

CELGENE CORP /DE/  
Form 10-Q  
May 03, 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 March 31, 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 0-16132**  
**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

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

At April 23, 2010, 460,862,551 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 Periods Ended March 31, 2010 and 2009 1

Consolidated Balance Sheets -  
As of March 31, 2010 and December 31, 2009 2

Consolidated Statements of Cash Flows -  
Three-Month Periods Ended March 31, 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 27

Item 3 Quantitative and Qualitative Disclosures About Market Risk 37

Item 4 Controls and Procedures 39

**PART II OTHER INFORMATION**

Item 1 Legal Proceedings 40

Item 1A Risk Factors 40

Item 2 Unregistered Sales of Equity Securities and Use of Proceeds 53

Item 3 Defaults Upon Senior Securities 53

Item 4 Submission of Matters to a Vote of Security Holders 53

Item 5 Other Information 53

Item 6 Exhibits 54

Signatures 55

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

---

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

|   | <b>Three-Month Periods Ended<br/>March 31,</b> |             |
|---|--|-------------|
|   | <b>2010</b>                                    | <b>2009</b> |
| Revenue:  |  |             |
| Net product sales   | \$ 759,411                                     | \$ 576,232  |
| Collaborative agreements and other revenue                                | 2,380  | 2,244       |
| Royalty revenue   | 29,463   | 26,577      |
| Total revenue   | 791,254  | 605,053     |
| Expenses:   |  |             |
| Cost of goods sold (excluding amortization of acquired intangible assets) | 61,915   | 64,299      |
| Research and development  | 204,657  | 181,248     |
| Selling, general and administrative                                       | 207,978  | 173,440     |
| Amortization of acquired intangible assets                                | 41,593   | 23,625      |
| Acquisition related charges   | 4,862  |             |
| Total costs and expenses  | 521,005  | 442,612     |
| Operating income  | 270,249  | 162,441     |
| Other income and expense:   |  |             |
| Interest and investment income, net                                       | 14,084   | 17,453      |
| Equity in (gains) losses of affiliated companies                          | (741)  | 771         |
| Interest expense  | 481  | 464         |
| Other income, net   | 3,766  | 32,610      |
| Income before income taxes  | 288,359  | 211,269     |
| Income tax provision  | 53,917   | 48,386      |
| Net income  | \$ 234,442                                     | \$ 162,883  |
| Net income per common share:  |  |             |
| Basic   | \$ 0.51  | \$ 0.35     |
| Diluted   | \$ 0.50  | \$ 0.35     |

Weighted average shares:

|         |         |         |
|---------|---------|---------|
| Basic   | 459,914 | 459,583 |
| Diluted | 467,655 | 468,105 |

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>March 31,<br/>2010</b> | <b>December 31,<br/>2009</b> |
|--|---------------------------|------------------------------|
| <b>Assets</b>  |                           |                              |
| Current assets:  |                           |                              |
| Cash and cash equivalents  | \$ 1,055,546              | \$ 1,102,172                 |
| Marketable securities available for sale   | 1,898,404                 | 1,894,580                    |
| Accounts receivable, net of allowances of \$9,677 and \$10,787 at March 31, 2010 and December 31, 2009, respectively | 481,072                   | 438,617                      |
| Inventory  | 102,479                   | 100,683                      |
| Deferred income taxes  | 70,472                    | 49,817                       |
| Other current assets   | 312,066                   | 258,935                      |
| Total current assets   | 3,920,039                 | 3,844,804                    |
| Property, plant and equipment, net   | 303,729                   | 297,792                      |
| Investment in affiliated companies   | 22,767                    | 21,476                       |
| Intangible assets, net   | 853,665                   | 349,542                      |
| Goodwill   | 764,622                   | 578,116                      |
| Other assets   | 120,801                   | 297,581                      |
| Total assets   | \$ 5,985,623              | \$ 5,389,311                 |
| <b>Liabilities and Stockholders Equity</b>   |                           |                              |
| Current liabilities:   |                           |                              |
| Accounts payable   | \$ 66,697                 | \$ 36,629                    |
| Accrued expenses   | 269,776                   | 315,608                      |
| Income taxes payable   | 33,603                    | 46,874                       |
| Current portion of deferred revenue  | 2,179                     | 1,827                        |
| Other current liabilities  | 87,192                    | 93,767                       |
| Total current liabilities  | 459,447                   | 494,705                      |
| Deferred revenue, net of current portion   | 7,695                     | 6,527                        |
| Non-current income taxes payable   | 444,597                   | 422,358                      |
| Other non-current liabilities  | 309,478                   | 71,115                       |
| Total liabilities  | 1,221,217                 | 994,705                      |

**Commitments and Contingencies**



**Stockholders Equity:**

|   |              |              |
|---|--------------|--------------|
| Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none outstanding at March 31, 2010 and December 31, 2009, respectively                         |              |              |
| Common stock, \$.01 par value per share, 575,000,000 shares authorized; issued 468,958,767 and 467,629,433 shares at March 31, 2010 and December 31, 2009, respectively | 4,690        | 4,676        |
| Common stock in treasury, at cost; 8,117,466 and 8,337,961 shares at March 31, 2010 and December 31, 2009, respectively   | (352,981)    | (362,521)    |
| Additional paid-in capital  | 5,504,417    | 5,474,122    |
| Accumulated deficit   | (397,804)    | (632,246)    |
| Accumulated other comprehensive income (loss)   | 6,084        | (89,425)     |
| Total stockholders equity   | 4,764,406    | 4,394,606    |
| Total liabilities and stockholders equity   | \$ 5,985,623 | \$ 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>Three-Month Periods Ended</b> |             |
|--|----------------------------------|-------------|
|  | <b>March 31,</b>                 |             |
|  | <b>2010</b>                      | <b>2009</b> |
| Cash flows from operating activities:  |                                  |             |
| Net income   | \$ 234,442                       | \$ 162,883  |
| Adjustments to reconcile net income to net cash provided by operating activities:  |                                  |             |
| Depreciation of long-term assets   | 11,951                           | 9,521       |
| Amortization of intangible assets  | 41,875                           | 23,762      |
| Allocation of pre-paid royalties   | 12,606                           | 7,844       |
| Provision for accounts receivable allowances                                       | (1,265)                          | 1,242       |
| Deferred income taxes  | (10,136)                         | (11,681)    |
| Acquisition related charges  | 4,862                            |             |
| Share-based compensation expense   | 41,428                           | 32,421      |
| Equity in (gains) losses of affiliated companies                                   | (741)                            | 771         |
| Share-based employee benefit plan expense  | 4,344                            | 1,773       |
| Unrealized change in value of foreign currency forward contracts                   | 6,571                            | (15,485)    |
| Realized gains on marketable securities available for sale                         | (4,962)                          | (4,967)     |
| Other, net   | 954                              | 1,436       |
| Change in current assets and liabilities, excluding the effect of the acquisition: |                                  |             |
| Accounts receivable  | (54,375)                         | (30,931)    |
| Inventory  | (233)                            | (2,564)     |
| Other operating assets   | 14,716                           | (3,124)     |
| Accounts payable and other operating liabilities                                   | (29,908)                         | (18,550)    |
| Income tax payable   | 10,697                           | (27,724)    |
| Deferred revenue   | 1,824                            | 490         |
| Net cash provided by operating activities  | 284,650                          | 127,117     |
| Cash flows from investing activities:  |                                  |             |
| Proceeds from sales of marketable securities available for sale                    | 1,196,864                        | 412,606     |
| Purchases of marketable securities available for sale                              | (1,200,626)                      | (704,613)   |
| Payments for acquisition of business, net of cash acquired                         | (337,608)                        |             |
| Capital expenditures   | (18,906)                         | (20,974)    |
| Investment in affiliated companies   | (550)                            | (1,064)     |
| Purchases of investment securities   | (2,725)                          | (750)       |
| Other  |                                  | 3,333       |
| Net cash used in investing activities  | (363,551)                        | (311,462)   |

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

|   |              |            |
|---|--------------|------------|
| Cash flows from financing activities:                           |              |            |
| Net proceeds from exercise of common stock options and warrants | 31,669       | 11,860     |
| Excess tax benefit from share-based compensation arrangements   | 12,228       | 44,751     |
| Net cash provided by financing activities                       | 43,897       | 56,611     |
| Effect of currency rate changes on cash and cash equivalents    | (11,622)     | (10,947)   |
| Net decrease in cash and cash equivalents                       | (46,626)     | (138,681)  |
| Cash and cash equivalents at beginning of period                | 1,102,172    | 1,092,386  |
| Cash and cash equivalents at end of period                      | \$ 1,055,546 | \$ 953,705 |

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>Three-Month Periods Ended</b> |             |
|---|----------------------------------|-------------|
|   | <b>March 31,</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 | \$ (5,603)                       | \$ (16)     |
| Matured shares tendered in connection with stock option exercises           | \$ (163)                         | \$          |
| Supplemental disclosure of cash flow information:                           |                                  |             |
| Income taxes paid   | \$ 40,525                        | \$ 42,491   |
| 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®, THALOMID® (inclusive of Thalidomide Celgene™ and Thalidomide Pharmion™) and VIDAZA®. FOCALIN® is sold exclusively to Novartis Pharma AG, or Novartis. 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. The Company also derives revenues from 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. For the ensuing two years, the Company will continue to earn residual payments based upon GSK s ALKERAN® revenues. 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 US 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 December 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-17, Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17, which changes how a company determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a company is required to consolidate an entity is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance. This amendment requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity and will require a company to provide additional disclosures about its involvement with variable interest entities, any significant changes in risk exposure due to that involvement and how its involvement with a variable interest entity affects the company's financial statements. This amendment was effective for the Company beginning January 1, 2010 and had no impact on its financial statements. The Company will comply with its rules and expanded disclosure requirements for all applicable future collaboration agreements. In October 2009, the FASB issued 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. The ASU also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. Further, the ASU 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. The ASU is 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 is 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.

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

In February 2010, the FASB issued ASU No. 2010-10, Amendments for Certain Investment Funds, or ASU 2010-10, which amends certain provisions of Statement 167 (codified in ASC 810-10). The ASU defers the application of Statement 167 for a reporting enterprise's interest in certain entities if all of the following conditions are met: (1) The entity either has all of the attributes specified in paragraphs 15-2(a) - (d) of ASC 946-10 or is an entity for which it is industry practice to apply guidance that is consistent with the measurement principles in ASC 946 (including recognizing changes in fair value currently in the statement of operations) for financial reporting purposes, (2) The reporting enterprise does not have an explicit or implicit obligation to fund losses of the entity that could potentially be significant to the entity and (3) The entity is not a securitization entity, an asset-backed financing entity, or an entity that was formerly considered a qualifying special-purpose entity. In addition, the application of Statement 167 is deferred for a reporting enterprise's interest in an entity that is required to comply with or operate in accordance with requirements that are similar to those included in Rule 2a-7 of the Investment Company Act of 1940 for registered money market funds. The ASU is effective as of the beginning of the first annual period that begins after November 15, 2009, and for interim periods within that first annual period. The amendment was effective for the Company beginning January 1, 2010 and the adoption did not have any impact on the Company's 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 this ASU 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 this ASU will apply to milestones in both single-deliverable and multiple-deliverable arrangements involving research or development transactions. The ASU 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 this ASU will have on its consolidated financial statements.

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

On January 15, 2010, Celgene 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 are 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.

The Company paid \$338.9 million in cash and may make additional 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.

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

The preliminary 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       |

Assets 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 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 will be amortized over its economic useful life of ten years. The compassionate use right asset will be 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 have 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.

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 preliminarily 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 Sheet and will not be amortized, but is subject to review for impairment in accordance with ASC 350 Goodwill and Other Intangible Assets.

**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**

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

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 will update its assumptions each reporting period based on new developments and record 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 products fail to gain market approval to \$300.0 million if both products 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 will measure the contingent consideration arrangement at fair value each period with changes in fair value recognized in operating earnings unless changes pertain to facts and circumstances that existed as of the acquisition date, in which case changes are recognized as adjustments to goodwill. Changes in fair values will 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.

**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<br>March 31, |            |
|--|--|------------|
|  | 2010                                   | 2009       |
| Net income   | \$ 234,442                             | \$ 162,883 |
| Weighted-average shares (in thousands):                        |  |            |
| Basic  | 459,914                                | 459,583    |
| Effect of dilutive securities:                                 |  |            |
| Options, restricted stock units, warrants and other incentives | 7,741                                  | 8,522      |
| Diluted  | 467,655                                | 468,105    |
| Net income per share:  |  |            |
| Basic  | \$ 0.51                                | \$ 0.35    |
| Diluted  | \$ 0.50                                | \$ 0.35    |

The total number of potential common shares excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 18,775,142 and 17,662,587 shares for the three-month periods ended March 31, 2010 and 2009, respectively.

In April 2009, the Company's Board of Directors approved a \$500.0 million common stock share repurchase program. As of March 31, 2010, an aggregate 4,314,625 shares of common stock of the Company have been repurchased under the program at a total cost of \$209.5 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.

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

|            | Three-Month Periods Ended<br>March 31, |            |
|------------|--|------------|
|            | 2010                                   | 2009       |
| Net income | \$ 234,442                             | \$ 162,883 |

Other comprehensive income:

Marketable securities:

|  |            |            |
|--|------------|------------|
| Net unrealized gains on marketable securities available for sale, net of tax                             | 5,112      | 1,827      |
| Reclassification adjustment for gains included in net income   | (4,976)    | (4,967)    |
| Total other comprehensive gains (losses) related to marketable securities available for sale, net of tax | 136        | (3,140)    |
| Net unrealized gains related to cash flow hedges, net of tax   | 57,003     | 52,759     |
| Currency translation adjustments   | 38,370     | (46,765)   |
| Total other comprehensive income items   | 95,509     | 2,854      |
| Comprehensive income   | \$ 329,951 | \$ 165,737 |

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Financial Instruments and Fair Value Measurement**

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of March 31, 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.

|  | Balance at<br>March 31, 2010 | Quoted Price<br>in<br>Active<br>Markets for<br>Identical<br>Assets<br>(Level 1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|--|------------------------------|---|---|--|
| <b>Assets:</b>                               |                              |   |   |  |
| Available-for-sale securities                | \$ 1,898,404                 | \$ 380  | \$ 1,898,024  | \$   |
| Warrants                                     | 1,598                        |   |   | 1,598  |
| Cash equivalents                             | 34,320                       |   | 34,320  |  |
| Forward currency contracts                   | 58,519                       |   | 58,519  |  |
| <b>Total assets</b>                          | <b>\$ 1,992,841</b>          | <b>\$ 380</b>   | <b>\$ 1,990,863</b>                                       | <b>\$ 1,598</b>                                    |
| <b>Liabilities:</b>                          |                              |   |   |  |
| Acquisition-related contingent consideration | \$ (235,063)                 | \$  | \$  | \$ (235,063)                                       |

|  | Balance at<br>December 31,<br>2009 | Quoted Price<br>in<br>Active<br>Markets for<br>Identical<br>Assets<br>(Level 1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|--|------------------------------------|---|---|--|
|--|------------------------------------|---|---|--|

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

Assets:

|                               |    |           |    |     |    |           |    |       |
|-------------------------------|----|-----------|----|-----|----|-----------|----|-------|
| 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     |    |       |
| Total assets                  | \$ | 2,086,410 | \$ | 512 | \$ | 2,084,300 | \$ | 1,598 |

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

There were no security transfers between Levels I and II during the three-month period ended March 31, 2010. The following tables represent a roll-forward of the fair value of Level 3 securities (significant unobservable inputs):

|                                     | Three-Month Periods Ended March |             |
|-------------------------------------|---------------------------------|-------------|
|                                     | 2010                            | 31,<br>2009 |
| Assets:                             |                                 |             |
| Balance at beginning of period      | \$ 1,598                        | \$ 11,054   |
| Amounts acquired or issued          |                                 |             |
| Net gains (realized and unrealized) |                                 |             |
| Settlements                         |                                 | (2,736)     |
| Transfers in and/or out of Level 3  |                                 |             |
| Balance at end of period            | \$ 1,598                        | \$ 8,318    |

|                                    | Three-Month Periods Ended March |             |
|------------------------------------|---------------------------------|-------------|
|                                    | 2010                            | 31,<br>2009 |
| Liabilities:                       |                                 |             |
| Balance at beginning of period     | \$                              | \$          |
| Amounts acquired or issued         | (230,201)                       |             |
| Net accretion                      | (4,862)                         |             |
| Settlements                        |                                 |             |
| Transfers in and/or out of Level 3 |                                 |             |
| Balance at end of period           | \$ (235,063)                    | \$          |

**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 March 31, 2010 and December 31, 2009 had settlement dates within 24 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   |                      |
|------------------|-------------------|----------------------|
|                  | March 31,<br>2010 | December 31,<br>2009 |
| Foreign Currency |                   |                      |

|                 |              |              |
|-----------------|--------------|--------------|
| Euro            | \$ 979,208   | \$ 1,107,340 |
| Canadian Dollar | 90,679       |              |
| Total           | \$ 1,069,887 | \$ 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 March 31, 2010 and December 31, 2009, credit risk did not materially change the fair value of the Company's foreign currency forward contracts.



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

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 in addition to non-functional currency denominated forecasted revenues and expenses of foreign subsidiaries where product approval has not yet occurred. 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 March 31, 2010 and December 31, 2009 were \$596.9 million and \$483.2 million, respectively.

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

| Instrument   | March 31, 2010                     |               |  |               |
|--|------------------------------------|---------------|--|---------------|
|  | Asset Derivatives<br>Balance Sheet |               | Liability Derivatives<br>Balance Sheet |               |
|  | Location                           | Fair<br>Value | Location                               | Fair<br>Value |
| Foreign currency forward contracts<br>designated<br>as hedging instruments*    | Other current assets               | \$ 42,432     | Other current assets                   | \$ 7,471      |
|  | Other current liabilities          | 2,017         | Other current liabilities              | 2,642         |
|  | Other non-current assets           | 23,475        | Other non-current assets               | 410           |
| Foreign currency forward contracts<br>not designated<br>as hedging instruments | Other current assets               | 4,376         | Other current assets                   | 583           |
|  | Other current liabilities          | 2,034         | Other current liabilities              | 9,805         |
|  | Other non-current assets           | 5,096         | Other non-current assets               |               |
| Total  |                                    | \$ 79,430     |  | \$ 20,911     |

| Instrument   | December 31, 2009                  |               |  |               |
|--|------------------------------------|---------------|--|---------------|
|  | Asset Derivatives<br>Balance Sheet |               | Liability Derivatives<br>Balance Sheet |               |
|  | Location                           | Fair<br>Value | Location                               | Fair<br>Value |
| Foreign currency forward<br>contracts designated<br>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<br>contracts not designated<br>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-month periods ended March 31, 2010 and 2009, respectively:

| Instrument                         | Amount of Gain/(Loss) Recognized in OCI on Derivative ( <i>Effective Portion</i> ) | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income ( <i>Effective Portion</i> ) | March 31, 2010   |  |  |
|------------------------------------|--|--|--|--|--|
|                                    |  |  | 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 | \$ 57,213(1)   | Net product sales Research and development   | \$ 213<br>\$ (3)   | Other income, net  | \$ (1,422)(2)  |

(1) Gains of \$37,855 are expected to be reclassified from Accumulated OCI into operations in the next 12 months.

(2) The amount of net losses recognized in income represents \$179 in gains related to the ineffective portion of the hedging relationships and \$1,601 of

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

March 31, 2009

| Instrument                         | Amount of Gain/(Loss) Recognized in OCI on Derivative ( <i>Effective Portion</i> ) | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income ( <i>Effective Portion</i> ) | March 31, 2009   |  |  |
|------------------------------------|--|--|--|--|--|
|                                    |  |  | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income ( <i>Effective Portion</i> ) | Location of Gain/(Loss) Recognized in Income on Derivative ( <i>Amount Excluded From Effectiveness Testing</i> ) | Amount of Gain/(Loss) Recognized in Income on Derivative ( <i>Amount Excluded From Effectiveness Testing</i> ) |
| Foreign currency forward contracts | \$ 53,025  | Net product sales Research and development   | \$ (750)<br>\$ 1,016   | Other income, net  | \$ (4,610)(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)**

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Operations for the three-month periods ended March 31, 2010 and 2009:

| Instrument | Location of Gain/(Loss) Recognized in Income on Derivative | Amount of Gain/(Loss) Recognized in |      |
|------------|--|-------------------------------------|------|
|            |  | Income on Derivative                |      |
|            |  | March 31,                           |      |
|            |  | 2010                                | 2009 |

|                                    |                   |           |           |
|------------------------------------|-------------------|-----------|-----------|
| Foreign currency forward contracts | Other income, net | \$ 18,512 | \$ 15,948 |
|------------------------------------|-------------------|-----------|-----------|

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

Money market funds of \$712.1 million and \$860.9 million at March 31, 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 March 31, 2010 and December 31, 2009 were as follows:

| March 31, 2010  | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Estimated Fair Value |
|---|----------------|-----------------------|-----------------------|----------------------|
| U.S. Treasury securities                                | \$ 433,134     | \$ 232                | \$ (786)              | \$ 432,580           |
| U.S. government-sponsored agency securities             | 707,909        | 1,387                 | (659)                 | 708,637              |
| U.S. government-sponsored agency MBS                    | 495,394        | 1,657                 | (1,228)               | 495,823              |
| Non-U.S. government agency and Supranational securities | 128,165        | 381                   | (69)                  | 128,477              |
| Corporate debt global (43% AAA/Aaa rated)               | 132,494        | 219                   | (206)                 | 132,507              |
| Marketable equity securities                            | 407            |                       | (27)                  | 380                  |
| Total available-for-sale marketable securities          | \$ 1,897,503   | \$ 3,876              | \$ (2,975)            | \$ 1,898,404         |

| 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                  |

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

|  |              |          |            |              |
|--|--------------|----------|------------|--------------|
| Total available-for-sale marketable securities | \$ 1,894,294 | \$ 5,908 | \$ (5,622) | \$ 1,894,580 |
|--|--------------|----------|------------|--------------|

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

U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by US 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 March 31, 2010 and December 31, 2009.

Duration periods of available-for-sale debt securities were as follows at March 31, 2010:

|                                      | Amortized<br>Cost | Fair<br>Value |
|--------------------------------------|-------------------|---------------|
| Duration of one year or less         | \$ 810,983        | \$ 811,944    |
| Duration of one through three years  | 1,031,791         | 1,031,938     |
| Duration of three through five years | 43,940            | 43,890        |
| Duration of over five years          | 10,382            | 10,252        |
| Total                                | \$ 1,897,096      | \$ 1,898,024  |

**9. Inventory**

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

|                 | March 31,<br>2010 | December 31,<br>2009 |
|-----------------|-------------------|----------------------|
| Raw materials   | \$ 24,089         | \$ 26,345            |
| Work in process | 62,983            | 41,282               |
| Finished goods  | 15,407            | 33,056               |
| Total           | \$ 102,479        | \$ 100,683           |

**Table of Contents****CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Investment in Affiliated Companies**

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

|  | March 31,<br>2010                      | December 31,<br>2009 |
|--|--|----------------------|
| Investment in Affiliated Companies                       |  |                      |
| Investment in affiliated companies <sup>(1)</sup>        | \$ 20,487                              | \$ 18,810            |
| Excess of investment over share of equity <sup>(2)</sup> | 2,280                                  | 2,666                |
| Investment in affiliated companies                       | \$ 22,767                              | \$ 21,476            |
|  |  |                      |
|  | Three-Month Periods Ended<br>March 31, |                      |
|  | 2010                                   | 2009                 |
| Equity in Losses of Affiliated Companies                 |  |                      |
| Affiliated companies (gains) losses <sup>(1)</sup>       | \$ (741)                               | \$ 771               |

<sup>(1)</sup> The Company records its interest and share of losses based on its ownership percentage.

<sup>(2)</sup> Consists of goodwill.

Additional equity method investments totaling \$0.5 million were made during the three-month period ended March 31, 2010.

**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. Remaining amortization periods related to these intangibles 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:

|                                   | Gross<br>Carrying<br>Value | Accumulated<br>Amortization | Intangible<br>Assets,<br>Net | Weighted<br>Average<br>Life (Years) |
|-----------------------------------|----------------------------|-----------------------------|------------------------------|-------------------------------------|
| March 31, 2010                    |                            |                             |                              |                                     |
| Amortizable intangible assets:    |                            |                             |                              |                                     |
| Acquired developed product rights | \$ 727,000                 | \$ (227,327)                | \$ 499,673                   | 5.6                                 |
| License                           | 4,250                      | (1,306)                     | 2,944                        | 13.8                                |
| Technology and other              | 3,092                      | (1,044)                     | 2,048                        | 4.4                                 |



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

|                                 |              |              |            |     |
|---------------------------------|--------------|--------------|------------|-----|
|                                 | 734,342      | (229,677)    | 504,665    | 5.6 |
| Nonamortized intangible assets: |              |              |            |     |
| Acquired IPR&D product rights   | 349,000      |              | 349,000    |     |
| Total intangible assets         | \$ 1,083,342 | \$ (229,677) | \$ 853,665 |     |

Table of Contents

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

| December 31, 2009                 | Gross<br>Carrying<br>Value | Accumulated<br>Amortization | Intangible<br>Assets,<br>Net | Weighted<br>Average<br>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                                 |
| Total intangible assets           | \$ 537,348                 | \$ (187,806)                | \$ 349,542                   | 6.5                                 |

The increase in gross carrying value of intangibles at March 31, 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 \$41.9 million and \$23.8 million for the three-month periods ended March 31, 2010 and 2009, respectively. The increase in amortization expense in 2010 compared to 2009 was primarily due to an acceleration of amortization related to the VIDAZA<sup>®</sup> intangible, which reflects an updated forecast related to VIDAZA<sup>®</sup> and the initiation of amortization related to the Gloucester intangibles. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for the next five years is now estimated to be approximately \$182.9 million for 2010, \$197.3 million for the year ending December 31, 2011 and \$51.9 million for each of the years ending December 31, 2012 through 2014.

**Goodwill:** At March 31, 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 goodwill related to the Gloucester acquisition reflects the preliminary purchase price allocation of the Gloucester purchase price.

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 | (401)      |
| Balance at March 31, 2010                                       | \$ 764,622 |

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. Share-Based Compensation**

The following table summarizes the components of share-based compensation expense in the consolidated statements of operations for the three-month periods ended March 31, 2010 and 2009:

|  | Three-Month Periods Ended<br>March 31, |           |
|--|--|-----------|
|  | 2010                                   | 2009      |
| Cost of good sold                      | \$ 1,520                               | \$ 971    |
| Research and development               | 19,129                                 | 14,699    |
| Selling, general and administrative    | 19,931                                 | 16,854    |
| Total share-based compensation expense | \$ 40,580                              | \$ 32,524 |

Share-based compensation cost included in inventory was \$2.2 million at March 31, 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 March 31, 2010 and 2009 was \$19.28 per share and \$23.85 per share, respectively. The \$4.57 decrease from March 31, 2009 to March 31, 2010 reflects the decrease in stock price volatility between the two periods. There have been no significant changes to the assumptions used to estimate the fair value of options granted during the three-month period ended March 31, 2010 compared to those disclosed for the year ended December 31, 2009 in Note 15 to the Consolidated Financial Statements included in the Company's 2009 Annual Report on Form 10-K.

Stock option transactions for the three-month period ended March 31, 2010 under all plans are as follows:

|  | Options     | Weighted<br>Average<br>Exercise<br>Price<br>Per Option | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(Years) | Aggregate<br>Intrinsic<br>Value |
|--|-------------|--|--|---------------------------------|
| Outstanding at December 31, 2009                           | 37,450,036  | \$ 44.63   | 7.0  | \$ 516,856                      |
| Changes during the period:                                 |             |  |  |                                 |
| Granted  | 2,329,235   | 57.32  |  |                                 |
| Exercised  | (1,326,371) | 24.07  |  |                                 |
| Forfeited  | (157,811)   | 54.15  |  |                                 |
| Expired  | (39,787)    | 37.16  |  |                                 |
| Outstanding at March 31, 2010                              | 38,255,302  | \$ 46.09   | 6.8  | \$ 651,186                      |
| Vested at March 31, 2010 or expected to vest in the future | 37,621,586  | \$ 45.95   | 6.8  | \$ 645,674                      |
| Vested at March 31, 2010                                   | 19,220,556  | \$ 36.67   | 5.0  | \$ 500,702                      |

The total fair value of shares vested during the three-month periods ended March 31, 2010 and 2009 were \$5.5 million and \$4.1 million, respectively. The total intrinsic value of stock options exercised during the three-month periods

ended March 31, 2010 and 2009 was \$25.8 million and \$28.9 million, respectively. The Company primarily utilizes newly issued shares to satisfy the exercise of stock options.

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

As of March 31, 2010, there was \$303.7 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 2.4 years.

**Restricted Stock Units:** Equity awards may, at the option of employee participants, be divided between stock options and restricted stock units, or RSUs, based on a two-thirds and one-third mix, respectively, 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 three-month period ended March 31, 2010 is as follows:

|                                | Share<br>Equivalent | Weighted<br>Average<br>Grant Date<br>Fair Value |
|--------------------------------|---------------------|---|
| Nonvested RSUs                 |                     |   |
| Nonvested at December 31, 2009 | 502,440             | \$ 40.41  |
| Changes during the period:     |                     |   |
| Granted                        | 30,141              | 57.94   |
| Vested                         | (2,055)             | 44.94   |
| Forfeited                      | (5,575)             | 39.01   |
| Nonvested at March 31, 2010    | 524,951             | \$ 41.42  |

A total of 2,055 RSUs vested during the three-month period ended March 31, 2010. The Company expects to primarily utilize newly issued shares to satisfy the vesting of RSUs.

As of March 31, 2010, there was \$14.6 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 2.1 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 periodically 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 reevaluates 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.

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

Unrecognized tax benefits, generally represented by liabilities on the consolidated balance sheet and all subject to tax examinations, arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. These unrecognized tax benefits relate primarily to issues common among multinational corporations. Virtually all of these unrecognized tax benefits, if recognized, would impact the effective income tax rate. The Company accounts for interest and potential penalties related to uncertain tax positions as part of its provision for income taxes. The Company believes that it is reasonably possible that unrecognized tax benefits, as of March 31, 2010, could decrease by approximately \$27.8 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 \$22.2 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.

During the first quarter of 2009, the Company effectively settled examinations with the IRS and with a foreign taxing jurisdiction. The foreign examination related to a subsidiary acquired in the Pharmion acquisition. These settlements resulted in a net tax benefit of \$5.3 million, a decrease in the liability for unrecognized tax benefits related to tax positions taken in prior years of \$35.1 million and an increase in tax assets of \$7.3 million.

**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 has retained the exclusive commercial rights to FOCALIN® and FOCALIN XR® for oncology-related disorders, such as chronic fatigue associated with chemotherapy. 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 the d-MPH and Ritalin® under its technology.

**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) 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<sup>®</sup> 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<sup>®</sup> 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 L<sup>®</sup> and Focalin XR<sup>®</sup> 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.

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 properties 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.





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

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 is eligible to receive quarterly research fees, as defined in the agreement, and is entitled to receive potential milestone payments of approximately \$129.0 million if certain development, regulatory and sales-based milestones are achieved. PTC will also 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 agreement will continue until the Company has satisfied all royalty payment obligations to PTC. Upon the Company's full satisfaction of its royalty payment obligations to PTC under the agreement, the license granted to the Company by PTC under the agreement will become a non-exclusive, fully paid-up, sub-licensable, royalty-free license to use certain intellectual property of PTC to market and sell the 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 following the first anniversary of the agreement, 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 PTC for a material breach by the Company, then all licenses granted to the Company under the agreement will terminate. If PTC materially breaches any of its obligations under the agreement, the Company can either terminate the agreement, in which case all licenses and rights granted under the agreement are terminated, or elect to continue the agreement, in which case all milestone obligations cease and future royalties payable by the Company under the agreement will be reduced by between 50% and 70%.

**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.



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

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.

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.

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

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)(x) 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 as well as \$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 properties 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.

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.



**Table of Contents**

**CELGENE CORPORATION AND SUBSIDIARIES**

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

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.

**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 consolidated balance sheets at March 31, 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.

**16. Subsequent Events**

The Company's management has evaluated its subsequent events for disclosure in these interim consolidated financial statements and has identified the following events:

On April 14, 2010, the Company and Agios Pharmaceuticals Inc., or Agios, entered into a pre-negotiated collaboration and licensing agreement focused on targeting cancer metabolism. Under terms of the agreement, the Company will pay Agios an aggregate \$130.0 million, consisting of a \$121.2 million non-refundable upfront payment which will be expensed by the Company to research and development in the second quarter of 2010 and an estimated \$8.8 million equity investment in Agios Series B Convertible Preferred Stock. 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 through additional funding. The Company has an exclusive option to license any resulting clinical candidates and will lead and fund global development and commercialization of licensed programs. On each program, Agios may receive up to \$120 million in milestones as well as royalties on sales, and may also participate in the development and commercialization of certain products in the United States.

On April 29, 2010, the Company announced its senior management succession plan. As of the Company's annual meeting, scheduled on June 16, 2010, Dr. Sol J. Barer currently Chairman of the Board of Directors and Chief Executive Officer, will be appointed Executive Chairman of the Board of Directors through December 31, 2010 and Robert J. Hugin, currently President and Chief Operating Officer, will be appointed Chief Executive Officer of the Company. Effective January 1, 2011, Dr. Barer will be named Non-Executive Chairman and will continue with the Company in a consulting capacity until December 31, 2012.

**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 or our ) 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®, THALOMID® (inclusive of Thalidomide Celgene™ and Thalidomide Pharmion™) and VIDAZA®.

REVLIMID® is an oral immunomodulatory drug marketed in the United States, Europe and Asia / Pacific for patients with multiple myeloma who have received at least one prior therapy and in the United States, Canada and certain countries in Latin America 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. THALOMID® is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy. VIDAZA® is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA® is licensed from Pfizer, and is marketed in the United States for the treatment of all subtypes of MDS and was granted orphan drug designation for the treatment of MDS through May 2011. VIDAZA® is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS according to the National Comprehensive Cancer Network, or NCCN. In Europe, VIDAZA® is marketed for the treatment of certain qualified adult patients and was granted orphan drug designation for the treatment of MDS and acute myeloid leukemia, or AML, in the European Union, or E.U., expiring December 2018. FOCALIN® is approved for the treatment of attention deficit hyperactivity disorder, or ADHD and is sold exclusively to Novartis Pharma AG, or Novartis. ISTODAX® (romidepsin) was obtained in the acquisition of Gloucester Pharmaceuticals, Inc., or Gloucester, and 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. Additionally, ISTODAX® 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 FDA. The European Agency for the Evaluation of Medicinal Products, or EMEA, has granted orphan status designation for ISTODAX® for the treatment of both CTCL and PTCL. ISTODAX® was launched in the United States in the first quarter of 2010.

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

We continue to invest substantially in research and development, and the drug candidates in our pipeline are at various stages of preclinical and clinical development. These candidates include our IMiDs® 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, 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 I, Item 1A of this Quarterly Report on Form 10-Q.





**Table of Contents**

The following table summarizes total revenue and earnings for the three-month periods ended March 31, 2010 and 2009:

| <i>(Amounts in thousands, except earnings per share)</i> | Three-Month Periods Ended |            |            | Percent Change |
|--|---------------------------|------------|------------|----------------|
|  | March 31,                 |            | Increase   |                |
|  | 2010                      | 2009       |            |                |
| Total revenue  | \$ 791,254                | \$ 605,053 | \$ 186,201 | 30.8%          |
| Net income   | \$ 234,442                | \$ 162,883 | \$ 71,559  | 43.9%          |
| Diluted earnings per share                               | \$ 0.50                   | \$ 0.35    | \$ 0.15    | 42.9%          |

The increase in revenue for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 was primarily due to continued growth of REVLIMID® and VIDAZA® in both U.S. and international markets. Net income and diluted earnings per share for the three-month period ended March 31, 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.

**Results of Operations:****Three-Month Periods Ended March 31, 2010 and 2009**

*Total Revenue:* Total revenue and related percentages for the three-month periods ended March 31, 2010 and 2009 were as follows:

| <i>(Amounts in thousands)</i>              | Three-Month Periods Ended |            |                     | Percent Change |
|--|---------------------------|------------|---------------------|----------------|
|  | March 31,                 |            | Increase (Decrease) |                |
|  | 2010                      | 2009       |                     |                |
| Net product sales:                         |                           |            |                     |                |
| REVLIMID®                                  | \$ 530,466                | \$ 362,516 | \$ 167,950          | 46.3%          |
| THALOMID®                                  | 104,017                   | 113,964    | (9,947)             | -8.7%          |
| VIDAZA®                                    | 120,345                   | 75,382     | 44,963              | 59.6%          |
| Other                                      | 4,583                     | 24,370     | (19,787)            | -81.2%         |
| Total net product sales                    | \$ 759,411                | \$ 576,232 | \$ 183,179          | 31.8%          |
| Collaborative agreements and other revenue | 2,380                     | 2,244      | 136                 | 6.1%           |
| Royalty revenue                            | 29,463                    | 26,577     | 2,886               | 10.9%          |
| Total revenue                              | \$ 791,254                | \$ 605,053 | \$ 186,201          | 30.8%          |

REVLIMID® net sales increased by \$168.0 million to \$530.5 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to increased unit sales in both U.S. and international markets. Increased market penetration and the increase in 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.

**Table of Contents**

THALOMID<sup>®</sup> net sales decreased by \$9.9 million to \$104.0 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009. The decrease was primarily due to lower unit volumes and an increase in sales adjustments in the United States, partly resulting from an increase in Medicaid rebate rates and the expanded use of REVLIMID<sup>®</sup>.

VIDAZA<sup>®</sup> net sales increased by \$45.0 million to \$120.3 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 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.

The other category for the three-month period ended March 31, 2010 includes sales of FOCALIN<sup>®</sup>, NISTODAX<sup>®</sup> and former Pharmion products to be divested. The other category for the three-month period ended March 31, 2009 included \$19.9 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 three-month period ended March 31, 2010 increased by \$183.2 million, or 31.8%, to \$759.4 million compared to the three-month period ended March 31, 2009. The change was comprised of net volume increases of \$132.8 million, price increases of \$27.8 million and the favorable impact from foreign exchange of \$22.6 million.

*Collaborative Agreements and Other Revenue:* Revenues from collaborative agreements and other sources increased by \$0.1 million to \$2.4 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009. Revenues for both three-month periods included the sales of services through our Cellular Therapeutics subsidiary and income from miscellaneous licensing agreements.

*Royalty Revenue:* Royalty revenue increased by \$2.9 million to \$29.5 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to 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. Royalty income also reflects amounts received from Novartis on sales of the entire family of RITALIN<sup>®</sup> drugs and FOCALIN XR<sup>®</sup>.

*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<sup>®</sup> is distributed in the United States under our *System for Thalidomide Education and Prescribing Safety*, or S.T.E.P.S.<sup>®</sup>, 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<sup>®</sup>. Internationally, THALOMID<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> is distributed in the United States primarily through contracted pharmacies under the RevAssist<sup>®</sup> program, which is a proprietary risk-management distribution program tailored specifically to help ensure the safe and appropriate distribution and use of REVLIMID<sup>®</sup>. Internationally, REVLIMID<sup>®</sup> 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<sup>®</sup>. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA<sup>®</sup> is distributed through the more traditional pharmaceutical industry supply chain. VIDAZA<sup>®</sup> is not subjected to the same risk-management distribution programs as THALOMID<sup>®</sup> and REVLIMID<sup>®</sup>.

**Table of Contents**

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 does 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<sup>®</sup> is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product. REVLIMID<sup>®</sup> 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. Recently passed U.S. healthcare reform legislation negatively impacted first quarter 2010 revenues by approximately \$4.0 million. We expect that full year 2010 revenues will be negatively impacted by U.S. healthcare reform legislation by approximately \$35-\$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.

Chargebacks 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.

**Table of Contents**

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended March 31, 2010 and 2009 were as follows:

| <i>(Amounts in thousands)</i><br>2010           | Returns<br>and<br>Allowances | Discounts | Government<br>Rebates | Chargebacks<br>and Dist.<br>Service Fees | Total     |
|---|------------------------------|-----------|-----------------------|--|-----------|
| Balance at December 31, 2009                    | \$ 7,360                     | \$ 3,598  | \$ 18,111             | \$ 29,241                                | \$ 58,310 |
| Allowances for sales during 2010                | 6,036                        | 10,878    | 17,160                | 27,270                                   | 61,344    |
| Credits/deductions issued for prior year sales  | (2,579)                      | (937)     | (7,894)               | (11,105)                                 | (22,515)  |
| Credits/deductions issued for sales during 2010 | (803)                        | (9,432)   | (5,335)               | (12,964)                                 | (28,534)  |
| Balance at March 31, 2010                       | \$ 10,014                    | \$ 4,107  | \$ 22,042             | \$ 32,442                                | \$ 68,605 |

| <i>(Amounts in thousands)</i><br>2009           | Returns<br>and<br>Allowances | Discounts | Government<br>Rebates | Chargebacks,<br>and Dist.<br>Service Fees | Total     |
|---|------------------------------|-----------|-----------------------|---|-----------|
| Balance at December 31, 2008                    | \$ 17,799                    | \$ 3,659  | \$ 10,810             | \$ 23,386                                 | \$ 55,654 |
| Allowances for sales during 2009                | 1,269                        | 8,278     | 8,815                 | 22,319                                    | 40,681    |
| Credits/deductions issued for prior year sales  | (5,828)                      | (2,177)   | (9,349)               | (7,646)                                   | (25,000)  |
| Credits/deductions issued for sales during 2009 | (2)                          | (4,281)   | (1,345)               | (8,087)                                   | (13,715)  |
| Balance at March 31, 2009                       | \$ 13,238                    | \$ 5,479  | \$ 8,931              | \$ 29,972                                 | \$ 57,620 |

A comparison of allowances for sales within each of the four categories noted above for the three-month periods ended March 31, 2010 and 2009, respectively, follows:

Returns and allowances increased by \$4.8 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to revenue increases in the 2010 three-month period compared to the 2009 three-month period and an approximate \$1.8 million anticipated unfavorable impact from a change in the distribution model in one of our international markets. In addition, the 2009 three-month period included a \$1.3 favorable adjustment which was not repeated in the 2010 three-month period.

Discounts increased by \$2.6 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to revenue increases in the United States and international markets, both of which offer different discount programs.

Government rebates increased by \$8.3 million in the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to reimbursement approvals in new markets as well as 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.

Chargebacks and distributor service fees increased by \$5.0 million in the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to higher distributor service fees partially offset by decreased chargebacks resulting from lower volumes of products with higher chargeback rates in the 2010 three-month period compared to the 2009 three-month period.



**Table of Contents**

*Operating Costs and Expenses:* Operating costs, expenses and related percentages for the three-month periods ended March 31, 2010 and 2009 were as follows:

| <i>(Amounts in thousands)</i>  | Three-Month Periods Ended |                   | Increase<br>(Decrease) | Percent<br>Change |
|--|---------------------------|-------------------|------------------------|-------------------|
|  | 2010                      | March 31,<br>2009 |                        |                   |
| Cost of goods sold (excluding amortization of<br>acquired intangible assets) | \$ 61,915                 | \$ 64,299         | \$ (2,384)             | -3.7%             |
| Percent of net product sales   | 8.2%                      | 11.2%             |                        |                   |
| Research and development   | \$ 204,657                | \$ 181,248        | \$ 23,409              | 12.9%             |
| Percent of total revenue   | 25.9%                     | 30.0%             |                        |                   |
| Selling, general and administrative  | \$ 207,978                | \$ 173,440        | \$ 34,538              | 19.9%             |
| Percent of total revenue   | 26.3%                     | 28.7%             |                        |                   |
| Amortization of acquired intangible assets                                   | \$ 41,593                 | \$ 23,625         | \$ 17,968              | 76.1%             |
| Acquisition related charges  | \$ 4,862                  | \$                | \$ 4,862               | N/A               |

*Cost of Goods Sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) decreased by \$2.4 million to \$61.9 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to the March 31, 2009 conclusion date of the ALKERAN<sup>®</sup> license with GSK, reducing cost of goods sold by \$15.8 million compared to the three-month period ended March 31, 2009. As a percent of net product sales, cost of goods sold (excluding amortization expense) decreased to 8.2% in the 2010 three-month period from 11.2% in the 2009 three-month period primarily due to the lack of ALKERAN<sup>®</sup> sales in the 2010 three-month period, which sales carried a higher cost-to-sales ratio relative to our other products. Excluding ALKERAN<sup>®</sup> in the three-month period ended March 31, 2009, the percent of net product sales would have been 8.7%.

*Research and Development:* Research and development expenses increased by \$23.4 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to spending increases 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>          | Three-Month Periods Ended |                   | Increase  |
|--|---------------------------|-------------------|-----------|
|  | 2010                      | March 31,<br>2009 |           |
| Human pharmaceutical clinical programs | \$ 100,418                | \$ 94,715         | \$ 5,703  |
| Other pharmaceutical programs (1)      | 73,057                    | 64,584            | 8,473     |
| Drug discovery and development         | 26,242                    | 18,605            | 7,637     |
| Placental stem cell                    | 4,940                     | 3,344             | 1,596     |
| Total                                  | \$ 204,657                | \$ 181,248        | \$ 23,409 |

(1) Other  
pharmaceutical  
programs

include  
spending for  
toxicology,  
analytical  
research and  
development,  
quality and  
regulatory  
affairs.



**Table of Contents**

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 PDE-4, which results in the inhibition of multiple proinflammatory mediators such as TNF- $\alpha$  and which is currently being evaluated in Phase II clinical trials in the treatment of psoriasis and psoriatic arthritis; pomalidomide, which is currently being evaluated in Phase I and II clinical trials; CC-11050, for which Phase II clinical trials are planned; our kinase and ligase inhibitor programs; as well as the placental stem cell program.

*Selling, General and Administrative:* Selling, general and administrative expenses increased by \$34.5 million to \$208.0 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009. The increase was partly due to a \$15.2 million increase in marketing and sales related expenses, which include ongoing product launch activities of VIDAZA<sup>®</sup> in Europe in addition to the continued expansion of our international commercial activities. The remaining \$19.3 million increase reflects the costs related to the expansion of our infrastructure, including additional headcount and facilities costs.

*Amortization of Acquired Intangible Assets:* Amortization of acquired intangible assets increased by \$18.0 million to \$41.6 million for the three-month period ended March 31, 2010 compared to the three-month period ended March 31, 2009 primarily due to a reduction in the amortizable life of the VIDAZA<sup>®</sup> intangible asset resulting from the Pharmion acquisition and the amortization of intangible assets resulting from the January 2010 acquisition of Gloucester.

*Acquisition Related Charges:* Acquisition related charges represents an accretion of the contingent consideration related to the acquisition of Gloucester. If all milestones are achieved, the total amount to be accreted through 2015 would be \$69.8 million.

*Interest and Investment Income, Net:* Interest and investment income was \$14.1 million for the three-month period ended March 31, 2010, representing a decrease of \$3.4 million from the \$17.5 million recorded for the three-month period ended March 31, 2009. The decrease was primarily due to lower yields on investments, partly offset by higher invested balances

*Equity in Losses of Affiliated Companies:* Under the equity method of accounting, we recorded a gain of \$0.7 million for the three-month period ended March 31, 2010 compared to a loss of \$0.8 million for the three-month period ended March 31, 2009. The gain in the current three-month period was primarily due to an increase in the fair value of investments held by one of the entities in which we have invested.

*Interest Expense:* Interest expense was \$0.5 million for each of the three-month periods ended March 31, 2010 and 2009.

*Other Income, Net:* Other income, net was \$3.8 million and \$32.6 million for the three-month periods ended March 31, 2010 and 2009, respectively. The \$28.8 million decrease in other income was due to a decrease in net gains on foreign currency forward contracts recorded in the first quarter of 2009 that have not been designated as hedges entered into in order to offset net foreign exchange gains and losses, partly offset by net realized and unrealized foreign exchange transaction gains.

*Income Tax Provision:* The income tax provision for the three-month period ended March 31, 2010 was \$53.9 million with an effective tax rate of 18.7%, 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. The income tax provision for the three-month period ended March 31, 2009 was \$48.4 million with an effective tax rate of 22.9%. Tax expense in 2009 included a net tax benefit of \$5.3 million related to the settlement of tax examinations.

**Table of Contents****Liquidity and Capital Resources**

Cash flows from operating, investing and financing activities for the three-month periods ended March 31, 2010 and 2009 were as follows:

| <i>(Amounts in thousands)</i>             | Three-Month Periods Ended |              | Change      |
|---|---------------------------|--------------|-------------|
|   | March 31,                 |              |             |
|   | 2010                      | 2009         |             |
| Net cash provided by operating activities | \$ 284,650                | \$ 127,117   | \$ 157,533  |
| Net cash used in investing activities     | \$ (363,551)              | \$ (311,462) | \$ (52,089) |
| Net cash provided by financing activities | \$ 43,897                 | \$ 56,611    | \$ (12,714) |

*Operating Activities:* Net cash provided by operating activities for the three-month period ended March 31, 2010 increased by \$157.5 million to \$284.7 million as compared to the three-month period ended March 31, 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 timing of receipts and payments in the ordinary course of business.

*Investing Activities:* Net cash used in investing activities for the three-month period ended March 31, 2010 increased by \$52.1 million to \$363.6 million as compared to the three-month period ended March 31, 2009. The 2010 investing activities are principally related to net cash used in the acquisition of Gloucester of \$337.6 million partly offset by a reduction of net purchases of marketable securities available for sale to close to zero in 2010 from \$292.0 million of net purchases in 2009.

*Financing Activities:* Net cash provided by financing activities for the three-month period ended March 31, 2010 was \$43.9 million as compared to net cash provided by financing activities of \$56.6 million for the three-month period ended March 31, 2009. The decrease in net cash provided by financing activities was attributable to a reduction in excess tax benefits from share-based compensation arrangements partly offset by an increase in net proceeds from exercise of common stock and warrants.

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

| <i>(Amounts in thousands)</i>                                       | March 31,<br>2010 | December 31,<br>2009 | Increase<br>(Decrease) |
|---|-------------------|----------------------|------------------------|
| Cash, cash equivalents and marketable securities available for sale | \$ 2,953,950      | \$ 2,996,752         | \$ (42,802)            |
| Working capital (1)   | \$ 3,392,299      | \$ 3,302,109         | \$ 90,190              |

(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 decrease in cash, cash equivalents and marketable securities available for sale at March 31, 2010 compared to December 31, 2009 was primarily due to the \$338.9 million cash payment made for the Gloucester acquisition, partly offset by increased cash from operations.

**Table of Contents**

*Accounts Receivable, Net:* Accounts receivable, net increased by \$42.4 million to \$481.1 million as of March 31, 2010 compared to December 31, 2009 primarily due to increased sales of REVLIMID® and VIDAZA®. Days of sales outstanding at both March 31, 2010 and December 31, 2009 amounted to 56 days and reflects the impact of a high level of international sales for which the collection period is longer than for U.S. sales. We expect this trend to continue as our international sales continue to expand.

*Inventory:* Inventory balances increased by \$1.8 million to \$102.5 million at March 31, 2010 compared to December 31, 2009, reflecting slight increases in levels of THALOMID® and REVLIMID® inventories.

*Other Current Assets:* Other current assets increased by \$53.1 million to \$312.1 million as of March 31, 2009 compared to December 31, 2009 primarily due an increase related to the fair value of foreign currency forward derivative contracts.

*Accounts Payable, Accrued Expenses and Other Current Liabilities:* Accounts payable, accrued expenses and other current liabilities decreased by \$22.3 million to \$423.7 million as of March 31, 2010 compared to December 31, 2009. The decrease was primarily due to a reduction in payroll-related accruals due to recent payments made, which were partly offset by changes in the fair value of foreign currency forward derivative contracts and sales related adjustments.

*Income Taxes Payable (Current and Non-Current):* Income taxes payable increased by \$9.0 million to \$478.2 million as of March 31, 2010 compared to December 31, 2009 primarily from the current provision for income taxes of \$63.3 million, mostly offset by tax payments of \$40.5 million and tax benefit of stock options of \$12.6 million.

We expect continued growth in our expenditures, particularly those related to research and product development, clinical trials, regulatory approvals, international expansion, commercialization of products and capital investments. However, we anticipate that existing cash, cash equivalents and marketable securities available for sale, combined with cash received from expected net product sales and royalty agreements, will provide sufficient capital resources to fund our operations for the foreseeable future.

**Financial Condition**

At March 31, 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 US 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 include obligations issued by investment-grade corporations including some issues that have been guaranteed by governments and government agencies.

**Table of Contents**

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

As of March 31, 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 March 31, 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.

**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.

**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 policies 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.

**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 March 31, 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 March 31, 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 US 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 March 31, 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:

| <i>(Amounts in thousands)</i> | Duration            |              |                 |                      | Total        |
|-------------------------------|---------------------|--------------|-----------------|----------------------|--------------|
|                               | Less than<br>1 Year | 1 to 3 Years | 3 to 5<br>Years | More Than<br>5 Years |              |
| Principal amount              | \$ 800,306          | \$ 1,016,425 | \$ 41,428       | \$ 9,575             | \$ 1,867,734 |
| Fair value                    | \$ 811,944          | \$ 1,031,938 | \$ 43,890       | \$ 10,252            | \$ 1,898,024 |
| Average interest rate         | 0.7%                | 1.4%         | 2.3%            | 2.8%                 | 1.1%         |

*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 March 31, 2010, the fair value of our note payable to Siegfried approximated the carrying value of the note of \$24.8 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 March 31, 2010 and December 31, 2009 had settlement dates within 24 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   |                      |
|------------------|-------------------|----------------------|
|                  | March 31,<br>2010 | December 31,<br>2009 |
| Euro             | \$ 979,208        | \$ 1,107,340         |
| Canadian dollar  | 90,679            |                      |
| Total            | \$ 1,069,887      | \$ 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 March 31, 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 \$0.2 million for the three-month period ended March 31, 2010 and a reduction of \$0.8 million for the three-month period ended March 31, 2009. 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-month period ended March 31, 2010 and a decrease in research and development expenses for the settlement of certain effective cash flow hedge instruments of \$1.0 million for the three-month period ended March 31, 2009. These settlements were recorded in the same period as the related forecasted research and development expenses occurred. We recognized an increase in other income, net for the settlement of certain effective cash flow hedge instruments of \$18.5 million for the three-month period ended March 31, 2010. These settlements were recorded in the same period as the related forecasted 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 March 31, 2010 and December 31, 2009 were \$596.9 million and \$483.2 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the March 31, 2010 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$95.5 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.

**Table of Contents**

**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 March 31, 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. There have not been any material changes since December 31, 2009 as it pertains to such legal proceedings nor have we engaged in any additional material legal proceedings.

**Item 1A. Risk Factors**

There have not been any material changes to our risk factors since December 31, 2009 contained in Part I, Item 1A of our 2009 Annual Report on Form 10-K, other than with respect to the newly enacted Health Care Reform Act as stated below:

***Sales of our products will be significantly reduced if access to and reimbursement for our products by governmental and other third-party payors 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 payors. Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payor of healthcare costs of patients. These health care management organizations and third-party payors 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 payors 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 pharmaceutical and medical device 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**

In addition to the revised risk factor presented above with respect to the newly enacted Health Care Reform Act, we have represented the other risk factors contained in Part I, Item 1A of our 2009 Annual Report on Form 10-K in this Part II, Item 1A for your convenience and review. The statements in this section describe the major risks to our business and should be considered carefully. Any of the factors described below 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.

***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 payors for our products;

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

the acquisition of new products and companies;

tax rates in the jurisdictions in which we operate;

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

ability to control our costs;

fluctuations in foreign currency exchange rates; and

economic and market instability.

**Table of Contents**

***We remain dependent on the continued commercial success of our primary products REVLIMID<sup>®</sup>, THALOMID<sup>®</sup> and VIDAZA<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>, THALOMID<sup>®</sup>, and VIDAZA<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 payors, such as government and private insurance plans, patent disputes and claims about adverse side effects.

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

Changes in law, government regulations or policies can have a significant impact on our results of operations. The discovery, preclinical development, clinical trials, manufacturing, risk evaluation and mitigation strategies (such as our S.T.E.P.S.<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.

**Table of Contents**

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, EC, the Swissmedic, the TGA 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;

**Table of Contents**

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.

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.

***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 manufactures are seeking to compete with our drugs and will become 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).





**Table of Contents**

Furthermore, even if our patent applications, or those we have licensed-in, are issued, our competitors may challenge the scope, validity or enforceability of such patents in court, requiring us to engage in complex, lengthy and costly litigation. Alternatively, our 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.

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.

**Table of Contents**

***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.

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 Federal Trade Commission (FTC). The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. We continue to cooperate with the FTC's request for information.

**Table of Contents**

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 this Annual Report on Form 10-K.

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

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

The stem cell products that we are developing through our 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.

**Table of Contents**

***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 cGMP regulations and guidelines. Our failure to comply, or failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

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

We have contracted with specialty distributors, to distribute REVLIMID®, THALOMID®, VIDAZA® and ISTODAX® 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.

**Table of Contents**

***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.

***We may face significant challenges in effectively integrating entities and businesses that we acquire and we may not realize the benefits that we anticipate from any such acquisition.***

Achieving the anticipated benefits of our acquisition of entities will depend in part upon whether we can integrate our businesses in an efficient and effective manner. Our integration of these entities 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;
- failure of the acquired entity to meet or exceed our expected returns;
- higher integration costs than anticipated;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;
- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, controls (including internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act of 2002) and related procedures and policies.

If we cannot successfully integrate acquired businesses, we may experience material negative consequences to our business, financial condition or results of operations.

**Table of Contents*****Our failure to attract and retain key managerial, technical, scientific, selling and marketing personnel 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 sales and marketing 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.

***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.

**Table of Contents**

***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 the recent tightening of 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.

***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, the current global economic crisis has 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;



**Table of Contents**

new accounting pronouncements or regulatory rulings;

public announcements regarding medical advances in the treatment of the disease states that we are targeting;

patent or proprietary rights developments;

changes in pricing and third-party reimbursement policies for our products;

the outcome of litigation involving our products or processes related to production and formulation of those products or uses of those products;

other litigation or governmental investigations;

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, 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.

***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**

The following table presents the total number of shares purchased during the quarter ended March 31, 2010, the average price paid per share, the number of shares that were purchased as part of a publicly announced repurchase program, and the approximate dollar value of shares that still could have been purchased:

| Period             | Total<br>Number of<br>Shares (or<br>Units)<br>Purchased | Average Price<br>Paid per<br>Share (or Unit) | Total Number<br>of<br>Shares (or<br>Units)<br>Purchased as<br>Part of<br>Publicly<br>Announced<br>Plans or<br>Programs | Maximum Number<br>(or<br>Approximate Dollar<br>Value) of Shares<br>(or<br>Units) that may yet<br>be<br>Purchased Under<br>the<br>Plans or Programs |
|--------------------|---|--|--|--|
| January 1-March 31 |   |  | N/A  | 350,637,924  |

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 authorizes 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 expires April 2011. The average price paid per share is based on the price paid per share in the open market and excludes any adjustments related to the share repurchase program.

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.

**Table of Contents**

**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 March 31, 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, tagged as blocks of text.

**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: May 3, 2010

By: /s/ David W. Gyska

David W. Gyska  
Sr. Vice President and  
Chief Financial Officer

DATE: May 3, 2010

By: /s/ Andre Van Hoek

Andre Van Hoek  
Corporate Controller and  
Chief Accounting Officer