables from most of the regional governmental authorities. 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 \$46.3 million to \$235.9 million at September 30, 2012 compared to December 31, 2011. The increase was primarily due to increases in REVLIMID®, VIDAZA® and ABRAXANE® inventories, attributable to higher anticipated sales levels.

*Other Current Assets:* Other current assets decreased by \$170.6 million to \$224.5 million as of September 30, 2012 compared to December 31, 2011 primarily due to a \$111.9 million decrease in prepaid taxes and a \$69.2 million decrease in the fair value of foreign currency forward contracts, partly offset by an increase in other prepaid accounts.

*Commercial Paper:* In September 2011, we entered into a commercial paper program, or the Program, under which we issue unsecured commercial paper notes, or Commercial Paper, on a private placement basis up to a maximum aggregate amount outstanding at any time of \$1.0 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 September 30, 2012, \$324.9 million of Commercial Paper was outstanding bearing an effective interest rate of 0.5%.

*Senior Unsecured Credit Facility:* In September 2011, we entered into a senior unsecured revolving credit facility, or the Credit Facility, providing for revolving credit in the aggregate amount of \$1.0 billion. 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 \$1.250 billion.

The Credit Facility has a five-year term and amounts may be borrowed for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of September 30, 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 debt covenants as of September 30, 2012.

*Accounts Payable, Accrued Expenses and Other Current Liabilities:* Accounts payable, accrued expenses and other current liabilities increased by \$50.7 million to \$1.012 billion as of September 30, 2012 compared to December 31, 2011. The increase was partly due to a \$62.9 million increase in clinical trial accruals and \$17.7 million increase in accrued interest, partly offset by a \$23.8 million decrease in compensation-related accruals and \$8.3 million decrease in the fair value of foreign currency forward derivative contracts.

*Income Taxes Payable (Current and Non-Current):* Income taxes payable decreased by \$466.1 million to \$180.4 million as of September 30, 2012 compared to December 31, 2011, primarily from tax payments of \$369.6 million, the application of previously refundable prepaid income taxes of \$74.3 million, a tax benefit of stock options of \$16.0 million, net deferred intercompany credits of \$59.9 million offset by the current provision for income taxes of \$54.6 million, which includes a benefit related to tax settlements of \$373.0 million.

*Senior Notes:* In August 2012, we issued an additional \$1.5 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, or the 2017 notes, and \$1.0 billion aggregate principal amount of 3.25% Senior Notes due 2022 (the 2022 notes and, together with the 2017 notes, referred to herein as the 2012 issued notes). The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

#### Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2012 and 2011 were as follows (in thousands):



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

	Nine-Month Periods Ended			Change
	September 30,			
	2012	2011		
Net cash provided by operating activities	\$ 1,528,162	\$ 1,338,473	\$	189,689
Net cash provided by (used in) investing activities	\$ (778,147)	\$ 312,004	\$	(1,090,151)
Net cash provided by (used in) financing activities	\$ 156,290	\$ (1,197,330)	\$	1,353,620

*Operating Activities:* Net cash provided by operating activities for the nine-month period ended September 30, 2012 increased by \$189.7 million to \$1.528 billion as compared to the nine-month period ended September 30, 2011. The increase in net cash provided by operating activities was primarily attributable to the receipt of \$154.3 million from customers in Spain during the second quarter for payment of aged receivables and the continued expansion of our operations and related increase in net earnings.

*Investing Activities:* Net cash used in investing activities for the nine-month period ended September 30, 2012 decreased by \$1.090 billion to a net cash use of \$778.1 million as compared to net cash provided by investing activities for the nine-month period ended September 30, 2011. The decrease in net cash provided by investing activities was principally related to a cash use of \$352.2 million related to the acquisition of Avila, a decrease in proceeds received from the sale of non-core assets and an increase in purchases of investment securities during the nine-month period ended September 30, 2012. Net purchases of marketable securities available for sale amounted to \$328.8 million during the nine-month period ended September 30, 2012 compared to net sales of \$487.7 million in the nine-month period ended September 30, 2011.

*Financing Activities:* Net cash provided by financing activities for the nine-month period ended September 30, 2012 was \$156.3 million compared to a net cash use of \$1.197 billion for the nine-month period ended September 30, 2011. The \$1.354 billion increase in net cash provided by financing activities during the nine-month period ended September 30, 2012 was primarily attributable to \$1.486 billion of cash received from the issuance of long-term debt, partially offset by \$201.0 million of net repayments of short-term borrowing.

### 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 2011 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2011 aside from those disclosed in Notes 3 and 14 of the Notes to the 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 2011 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 2011 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, 2011.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

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

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At September 30, 2012, our market risk sensitive instruments consisted of marketable securities available for sale, our long-term debt, certain foreign currency forward contracts, foreign currency option contracts, and interest rate swap contracts.

*Marketable Securities Available for Sale:* At September 30, 2012, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities, global corporate debt 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 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.

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 September 30, 2012, 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 (in thousands):

	Duration			Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	
Principal amount	\$ 442,198	\$ 587,198	\$ 62,595	\$ 1,091,991
Fair value	\$ 450,044	\$ 602,095	\$ 64,778	\$ 1,116,917
Weighted average interest rate	0.5%	0.5%	0.6%	0.5%

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

*Long-Term Debt:* In August 2012, we issued a total of \$1.5 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017 and \$1.0 billion aggregate principal amount of 3.25% Senior Notes due 2022. The 2012 issued notes were issued at



99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If a change of control of the Company occurs accompanied by a downgrade of the debt to below investment grade, the Company will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. The Company is subject to covenants which limit the ability of the Company to pledge properties as security under borrowing arrangements and limit the ability of the Company to perform sale and leaseback transactions involving the property of the Company.

On October 7, 2010, we issued a total of \$1.25 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes due 2015, \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040. The notes were issued at 99.854%, 99.745% and 99.813% of par, respectively, and the discount amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$10.5 million have been recorded as debt issuance costs on our consolidated balance sheet and are amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on April 15 and October 15 of each year and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

At September 30, 2012, the fair value of our senior notes outstanding was \$2.866 billion.

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.

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 no more than three years into



the future. 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 September 30, 2012 and December 31, 2011 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), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2012 and December 31, 2011:

Foreign Currency	Notional Amount	
	September 30, 2012	December 31, 2011
Australian Dollar	\$ 11,483	\$ 17,169
British Pound	94,407	53,764
Canadian Dollar	163,078	67,281
Euro	389,452	714,446
Japanese Yen	504,668	606,538
Swiss Franc	337	49,182
Total	\$ 1,163,425	\$ 1,508,380

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of September 30, 2012, 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 September 30, 2012 and December 31, 2011 were \$947.9 million and \$916.9 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2012 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$205.1 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.



*Foreign Currency Option Contracts:* During the three-month period ended September 30, 2012, we hedged 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. At the same time, in order to offset the upfront cost of this collar, a local currency put option is sold with a lower strike price and the same expiration dates and amounts as the option contracts that are used to hedge sales. The written put is not designated as a hedging instrument and gains and losses associated with the written put option are recorded on the income statement as other income (expense), net. If the U.S. dollar strengthens relative to the currency of the hedged foreign currency sales to levels that reduce the exchange rate of the foreign currency below the strike price of this written put option, the put option would increase in value, resulting in losses to us equal to the difference between the strike price and the actual exchange rate multiplied by the notional amount of the hedged foreign currency sales.

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2012 and December 31, 2011:

Foreign Currency Option	Notional Amount*	
	September 30, 2012	December 31, 2011
Designated as hedging activity:		
Purchased Put	\$ 228,779	\$ -
Written Call	\$ 235,920	\$ -
Not designated as hedging activity:		
Written Put	\$ 215,952	\$ -

\* 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, written call, and written put options are equal to each other.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2012 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 \$20.0 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 September 30, 2012 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 decrease by approximately \$9.8 million if the U.S. Dollar were to strengthen, and would increase by approximately \$1.7 million if the U.S. Dollar were to weaken. 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:* During the nine-month period ended September 30, 2012, we entered into treasury rate lock agreements, or treasury rate locks, in anticipation of issuing fixed-rate notes that were



issued in August 2012. With the exception of a short period in June when certain outstanding treasury rate locks were not designated as hedges, our treasury rate locks are designated as cash flow hedges and, to the extent effective, any realized or unrealized gains or losses on them are reported in OCI and will be recognized in income over the life of the anticipated fixed-rate notes. Treasury rate locks were settled during the nine-month period ended September 30, 2012 which resulted in losses of \$35.3 million that were recorded to OCI. During the short period in June when we had outstanding treasury rate locks that were not considered hedging instruments, we recorded the change in fair value of \$3.7 million in other income (expense), net. No material amounts were recorded in income during the nine-month periods ended September 30, 2012 or 2011 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. At September 30, 2012 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 swaps are recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense.

At September 30, 2012, 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. Our swap contracts outstanding at September 30, 2012 will mature in 2022, with an aggregate notional amount of \$200.0 million, which effectively converts a portion of our \$1,000.0 million, 3.25% fixed-rate notes due in 2022 to a floating rate. In August 2011, we settled outstanding interest rate swap contracts we entered into with respect to our \$500.0 million 2.45% fixed notes due in 2015 resulting in the receipt of \$34.3 million. The proceeds from the settlements are being accounted for as a reduction of current and future interest expense associated with these notes.

#### **Item 4. Controls and Procedures**

##### *Evaluation of Disclosure Controls and Procedures*

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

##### *Changes in internal control over financial reporting*

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2012 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, Unaudited 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:

- 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;

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

- regulatory approvals for our products and pricing determinations with respect to our products;
- regulatory approvals for our and our competitors' manufacturing facilities;
- 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® and ABRAXANE®, 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® and ABRAXANE®. We cannot predict whether 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 our products, physician and patient comfort with the product could be undermined, the commercial success of such products 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 Food and Drug Administration, or FDA, or similar bodies in other countries if our products are associated with a death or serious injury. These adverse events, among others, could result in additional regulatory controls, such as the performance of costly post-approval clinical studies or revisions to our approved labeling, which could limit the indications or patient population for our products or could even lead to the withdrawal of a product from the market. Similarly, the occurrence of serious adverse events known or suspected to be related to the products could negatively impact product sales. For example, THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities in the baby. REVLIMID® 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 and advantages, 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

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

Amendments Act, the U.S. Foreign Corrupt Practices Act, the Sherman Antitrust Act, patent laws, environmental laws, privacy laws and other federal and state statutes, including anti-kickback, antitrust and false claims laws, as well as similar laws in foreign jurisdictions. Enforcement of and 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, or 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, or 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, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first or receives approval of other labeled indications;
- Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or legislation;
- The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and reimbursed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the drug;
- 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®, 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, prohibition on off-label promotion and the promotion of unapproved products, such agencies may bring enforcement actions against us that could inhibit our commercial capabilities as well as result in significant penalties.

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

- changes in laws and regulations, including without limitation, patent, environmental, privacy, health care and competition laws;
- 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 our stem cell banking businesses. 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, or 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 the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We encounter similar regulatory and legislative issues in most countries outside the United States. International operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on access to and reimbursement for our products. Although we cannot predict the extent to which our business may be affected by future cost-containment measures or other potential legislative or regulatory developments, additional 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 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 assured 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, or 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. Any termination of material licenses granted to us could have a material adverse effect on our business, financial condition and results of operations.

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

Our intellectual property rights will further be affected in ways that are difficult to anticipate at this time by the provisions of the America Invents Act, signed into law on September 16, 2011. 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 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.

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, or 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 pharmaceutical or biotechnology 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.

If an ANDA filer or a generic manufacturer 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 two Paragraph IV Certification Letters dated August 30, 2010 and June 12, 2012, respectively, advising us that Natco Pharma Limited of Hyderabad, India, or Natco, submitted an ANDA to the FDA. See Part I, Item 1, Note 16, to Notes to Unaudited Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

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

The pharmaceutical and biotech industry in which we operate is 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 Co., Ltd., SuperGen, Inc. and Johnson & Johnson, which compete or may potentially compete with VIDAZA®, in addition Eisai Co., Ltd. potentially competes with ABRAXANE®, and in other oncology products in general;
- Amgen, which potentially competes with our TNF- and kinase inhibitors;
- AstraZeneca PLC, which potentially competes in clinical trials with our compounds and TNF- inhibitors;

- Biogen Idec Inc. is generally developing drugs that address the oncology and immunology markets;
- Bristol Myers Squibb Co., 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 Ltd., which potentially competes in clinical trials with our ®TNF- inhibitors, in addition to other oncology products in general;
- Johnson & Johnson, which potentially competes with certain of our proprietary programs, including our oral anti-inflammatory programs;
- Abbott Laboratories, which potentially competes 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 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 Quarterly Report on Form 10-Q, under the caption Liquidity and Capital Resources 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, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, whistleblower, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business as currently conducted or as conducted in the future.

In particular, we are 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.

Pharmaceutical companies involved in Hatch-Waxman litigation are often subject to follow-on lawsuits and governmental investigations, which may be costly and could result in lower-priced generic products that are competitive with our products being introduced to the market.

In the fourth quarter of 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission, or the 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 respond to requests for information.

In the first quarter of 2011, the United States Attorney for the Central District of California informed us that we were under investigation relating to our promotion of the drugs THALOMID® and REVLIMID® regarding alleged off-label marketing and improper payments to physicians. 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 in connection with these investigations.

On January 20, 2011, the Supreme Court of Canada ruled that the jurisdiction of the Patented Medicine Prices Review Board, or the PMPRB, extends to sales of drugs to Canadian patients even if the locus of sale is within the United States. This means that our U.S. sales of THALOMID® brand drug to Canadian patients under the special access program are subject to PMPRB jurisdiction from and after January 12, 1995. In accordance with the ruling of the Supreme Court of Canada, we have provided to-date data regarding these special access program sales to the PMPRB. In light of the approval of THALOMID® brand drug by Health Canada on August 4, 2010, this drug is now sold through our Canadian entity and is no longer sold to Canadian patients from the United States. On January 20, 2012, we received confirmation that PMPRB accepted a Voluntary Compliance Undertaking for THALOMID® brand drug, which required us to make a payment of CAD \$10 million to the Government of Canada in February 2012.

Litigation and governmental investigations are inherently unpredictable and may:

- result in rulings that are materially unfavorable to us, including claims for significant damages, 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;

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

- cause us to change our business operations to avoid perceived risks associated with such litigation or investigations;
- have an adverse affect on our reputation and the demand for our products; and

- require the 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 position. See also Legal Proceedings contained in Part II, Item 1 of this report.

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

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process involves a high degree of risk and takes many years. Our product development efforts with respect to a product candidate may fail for many reasons, including the failure of the product candidate in preclinical studies; adverse patient reactions to the product candidate or indications or other safety concerns; insufficient clinical trial data to support the effectiveness or superiority of the product candidate; our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate; or changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer desirable. Moreover, our commercially available products may require additional studies with respect to approved indications as well as new indications pending approval.

The stem cell products that we are developing through our Celgene Cellular Therapeutics, or 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, or API, encapsulation, finishing services packaging and distribution services to meet our needs. These risks 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





additional cost of any disruption. For these reasons, a significant disruptive event at certain of our manufacturing facilities or sites could materially and adversely affect our business and results of operations. In addition, if we fail to 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.

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, results of operations and reputation.

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

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

- demands on management related to the increase in our size after the acquisition;
- the diversion of management's attention from the management of daily operations to the integration of operations;
- higher integration costs than anticipated;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;
- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, 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 offerings and expanded geographic market coverage and, to some degree, to eliminate redundant and excess costs. Because of difficulties in combining geographically distant operations, we may not be able to achieve the benefits that we hope to achieve as a result of the acquisition of acquired businesses.

***Our 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.

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

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 shares and options management and our board of directors grants 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 dependent upon the distribution of income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, the accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other jurisdictions, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets, and changes in overall levels of pre-tax earnings. The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have an impact on our results of operations.

*Currency fluctuations and changes in exchange rates could increase our costs and may 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. For additional information, see Note 7 to Notes to Unaudited Consolidated Financial Statements.

*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;
- 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 affected by conditions in the global markets and economic conditions throughout the world. The global market and economic climate may deteriorate because of many factors beyond our control, including economic instability and market volatility, sovereign debt issues, rising interest rates or inflation, terrorism or political uncertainty. In the event of a market downturn in general and/or the biopharmaceutical sector in particular, the market price of our common stock may be adversely affected.

*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, a senior unsecured credit facility and a credit facility. Our ability to pay interest, principal amounts when due at maturity, to comply with debt covenants or to repurchase the senior notes if a change of control occurs will depend upon, among other things, continued commercial success of our products and other factors that affect our future financial and operating performance, including, without limitation, prevailing economic conditions and financial, business, and regulatory factors, many of which are beyond our control.

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

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

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

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

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy breaches by employees and others who access our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to protect our data and information technology 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 5,000,000 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 board of directors has adopted certain amendments to our by-laws 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, contingent value right, or CVR, holders 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. A copy of the CVR Agreement was filed on Form 8-A with the

SEC on October 15, 2010. 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 Note 2 of Notes to Consolidated Financial Statements contained in the 2011 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 develop 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;
- because a public market for the CVRs has a limited history, the market price and trading volume of the CVRs may be volatile;
- if the clinical approval milestones specified in the CVR Agreement are not achieved for any reason within the time periods specified therein, and if net sales do not exceed the thresholds set forth in the CVR Agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire valueless;
- since the U.S. federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;
- any payments in respect of the CVRs are subordinated to the right of payment of certain of our other indebtedness;
- we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations to achieve each of the CVR milestones and to commercialize ABRAXANE® or any of the other Abraxis pipeline products, we may discontinue such efforts, which would have an adverse effect on the value, if any, of the CVRs.

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

(c) Issuer Purchases of Equity Securities

The following table presents the total number of shares purchased during the three-month period ended September 30, 2012, the average price paid per share, the number of shares that were purchased and the approximate dollar value of shares that may yet be purchased, pursuant to our publicly announced repurchase program:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs
July 1 - July 31	4,396,158	\$ 66.00	4,396,158	\$ 2,870,675,560
August 1 - August 31	5,469,919	\$ 70.27	5,469,919	\$ 2,486,292,395
September 1 - September 30	900,000	\$ 76.87	900,000	\$ 2,417,110,945

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.5 billion of our common stock, including \$2.5 billion approved by our Board of Directors in June 2012. Approved amounts exclude share repurchase transaction fees.

As of September 30, 2012, an aggregate 67,008,026 shares of common stock were repurchased under the program at an average price per share of \$60.93 and a total cost of \$4.084 billion, including share repurchase transaction fees.

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

**Item 6. Exhibits.**

31.1 Certification by the Company's Chief Executive Officer.

31.2 Certification by the Company's Chief Financial Officer.

32.1 Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.

32.2 Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.

101 The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, 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.

SIGNATURES

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

CELGENE CORPORATION

DATE: October 29, 2012

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

Chief Financial Officer  
(principal financial and accounting officer)