

CELGENE CORP /DE/  
Form 10-Q  
November 02, 2010

**Table of Contents**

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

**(Mark one)**

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

**For the quarterly period ended September 30, 2010  
OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-34912**

**CELGENE CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**

**22-2711928**

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

**86 Morris Avenue, Summit, NJ**

**07901**

(Address of principal executive offices)

(Zip Code)

**(908) 673-9000**

(Registrant's telephone number, including area code)

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

Yes  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  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  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a 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

At October 26, 2010, 470,640,374 shares of Common Stock, par value \$.01 per share, were outstanding.



**CELGENE CORPORATION**  
**FORM 10-Q TABLE OF CONTENTS**

Page No.

**PART I FINANCIAL INFORMATION**

Item 1 Unaudited Consolidated Financial Statements

Consolidated Statements of Operations

Three-Month and Nine-Month Periods Ended September 30, 2010 and 2009

1

Consolidated Balance Sheets

As of September 30, 2010 and December 31, 2009

2

Consolidated Statements of Cash Flows

Nine-Month Periods Ended September 30, 2010 and 2009

3

Notes to Unaudited Consolidated Financial Statements

5

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

31

Item 3 Quantitative and Qualitative Disclosures About Market Risk

47

Item 4 Controls and Procedures

49

**PART II OTHER INFORMATION**

Item 1 Legal Proceedings

50

Item 1A Risk Factors

51

Item 2 Unregistered Sales of Equity Securities and Use of Proceeds

66

Item 3 Defaults Upon Senior Securities

66

Item 4 Submission of Matters to a Vote of Security Holders

66

Item 5 Other Information

66

Item 6 Exhibits

66

Signatures

67

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

Exhibit 32.2

EX-101 INSTANCE DOCUMENT

EX-101 SCHEMA DOCUMENT

EX-101 CALCULATION LINKBASE DOCUMENT

EX-101 LABELS LINKBASE DOCUMENT

EX-101 PRESENTATION LINKBASE DOCUMENT

EX-101 DEFINITION LINKBASE DOCUMENT

---

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)****(In thousands, except per share amounts)**

	<b>Three-Month Periods Ended September 30,</b>		<b>Nine-Month Periods Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Revenue:				
Net product sales	\$ 885,656	\$ 667,967	\$ 2,468,164	\$ 1,842,353
Collaborative agreements and other revenue	2,241	2,381	7,165	6,979
Royalty revenue	22,214	24,789	78,728	79,524
Total revenue	910,111	695,137	2,554,057	1,928,856
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	63,542	52,058	193,450	167,259
Research and development	253,547	193,362	800,965	593,109
Selling, general and administrative	228,281	192,512	655,522	542,264
Amortization of acquired intangible assets	46,540	21,111	135,201	67,403
Acquisition related charges	7,495		20,193	
Total costs and expenses	599,405	459,043	1,805,331	1,370,035
Operating income	310,706	236,094	748,726	558,821
Other income and expense:				
Interest and investment income, net	12,801	20,468	37,010	61,994
Equity in losses of affiliated companies	1,384	329	746	944
Interest expense	414	466	1,321	1,457
Other income, net	8,453	14,935	7,130	52,720
Income before income taxes	330,162	270,702	790,799	671,134
Income tax provision	49,011	53,887	119,854	148,602
Net income	\$ 281,151	\$ 216,815	\$ 670,945	\$ 522,532
Net income per common share:				
Basic	\$ 0.61	\$ 0.47	\$ 1.46	\$ 1.14
Diluted	\$ 0.60	\$ 0.46	\$ 1.44	\$ 1.12

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

Weighted average shares:

Basic	459,653	458,834	459,957	459,332
Diluted	466,332	467,057	467,137	467,469

See accompanying Notes to Unaudited Consolidated Financial Statements

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS****(Unaudited)****(Dollars in thousands, except per share amounts)**

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,831,985	\$ 1,102,172
Marketable securities available for sale	698,280	1,894,580
Accounts receivable, net of allowances of \$9,739 and \$10,787 at September 30, 2010 and December 31, 2009, respectively	593,086	438,617
Inventory	108,672	100,683
Deferred income taxes	73,173	49,817
Other current assets	240,681	258,935
Total current assets	4,545,877	3,844,804
Property, plant and equipment, net	318,669	297,792
Investment in affiliated companies	22,640	21,476
Intangible assets, net	759,499	349,542
Goodwill	763,589	578,116
Other assets	144,285	297,581
Total assets	\$ 6,554,559	\$ 5,389,311
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 49,852	\$ 36,629
Accrued expenses	392,708	315,608
Income taxes payable	9,905	46,874
Current portion of deferred revenue	4,321	1,827
Other current liabilities	286,818	93,767
Total current liabilities	743,604	494,705
Deferred revenue, net of current portion	11,501	6,527
Non-current income taxes payable	479,541	422,358
Other non-current liabilities	174,219	71,115
Total liabilities	1,408,865	994,705

**Commitments and Contingencies**



**Stockholders Equity:**

Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none outstanding at September 30, 2010 and December 31, 2009, respectively		
Common stock, \$.01 par value per share, 575,000,000 shares authorized; issued 470,322,714 and 467,629,433 shares at September 30, 2010 and December 31, 2009, respectively	4,703	4,676
Common stock in treasury, at cost; 10,382,757 and 8,337,961 shares at September 30, 2010 and December 31, 2009, respectively	(466,489)	(362,521)
Additional paid-in capital	5,618,525	5,474,122
Retained earnings (deficit)	38,699	(632,246)
Accumulated other comprehensive loss	(49,744)	(89,425)
Total stockholders equity	5,145,694	4,394,606
Total liabilities and stockholders equity	\$ 6,554,559	\$ 5,389,311

See accompanying Notes to Unaudited Consolidated Financial Statements

**Table of Contents**

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

	<b>Nine-Month Periods Ended</b>	
	<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>
Cash flows from operating activities:		
Net income	\$ 670,945	\$ 522,532
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation of long-term assets	38,880	29,671
Amortization of intangible assets	136,048	68,104
Allocation of pre-paid royalties	37,299	26,109
Provision for accounts receivable allowances	(1,485)	3,840
Deferred income taxes	(36,854)	(34,971)
Acquisition related charges accretion	16,697	
Share-based compensation expense	134,540	105,927
Equity in (gains) losses of affiliated companies	746	748
Share-based employee benefit plan expense	11,072	8,976
Unrealized change in value of foreign currency forward contracts	12,060	(28,076)
Realized gains on marketable securities available for sale	(12,576)	(27,051)
Other, net	3,155	2,884
Change in current assets and liabilities, excluding the effect of the acquisition:		
Accounts receivable	(158,899)	(88,471)
Inventory	(6,372)	17,610
Other operating assets	9,412	(23,062)
Accounts payable and other operating liabilities	89,560	(18,990)
Income tax payable	25,002	20,888
Deferred revenue	7,481	2,626
Net cash provided by operating activities	976,711	589,294
Cash flows from investing activities:		
Proceeds from sales of marketable securities available for sale	3,774,568	1,552,721
Purchases of marketable securities available for sale	(2,564,876)	(2,011,969)
Payments for acquisition of business, net of cash acquired	(337,608)	
Capital expenditures	(59,138)	(60,069)
Investment in affiliated companies	(1,759)	(3,603)
Purchases of investment securities	(14,020)	(10,981)
Other		3,333
Net cash provided by (used in) investing activities	797,167	(530,568)
Cash flows from financing activities:		

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

Payment for treasury shares	(105,436)	(149,362)
Net proceeds from exercise of common stock options and warrants	56,033	34,384
Excess tax benefit from share-based compensation arrangements	9,081	99,950
Net cash used in financing activities	(40,322)	(15,028)
Effect of currency rate changes on cash and cash equivalents	(3,743)	14,971
Net increase in cash and cash equivalents	1,729,813	58,669
Cash and cash equivalents at beginning of period	1,102,172	1,092,386
Cash and cash equivalents at end of period	\$ 2,831,985	\$ 1,151,055

See accompanying Notes to Unaudited Consolidated Financial Statements

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**  
**(Unaudited)**  
**(Dollars in thousands)**

	<b>Nine-Month Periods Ended</b>	
	<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>
Supplemental schedule of non-cash investing and financing activity:		
Change in net unrealized (gain) on marketable securities available for sale	\$ (17,480)	\$ (9,659)
Matured shares tendered in connection with stock option exercises	\$ (8,236)	\$ (997)
Supplemental disclosure of cash flow information:		
Income taxes paid	\$ 115,291	\$ 60,992
See accompanying Notes to Unaudited Consolidated Financial Statements		

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**  
**(In all accompanying tables, amounts of dollars expressed in thousands,**  
**except per share amounts, unless otherwise indicated)**

**1. Nature of Business and Basis of Presentation**

Celgene Corporation and its subsidiaries (collectively 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.

The Company s primary commercial stage products include REVLIMID®, VIDAZA® and THALOMID® (inclusive of Thalidomide Celgene® and Thalidomide Pharmion®). Other commercial stage products include ISTODAX® and FOCALIN®. ISTODAX®, which was obtained in the acquisition of Gloucester Pharmaceuticals, Inc., or Gloucester, was approved in November 2009 by the U.S. Food and Drug Administration, or FDA, for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy and was launched in the first quarter of the year ending December 31, 2010. FOCALIN® is sold exclusively to Novartis Pharma AG, or Novartis. The Company s other sources of revenues include a licensing agreement with Novartis, which entitles it to royalties on FOCALIN XR® and the entire RITALIN® family of drugs. ALKERAN® was licensed from GlaxoSmithKline, or GSK, and sold under the Celgene label through March 31, 2009, the conclusion date of the ALKERAN® license with GSK. The Company continues to earn residual payments based upon GSK s ALKERAN® revenues through March 31, 2011. The Company also derives revenues from the sale of services through its Cellular Therapeutics subsidiary and miscellaneous licensing agreements.

The accompanying unaudited consolidated financial statements have been prepared from the books and records of the Company pursuant to U.S. generally accepted accounting principles for interim information and the rules and regulations of the Securities and Exchange Commission for interim reporting. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted. The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. All intercompany transactions and balances have been eliminated. Investments in limited partnerships and interests in which the Company has an equity interest of 50% or less and does not otherwise have a controlling financial interest are accounted for by either the equity or cost method. The interim consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2009, or the 2009 Annual Report on Form 10-K.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. The Company is subject to certain risks and uncertainties related to product development, regulatory approval, market acceptance, scope of patent and proprietary rights, competition, 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 financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim consolidated financial statements. Effective January 1, 2010, the Company changed the functional currency of Celgene International Sarl from the Euro to the U.S. Dollar. Significant changes in economic facts and circumstances supported this change in functional currency and the change was applied on a prospective basis.

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies**

The Company's significant accounting policies are described in Note 1 of the Notes to the Consolidated Financial Statements included in the 2009 Annual Report on Form 10-K.

**New Accounting Pronouncements:** In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC 605. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the impact, if any, that the adoption of this amendment will have on its consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which amends ASC 820 to add new requirements for disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances, and settlements relating to Level 3 measurements. ASU 2010-06 also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. Further, ASU 2010-06 amends guidance on employers' disclosures about postretirement benefit plan assets under ASC 715 to require that disclosures be provided by classes of assets instead of by major categories of assets. ASU 2010-06 was effective for the first reporting period (including interim periods) beginning after December 15, 2009, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will be effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. Early adoption is permitted. The section of the amendment pertaining to transfers into and out of Levels 1 and 2 was effective for the Company beginning January 1, 2010. The adoption of this section of the amendment did not have any impact on the Company's consolidated financial statements. The section of the amendment pertaining to Level 3 measurements will be effective for the Company beginning January 1, 2011. The Company is currently evaluating the impact, if any, that the adoption of this amendment will have on its consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, Milestone Method of Revenue Recognition, or ASU 2010-17, to (1) limit the scope of this ASU to research or development arrangements and (2) require that guidance in this ASU be met for an entity to apply the milestone method (record the milestone payment in its entirety in the period received). However, the FASB clarified that, even if the requirements in ASU 2010-17 are met, entities would not be precluded from making an accounting policy election to apply another appropriate accounting policy that results in the deferral of some portion of the arrangement consideration. The guidance in ASU 2010-17 will apply to milestones in both single-deliverable and multiple-deliverable arrangements involving research or development transactions. ASU 2010-17 will be effective for fiscal years (and interim periods within those fiscal years) beginning on or after June 15, 2010. Early application is permitted. Entities can apply this guidance prospectively to milestones achieved after adoption. However, retrospective application to all prior periods is also permitted. The Company is currently evaluating the impact, if any, that the adoption of ASU 2010-17 will have on its consolidated financial statements.

**3. Acquisition of Gloucester Pharmaceuticals, Inc.**

On January 15, 2010, the Company acquired all of the outstanding common stock and stock options of Gloucester in a transaction accounted for under the acquisition method of accounting for business combinations, ASC No. 805, Business Combinations, or ASC 805. Under the acquisition method of accounting, the assets acquired and liabilities assumed of Gloucester were recorded as of the acquisition date, at their respective fair values, and consolidated with those of the Company. The reported consolidated financial condition and results of operations of the Company after completion of the acquisition reflect these fair values. Gloucester's results of operations are included in the Company's consolidated financial statements from the date of acquisition. Gloucester's results of operations prior to the acquisition were determined to be immaterial to the Company; therefore, proforma financial statements are not required to be

presented.  
\

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

The Company paid \$338.9 million in cash before milestone payments and may make additional future payments of \$300.0 million in contingent regulatory milestone payments. Prior to the acquisition, Gloucester was a privately held biopharmaceutical company that acquired clinical-stage oncology drug candidates with the goal of advancing them through regulatory approval and commercialization. The Company acquired Gloucester to enhance its portfolio of therapies for patients with life-threatening illnesses worldwide.

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:

	January 15, 2010
Current assets	\$ 3,132
Developed product rights	197,000
IPR&D product rights	349,000
Other noncurrent assets	54
Assets acquired	549,186
Contingent consideration	(230,201)
Net deferred taxes	(145,635)
Other liabilities assumed	(21,347)
Net assets acquired	152,003
Goodwill	186,907
Cash paid	\$ 338,910

Asset categories acquired in the Gloucester acquisition included working capital, inventory, fixed assets, developed product right assets and in-process research and development, or IPR&D, product right assets. Fair values of working capital and fixed assets were determined to approximate book values while the fair value of inventory was determined to be greater than book value.

The fair value of developed product right assets was based on expected cash flows from developed product right sales of ISTODAX<sup>®</sup> (romidepsin), a novel histone deacetylase (HDAC) inhibitor, which was approved for marketing in the United States in November 2009 by the FDA for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy. Prior to the acquisition, Gloucester was also conducting a registration trial in peripheral T-cell lymphoma, or PTCL, in the United States with an anticipated supplemental New Drug Application filing in 2010 for this indication. Fair values were derived using probability-weighted cash flows. The U.S. CTCL developed product right asset is being amortized over its economic useful life of ten years. The compassionate use right asset is being amortized evenly over the asset's economic useful life of 1.5 years.

The fair value of IPR&D product right assets was based on expected cash flows from sales of ISTODAX<sup>®</sup> (romidepsin) for the treatment of PTCL, which had not yet achieved regulatory approval for marketing and has no future alternative use. The \$349.0 million estimated fair value of IPR&D product rights was derived using probability-weighted cash flows. The fair value was based on expected cash flows from the treatment of PTCL in the United States and PTCL in the European Union, or E.U., based on key assumptions such as estimates of sales and operating profits related to the programs considering their stages of development; the time and resources needed to complete the regulatory approval process for the products and the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in obtaining regulatory approvals.





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

The U.S. PTCL IPR&D product right asset was assigned a value of \$287.0 million based on related future net cash flows estimated using a risk-adjusted discount rate of 14.5% and an anticipated regulatory approval date in mid-2011 with market exclusivity rights expected to continue through 2017. The E.U. PTCL IPR&D product right asset was assigned a value of \$62.0 million based on future net cash flows using a risk-adjusted discount rate of 14.5% and an anticipated regulatory approval date in mid-2015 with market exclusivity rights expected to continue through 2021.

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 Company does not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the Company's acquisition of Gloucester has been recorded as a noncurrent asset in its Consolidated Balance Sheets and is not amortized, but is subject to review for impairment in accordance with ASC 350, Goodwill and Other Intangible Assets.

The Company accounts for contingent consideration in accordance with applicable guidance provided within the business combination rules of ASC 805. As part of the Company's consideration for the Gloucester acquisition, it is contractually obligated to pay certain consideration resulting from the outcome of future events. The Company updates its assumptions each reporting period based on new developments and records such amounts at fair value until such consideration is satisfied.

The Gloucester acquisition included two contingent considerations which would obligate the Company to make a \$180.0 million cash milestone payment to the former Gloucester shareholders upon the marketing approval for the U.S. PTCL IPR&D product right asset and a \$120.0 million cash milestone payment upon the marketing approval for the E.U. PTCL IPR&D product right asset.

The initial fair value of contingent considerations was \$230.2 million, consisting of \$156.7 million based on the \$180.0 million milestone payment upon U.S. PTCL approval and \$73.5 million based on the \$120.0 million milestone payment upon E.U. PTCL approval. The Company determined the fair value of these obligations to pay additional milestone payments upon approvals based on a probability-weighted income approach. This fair value measurement is based on significant input not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a Baa rated debt yield of 6.15 percent, which the Company believes is appropriate and representative of a market participant assumption. The range of estimated milestone payments is from no payment if both product indications fail to gain market approval to \$300.0 million if both product indications gain market approval. The Company classified the contingent considerations as liabilities, which were measured at fair value as of the acquisition date. Fair value is based on the future milestone payments adjusted for the probability of each payment and the time until each payment is expected to be made.

Subsequent to the acquisition date, the Company has measured the contingent consideration arrangement at fair value each period with changes in fair value recognized in operating earnings. Changes pertaining to facts and circumstances that existed as of the acquisition date will be recognized as adjustments to goodwill. Changes in fair values reflect new information about the IPR&D assets and the passage of time. In the absence of new information, changes in fair value will only reflect the passage of time as development work towards the achievement of the milestones progresses and will be accrued based on an accretion schedule. At September 30, 2010, the balance of the contingent consideration was \$246.9 million, of which \$167.8 million is included in other current liabilities and \$79.1 million included in other non-current liabilities.

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Earnings Per Share**

Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period increased to include all additional common shares that would have been outstanding assuming potentially dilutive common shares resulting from option exercises, restricted stock units, warrants and other incentives had been issued and any proceeds thereof used to repurchase common stock at the average market price during the period. The assumed proceeds used to repurchase common stock are the sum of the amount to be paid to the Company upon exercise of options, the amount of compensation cost attributed to future services and not yet recognized and, if applicable, the amount of excess income tax benefit that would be credited to paid-in capital upon exercise.

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2010	2009	2010	2009
Net income	\$ 281,151	\$ 216,815	\$ 670,945	\$ 522,532
Weighted-average shares (in thousands):				
Basic	459,653	458,834	459,957	459,332
Effect of dilutive securities:				
Options, restricted stock units, warrants and other incentives	6,679	8,223	7,180	8,137
Diluted	466,332	467,057	467,137	467,469
Net income per share:				
Basic	\$ 0.61	\$ 0.47	\$ 1.46	\$ 1.14
Diluted	\$ 0.60	\$ 0.46	\$ 1.44	\$ 1.12

The total number of potential common shares excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 24,472,208 and 20,547,394 shares for the three-month periods ended September 30, 2010 and 2009, respectively. The total number of potential common shares excluded for the nine-month periods ended September 30, 2010 and 2009 was 23,624,432 and 21,515,514, respectively.

In April 2009, the Company's Board of Directors approved a \$500.0 million common stock share repurchase program. As of September 30, 2010, an aggregate 6,168,425 shares of common stock of the Company have been repurchased under the program at a total cost of \$313.5 million.

**5. Comprehensive Income**

The components of comprehensive income consist of net income, 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.

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

A summary of accumulated other comprehensive income, net of tax, is summarized as follows:

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2010	2009	2010	2009
Net income	\$ 281,151	\$ 216,815	\$ 670,945	\$ 522,532
Other comprehensive income (loss):				
Marketable securities:				
Net unrealized gains on marketable securities available for sale, net of tax	4,682	9,413	17,681	16,345
Reclassification adjustment for gains included in net income	(6,560)	(9,880)	(12,432)	(27,051)
Total other comprehensive gains (losses) related to marketable securities available for sale, net of tax	(1,878)	(467)	5,249	(10,706)
Net unrealized gains (losses) related to cash flow hedges, net of tax	(118,501)	(14,981)	1,663	11,862
Currency translation adjustments	11,709	12,980	32,769	(2,720)
Total other comprehensive income (loss) items	(108,670)	(2,468)	39,681	(1,564)
Comprehensive income	\$ 172,481	\$ 214,347	\$ 710,626	\$ 520,968

**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, 2010 and the valuation techniques the Company 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. The Company's 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. The Company's 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 and forward currency 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. The Company's Level 3 assets consist of warrants for the purchase of equity securities in a non-publicly traded company in which the Company has invested and which is party to a collaboration and option agreement with the Company. The Company's Level 3 liabilities consist of a contingent consideration related to undeveloped product rights resulting from the Gloucester acquisition.



**Table of Contents**

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

	Balance at September 30, 2010	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Available-for-sale securities	\$ 698,280	\$ 321	\$ 697,959	\$
Warrants	1,757			1,757
Cash equivalents				
Forward currency contracts	488		488	
<b>Total assets</b>	<b>\$ 700,525</b>	<b>\$ 321</b>	<b>\$ 698,447</b>	<b>\$ 1,757</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ (246,898)	\$	\$	\$ (246,898)

	Balance at December 31, 2009	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Available-for-sale securities	\$ 1,894,580	\$ 512	\$ 1,894,068	\$
Warrants	1,598			1,598
Cash equivalents	183,224		183,224	
Forward currency contracts	7,008		7,008	
<b>Total assets</b>	<b>\$ 2,086,410</b>	<b>\$ 512</b>	<b>\$ 2,084,300</b>	<b>\$ 1,598</b>

There were no security transfers between Levels I and II during the nine-month period ended September 30, 2010. The following tables represent a roll-forward of the fair value of Level 3 securities (significant unobservable inputs):

	Nine-Month Periods Ended September 30,	
	2010	2009
<b>Assets:</b>		
Balance at beginning of period	\$ 1,598	\$ 11,054

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

Amounts acquired or issued					
Net gains (losses) (realized and unrealized)		(10)		2,451	
Net purchases, issuances and settlements		169		(12,660)	
Transfers in and/or out of Level 3					
Balance at end of period		\$	1,757	\$	845

**Table of Contents**

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

	Nine-Month Periods Ended September 30,	
	2010	2009
Liabilities:		
Balance at beginning of period	\$	\$
Amounts acquired or issued	(230,201)	
Net accretion	(16,697)	
Settlements		
Transfers in and/or out of Level 3		
Balance at end of period	\$ (246,898)	\$

**7. Derivative Instruments and Hedging Activities**

**Foreign Currency Forward Contracts:** The Company uses 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.

The Company enters 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, 2010 and December 31, 2009 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, net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows:

	Notional Amount	
	September 30, 2010	December 31, 2009
Foreign Currency		
British Pound	\$ 58,440	\$
Canadian Dollar	96,410	
Euro	886,381	1,107,340
Japanese Yen	526,232	
Swiss Franc	71,015	
Others less than \$50 million	35,821	
Total	\$ 1,674,299	\$ 1,107,340

The Company considers the impact of its 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, 2010 and December 31, 2009, credit risk did not materially change the fair value of the Company's foreign currency forward contracts.

The Company also enters 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 in other



income, net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2010 and December 31, 2009 were \$554.0 million and \$483.2 million, respectively.

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

The following table summarizes the fair value and presentation in the consolidated balance sheets for derivative instruments as of September 30, 2010 and December 31, 2009:

Instrument	September 30, 2010			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Foreign currency forward contracts designated as hedging instruments*	Other current assets	\$ 29,725	Other current assets	\$ 9,669
	Other current liabilities	5,299	Other current liabilities	6,603
	Other non-current assets	6,968	Other non-current assets	
	Other non-current liabilities	3,510	Other non-current liabilities	21,419
Foreign currency forward contracts not designated as hedging instruments*	Other current assets	5,593	Other current assets	17
	Other current liabilities	641	Other current liabilities	13,540
Total		\$ 51,736		\$ 51,248

Instrument	December 31, 2009			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Foreign currency forward contracts designated as hedging instruments*	Other current assets	\$ 25,403	Other current assets	\$ 21,346
	Other current liabilities		Other current liabilities	14,591
	Other non-current assets	11,645	Other non-current assets	
	Other non-current liabilities	28	Other non-current liabilities	89
Foreign currency forward contracts not designated as hedging instruments*	Other current assets	6,593	Other current assets	547
	Other current liabilities	75	Other current liabilities	164
Total		\$ 43,744		\$ 36,737

\* Derivative instruments in this category are

subject to  
master netting  
arrangements  
and are  
presented on a  
net basis in the  
Consolidated  
Balance Sheets  
in accordance  
with ASC  
210-20.

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

The following tables summarize the effect of derivative instruments designated as hedging instruments on the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010 and 2009, respectively:

Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative	For the Three-Month Period Ended September 30, 2010			
		Location of Gain/(Loss) Recognized in OCI on Derivative	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Recognized in OCI on Derivative	Amount of Gain/(Loss) Recognized in OCI on Derivative
		Reclassified from Accumulated OCI into Income	Reclassified from Accumulated OCI into Income	Recognized in Income on Derivative	Recognized in Income on Derivative
				(Ineffective Portion and Amount Excluded From Effectiveness Testing)	(Ineffective Portion and Amount Excluded From Effectiveness Testing)
Foreign currency forward contracts	\$ (97,916)(1)	Net product sales Research and development	\$ 20,585 \$ (1)	Other income, net	\$ 5,975(2)

(1) Gains of \$20,416 are expected to be reclassified from Accumulated OCI into operations in the next 12 months.

(2) The amount of net gains recognized in income represents \$394 in gains related to the ineffective portion of the hedging

relationships, and \$5,581 of gains related to amounts excluded from the assessment of hedge effectiveness.

Instrument	For the Three-Month Period Ended September 30, 2009				
	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Effective Portion)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>	<i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i>
Foreign currency forward contracts	\$ (25,465)	Net product sales Research and development	\$ (11,895) \$ (493)	Other income, net	\$ 2,657(1)

(1) Hedge ineffectiveness was insignificant and included with the amount excluded from effectiveness testing.

**Table of Contents**

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

Instrument	For the Nine-Month Period Ended September 30, 2010				
	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 currency forward contracts	\$ 43,377(1)	Net product sales Research and development	\$ 41,718  \$ (4)	Other income, net	\$ 3,019(2)

(1) Gains of \$20,416 are expected to be reclassified from Accumulated OCI into operations in the next 12 months.

(2) The amount of net gain recognized in income represents \$415 in losses related to the ineffective portion of the hedging relationships and \$3,434 of

gains related to amounts excluded from the assessment of hedge effectiveness.

Instrument	For the Nine-Month Period Ended September 30, 2009				
	Amount of Gain/(Loss) Recognized in OCI on Derivative	Location of Gain/(Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	Location of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded From Effectiveness Testing)
Foreign currency forward contracts	\$ (3,581)	Net product sales	\$ (18,455)	Other income, net	\$ (1,579)(1)
		Research and development	\$ 1,109		

(1) Hedge ineffectiveness was insignificant and included with the amount excluded from effectiveness testing.

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010 and 2009:

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,	
		2010	2009	2010	2009
Foreign currency forward contracts	Other income, net	\$ (49,661)	\$ (11,504)	\$ (4,177)	\$ 6,051

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 on the Consolidated Statements of Operations in other income, net for all periods presented.



**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Cash, Cash Equivalents and Marketable Securities Available-for-Sale**

Money market funds of \$2.210 billion and \$860.9 million at September 30, 2010 and December 31, 2009, 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, 2010 and December 31, 2009 were as follows:

September 30, 2010	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 182,257	\$ 1,411	\$ (2)	\$ 183,666
U.S. government-sponsored agency securities	148,195	1,174	(2)	149,367
U.S. government-sponsored agency MBS	235,034	1,521	(791)	235,764
Non-U.S. government, agency and Supranational securities	23,547	451	(3)	23,995
Corporate debt global (20% AAA/Aaa rated)	103,520	1,662	(15)	105,167
Marketable equity securities	407		(86)	321
Total available-for-sale marketable securities	\$ 692,960	\$ 6,219	\$ (899)	\$ 698,280

December 31, 2009	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury securities	\$ 502,112	\$ 244	\$ (1,573)	\$ 500,783
U.S. government-sponsored agency securities	523,241	1,743	(1,383)	523,601
U.S. government-sponsored agency MBS	654,251	3,317	(2,034)	655,534
Non-U.S. government, agency and Supranational securities	176,846	484	(448)	176,882
Corporate debt global (100% AAA/Aaa rated)	37,437	15	(184)	37,268
Marketable equity securities	407	105		512
Total available-for-sale marketable securities	\$ 1,894,294	\$ 5,908	\$ (5,622)	\$ 1,894,580

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, includes 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, 2010 and December 31, 2009.



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

Duration periods of available-for-sale debt securities were as follows at September 30, 2010:

	Amortized Cost	Fair Value
Duration of one year or less	\$ 239,910	\$ 240,198
Duration of one through three years	415,054	419,704
Duration of three through five years	34,460	35,057
Duration of over five years	3,128	3,000
Total	\$ 692,552	\$ 697,959

**9. Inventory**

A summary of inventories by major category at September 30, 2010 and December 31, 2009 follows:

	September 30, 2010	December 31, 2009
Raw materials	\$ 19,031	\$ 26,345
Work in process	59,817	41,282
Finished goods	29,824	33,056
Total	\$ 108,672	\$ 100,683

**10. Investment in Affiliated Companies**

A summary of the Company's equity investment in affiliated companies follows:

	September 30, 2010	December 31, 2009
Investment in Affiliated Companies		
Investment in affiliated companies <sup>(1)</sup>	\$ 20,837	\$ 18,810
Excess of investment over share of equity <sup>(2)</sup>	1,803	2,666
Investment in affiliated companies	\$ 22,640	\$ 21,476

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2010	2009	2010	2009
Equity in Losses of Affiliated Companies				
Affiliated companies losses <sup>(1)</sup>	\$ 1,384	\$ 329	\$ 746	\$ 944

<sup>(1)</sup> The Company records its interest and

share of losses  
based on its  
ownership  
percentage.

- (2) Consists of  
goodwill.

Additional equity method investments totaling \$2.0 million, net of investment returns, were made during the nine-month period ended September 30, 2010.

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Intangible Assets and Goodwill**

**Intangible Assets:** The Company's intangible assets consist of developed product rights from the Pharmion Corporation, or Pharmion, and Gloucester acquisitions, IPR&D product rights from the Gloucester acquisition, contract-based licenses, technology and other. The amortization periods related to these intangibles primarily range from two to ten years. The following summary of intangible assets by category includes intangibles currently being amortized and intangibles not yet subject to amortization:

September 30, 2010	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
Amortizable intangible assets:				
Acquired developed product rights	\$ 727,000	\$ (320,829)	\$ 406,171	5.6
License	4,250	(1,459)	2,791	13.8
Technology and other	3,116	(1,579)	1,537	4.0
	734,366	(323,867)	410,499	5.6
Nonamortized intangible assets:				
Acquired IPR&D product rights	349,000		349,000	
<b>Total intangible assets</b>	<b>\$ 1,083,366</b>	<b>\$ (323,867)</b>	<b>\$ 759,499</b>	
December 31, 2009	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Weighted Average Life (Years)
Amortizable intangible assets:				
Acquired developed product rights	\$ 530,000	\$ (185,733)	\$ 344,267	6.5
License	4,250	(1,229)	3,021	13.8
Technology and other	3,098	(844)	2,254	4.4
<b>Total intangible assets</b>	<b>\$ 537,348</b>	<b>\$ (187,806)</b>	<b>\$ 349,542</b>	<b>6.5</b>

The increase in gross carrying value of intangibles at September 30, 2010 compared to December 31, 2009 was primarily due to the acquisition of Gloucester, which resulted in a \$546.0 million increase in developed and IPR&D product rights.

Amortization of intangible assets was \$46.8 million and \$21.6 million for the three-month periods ended September 30, 2010 and 2009, respectively. Amortization expense for the three-month period ended September 30, 2010 included \$23.9 million of expense associated with an acceleration of amortization in 2010 for the VIDAZA<sup>®</sup> intangible, which reflects an updated forecast related to VIDAZA<sup>®</sup>, \$6.6 million from the amortization related to the intangible assets acquired in the Gloucester acquisition, partially offset by a reduction of \$5.1 million associated with certain acquired developed product rights becoming fully amortized in late 2009. Amortization for the nine-month periods ended September 30, 2010 and 2009 was \$136.0 million and \$68.1 million, respectively. Amortization expense for the nine-month period ended September 30, 2010 included \$71.8 million of expense associated with an

acceleration of amortization in 2010 for the VIDAZA<sup>®</sup> intangible, \$15.3 million due to the initiation of amortization related to the Gloucester intangibles, partially offset by a reduction of \$19.4 million associated with certain acquired developed product rights becoming fully amortized during 2009. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for the next five years is estimated to be approximately \$182.9 million for 2010, \$197.3 million for 2011, \$51.9 million for each of 2012 and 2013 and \$51.7 million for 2014.

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

**Goodwill:** At September 30, 2010, the Company's goodwill related to the January 2010 acquisition of Gloucester, the March 2008 acquisition of Pharmion and the October 2004 acquisition of Penn T Limited.

The change in carrying value of goodwill is summarized as follows:

Balance at December 31, 2009	\$ 578,116
Acquisition of Gloucester	186,907
Tax benefit on the exercise of Pharmion converted stock options	(612)
Reclassify excess restructuring liability from the acquisition of Pharmion	(822)
Balance at September 30, 2010	\$ 763,589

**12. Share-Based Compensation**

The following table summarizes the components of share-based compensation expense in the consolidated statements of operations for the three- and nine-month periods ended September 30, 2010 and 2009:

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2010	2009	2010	2009
Cost of good sold	\$ 1,788	\$ 1,331	\$ 4,909	\$ 3,304
Research and development	21,220	15,178	60,373	44,841
Selling, general and administrative	24,160	20,167	66,276	56,384
Total share-based compensation expense	\$ 47,168	\$ 36,676	\$ 131,558	\$ 104,529

Share-based compensation cost included in inventory was \$2.4 million at September 30, 2010 and \$1.9 million at December 31, 2009.

**Stock Options:** The weighted-average grant date fair value of the stock options granted during the three-month periods ended September 30, 2010 and 2009 was \$18.16 per share and \$18.35 per share, respectively. The weighted-average grant date fair value of the stock options issued during the nine-month periods ended September 30, 2010 and 2009 was \$18.91 per share and \$19.98 per share, respectively. There have been no significant changes to the assumptions used to estimate the fair value of options granted during the nine-month period ended September 30, 2010 compared to those granted for the year ended December 31, 2009 disclosed in Note 15 to the Consolidated Financial Statements included in the Company's 2009 Annual Report on Form 10-K.

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

Stock option transactions for the nine-month period ended September 30, 2010 under all plans are as follows:

	Options	Weighted Average Exercise Price  Per Option	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic  Value
Outstanding at December 31, 2009	37,450,036	\$ 44.63	7.0	\$ 516,856
Changes during the period:				
Granted	6,842,390	56.79		
Exercised	(2,400,534)	26.48		
Forfeited	(1,055,695)	56.09		
Expired	(985,393)	48.12		
Outstanding at September 30, 2010	39,850,804	\$ 47.42	6.8	\$ 489,321
Vested at September 30, 2010 or expected to vest in the future	39,155,242	\$ 47.29	6.7	\$ 486,364
Vested at September 30, 2010	20,278,274	\$ 39.40	5.1	\$ 406,675

The total fair value of shares vested during the nine-month periods ended September 30, 2010 and 2009 were \$26.9 million and \$21.9 million, respectively. The total intrinsic value of stock options exercised during the nine-month periods ended September 30, 2010 and 2009 was \$75.7 million and \$108.2 million, respectively. The Company primarily utilizes newly issued shares to satisfy the exercise of stock options.

As of September 30, 2010, there was \$305.4 million of unrecognized compensation expense related to the Company's stock option plan. These costs will be recognized over an expected remaining weighted-average period of 2.3 years.

**Restricted Stock Units:** Equity awards may, at the option of employee participants, be divided between stock options and restricted stock units, or RSUs. The employee has three choices: (1) 100% stock options; (2) a mix of stock options and RSUs based on a two-thirds and one-third mix, using a three-to-one ratio of stock options to RSUs in calculating the number of RSUs to be granted; or (3) a mix of stock options and RSUs based on a fifty-fifty mix, using a three-to-one ratio of stock options to RSUs in calculating the number of RSUs to be granted. The fair value of RSUs is determined based on the closing price of the Company's common stock on the grant dates. Information regarding the Company's RSUs during the nine-month period ended September 30, 2010 is as follows:

	Share Equivalent	Weighted Average Grant Date Fair Value
Nonvested RSUs		
Nonvested at December 31, 2009	502,440	\$ 40.41
Changes during the period:		
Granted	948,802	60.51
Vested	(6,165)	44.94
Forfeited	(44,842)	46.49



Nonvested at September 30, 2010	1,400,235	\$	53.67
---------------------------------	-----------	----	-------

A total of 6,165 RSUs vested during the nine-month period ended September 30, 2010. The Company expects to primarily utilize newly issued shares to satisfy the vesting of RSUs.

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

As of September 30, 2010, there was \$59.0 million of total unrecognized compensation cost related to non-vested awards of RSUs. That cost is expected to be recognized over a weighted-average period of 2.3 years. The Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award, as adjusted for expected forfeitures.

**13. Income Taxes**

The Company regularly evaluates the likelihood of the realization of its deferred tax assets and reduces the carrying amount of those deferred tax assets by a valuation allowance to the extent it believes a portion will not be realized. The Company considers many factors when assessing the likelihood of future realization of its deferred tax assets, including recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, the carryforward periods available to it for tax reporting purposes and other relevant factors. Significant judgment is required in making this assessment.

The Company's U.S. federal income tax returns have been audited by the Internal Revenue Service, or the IRS, through the year ended December 31, 2005. Tax returns for the years ended December 31, 2006, 2007, and 2008 are currently under examination by the IRS. The Company is 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 the Company has operations.

The Company regularly evaluates its tax positions and the associated interest and potential 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. The Company believes that its 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. The Company applies a variety of methodologies in making these estimates and assumptions which include studies performed by independent economists, advice from industry and subject matter experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as the Company's 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, the Company's 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. The Company accounts for interest and potential penalties related to uncertain tax positions as part of its provision for income taxes. During the second quarter of 2010, the Company effectively settled a tax examination. This settlement resulted in a net tax benefit of \$12.5 million, which was primarily due to a decrease in the liability for unrecognized tax benefits related to tax positions taken in prior years of \$29.3 million, offset by a decrease in deferred tax and other assets of \$15.9 million and an increase in additional paid-in-capital of \$0.9 million. The Company believes that it is reasonably possible that unrecognized tax benefits, as of September 30, 2010, could decrease by approximately \$4.8 million over the next 12 months related to the settlement of routine examinations or through the expiration of the statute of limitations. Increases to the amount of unrecognized tax benefits from January 1, 2010 of approximately \$63.4 million relate primarily to current year operations. The liability for unrecognized tax benefits is expected to increase in the next 12 months relating to operations occurring in that period.



**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****14. Collaboration Agreements**

**Novartis Pharma AG:** The Company entered into an agreement with Novartis in which the Company granted to Novartis an exclusive worldwide license (excluding Canada) to develop and market FOCALIN® (d-methylphenidate, or d-MPH) and FOCALIN XR®, the long-acting drug formulation for attention deficit disorder, or ADD, and attention deficit hyperactivity disorder, or ADHD. The Company also granted Novartis rights to all of its related intellectual property and patents, including formulations of the currently marketed RITALIN LA®. Under the agreement, the Company is entitled to receive up to \$100.0 million in upfront and regulatory achievement milestone payments. To date, the Company has received upfront and regulatory achievement milestone payments totaling \$55.0 million. The Company also sells FOCALIN® to Novartis and currently receives royalties of between 35% and 30% on sales of all of Novartis FOCALIN XR® and RITALIN® family of ADHD-related products.

The agreement will continue until the later of (i) the tenth anniversary of the first commercial launch on a country-by-country basis or (ii) when the last applicable patent expires with respect to that country. At the expiration date, the Company shall grant Novartis a perpetual, non-exclusive, royalty-free license to make, have made, use, import and sell d-MPH and Ritalin® under its technology.

Prior to its expiration as described above, the agreement may be terminated by:

- (i) Novartis at their sole discretion, effective 12 months after written notice to the Company, or
- (ii) by:
  - a. either party if the other party materially breaches any of its material obligations under the agreement,
  - b. the Company if Novartis fails to pay amounts due under the agreement two or more times in a 12-month period,
  - c. either party, on a product-by-product and country-by-country basis, in the event of withdrawal of the d-MPH product or Ritalin® product from the market because of regulatory mandate,
  - d. either party if the other party files for bankruptcy.

If the agreement is terminated by the Company then all licenses granted to Novartis under the agreement will terminate and Novartis will also grant the Company a non-exclusive license to certain of their intellectual property related to the compounds and products.

If the agreement is terminated by Novartis then all licenses granted to Novartis under the agreement will terminate.

If the agreement is terminated by Novartis because of a material breach by the Company, then Novartis can make a claim for damages against the Company and the Company shall grant Novartis a perpetual, non-exclusive, royalty-free license to make, have made, use, import and sell d-MPH and Ritalin® under the Company's technology.

When generic versions of long-acting methylphenidate hydrochloride and dexmethylphenidate hydrochloride enter the market, the Company expects Novartis' sales of Ritalin LA® and Focalin XR® products to decrease and therefore its royalties under this agreement to also decrease.

**Array BioPharma Inc.:** The Company has a research collaboration agreement with Array BioPharma Inc., or Array, focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. As part of this agreement, the Company made an upfront payment in September 2007 to Array of \$40.0 million, which was recorded as research and development expense, in return for an option to receive exclusive worldwide rights for compounds developed against two of the four research targets defined in the agreement, except for Array's limited U.S. co-promotional rights. In June 2009, the Company made an additional upfront payment of \$4.5 million to expand the research targets defined in the agreement, which was recorded as research and development expense. Array will be responsible for all discovery and clinical development through Phase I or Phase IIa and be entitled to receive, for each compound, potential milestone payments of approximately \$200.0 million if certain discovery, development and regulatory milestones are achieved, and \$300.0 million if certain commercial milestones are achieved as well as

royalties on net sales.

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

The Company's option will terminate upon the earlier of either a termination of the agreement, the date the Company has exercised its options for compounds developed against two of the four research targets defined in the agreement, or September 21, 2012, unless the term is extended. The Company may unilaterally extend the option term for two additional one-year terms until September 21, 2014 and the parties may mutually extend the term for two additional one-year terms until September 21, 2016. Upon exercise of a Company option, the agreement will continue until the Company has satisfied all royalty payment obligations to Array. Upon the expiration of the agreement, Array will grant the Company a fully paid-up, royalty-free license to use certain intellectual property of Array to market and sell the compounds and products developed under the agreement. The agreement may expire on a product-by-product and country-by-country basis as the Company satisfies its royalty payment obligation with respect to each product in each country.

Prior to its expiration as described above, the agreement may be terminated by:

- (i) the Company at its sole discretion, or
- (ii) either party if the other party:
  - a. materially breaches any of its material obligations under the agreement, or
  - b. files for bankruptcy.

If the agreement is terminated by the Company at its sole discretion or by Array for a material breach by the Company, then the Company's rights to the compounds and products developed under the agreement will revert to Array. If the agreement is terminated by Array for a material breach by the Company, then the Company will also grant to Array a non-exclusive, royalty-free license to certain intellectual property controlled by the Company necessary to continue the development of such compounds and products. If the agreement is terminated by the Company for a material breach by Array, then, among other things, the Company's payment obligations under the agreement could be either reduced by 50% or terminated entirely.

***PTC Therapeutics, Inc.:*** In September 2007, the Company invested \$20.0 million, of which \$1.1 million represented research and development expense, in Series F-2 Convertible Preferred Stock of PTC Therapeutics, Inc., or PTC, and, in December 2009, the Company invested an additional \$1.5 million in Series G Convertible Preferred Stock of PTC. In September 2007, the Company also entered into a separate research and option agreement whereby PTC would perform discovery research activities. Under the agreement, both parties could subsequently agree to advance research on certain discovery targets and enter into a separate pre-negotiated collaboration and license agreement which would replace the original research and option agreement.

On July 16, 2009, the Company and PTC agreed to advance research on one discovery target and entered into a pre-negotiated collaboration and license agreement under which PTC was eligible to receive quarterly research fees, as defined in the agreement, and was entitled to receive potential milestone payments of approximately \$129.0 million if certain development, regulatory and sales-based milestones were achieved. The agreement also entitled PTC to receive tiered royalties on worldwide net sales. Under the agreement, the Company may transfer certain research and development activities from PTC to the Company and upon such transfer the Company will no longer fund such quarterly research fees to PTC.

The pre-negotiated collaboration and license agreement was terminated in August 2010 by the mutual agreement of the Company and PTC in accordance with the termination provisions in the agreement, ending the obligation of the Company to make payments under the agreement beyond any quarterly research fees already incurred.

The Company continues to hold investments in Series F-2 Convertible Preferred Stock and Series G Convertible Preferred Stock of PTC.

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

**Acceleron Pharma:** The Company has a worldwide strategic collaboration with Acceleron Pharma, or Acceleron, for the joint development and commercialization of ACE-011, currently being studied for treatment of chemotherapy-induced anemia, metastatic bone disease and renal anemia. The collaboration combines both companies resources and commitment to developing products for the treatment of cancer and cancer-related bone loss. The agreement also includes an option for certain discovery stage programs. Under the terms of the agreement, the Company and Acceleron will jointly develop, manufacture and commercialize Acceleron's products for bone loss. The Company made an upfront payment to Acceleron in February 2008 of \$50.0 million, which included a \$5.0 million equity investment in Acceleron, with the remainder recorded as research and development expense. In addition, in the event of an initial public offering of Acceleron, the Company will purchase a minimum of \$7.0 million of Acceleron common stock.

Acceleron will retain responsibility for initial activities, including research and development, through the end of Phase IIa clinical trials, as well as manufacturing the clinical supplies for these studies. In turn, the Company will conduct the Phase IIb and Phase III clinical studies and will oversee the manufacture of Phase III and commercial supplies. Acceleron will pay a share of the development expenses and is eligible to receive development, regulatory approval and sales-based milestones of up to \$510.0 million for the ACE-011 program and up to an additional \$437.0 million for each of the three discovery stage programs. The companies will co-promote the products in North America. Acceleron will receive tiered royalties on worldwide net sales.

The agreement will continue until the Company has satisfied all royalty payment obligations to Acceleron and the Company has either exercised or forfeited all of its options under the agreement. Upon the Company's full satisfaction of its royalty payment obligations to Acceleron under the agreement, all licenses granted to the Company by Acceleron under the agreement will become fully paid-up, perpetual, non-exclusive, irrevocable and royalty-free licenses. The agreement may expire on a product-by-product and country-by-country basis as the Company satisfies its royalty payment obligation with respect to each product in each country.

Prior to its expiration as described above, the agreement may be terminated by:

- (i) the Company at its sole discretion, or
- (ii) either party if the other party:
  - a. materially breaches any of its material obligations under the agreement, or
  - b. files for bankruptcy.

If the agreement is terminated by the Company at its sole discretion or by Acceleron for a material breach by the Company, then all licenses granted to the Company under the agreement will terminate and the Company will also grant to Acceleron a non-exclusive license to certain intellectual property of the Company related to the compounds and products. If the agreement is terminated by the Company for a material breach by Acceleron, then, among other things, (A) the licenses granted to Acceleron under the agreement will terminate, (B) the licenses granted to the Company will continue in perpetuity, (C) all future royalties payable by the Company under the agreement will be reduced by 50% and (D) the Company's obligation to make any future milestone payments will terminate.

**Cabrellis Pharmaceuticals Corp.:** The Company, as a result of its acquisition of Pharmion, obtained an exclusive license to develop and commercialize amrubicin in North America and Europe pursuant to a license agreement with Dainippon Sumitomo Pharma Co. Ltd, or DSP. Pursuant to Pharmion's acquisition of Cabrellis Pharmaceuticals Corp., or Cabrellis, prior to the Company's acquisition of Pharmion, the Company will pay \$12.5 million for each approval of amrubicin in an initial indication by regulatory authorities in the United States and the E.U. to the former shareholders of Cabrellis. Upon approval of amrubicin for a second indication in the United States or the E.U., the Company will pay an additional \$10.0 million for each market to the former shareholders of Cabrellis. Under the terms of the license agreement for amrubicin, the Company is required to make milestone payments of \$7.0 million and \$1.0 million to DSP upon regulatory approval of amrubicin in the United States and upon receipt of the first approval in the E.U., respectively, and up to \$17.5 million upon achieving certain annual sales levels in the United States. Pursuant to the

supply agreement for amrubicin, the Company is to pay DSP a semiannual supply price calculated as a percentage of net sales for a period of ten years. In September 2008, amrubicin was granted fast-track product designation by the FDA for the treatment of small cell lung cancer after first-line chemotherapy.



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

The amrubicin license expires on a country-by-country basis and on a product-by-product basis upon the later of (i) the tenth anniversary of the first commercial sale of the applicable product in a given country after the issuance of marketing authorization in such country and (ii) the first day of the first quarter for which the total number of generic product units sold in a given country exceeds 20% of the total number of generic product units sold plus licensed product units sold in the relevant country during the same calendar quarter.

Prior to its expiration as described above, the amrubicin license may be terminated by:

- (i) the Company at its sole discretion,
- (ii) either party if the other party:
  - a. materially breaches any of its material obligations under the agreement, or
  - b. files for bankruptcy,
- (iii) DSP if the Company takes any action to challenge the title or validity of the patents owned by DSP, or
- (iv) DSP in the event of a change in control of the Company.

If the agreement is terminated by the Company at its sole discretion or by DSP under circumstances described in clauses (ii)(a) and (iii) above, then the Company will transfer its rights to the compounds and products developed under the agreement to DSP and will also grant to DSP a non-exclusive, perpetual, royalty-free license to certain intellectual property controlled by the Company necessary to continue the development of such compounds and products. If the agreement is terminated by the Company for a material breach by DSP, then, among other things, DSP will grant to the Company an exclusive, perpetual, paid-up license to all of the intellectual property of DSP necessary to continue the development, marketing and selling of the compounds and products subject to the agreement.

**GlobeImmune, Inc.:** In September 2007, the Company made a \$3.0 million equity investment in GlobeImmune, Inc., or GlobeImmune. In April 2009 and May 2009, the Company made additional \$0.1 million and \$10.0 million equity investments, respectively, in GlobeImmune. In addition, the Company has a collaboration and option agreement with GlobeImmune focused on the discovery, development and commercialization of novel therapeutics in cancer. As part of this agreement, the Company made an upfront payment in May 2009 of \$30.0 million, which was recorded as research and development expense, to GlobeImmune in return for the option to license compounds and products based on the GI-4000, GI-6200, GI-3000 and GI-10000 oncology drug candidate programs as well as oncology compounds and products resulting from future programs controlled by GlobeImmune. GlobeImmune will be responsible for all discovery and clinical development until the Company exercises its option with respect to a drug candidate program and GlobeImmune will be entitled to receive potential milestone payments of approximately \$230.0 million for the GI-4000 program, \$145.0 million for each of the GI-6200, GI-3000 and GI-10000 programs and \$161.0 million for each additional future program if certain development, regulatory and sales-based milestones are achieved. GlobeImmune will also receive tiered royalties on worldwide net sales.

The Company's options with respect to the GI-4000, GI-6200, GI-3000 and GI-10000 oncology drug candidate programs will terminate if the Company does not exercise its respective options after delivery of certain reports from GlobeImmune on the completed clinical trials with respect to each drug candidate program, as set forth in the initial development plan specified in the agreement. If the Company does not exercise its options with respect to any drug candidate program or future program, the Company's option with respect to the oncology products resulting from future programs controlled by GlobeImmune will terminate three years after the last of the options with respect to the GI-4000, GI-6200, GI-3000 and GI-10000 oncology drug candidate programs terminates. Upon exercise of a Company option, the agreement will continue until the Company has satisfied all royalty payment obligations to GlobeImmune. Upon the expiration of the agreement, on a product-by-product, country-by-country basis, GlobeImmune will grant the Company an exclusive, fully paid-up, royalty-free, perpetual license to use certain intellectual property of GlobeImmune to market and sell the compounds and products developed under the agreement. The agreement may expire on a product-by-product and country-by-country basis as the Company satisfies its royalty

payment obligation with respect to each product in each country.

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**

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

Prior to its expiration as described above, the agreement may be terminated by:

- (i) the Company at its sole discretion, or
- (ii) either party if the other party:
  - a. materially breaches any of its material obligations under the agreement, or
  - b. files for bankruptcy.

If the agreement is terminated by the Company at its sole discretion or by GlobeImmune for a material breach by the Company, then the Company's rights to the compounds and products developed under the agreement will revert to GlobeImmune. If the agreement is terminated by the Company for a material breach by GlobeImmune, then, among other things, the Company's royalty payment obligations under the agreement will be reduced by 50%, the Company's development milestone payment obligations under the agreement will be reduced by 50% or terminated entirely and the Company's sales milestone payment obligations under the agreement will be terminated entirely.

**Agios Pharmaceuticals, Inc.:** On April 14, 2010, the Company entered into a discovery and development collaboration and license agreement with Agios Pharmaceuticals, Inc., or Agios, which focuses on cancer metabolism targets and the discovery, development and commercialization of associated therapeutics. As part of the agreement, the Company paid Agios a \$121.2 million non-refundable, upfront payment, which was expensed by the Company as research and development in the second quarter of 2010. The Company also made an \$8.8 million equity investment in Agios Series B Convertible Preferred Stock, representing approximately a 10.94% ownership interest in Agios and is included in other non-current assets in the Company's Consolidated Balance Sheet. The Company receives an initial period of exclusivity during which it has the option to develop any drugs resulting from the Agios cancer metabolism research platform and may extend this exclusivity period by providing Agios additional funding. The Company has an exclusive option to license any resulting clinical candidates developed during this period and will lead and fund global development and commercialization of certain licensed programs. With respect to each product in a program that the Company chooses to license, Agios could receive up to \$120.0 million upon achievement of certain milestones plus royalties on sales, and Agios may also participate in the development and commercialization of certain products in the United States. Agios may also receive a one-time milestone payment of \$25.0 million upon dosing of the final human subject in a Phase II study, such payment to be made only once with respect to only one program.

Unless the agreement is earlier terminated or the option term is extended, the Company's option will terminate on April 14, 2013. However, if certain development targets are not met, the Company may unilaterally extend the option term: (a) for up to an additional one year without payment; (b) subject to certain criteria and upon payment of certain predetermined amounts to Agios, for up to two additional years thereafter.

Following expiration of the option, the agreement will continue in place with respect to programs to which the Company has exercised its option or otherwise is granted rights to develop. The agreement may expire on a product-by-product and country-by-country basis as the Company satisfies its payment obligation with respect to each product in each country. Upon the expiration of the agreement with respect to a product in a country, all licenses granted by one party to the other party for such product in such country shall become fully paid-up, perpetual, sub licensable, irrevocable and royalty-free.

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**

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

Prior to its expiration as described above, the agreement may be terminated by:

- (i) the Company at its sole discretion after October 14, 2010, or
- (ii) either party if the other party:
  - a. materially breaches the agreement and fails to cure such breach within the specified period, or
  - b. files for bankruptcy.

The party terminating under (i) or (ii)(a) above has the right to terminate on a program-by-program basis leaving the agreement in effect with respect to remaining programs. If the agreement or any program is terminated by the Company for convenience or by Agios for a material breach or bankruptcy by the Company, then, among other things, depending on the type of program and territorial rights: (a) certain licenses granted by the Company to Agios shall stay in place, subject to Agios' payment of certain royalties to the Company; and (b) Celgene will grant Agios a non-exclusive, perpetual, royalty-free license to certain technology developed in the conduct of the collaboration and used in the program (which license is exclusive with respect to certain limited collaboration technology). If the agreement or any program is terminated by the Company for a material breach or bankruptcy by Agios, then, among other things, all licenses granted by Celgene to Agios will terminate and: (i) Celgene's license from Agios will continue in perpetuity and all payment obligations will be reduced or will terminate; (ii) Celgene's license for certain programs will become exclusive worldwide; and (iii) with regard to any program where the Company has exercised buy-in rights, Agios shall continue to pay certain royalties to Celgene.

The Company has determined that Agios is a variable interest entity; however, the Company is not the primary beneficiary of Agios. Although the Company would have the right to receive the benefits from the collaboration and license agreement and it is probable that this agreement incorporates the activities that most significantly impact the economic performance of Agios for up to six years, the Company does not have the power to direct the activities under the collaboration and license agreement as Agios has the decision-making authority for the Joint Steering Committee and Joint Research Committee until the Company exercises its option to license a product. The Company's interest in Agios is limited to its 10.94% equity ownership and it does not have any obligations or rights to the future losses or returns of Agios beyond this ownership. The collaboration agreement, including the upfront payment and series B convertible preferred stock investment, does not entitle the Company to participate in future returns beyond the 10.94% ownership and it does not obligate the Company to absorb future losses beyond the \$8.8 million investment in Agios Series B Convertible Preferred Stock. In addition, there are no other agreements other than the collaboration agreement that entitle the Company to receive returns beyond the 10.94% ownership or obligate the Company to absorb additional losses.

**15. Commitments and Contingencies**

**Collaboration Arrangements:** The Company has 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. The Company's 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 the Company's accompanying Consolidated Balance Sheets at September 30, 2010 or December 31, 2009.

**Contingencies:** The Company believes it maintains insurance coverage adequate for its current needs. The Company's 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. The Company reviews the effects of such laws and regulations on its operations and modifies its operations as appropriate. The Company believes it is in substantial compliance with all applicable environmental laws and regulations.



**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. Subsequent Events****Acquisition of Abraxis BioScience, Inc.**

On October 15, 2010, or the acquisition date, Celgene acquired all of the outstanding common stock of Abraxis BioScience, Inc., or Abraxis, resulting in Abraxis becoming a wholly owned subsidiary of the Company. The transaction, referred to as the Merger, will be accounted for in accordance with the acquisition method of accounting for business combinations described in ASC 805. Under the acquisition method of accounting for business combinations, the assets and liabilities of Abraxis will be recorded at their respective fair values on the acquisition date and consolidated with those of the Company.

Prior to the Merger, Abraxis was a fully integrated global biotechnology company dedicated to the discovery, development and delivery of next-generation therapeutics and core technologies that offer patients treatments for cancer and other critical illnesses. Abraxis' portfolio includes an oncology compound, ABRAXANE<sup>®</sup>, which is based on Abraxis' proprietary tumor targeting platform known as nab<sup>®</sup> technology. ABRAXANE<sup>®</sup>, the first FDA approved product to use the nab<sup>®</sup> technology, was launched in 2005 for the treatment of metastatic breast cancer and is now approved in over 40 countries. Abraxis has continued to expand the nab<sup>®</sup> technology through a clinical program and a product pipeline containing a number of nab<sup>®</sup> technology products in development.

Each share of Abraxis common stock outstanding, other than treasury shares of Abraxis, was cancelled and the holder received (i) \$58.00 in cash, (ii) 0.2617 of a share of Celgene common stock and (iii) one contingent value right, or CVR, issued by the Company. As discussed further in the section entitled "Contingent Value Rights" below, a holder of a CVR is entitled to receive a pro rata portion of cash payments that the Company is obligated to pay to all holders of CVRs, which is determined by achievement of certain net sales and U.S. regulatory approval milestones. A total of approximately \$2.480 billion in cash was paid and 10,660,196 shares of Celgene common stock and 43,273,855 CVRs were issued as consideration for the Merger.

Due to the limitations on access to Abraxis information prior to the acquisition date and the limited time since the acquisition date, the initial accounting for the business combination is incomplete at this time. As a result, the Company is unable to provide contingent consideration disclosures and the amounts recognized as of the acquisition date for the major classes of assets acquired and liabilities assumed, including the information required for accounts receivable, inventory, pre-acquisition contingencies, intangible assets and goodwill. Because the initial accounting for the business combination is incomplete at this time, the Company is also unable to provide the pro forma revenues and earnings of the combined entity. This information will be included in the Company's 2010 Annual Report on Form 10-K.

Through September 30, 2010, the Company has expensed \$3.5 million of costs relating to legal, financial and accounting advisory services performed in connection with the proposed Merger with Abraxis, which are included in acquisition related charges in the accompanying Statement of Consolidated Operations.

**Contingent Value Rights**

In connection with the Merger on October 15, 2010, CVRs were issued under a CVR agreement entered into by Celgene and American Stock Transfer & Trust Company, LLC, the trustee. A copy of the CVR agreement was filed on Form 8-A with the SEC on October 15, 2010.

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**

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

Each holder of a CVR is entitled to receive a *pro rata* portion, based on the number of CVRs then outstanding, of each of the following contingent cash payments:

*Milestone Payment #1.* \$250 million upon FDA approval of ABRAXANE® for use in the treatment of non-small cell lung cancer, which approval permits Celgene to market ABRAXANE® under a label that includes a progression free survival claim, but only if the foregoing milestone is achieved no later than the fifth anniversary of the Merger.

*Milestone Payment #2.* \$400 million (if achieved no later than April 1, 2013) or \$300 million (if achieved after April 1, 2013 and before the fifth anniversary of the Merger) upon FDA approval of ABRAXANE® for use in the treatment of pancreatic cancer, which approval permits Celgene to market ABRAXANE® under a label that includes an overall survival claim.

*Net Sales Payments.* For each full one-year period ending December 31st during the term of the CVR agreement, which we refer to as a net sales measuring period (with the first net sales measuring period beginning January 1, 2011 and ending December 31, 2011):

2.5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$1 billion but are less than or equal to \$2 billion for such period, plus

an additional amount equal to 5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$2 billion but are less than or equal to \$3 billion for such period, plus

an additional amount equal to 10% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$3 billion for such period.

No payments will be due under the CVR agreement with respect to net sales of ABRAXANE® and the Abraxis pipeline products achieved after December 31, 2025, which we refer to as the net sales payment termination date, unless net sales for the net sales measuring period ending on December 31, 2025 are equal to or greater than \$1 billion, in which case the net sales payment termination date will be extended until the last day of the net sales measuring period subsequent to December 31, 2025 during which net sales of ABRAXANE® and the Abraxis pipeline products are less than \$1 billion or, if earlier, December 31, 2030.

Celgene may, at any time on and after the date that 50% of the CVRs issued pursuant to the terms of the merger agreement either are no longer outstanding, and/or repurchased, acquired, redeemed or retired by Celgene, redeem all, but not less than all, of the outstanding CVRs at a cash redemption price equal to the average price per CVR paid for all CVRs by Celgene in prior transactions.

The CVRs are unsecured obligations of Celgene, subordinated to an unlimited amount of Celgene's senior obligations.

**Table of Contents**

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

**Debt Issuance**

On October 7, 2010, the Company issued a total of \$1.25 billion principal amount of senior notes consisting of \$500 million aggregate principal amount of 2.45% Senior Notes due 2015 (the 2015 notes ), \$500 million aggregate principal amount of 3.95% Senior Notes due 2020 (the 2020 notes ) and \$250 million aggregate principal amount of 5.7% Senior Notes due 2040 (the 2040 notes and, together with the 2015 notes and the 2020 notes, referred to herein as the notes ). Interest on the notes is payable semi-annually in arrears on April 15 and October 15 each year beginning April 15, 2011. The notes may be redeemed at the option of the Company, 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 a change of control of the Company occurs 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. The notes will be the Company's senior unsecured obligations and will rank equally with any of its future senior unsecured indebtedness.



**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Forward-Looking Information**

Certain statements contained or incorporated by reference in this Quarterly Report on Form 10-Q are forward-looking statements concerning our business, results of operations, economic performance and financial condition based on our current expectations. These forward-looking statements are not guarantees of future performance and involve risks and uncertainties that could cause actual results to differ materially from those implied by such forward-looking statements. Given these risks and uncertainties, you are cautioned not to place undue reliance on any forward-looking statements.

**Executive Summary**

Celgene Corporation and its subsidiaries (collectively we, our or us) is a global integrated biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases.

Our primary commercial stage products include REVLIMID<sup>®</sup>, THALOMID<sup>®</sup> (inclusive of Thalidomide Celgene<sup>®</sup> and Thalidomide Pharmion<sup>®</sup>) and VIDAZA<sup>®</sup>. REVLIMID<sup>®</sup> is an oral immunomodulatory drug marketed in the United States and select international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy and 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. In June 2010, Japan's Ministry of Health, Labor and Welfare granted REVLIMID<sup>®</sup> full marketing authorization for use in combination with dexamethasone as a treatment for patients with relapsed or refractory multiple myeloma who have received at least one prior standard therapy and in August 2010, for treatment of patients with MDS associated with a deletion of 5Q cytogenetic abnormality. THALOMID<sup>®</sup> 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. VIDAZA<sup>®</sup>, which is licensed from Pfizer, is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA<sup>®</sup> is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS according to the National Comprehensive Cancer Network, or NCCN and is marketed in the United States for the treatment of all subtypes of MDS. VIDAZA<sup>®</sup> has been granted orphan drug designation for the treatment of MDS through May 2011. In Europe, VIDAZA<sup>®</sup> is marketed for the treatment of certain qualified adult patients and has been granted orphan drug designation for the treatment of MDS and acute myeloid leukemia, or AML, expiring December 2018.

Other commercial stage products include ISTODAX<sup>®</sup> and FOCALIN<sup>®</sup>. ISTODAX<sup>®</sup> (romidepsin) was obtained in the acquisition of Gloucester Pharmaceuticals, Inc., or Gloucester, and is marketed 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, ISTODAX<sup>®</sup> has received both orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, which includes CTCL and peripheral T-cell lymphoma, or PTCL, and fast-track status in PTCL from the U.S. Food and Drug Administration, or FDA. The European Agency for the Evaluation of Medicinal Products, or EMA, has granted orphan status designation for ISTODAX<sup>®</sup> for the treatment of both CTCL and PTCL. FOCALIN<sup>®</sup> is approved for the treatment of attention deficit hyperactivity disorder, or ADHD, and is sold exclusively to Novartis Pharma AG, or Novartis.

Additional sources of revenue include a licensing agreement with Novartis, which entitles us to royalties on FOCALIN XR<sup>®</sup> and the entire RITALIN<sup>®</sup> family of drugs, residual payments from GlaxoSmithKline, or GSK, based upon GSK's ALKERAN<sup>®</sup> revenues through the end of March 2011, sale of services through our Cellular Therapeutics subsidiary and other miscellaneous licensing agreements.

**Table of Contents**

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 our IMiDs<sup>®</sup> compounds, which are a class of compounds proprietary to us and having certain immunomodulatory and other biologically important properties, in addition to our leading oral anti-inflammatory agents and cell products. 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 both new products and expanded use of existing products provide the catalysts for future growth. See also Risk Factors contained in Part II, Item 1A of this Quarterly Report on Form 10-Q. The following table summarizes total revenue and earnings for the three- and nine-month periods ended September 30, 2010 and 2009:

<i>(Amounts in thousands, except earnings per share)</i>	Three-Month Periods Ended			Percent Change
	September 30,			
	2010	2009	Increase	
Total revenue	\$ 910,111	\$ 695,137	\$ 214,974	30.9%
Net income	\$ 281,151	\$ 216,815	\$ 64,336	29.7%
Diluted earnings per share	\$ 0.60	\$ 0.46	\$ 0.14	30.4%

<i>(Amounts in thousands, except earnings per share)</i>	Nine-Month Periods Ended			Percent Change
	September 30,			
	2010	2009	Increase	
Total revenue	\$ 2,554,057	\$ 1,928,856	\$ 625,201	32.4%
Net income	\$ 670,945	\$ 522,532	\$ 148,413	28.4%
Diluted earnings per share	\$ 1.44	\$ 1.12	\$ 0.32	28.6%

The increase in revenue for the three- and nine-month periods ended September 30, 2010 compared to the three- and nine-month periods ended September 30, 2009 was primarily due to continued growth of REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup> in both U.S. and international markets. Net income and diluted earnings per share for the three- and nine-month periods ended September 30, 2010 reflect the continued growth in sales, partly offset by increased spending for new product launches, research and development activities and expansion of our international operations. Net income for the nine-month period ended September 30, 2010 includes an \$86.7 million increase in upfront payments related to research and development collaboration arrangements compared to the nine-month period ended September 30, 2009.

*Acquisition of Abraxis BioScience, Inc.:* On October 15, 2010, or the acquisition date, we acquired all of the outstanding common stock of Abraxis BioScience, Inc., or Abraxis, resulting in Abraxis becoming our wholly owned subsidiary. The transaction, referred to as the Merger, will be accounted for under the acquisition method of accounting for business combinations, ASC 805, Business Combinations, or ASC 805. Under the acquisition method of accounting for business combinations, the assets and liabilities of Abraxis will be recorded at their respective fair values on the acquisition date and consolidated with ours. For the year ended December 31, 2009, Abraxis reported total revenues of \$359.1 million and total assets of \$1.068 billion.

Prior to the Merger, Abraxis was a fully integrated global biotechnology company dedicated to the discovery, development and delivery of next-generation therapeutics and core technologies that offer patients treatments for cancer and other critical illnesses. Abraxis' portfolio includes an oncology compound (ABRAXANE<sup>®</sup>), which is based on Abraxis' proprietary tumor targeting technology known as the nab<sup>®</sup> platform. ABRAXANE<sup>®</sup>, the first FDA approved product to use the nab<sup>®</sup> platform, was launched in 2005 for the treatment of metastatic breast cancer and is now approved in over 40 countries. Abraxis has continued to expand the nab<sup>®</sup> platform through a clinical program and a product pipeline containing a number of products in development.

**Table of Contents**

Each share of Abraxis common stock outstanding, other than treasury shares of Abraxis, was cancelled and the holder received (i) \$58.00 in cash, (ii) 0.2617 of a share of Celgene Common Stock and (iii) one contingent value right, or CVR, issued by us. A holder of a CVR is entitled to receive a *pro rata* portion of cash payments that we are obligated to pay to all holders of CVRs, which is determined by achievement of certain net sales and U.S. regulatory approval milestones. A total of approximately \$2.480 billion in cash was paid and 10,660,196 shares of Celgene common stock and 43,273,855 CVRs were issued as consideration for the Merger.

The initial accounting for the business combination is incomplete at this time we are unable to provide the *pro forma* revenues and earnings of the combined entity. This information will be included in our Annual Report on Form 10-K for the year ending December 31, 2010 ( 2010 Annual Report on Form 10-K ).

*Debt Issuance:* On October 7, 2010, we issued a total of \$1.25 billion principal amount of senior notes consisting of \$500 million aggregate principal amount of 2.45% Senior Notes due 2015 (referred to as the 2015 notes), \$500 million aggregate principal amount of 3.95% Senior Notes due 2020 (referred to as the 2020 notes) and \$250 million aggregate principal amount of 5.7% Senior Notes due 2040 (referred to as the 2040 notes) and, together with the 2015 notes and the 2020 notes, referred to as the notes). Interest on the notes is payable semi-annually in arrears on April 15 and October 15 each year beginning April 15, 2011. 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 incur a change of control, 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.

We intend to use the net proceeds of the notes for general corporate purposes, which may include, without limitation, further development of our clinical and pre-clinical programs, expansion of our international operations, capital expenditures, strategic transactions and to meet working capital needs.

**Table of Contents****Results of Operations:****Three-Month Periods Ended September 30, 2010 and 2009**

*Total Revenue:* Total revenue and related percentages for the three-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i>	Three-Month Periods Ended		Increase (Decrease)	Percent Change
	2010	September 30, 2009		
Net product sales:				
REVLIMID®	\$ 641,272	\$ 449,586	\$ 191,686	42.6%
VIDAZA®	141,422	103,096	38,326	37.2%
THALOMID®	94,179	110,019	(15,840)	-14.4%
Other	8,783	5,266	3,517	66.8%
Total net product sales	\$ 885,656	\$ 667,967	\$ 217,689	32.6%
Collaborative agreements and other revenue	2,241	2,381	(140)	-5.9%
Royalty revenue	22,214	24,789	(2,575)	-10.4%
Total revenue	\$ 910,111	\$ 695,137	\$ 214,974	30.9%

REVLIMID® net sales increased by \$191.7 million to \$641.3 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to increased unit sales in both U.S. and international markets. Increased market penetration and the increase in treatment duration of patients using REVLIMID® in multiple myeloma contributed to U.S. growth. The growth in international markets reflects the expansion of our commercial activities in over 65 countries in addition to product reimbursement approvals.

VIDAZA® net sales increased by \$38.3 million to \$141.4 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to increased sales in international markets resulting from the completion of product launches in key European regions during the latter part of 2009.

THALOMID® net sales decreased by \$15.8 million to \$94.2 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009. The decrease was primarily due to lower unit volumes in the United States.

The other net product sales category for the three-month period ended September 30, 2010 includes \$5.4 million in sales of ISTODAX®, which we obtained in our acquisition of Gloucester in January 2010, in addition to sales of FOCALIN® and a certain former Pharmion product to be divested.

Total net product sales for the three-month period ended September 30, 2010 increased by \$217.7 million, or 32.6%, to \$885.7 million compared to the three-month period ended September 30, 2009. The change was comprised of net volume increases of \$210.5 million, price decreases of \$2.7 million primarily resulting from increases in Medicaid rebates and the favorable impact from foreign exchange of \$9.9 million.

*Collaborative Agreements and Other Revenue:* Revenues from collaborative agreements and other sources decreased by \$0.1 million to \$2.2 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009. Revenues for both three-month periods included the sales of services through our Cellular Therapeutics subsidiary and income from miscellaneous licensing agreements.

**Table of Contents**

*Royalty Revenue:* Royalty revenue decreased by \$2.6 million to \$22.2 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009. The decrease resulted from a reduction in residual payments earned by us based upon GSK's ALKERAN® revenues subsequent to the conclusion of the ALKERAN® license with GSK and a slight reduction in royalties earned from Novartis based upon their RITALIN® sales.

*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.

THALOMID® is distributed in the United States under our *System for Thalidomide Education and Prescribing Safety*, or S.T.E.P.S.®, program which we developed and is a proprietary 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 also 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. 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 also 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 REVLIMID®. 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® is distributed through the more traditional pharmaceutical industry supply chain. VIDAZA® is not subjected to the same risk-management distribution programs as THALOMID® and REVLIMID®.

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. THALOMID® is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product. 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 to date.

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 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. We expect that full year 2010 revenues will be negatively impacted by U.S. healthcare reform legislation by approximately \$35 million to \$40 million. The primary components of the legislation that are expected to impact our business during 2010 include an increase in the Medicaid rebate from 15.1% to 23.1% and an extension of that rebate to Medicaid Managed Care Organizations. 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.

**Table of Contents**

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 for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i> 2010	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Dist. Service Fees	Total
Balance at June 30, 2010	\$ 6,483	\$ 4,435	\$ 38,833	\$ 32,526	\$ 82,277
Allowances for sales during 2010	1,101	13,931	36,353	30,973	82,358
Credits/deductions issued for prior year sales	(894)	(2,305)	(3,880)	(4,182)	(11,261)
Credits/deductions issued for sales during 2010	(111)	(10,047)	(13,104)	(19,242)	(42,504)
Balance at September 30, 2010	\$ 6,579	\$ 6,014	\$ 58,202	\$ 40,075	\$ 110,870

<i>(Amounts in thousands)</i> 2009	Returns and Allowances	Discounts	Government Rebates	Chargebacks, and Dist. Service Fees	Total
Balance at June 30, 2009	\$ 8,589	\$ 4,162	\$ 9,401	\$ 27,035	\$ 49,187
Allowances for sales during 2009	5,421	9,897	14,513	22,904	52,735
Credits/deductions issued for prior year sales				(5)	(5)
Credits/deductions issued for sales during 2009	(6,886)	(9,680)	(8,811)	(18,621)	(43,998)
Balance at September 30, 2009	\$ 7,124	\$ 4,379	\$ 15,103	\$ 31,313	\$ 57,919

A comparison of allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2010 and 2009, respectively, follows:

Returns and allowances decreased by \$4.3 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to reduced U.S. allowances resulting from a decrease in revenue from products with higher return rates.

Discounts increased by \$4.0 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to revenue increases in the United States and expansion into new international markets, which offer discount programs.

Government rebates increased by \$21.8 million in the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to an increase in Medicaid rebate rates resulting from the Patient Protection and Affordable Care Act, or the Health Care Reform Act, enacted on March 23, 2010,

reimbursement rate increases in certain international markets and approvals in new markets.

**Table of Contents**

Chargebacks and distributor service fees increased by \$8.1 million in the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to an increase in chargebacks resulting from both an increase in sales and an increase in certain chargeback rates, which are closely aligned with Medicaid rebate rates. In addition, provisions for Tricare have increased due to increased utilization in the current year.

*Operating Costs and Expenses:* Operating costs, expenses and related percentages for the three-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i>	Three-Month Periods Ended			Percent Change
	September 30, 2010	September 30, 2009	Increase	
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 63,542	\$ 52,058	\$ 11,484	22.1%
Percent of net product sales	7.2%	7.8%		
Research and development	\$ 253,547	\$ 193,362	\$ 60,185	31.1%
Percent of total revenue	27.9%	27.8%		
Selling, general and administrative	\$ 228,281	\$ 192,512	\$ 35,769	18.6%
Percent of total revenue	25.1%	27.7%		
Amortization of acquired intangible assets	\$ 46,540	\$ 21,111	\$ 25,429	120.5%
Acquisition related charges	\$ 7,495	\$ 7,495	\$ 7,495	N/A

*Cost of Goods Sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$11.5 million to \$63.5 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to increased sales activity, including REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup>. As a percent of net product sales, cost of goods sold (excluding amortization expense) decreased to 7.2% in the 2010 three-month period from 7.8% in the 2009 three-month period, primarily due to increased sales of REVLIMID<sup>®</sup>, which more than offset the negative impact from increased sales of VIDAZA<sup>®</sup>, which carries a higher cost than our other primary products.

*Research and Development:* Research and development expenses increased by \$60.2 million to \$253.5 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to spending increases in support of multiple programs across a broad range of diseases, including expenses related to Phase III trials for REVLIMID<sup>®</sup> in treatment of patients with newly diagnosed multiple myeloma and for VIDAZA<sup>®</sup> in treatment of elderly patients with newly diagnosed acute myeloid leukemia and higher spending related to collaborative agreements.



**Table of Contents**

The following table provides a breakdown of research and development expenses:

<i>(Amounts in thousands)</i>	Three-Month Periods Ended		Increase
	2010	September 30, 2009	
Human pharmaceutical clinical programs	\$ 124,288	\$ 100,497	\$ 23,791
Other pharmaceutical programs (1)	93,211	66,810	26,401
Drug discovery and development	30,534	22,535	7,999
Placental stem cell	5,514	3,520	1,994
Total	\$ 253,547	\$ 193,362	\$ 60,185

(1) Other pharmaceutical programs include spending for toxicology, analytical research and development, quality, regulatory affairs and upfront payments for research and development collaboration arrangements.

Research and development expenditures support multiple ongoing clinical proprietary development programs for REVLIMID<sup>®</sup> and other IMiDs<sup>®</sup> compounds; VIDAZA<sup>®</sup>; amrubicin, our lead compound for small cell lung cancer; apremilast (CC-10004), our lead anti-inflammatory compound that inhibits multiple proinflammatory mediators and which is currently being evaluated in Phase III clinical trials for the treatment of psoriasis and psoriatic arthritis; pomalidomide, which is currently being evaluated in Phase I, II and III clinical trials; CC-11050, for which Phase II clinical trials are planned; our kinase inhibitor programs; as well as our cell therapy programs.

*Selling, General and Administrative:* Selling, general and administrative expenses increased by \$35.8 million to \$228.3 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, partly due to higher marketing and sales related expenses resulting from ongoing product launch activities of VIDAZA<sup>®</sup> in Europe and ISTODAX<sup>®</sup> in the United States. In addition, facilities costs have increased by \$7.0 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, reflecting an expansion of our global operations.

*Amortization of Acquired Intangible Assets:* Amortization of acquired intangible assets increased by \$25.4 million to \$46.5 million for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009, primarily due to \$23.9 million of expense associated with an acceleration of amortization beginning in 2010 related to the VIDAZA<sup>®</sup> intangible. The revised monthly amortization reflects an updated forecast related to VIDAZA<sup>®</sup>. An increase in amortization expense due to the amortization related to the Gloucester intangibles

was partially offset by a reduction in expense associated with certain acquired developed product rights becoming fully amortized during 2009.

*Acquisition Related Charges:* Acquisition related charges of \$7.5 million for the three-month period ended September 30, 2010 included a \$5.9 million accretion of the contingent consideration related to the acquisition of Gloucester in January 2010. If all milestones are achieved, the total amount to be accreted through 2015 would be \$69.8 million. Also included in acquisition related charges are \$1.6 million in costs related to the acquisition of Abraxis.

*Interest and Investment Income, Net:* Interest and investment income was \$12.8 million for the three-month period ended September 30, 2010, representing a decrease of \$7.7 million from the \$20.5 million recorded for the three-month period ended September 30, 2009. The decrease was primarily due to a \$4.8 million reduction in interest income due to lower yields on investments and a \$3.3 million net reduction in gains on sales of marketable securities for the three-month period ended September 30, 2010 compared to the three-month period ended September 30, 2009.

**Table of Contents**

*Equity in Losses of Affiliated Companies:* Under the equity method of accounting, we recorded losses of \$1.4 million and \$0.3 million for the three-month periods ended September 30, 2010 and 2009, respectively.

*Other Income, Net:* Other income, net was \$8.5 million and \$14.9 million for the three-month periods ended September 30, 2010 and 2009, respectively. The \$6.4 million decrease in other income was primarily due to a reduction in net gains on foreign currency forward contracts that were not designated as hedges entered into in order to offset net foreign exchange gains and losses.

*Income Tax Provision:* The income tax provision for the three-month period ended September 30, 2010 was \$49.0 million with an effective tax rate of 14.8%, which reflects the impact from our low tax manufacturing operations and our overall global mix of income. Tax expense included a net tax benefit of \$8 million which was primarily the result of filing our 2009 income tax returns with certain items being more favorable than originally estimated. The income tax provision for the three-month period ended September 30, 2009 was \$53.9 million with an effective tax rate of 19.9%.

**Nine-month Periods Ended September 30, 2010 and 2009**

*Total Revenue:* Total revenue and related percentages for the nine-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i>	Nine-Month Periods Ended		Increase (Decrease)	Percent Change
	2010	September 30, 2009		
Net product sales:				
REVLIMID <sup>®</sup>	\$ 1,758,881	\$ 1,209,375	\$ 549,506	45.4%
VIDAZA <sup>®</sup>	393,561	270,487	123,074	45.5%
THALOMID <sup>®</sup>	296,017	329,226	(33,209)	-10.1%
Other	19,705	33,265	(13,560)	-40.8%
Total net product sales	\$ 2,468,164	\$ 1,842,353	\$ 625,811	34.0%
Collaborative agreements and other revenue	7,165	6,979	186	2.7%
Royalty revenue	78,728	79,524	(796)	-1.0%
Total revenue	\$ 2,554,057	\$ 1,928,856	\$ 625,201	32.4%

REVLIMID<sup>®</sup> net sales increased by \$549.5 million to approximately \$1.759 billion for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to increased unit sales in both U.S. and international markets. Increased market penetration and the increase in treatment duration of patients using REVLIMID<sup>®</sup> in multiple myeloma contributed to U.S. growth. The growth in international markets reflects the expansion of our commercial activities in over 65 countries in addition to product reimbursement approvals.

VIDAZA<sup>®</sup> net sales increased by \$123.1 million to \$393.6 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to increased sales in international markets resulting from the completion of product launches in key European regions during the latter part of 2009.

THALOMID<sup>®</sup> net sales decreased by \$33.2 million to \$296.0 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009. The decrease was primarily due to lower unit volumes in the United States.

**Table of Contents**

The other net product sales category for the nine-month period ended September 30, 2010 included \$9.6 million in sales of ISTODAX<sup>®</sup>, which we obtained in our acquisition of Gloucester in January 2010, in addition to sales of FOCALIN<sup>®</sup> and former Pharmion products to be divested. The other net product sales category for the nine-month period ended September 30, 2009 included \$20.1 million in sales of ALKERAN<sup>®</sup>, which was licensed from GSK and sold under our label through March 31, 2009, the conclusion date of the ALKERAN<sup>®</sup> license with GSK, in addition to sales of FOCALIN<sup>®</sup> and former Pharmion products to be divested.

Total net product sales for the nine-month period ended September 30, 2010 increased by \$625.8 million, or 34.0%, to \$2.468 billion compared to the nine-month period ended September 30, 2009. The change was comprised of net volume increases of \$557.4 million, price increases of \$22.2 million and the favorable impact from foreign exchange of \$46.2 million.

*Collaborative Agreements and Other Revenue:* Revenues from collaborative agreements and other sources increased by \$0.2 million to \$7.2 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009. Revenues for both nine-month periods included the sales of services through our Cellular Therapeutics subsidiary and income from miscellaneous licensing agreements.

*Royalty Revenue:* Royalty revenue decreased by \$0.8 million to \$78.7 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009. A decrease in residual payments earned by us based upon GSK's ALKERAN<sup>®</sup> revenues subsequent to the conclusion of the ALKERAN<sup>®</sup> license with GSK was partly offset by a net increase in royalties earned from Novartis based upon its FOCALIN XR<sup>®</sup> and RITALIN<sup>®</sup> sales.

*Gross to Net Sales Accruals:* Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i> 2010	Returns and Allowances	Discounts	Government Rebates	Chargebacks and Dist. Service Fees	Total
Balance at December 31, 2009	\$ 7,360	\$ 3,598	\$ 18,111	\$ 29,241	\$ 58,310
Allowances for sales during 2010	6,927	36,906	79,293	83,864	206,990
Credits/deductions issued for prior year sales	(4,881)	(3,243)	(12,229)	(15,881)	(36,234)
Credits/deductions issued for sales during 2010	(2,827)	(31,247)	(26,973)	(57,149)	(118,196)
Balance at September 30, 2010	\$ 6,579	\$ 6,014	\$ 58,202	\$ 40,075	\$ 110,870

<i>(Amounts in thousands)</i> 2009	Returns and Allowances	Discounts	Government Rebates	Chargebacks, and Dist. Service Fees	Total
Balance at December 31, 2008	\$ 17,799	\$ 3,659	\$ 10,810	\$ 23,386	\$ 55,654
Allowances for sales during 2009	11,516	27,740	34,293	67,630	141,179
Credits/deductions issued for prior year sales	(13,168)	(2,306)	(11,042)	(10,340)	(36,856)
Credits/deductions issued for sales during 2009	(9,023)	(24,714)	(18,958)	(49,363)	(102,058)
Balance at September 30, 2009	\$ 7,124	\$ 4,379	\$ 15,103	\$ 31,313	\$ 57,919



**Table of Contents**

A comparison of allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2010 and 2009, respectively, follows:

Returns and allowances decreased by \$4.6 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to reduced U.S. provisions resulting from decreased revenue from products with higher return rates.

Discounts increased by \$9.2 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to revenue increases in the United States and international markets, both of which offer different discount programs and expansion into new international markets.

Government rebates increased by \$45.0 million in the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to an increase in Medicaid rebates resulting from the Health Care Reform Act, reimbursement rate increases in certain international markets and approvals in new markets.

Chargebacks and distributor service fees increased by \$16.2 million in the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to an increase in chargebacks resulting from both an increase in sales and an increase in certain chargeback rates, which are closely aligned with Medicaid rebate rates. In addition, provisions for Tricare have increased due to increased utilization in the current year and provisions for distributor service fees have increased.

*Operating Costs and Expenses:* Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i>	Nine-Month Periods Ended		Increase	Percent Change
	September 30, 2010	September 30, 2009		
Cost of goods sold (excluding amortization of acquired intangible assets)	\$ 193,450	\$ 167,259	\$ 26,191	15.7%
Percent of net product sales	7.8%	9.1%		
Research and development	\$ 800,965	\$ 593,109	\$ 207,856	35.0%
Percent of total revenue	31.4%	30.7%		
Selling, general and administrative	\$ 655,522	\$ 542,264	\$ 113,258	20.9%
Percent of total revenue	25.7%	28.1%		
Amortization of acquired intangible assets	\$ 135,201	\$ 67,403	\$ 67,798	100.6%
Acquisition related charges	\$ 20,193	\$	\$ 20,193	N/A

*Cost of Goods Sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$26.2 million to \$193.5 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009. The increase was primarily due to increased sales activity, including REVLIMID® and VIDAZA® and was partly offset by the elimination of higher cost ALKERAN® sales, resulting from the March 31, 2009 conclusion of the GSK license agreement. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 7.8% in the 2010 nine-month period from 9.1% in the 2009 nine-month period, primarily due to increased sales of low cost REVLIMID® and the lack of ALKERAN® sales in the 2010 nine-month period. Excluding ALKERAN® in the nine-month period ended September 30, 2009, the percent of net product sales would have been 8.3%.

**Table of Contents**

*Research and Development:* Research and development expenses increased by \$207.9 million to \$801.0 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to a \$121.2 million upfront payment to Agios Pharmaceuticals, Inc., or Agios, related to a research and development collaboration arrangement, representing an increase of \$86.7 million from the \$34.5 million in upfront payments made during the nine-month period ended September 30, 2009. In addition, spending increased in support of multiple programs across a broad range of diseases.

The following table provides a breakdown of research and development expenses:

<i>(Amounts in thousands)</i>	Nine-Month Periods Ended		Increase
	September 30,		
	2010	2009	
Human pharmaceutical clinical programs	\$ 326,141	\$ 285,944	\$ 40,197
Other pharmaceutical programs (1)	378,845	235,240	143,605
Drug discovery and development	80,413	62,089	18,324
Placental stem cell	15,566	9,836	5,730
Total	\$ 800,965	\$ 593,109	\$ 207,856

(1) Other pharmaceutical programs include spending for toxicology, analytical research and development, quality and regulatory affairs and upfront payments for research and development collaboration arrangements.

Research and development expenditures support ongoing clinical progress in multiple proprietary development programs for REVLIMID<sup>®</sup> and other IMiDs<sup>®</sup> compounds; VIDAZA<sup>®</sup>; amrubicin, our lead compound for small cell lung cancer; apremilast (CC-10004), our lead anti-inflammatory compound that inhibits multiple proinflammatory mediators and which is currently being evaluated in Phase III clinical trials for the treatment of psoriasis and psoriatic arthritis; pomalidomide, which is currently being evaluated in Phase I, II and III clinical trials; CC-11050, for which Phase II clinical trials are planned; our kinase inhibitor programs; as well as our cell therapy programs.

*Selling, General and Administrative:* Selling, general and administrative expenses increased by \$113.3 million to \$655.5 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, partly due to a \$26.8 million increase in donations to non-profit foundations. The remaining increase includes higher marketing and sales related expenses, resulting from ongoing product launch activities of VIDAZA<sup>®</sup> in Europe and ISTODAX<sup>®</sup> in the United States, in addition to the continued expansion of our international

commercial activities and an increase in facilities costs.

*Amortization of Acquired Intangible Assets:* Amortization of acquired intangible assets increased by \$67.8 million to \$135.2 million for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009, primarily due to \$71.8 million of expense associated with an acceleration of amortization beginning in 2010 related to the VIDAZA<sup>®</sup> intangible. The revised monthly amortization reflects an updated forecast related to VIDAZA<sup>®</sup>. An increase in amortization expense due to the initiation of amortization related to the Gloucester intangibles was more than offset by a reduction in expense associated with certain acquired developed product rights becoming fully amortized during 2009.

*Acquisition Related Charges:* Acquisition related charges of \$20.2 million in 2010 included \$16.7 million for accretion of the contingent consideration related to the acquisition of Gloucester in January 2010 and \$3.5 million in costs related to the acquisition of Abraxis.

*Interest and Investment Income, Net:* Interest and investment income was \$37.0 million for the nine-month period ended September 30, 2010, representing a decrease of \$25.0 million from the \$62.0 million recorded for the nine-month period ended September 30, 2009. The decrease was primarily due to a \$9.5 million reduction in interest income due to lower yields on investments and a \$14.6 million net reduction in gains on sales of marketable securities for the nine-month period ended September 30, 2010 compared to the nine-month period ended September 30, 2009.



**Table of Contents**

*Equity in Losses of Affiliated Companies:* Under the equity method of accounting, we recorded losses of \$0.7 million and \$0.9 million for the nine-month periods ended September 30, 2010 and 2009, respectively.

*Other Income, Net:* Other income, net was \$7.1 million and \$52.7 million for the nine-month periods ended September 30, 2010 and 2009, respectively. The \$45.6 million decrease in other income was due to a reduction in net gains on foreign currency forward contracts that have not been designated as hedges entered into in order to offset net foreign exchange gains and losses.

*Income Tax Provision:* The income tax provision for the nine-month period ended September 30, 2010 was \$119.9 million with an effective tax rate of 15.2%, which reflects the impact from our low tax manufacturing operations and our overall global mix of income. Tax expense included the favorable impact of a shift in projected earnings between U.S. and lower foreign tax jurisdictions. Tax expense also included a net tax benefit of \$12.5 million related to the settlement of a tax examination in the second quarter of 2010 and a net tax benefit of \$8 million, which was primarily the result of filing our 2009 income tax returns with certain items being more favorable than originally estimated in the third quarter of 2010. The income tax provision for the nine-month period ended September 30, 2009 was \$148.6 million with an effective tax rate of 22.1%. Tax expense in 2009 included a net tax benefit of \$5.3 million related to the settlement of tax examinations.

**Liquidity and Capital Resources**

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2010 and 2009 were as follows:

<i>(Amounts in thousands)</i>	Nine-Month Periods Ended		Change
	2010	September 30, 2009	
Net cash provided by operating activities	\$ 976,711	\$ 589,294	\$ 387,417
Net cash provided by (used in) investing activities	\$ 797,167	\$ (530,568)	\$ 1,327,735
Net cash used in financing activities	\$ (40,322)	\$ (15,028)	\$ (25,294)

*Operating Activities:* Net cash provided by operating activities for the nine-month period ended September 30, 2010 increased by \$387.4 million to \$976.7 million as compared to the nine-month period ended September 30, 2009. The increase in net cash provided by operating activities was primarily attributable to an expansion of our operations and related increase in net earnings, partially offset by the upfront payment to Agios, increase in accounts receivable associated with expanding international sales and the timing of receipts and payments in the ordinary course of business.

*Investing Activities:* Net cash provided by investing activities for the nine-month period ended September 30, 2010 increased by \$1.328 billion to \$797.2 million as compared to a net cash use for the nine-month period ended September 30, 2009. The 2010 investing activities are principally related to proceeds from the sales of marketable securities that were sold in preparation for the purchase of Abraxis and net cash used in the acquisition of Gloucester of \$337.6 million. Net sales of marketable securities available for sale amounted to \$1.210 billion in the nine-month period ended September 30, 2010 compared to net purchases of \$459.2 million in the nine-month period ended September 30, 2009.

*Financing Activities:* Net cash used in financing activities for the nine-month periods ended September 30, 2010 and 2009 was \$40.3 million and \$15.0 million, respectively. The \$25.3 million increase in net cash used in financing activities for the nine-month period ended September 30, 2010 was primarily attributable to a reduction in excess tax benefits from share-based compensation arrangements partly offset by a decrease in the amount of cash used for treasury stock purchases and an increase in net proceeds from exercise of common stock and warrants.

**Table of Contents**

*Cash, Cash Equivalents, Marketable Securities Available for Sale and Working Capital:* Cash, cash equivalents, marketable securities available for sale and working capital as of September 30, 2010 and December 31, 2009 were as follows:

<i>(Amounts in thousands)</i>	September 30, 2010	December 31, 2009	Increase
Cash, cash equivalents and marketable securities available for sale	\$ 3,530,265	\$ 2,996,752	\$ 533,513
Working capital (1)	\$ 3,733,421	\$ 3,302,109	\$ 431,312

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

*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 increase in cash, cash equivalents and marketable securities available for sale at September 30, 2010 compared to December 31, 2009 was primarily due to increased cash generated from operations, partly offset by the \$337.6 million cash payment made for the Gloucester acquisition, \$121.2 million upfront payment made to Agios related to a research and development collaboration arrangement and \$104.0 million cash paid out under our share repurchase program announced in April 2009.

*Accounts Receivable, Net:* Accounts receivable, net increased by \$154.5 million to \$593.1 million as of September 30, 2010 compared to December 31, 2009, primarily due to increased U.S. and international sales of REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup> among existing customers as well as new customers in countries we have recently entered. Days of sales outstanding at September 30, 2010 increased to 63 days compared to 56 days at December 31, 2009. The increase in days of sales outstanding was primarily due to increased international sales in countries where payment terms are typically greater than 60 days, thereby extending collection periods beyond those in the U.S. We expect this trend to continue as our international sales continue to expand.

*Inventory:* Inventory balances increased by \$8.0 million to \$108.7 million as of September 30, 2010 compared to December 31, 2009. The increase was primarily related to an increase in Thalomid inventory.

*Other Current Assets:* Other current assets decreased by \$18.3 million to \$240.7 million as of September 30, 2010 compared to December 31, 2009 due to decreases in prepaid royalties related to Vidaza sales and interest receivable on short-term investments, which were partly offset by an increase in the fair value of foreign currency forward contracts.

*Accounts Payable, Accrued Expenses and Other Current Liabilities:* Accounts payable, accrued expenses and other current liabilities increased by \$283.4 million to \$729.4 million as of September 30, 2010 compared to December 31, 2009. The increase was primarily due to the current portion of the contingent consideration related to the acquisition of Gloucester and increases in governmental rebates and Medicaid reimbursements.

**Table of Contents**

*Income Taxes Payable (Current and Non-Current)*: Income taxes payable increased by \$20.2 million to \$489.4 million as of September 30, 2010 compared to December 31, 2009 primarily from the current provision for income taxes of \$149.2 million, mostly offset by tax payments of \$115.3 million and tax benefit of stock options of \$12.4 million.

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, including proceeds from our October 2010 debt issuance and marketable securities available for sale combined with cash generated from future net product sales, will provide sufficient capital resources to fund our normal operations for the foreseeable future. The net \$2.48 billion cash payment related to our October 2010 acquisition of Abraxis was funded through existing cash balances. The \$1.24 billion in net proceeds from our debt issuance in October 2010 will provide additional liquidity to support our future operations.

**Financial Condition**

At September 30, 2010, 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 mortgage-backed securities, or MBS, includes 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, 2010, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. 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 and forward currency 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. Our Level 3 asset securities at September 30, 2010 consist of warrants for the purchase of equity securities in a non-publicly traded company in which we have invested and which is party to a collaboration and option agreement with us. Our Level 3 liabilities consist of a contingent consideration related to undeveloped product rights resulting from the Gloucester acquisition.

A majority of our financial assets and liabilities have been classified as Level 2. These assets and liabilities were initially valued at the transaction price and subsequently valued based on inputs utilizing observable quoted prices for similar assets and liabilities in active markets and observable quoted prices from identical or similar assets in markets that are not very active.



**Table of Contents**

**Contractual Obligations**

For a discussion of our contractual obligations, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, in our 2009 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2009 except for a pre-negotiated collaboration and licensing agreement entered into on April 14, 2010 with Agios, and the termination of a collaboration and license agreement with PTC Therapeutics, Inc., both of which are disclosed in Note 14 of the Notes to the Consolidated Financial Statements contained in this report. Potential milestone payments total approximately \$3.8 billion, including approximately \$2.3 billion contingent on the achievement of various research, development and regulatory approval milestones and approximately \$1.5 billion in sales-based milestones.

**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 2009 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 2009 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, 2009.

**Table of Contents****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, 2010, our market risk sensitive instruments consisted of marketable securities available for sale, our note payable and certain foreign currency forward contracts.

*Marketable Securities Available for Sale:* At September 30, 2010, 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 include 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, 2010, 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:

	Duration				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	
<i>(Amounts in thousands)</i>					
Principal amount	\$ 234,944	\$ 408,013	\$ 33,312	\$ 3,000	\$ 679,269
Fair value	\$ 240,198	\$ 419,704	\$ 35,057	\$ 3,000	\$ 697,959
Average interest rate	0.8%	0.8%	1.7%	3.0%	0.9%

*Note Payable:* In December 2006, we purchased an active pharmaceutical ingredient, or API, manufacturing facility and certain other assets and liabilities from Siegfried Ltd. and Siegfried Dienste AG (together referred to herein as Siegfried). At September 30, 2010, the fair value of our note payable to Siegfried approximated the carrying value of the note of \$23.4 million. Assuming other factors are held constant, an increase in interest rates generally will result in a decrease in the fair value of the note. The note is denominated in Swiss francs and its fair value will also be affected by changes in the U.S. dollar / Swiss franc exchange rate. The carrying value of the note reflects the U.S. dollar / Swiss franc exchange rate and Swiss interest rates.





**Table of Contents**

*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, 2010 and December 31, 2009 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges under ASC 815 and, accordingly, 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, net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows:

Foreign Currency	Notional Amount	
	September 30, 2010	December 31, 2009
British Pound	\$ 58,440	\$
Canadian Dollar	96,410	
Euro	886,381	1,107,340
Japanese Yen	526,232	
Swiss Franc	71,015	
Others less than \$50 million	35,821	
Total	\$ 1,674,299	\$ 1,107,340

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. As of September 30, 2010 and December 31, 2009, credit risk did not materially change the fair value of our foreign currency forward contracts.

We recognized an increase in net product sales for certain effective cash flow hedge instruments of \$20.6 million and \$41.7 million for the three- and nine-month periods ended September 30, 2010, respectively, and a reduction of \$11.9 million and \$18.5 million for the three- and nine-month periods ended September 30, 2009, respectively. These settlements were recorded in the same period as the related forecasted sales occurred. We recognized an immaterial increase in research and development expenses for the settlement of certain effective cash flow hedge instruments for the three- and nine-month periods ended September 30, 2010. We recognized an increase in research and development expenses for the settlement of certain effective cash flow hedge instruments of \$0.5 million for the three-month period ended September 30, 2009 and a decrease in research and development expenses for the settlement of certain effective cash flow hedge instruments of \$1.1 million for the nine-month period ended September 30, 2009. These settlements were recorded in the same period as the related forecasted research and development expenses occurred. Changes in time value, which we excluded from the hedge effectiveness assessment, were included in other income, net.

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 under ASC 815 and, accordingly, any changes in their fair value are recognized in other income, net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2010 and December 31, 2009 were \$554.0 million and \$483.2 million, respectively.



**Table of Contents**

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, 2010 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$233.5 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or remeasured through earnings each period along with the underlying asset or liability.

**Item 4. Controls and Procedures**

- (a) 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.

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****PART II OTHER INFORMATION****Item 1. Legal Proceedings**

Our legal proceedings are described in Part I, Item 3, Legal Proceedings, of our 2009 Annual Report on Form 10-K and in Part II, Item 1, of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010. All legal proceedings in the above-mentioned reports have been either dismissed or settled. In addition we have engaged in the following legal proceedings:

**REVLIMID®**

We have publicly announced that we have received a notice letter dated August 30, 2010, sent from Natco Pharma Limited of India ( Natco ) notifying us of a Paragraph IV certification alleging that patents listed for REVLIMID® in the Orange Book are invalid, and/or not infringed (the Notice Letter). The 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 capsules of REVLIMID®. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification ) challenging the validity or infringement of a patent listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book ) four years after the pioneer company obtains approval of its New Drug Application, or an NDA. On October 8, 2010, Celgene filed an infringement action in the United States District Court of New Jersey against Natco in response to the Notice Letter with respect to United States Patent Nos. 5,635,517 (the 517 patent ), 6,045,501 (the 501 patent ), 6,281,230 (the 230 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 ). If Natco is successful in challenging our patents listed in the Orange Book, and the FDA were to approve the 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 lenalidomide product, consequently reducing our revenue.

**ELAN PHARMA INTERNATIONAL LIMITED**

On July 19, 2006, Elan Pharmaceutical International Ltd. filed a lawsuit against the predecessor entity of Abraxis ( Old Abraxis ) in the U.S. District Court for the District of Delaware alleging that Old Abraxis willfully infringed two of its patents by making, using and selling the ABRAXANE® brand drug. Elan sought unspecified damages and an injunction. In response, Old Abraxis contended that it did not infringe the Elan patents and that the Elan patents are invalid and unenforceable. Before trial, Elan dropped its claim that Old Abraxis infringed one of the two asserted patents. Elan also dropped its request for an injunction as to the remaining patent. On June 13, 2008, after a trial with respect to the remaining patent, a jury ruled that Old Abraxis had infringed that patent, that Abraxis' infringement was not willful, and that the patent was valid and enforceable. The jury awarded Elan \$55.2 million in damages for sales of ABRAXANE® through the judgment date. The patent expires on January 25, 2011. Abraxis filed various post-trial motions and is seeking to overturn the jury verdict. Elan filed post-trial motions seeking, among other things, pre-judgment interest and post-verdict royalties. On October 26, 2010, Elan filed a motion with the court seeking to modify certain aspects of the claim construction of the other patent, which runs until 2016, that Elan contends relates to the administration of ABRAXANE® brand drug. This motion is pending. Celgene intends to vigorously pursue all legal options available.

**Table of Contents**

**ABRAXIS SHAREHOLDER LAWSUIT**

Abraxis, the members of the Abraxis board of directors and the Celgene Corporation are named as defendants in putative class action lawsuits brought by Abraxis stockholders challenging the Merger in Los Angeles County Superior Court. The plaintiffs in such actions assert claims for breaches of fiduciary duty arising out of the Merger and allege that Abraxis directors engaged in self-dealing and obtained for themselves personal benefits and failed to provide stockholders with material information relating to the Merger. The plaintiffs also allege claims for aiding and abetting breaches of fiduciary duty against us and Abraxis.

On September 14, 2010, the parties reached an agreement in principle to settle the actions pursuant to the Memorandum of Understanding, or the MOU. Without admitting the validity of any allegations made in the actions, or any liability with respect thereto, the defendants elected to settle the actions in order to avoid the cost, disruption and distraction of further litigation. Under the MOU, the defendants agreed, among other things, to make additional disclosures relating to the Merger, and to provide the plaintiffs counsel with limited discovery to confirm the fairness and adequacy of the settlement. Abraxis, on behalf of itself and for the benefit of the other defendants in the actions, also agreed to pay the plaintiffs counsel \$600,000 for their fees and expenses. The parties agreed to use their best efforts to agree upon, execute and present to the court a formal stipulation of settlement and such other documents as may be necessary to obtain approval by the court of the settlement and the dismissal with prejudice of the actions. The parties intend to present the stipulation in advance of a preliminary approval hearing currently scheduled for November 8, 2010. Pending execution of such stipulation, the parties agreed to stay all proceedings in the actions, except those relating to the settlement.

**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, our results and operations.

**Table of Contents**

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

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

- demand or lack of demand for our products, including demand that adversely affects our ability to optimize the use of our manufacturing facilities;
- the introduction and pricing of products competitive with ours, including generic competition;
- developments regarding the safety or efficacy of our products;
- regulatory approvals for our products and pricing determinations with respect to our products;
- regulatory approvals for our and our competitor's 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;

**Table of Contents**

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<sup>®</sup>, VIDAZA<sup>®</sup>, THALOMID<sup>®</sup> and ABRAXANE<sup>®</sup> 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<sup>®</sup>, VIDAZA<sup>®</sup>, THALOMID<sup>®</sup>, and ABRAXANE<sup>®</sup>. 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 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<sup>®</sup> 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<sup>®</sup> is also considered fetal toxic and there are warnings against use of VIDAZA<sup>®</sup> in pregnant women as well. While we have restricted distribution systems for both THALOMID<sup>®</sup> and REVLIMID<sup>®</sup> 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 as well as our other products including ISTODAX<sup>®</sup>, FOCALIN XR<sup>®</sup> and the RITALIN<sup>®</sup> family of drugs. 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.

**Table of Contents**

***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.<sup>®</sup> and RevAssist<sup>®</sup> programs), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and regulations, including, without limitation, the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, Medicare Modernization Act, Food and Drug Administration Amendments Act, 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, or EC, the Swissmedic, the Australian Therapeutic Goods Administration and Health Canada. Certain of our pharmaceutical products, such as FOCALIN<sup>®</sup>, 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<sup>®</sup>, that are subject to accelerated approval can be subject to an expedited withdrawal if the post-marketing study commitments are not completed with due diligence, 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.

**Table of Contents**

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 U.S. 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. The FDA recently announced that as of October 21, 2011, a BLA will be required to distribute cord blood for unrelated allogeneic use. 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 revenues.

***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 newly enacted Health Care Reform Act has provided sweeping health care reform, which may impact the prices of drugs. In addition to the newly enacted 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 Health Care Reform Act, 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 the price and usage of 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 the amount that we are able to charge for our current and future products, which could adversely affect our revenue and results of operations.

**Table of Contents*****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. Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions including those related to our risk evaluation and mitigation strategies (such as our S.T.E.P.S.<sup>®</sup> and RevAssist<sup>®</sup> programs).

Furthermore, 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 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 and to implicate drug products with even relatively modest revenues. 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.

We have received a Paragraph IV Certification Letter dated August 30, 2010, advising us that Natco Pharma Limited of Hyderabad, India, or Natco, submitted an ANDA to the FDA. See Item 1, Legal Proceedings Revisited of this report for further discussion.

**Table of Contents**

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.

***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, compete with REVLIMID<sup>®</sup> and THALOMID<sup>®</sup> in the treatment of multiple myeloma and in clinical trials with our compounds;

Eisai Co., Ltd., SuperGen, Inc. and Johnson & Johnson compete or may potentially compete with VIDAZA<sup>®</sup>;

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. and Genzyme Corporation, both of which are generally developing drugs that address the oncology and immunology markets;

Bristol Myers Squibb Co., which potentially competes in clinical trials with our compounds and TNF-inhibitors;

F. Hoffman-La Roche Ltd., which potentially competes in clinical trials with our IMiDs<sup>®</sup> compounds and TNF- inhibitors;

Johnson & Johnson, which potentially competes with certain of our proprietary programs, including our oral anti-inflammatory programs;

Novartis, which potentially competes with our compounds and kinase programs; and

Pfizer, which potentially competes in clinical trials with our kinase inhibitors.

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.

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

From time to time, we may be subject to governmental investigation or litigation on a variety of matters, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, 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.

**Table of Contents**

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 inquiry and demand from the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID<sup>®</sup> and THALOMID<sup>®</sup> brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. We continue to cooperate with the FTC's request for information.

Litigation and governmental investigations are inherently unpredictable and may:

- result in rulings that are materially unfavorable to us, including a requirement that we pay significant damages, fines or penalties or prevent us from operating our business in a certain manner;

- 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 I, Item 3 of our 2009 Annual Report on Form 10-K and Part II, Item 1 of this Quarterly Report on Form 10-Q.

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

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

**Table of Contents**

The stem cell products that we are developing through our 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 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 API, encapsulation, finishing services packaging and distribution services to meet our needs. These risks include the possibility that our or our suppliers' manufacturing processes 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.

**Table of Contents**

We have contracted with specialty distributors, to distribute REVLIMID<sup>®</sup>, THALOMID<sup>®</sup>, VIDAZA<sup>®</sup> and ISTODAX<sup>®</sup> in the United States. 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 control a significant share of the market. We expect that consolidation of drug wholesalers 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 Abraxis and other acquired businesses may present significant challenges to us.***

We may face significant challenges in effectively integrating entities and businesses that we acquire, such as Abraxis, and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquisition of Abraxis will depend in part upon whether we can integrate our businesses in an efficient and effective manner. Our integration of Abraxis 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 cost savings;

difficulties in the assimilation and retention of employees;



**Table of Contents**

difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and

difficulties in the integration of departments, systems, including accounting systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, 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 Abraxis we may experience material negative consequences to our business, financial condition or results of operations. Successful integration of Abraxis 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 with Abraxis.

***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.

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 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.

**Table of Contents**

***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 to manage foreign currency risk, but not to engage in currency speculation. We use these forward contracts to hedge certain forecasted transactions and balance sheet exposures denominated in foreign currencies. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements in foreign exchange rates. The use of these derivative instruments mitigates the exposure of these risks with the intent to reduce our risk or cost but may not fully offset any change in operating results that result from fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations.

***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 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 the current 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 increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales, revenue and cash flows.

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.

**Table of Contents**

***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 disruptions that could cause volatility in its price. In general, current global economic conditions have caused substantial market volatility and instability. Any such disruptions or continuing volatility may adversely affect the value of our common stock. In addition to current global economic instability in general, 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, including the current global economic and market instability. The global market and economic climate may continue to deteriorate because of many factors beyond our control, including continued economic instability and market volatility, sovereign debt issues, rising interest rates or inflation, terrorism or political uncertainty. In the event of a continued or future market downturn in general and/or the biotechnology sector in particular, the market price of our common stock may be adversely affected.

***In addition to the risks relating to our common stock, CVR holders are subject to additional risks.***

As described elsewhere in this report, in connection with the Merger, on October 15, 2010, CVRs were issued under a CVR agreement entered into by Celgene and American Stock Transfer & Trust Company, LLC, the 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, each of the following cash payments that we are obligated to pay. See Note 16, Subsequent Events, Acquisition of Abraxis.

**Table of Contents**

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 there has not been any public market for the CVRs, the market price and trading volume of the CVRs may be volatile;
- if the 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 indebtedness of ours;
- we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations to use diligent efforts to achieve each of the CVR milestones and to sell 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.

***Our business could be adversely affected if we are unable to service our obligations under our recently incurred indebtedness.***

On October 7, 2010, we issued a total of \$1.25 billion principal amount of senior notes, consisting of the 2015 notes, the 2020 notes and the 2040 notes, collectively referred to as the notes. Our ability to pay interest on the notes, to repay the principal amount of the notes when due at maturity or to repurchase the 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 the notes, we may be forced to take actions such as:

- restructuring or refinancing our debt, including the notes;
- seeking additional debt or equity capital;
- reducing or delaying our business activities, acquisitions, investments or capital expenditures; or
- selling assets.

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

**Table of Contents**

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

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, 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.

**Table of Contents**

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

(c) Issuer Purchases of Equity Securities

On April 24, 2009, the Board of Directors approved a common stock share repurchase program which was publicly announced by us on April 27, 2009. The program authorized the purchase of up to \$500.0 million (or approximately 12.5 million shares at the approval date) of our outstanding common stock in the open market or through privately negotiated transactions, directly or through brokers or agents, and will expire April 2011. No shares were purchased under the repurchase program during the three-month period ended September 30, 2010. Approximately \$186.5 million remains authorized under the program for future share purchases.

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 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Item 5. Other Information**

None.

**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, 2010, formatted in XBRL (Extensible Business Reporting Language):
  - (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.

**Table of Contents**

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: November 2, 2010

By: /s/ Jacquelyn A. Fouse  
Jacquelyn A. Fouse  
Senior Vice President and  
Chief Financial Officer

DATE: November 2, 2010

By: /s/ Andre Van Hoek  
Andre Van Hoek  
Corporate Controller and  
Chief Accounting Officer