

CELGENE CORP /DE/
Form 10-Q
November 02, 2011
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from _____ to _____

Commission File Number 001-34912

CELGENE CORPORATION

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(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation
or organization)

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

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

07901
(Zip Code)

(908) 673-9000

(Registrant's telephone number, including area code)

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

Yes No

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

Yes No

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

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

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

Yes No

At October 25, 2011, 443,930,657 shares of Common Stock, par value \$.01 per share, were outstanding.

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CELGENE CORPORATION

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****CELGENE CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME****(Unaudited)****(In thousands, except per share amounts)**

| | Three-Month Periods Ended | | Nine-Month Periods Ended | |
|---|----------------------------------|-------------|---------------------------------|--------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Revenue: | | | | |
| Net product sales | \$ 1,219,118 | \$ 885,656 | \$ 3,457,055 | \$ 2,468,164 |
| Collaborative agreements and other revenue | 3,766 | 2,241 | 16,468 | 7,165 |
| Royalty revenue | 26,853 | 22,214 | 84,650 | 78,728 |
| Total revenue | 1,249,737 | 910,111 | 3,558,173 | 2,554,057 |
| Expenses: | | | | |
| Cost of goods sold (excluding amortization of acquired intangible assets) | 94,645 | 63,542 | 348,356 | 193,450 |
| Research and development | 356,839 | 253,547 | 1,163,837 | 800,965 |
| Selling, general and administrative | 303,303 | 228,281 | 911,207 | 655,522 |
| Amortization of acquired intangible assets | 75,044 | 46,540 | 214,181 | 135,201 |
| Acquisition related (gains) charges and restructuring, net | (11,209) | 7,495 | (117,430) | 20,193 |
| Total costs and expenses | 818,622 | 599,405 | 2,520,151 | 1,805,331 |
| Operating income | 431,115 | 310,706 | 1,038,022 | 748,726 |
| Other income and expense: | | | | |
| Interest and investment income, net | 8,481 | 12,801 | 18,948 | 37,010 |
| Equity in losses of affiliated companies | 1,661 | 1,384 | 966 | 746 |
| Interest expense | 10,292 | 414 | 31,460 | 1,321 |
| Other income (expense), net | (15,002) | 8,453 | (6,684) | 7,130 |
| Income before income taxes | 412,641 | 330,162 | 1,017,860 | 790,799 |
| Income tax provision | 39,657 | 49,011 | 110,582 | 119,854 |
| Net income | 372,984 | 281,151 | 907,278 | 670,945 |
| Less: Net loss attributable to non-controlling interest | | | 694 | |
| Net income attributable to Celgene | \$ 372,984 | \$ 281,151 | \$ 907,972 | \$ 670,945 |

Net income per share attributable to Celgene:

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| | | | | | | | | |
|---------|----|------|----|------|----|------|----|------|
| Basic | \$ | 0.83 | \$ | 0.61 | \$ | 1.97 | \$ | 1.46 |
| Diluted | \$ | 0.81 | \$ | 0.60 | \$ | 1.94 | \$ | 1.44 |

Weighted average shares:

| | | | | |
|---------|---------|---------|---------|---------|
| Basic | 452,019 | 459,653 | 460,161 | 459,957 |
| Diluted | 459,530 | 466,332 | 467,052 | 467,137 |

See accompanying Notes to Consolidated Financial Statements

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

| | September 30, 2011 | December 31, 2010 |
|---|-------------------------------|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 1,794,927 | \$ 1,351,128 |
| Marketable securities available for sale | 784,160 | 1,250,173 |
| Accounts receivable, net of allowances of \$25,293 and \$13,104 at September 30, 2011 and December 31, 2010, respectively | 888,168 | 706,429 |
| Inventory | 187,525 | 260,130 |
| Deferred income taxes | 152,365 | 151,779 |
| Other current assets | 242,937 | 275,005 |
| Assets held for sale | 52,462 | 348,555 |
| Total current assets | 4,102,544 | 4,343,199 |
| Property, plant and equipment, net | 490,192 | 509,919 |
| Investment in affiliated companies | 27,470 | 23,073 |
| Intangible assets, net | 2,920,012 | 3,248,498 |
| Goodwill | 1,896,283 | 1,896,344 |
| Other assets | 326,606 | 156,129 |
| Total assets | \$ 9,763,107 | \$ 10,177,162 |
| Liabilities and Stockholders Equity | | |
| Current liabilities: | | |
| Short-term borrowings | \$ 269,125 | \$ 94,465 |
| Accounts payable | 98,405 | 94,465 |
| Accrued expenses | 640,247 | 592,336 |
| Income taxes payable | 10,078 | 11,423 |
| Current portion of deferred revenue | 13,626 | 16,362 |
| Other current liabilities | 132,946 | 309,214 |
| Liabilities of disposal group | 7,531 | 46,582 |
| Total current liabilities | 1,171,958 | 1,070,382 |
| Deferred revenue, net of current portion | 12,616 | 12,785 |
| Income taxes payable | 631,376 | 551,896 |
| Deferred income taxes | 786,046 | 882,870 |
| Other non-current liabilities | 278,705 | 416,173 |
| Long-term debt, net of discount | 1,277,316 | 1,247,584 |
| Total liabilities | 4,158,017 | 4,181,690 |

Commitments and Contingencies**Equity:**

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| | | | |
|---|----|-------------|---------------|
| Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none outstanding at September 30, 2011 and December 31, 2010 | | | |
| Common stock, \$.01 par value per share, 575,000,000 shares authorized; issued 485,070,329 and 482,164,353 shares at September 30, 2011 and December 31, 2010, respectively | | 4,851 | 4,822 |
| Common stock in treasury, at cost; 39,654,766 and 11,776,036 shares at September 30, 2011 and December 31, 2010, respectively | | (2,109,066) | (545,588) |
| Additional paid-in capital | | 6,618,937 | 6,350,240 |
| Retained earnings | | 1,156,238 | 248,266 |
| Accumulated other comprehensive loss | | (65,870) | (73,767) |
| Total stockholders' equity | | 5,605,090 | 5,983,973 |
| Non-controlling interest | | | 11,499 |
| Total equity | | 5,605,090 | 5,995,472 |
| Total liabilities and equity | \$ | 9,763,107 | \$ 10,177,162 |

See accompanying Notes to Consolidated Financial Statements

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

| | Nine-Month Periods Ended September 30, | |
|--|---|-------------|
| | 2011 | 2010 |
| Cash flows from operating activities: | | |
| Net income | \$ 907,278 | \$ 670,945 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation of long-term assets | 53,051 | 38,880 |
| Amortization | 215,961 | 136,048 |
| Allocation of pre-paid royalties | 16,214 | 37,299 |
| Provision (benefit) for accounts receivable allowances | 3,375 | (1,485) |
| Deferred income taxes | (101,510) | (36,854) |
| Impairment of acquired in-process research and development | 118,000 | |
| Change in value of contingent consideration | (122,547) | 16,697 |
| Share-based compensation expense | 168,641 | 134,540 |
| Equity in losses of affiliated companies | 966 | 746 |
| Share-based employee benefit plan expense | 14,567 | 11,072 |
| Unrealized change in value of foreign currency forward contracts | (30,004) | 12,060 |
| Realized (gain) loss on marketable securities available for sale | (1,616) | (12,576) |
| Other, net | (7,643) | 3,155 |
| Change in current assets and liabilities, excluding the effect of acquisitions: | | |
| Accounts receivable | (188,503) | (158,899) |
| Inventory | 73,776 | (6,372) |
| Other operating assets | 48,113 | 9,412 |
| Assets held for sale, net | 2,647 | |
| Accounts payable and other operating liabilities | 90,344 | 89,560 |
| Income tax payable | 80,119 | 25,002 |
| Deferred revenue | (2,756) | 7,481 |
| Net cash provided by operating activities | 1,338,473 | 976,711 |
| Cash flows from investing activities: | | |
| Proceeds from sales of marketable securities available for sale | 1,814,974 | 3,774,568 |
| Purchases of marketable securities available for sale | (1,327,244) | (2,564,876) |
| Payments for acquisition of business, net of cash acquired | (180,000) | (337,608) |
| Proceeds from the sale of non-core assets, net | 93,185 | |
| Capital expenditures | (90,559) | (59,138) |
| Investment in affiliated companies | (2,949) | (1,759) |
| Purchases (refunds) of investment securities | 6,597 | (14,020) |
| Other investing activities | (2,000) | |
| Net cash provided by investing activities | 312,004 | 797,167 |
| Cash flows from financing activities: | | |
| Payment for treasury shares | (1,574,415) | (105,436) |

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| | | |
|---|--------------|--------------|
| Proceeds from short-term borrowing | 404,843 | |
| Principal repayments on short-term borrowing | (135,750) | |
| Net proceeds from exercise of common stock options and warrants | 92,258 | 56,033 |
| Excess tax benefit from share-based compensation arrangements | 15,734 | 9,081 |
| Net cash (used in) financing activities | (1,197,330) | (40,322) |
| Effect of currency rate changes on cash and cash equivalents | (9,348) | (3,743) |
| Net increase in cash and cash equivalents | 443,799 | 1,729,813 |
| Cash and cash equivalents at beginning of period | 1,351,128 | 1,102,172 |
| Cash and cash equivalents at end of period | \$ 1,794,927 | \$ 2,831,985 |

See accompanying Notes to Consolidated Financial Statements

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

| | Nine-Month Periods Ended September 30, | |
|--|---|-------------|
| | 2011 | 2010 |
| Supplemental schedule of non-cash investing and financing activity: | | |
| Contingent consideration issued in acquisition of Gloucester | \$ | \$ 230,201 |
| Change in net unrealized (gain) loss on marketable securities available for sale | \$ (4,928) | \$ (17,480) |
| Matured shares tendered in connection with stock option exercises | \$ (16) | \$ (8,236) |
| Supplemental disclosure of cash flow information: | | |
| Interest paid | \$ 2,026 | \$ 1,638 |
| Income taxes paid | \$ 79,159 | \$ 115,291 |

See accompanying Notes to Consolidated Financial Statements

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 is dedicated to innovative research and development which is designed to bring new therapies to market and is involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmunity and placental cell, including stem and progenitor cell, research.

The Company's primary commercial stage products include REVLIMID®, VIDAZA®, THALOMID® (inclusive of Thalidomide Celgene® and Thalidomide Pharmion®), ABRAXANE® and ISTODAX®. Additional sources of revenue include a licensing agreement with Novartis Pharma AG, or Novartis, which entitles the Company to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through its Cellular Therapeutics subsidiary and other licensing agreements.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Certain entities obtained in the acquisition of Abraxis BioScience, Inc., or Abraxis, in October 2010 were determined to be non-core to the Company and a large portion were divested in April 2011 (see Note 3). Investments in limited partnerships and interests where 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 Company records net income or loss attributable to non-controlling interest in its Consolidated Statements of Income equal to the percentage of ownership interest retained in the respective operations by the non-controlling parties.

The preparation of these unaudited consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. 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 unaudited consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited consolidated financial statements.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 1 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, or the 2010 Annual Report on Form 10-K.

New Accounting Pronouncements: In September 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-08, Intangibles - Goodwill and Other (Topic 350): Testing Goodwill for Impairment, or ASU 2011-08. The update simplifies how a company tests goodwill for impairment.

ASU 2011-08 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under that option, an entity would no longer be required to calculate the fair value of a reporting unit unless the entity determines, based on that qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount.

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. The adoption of ASU 2011-08 is not expected to have a material impact on the Company as the Company has only one reporting unit.

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220), or ASU 2011-05. ASU 2011-05 was issued to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 will be effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2011. The Company is currently evaluating the impact that the adoption of ASU 2011-05 will have on its consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820), or ASU 2011-04. ASU 2011-04 was issued to improve the comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and International Financial Reporting Standards, or IFRS. The guidance in ASU 2011-04 explains how to measure fair value, but does not require additional fair value measurements and is not intended to establish valuation standards or affect valuation practices outside of financial reporting. ASU 2011-04 will be effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2011. The Company is currently evaluating the impact that the adoption of ASU 2011-04 will have on its consolidated financial statements.

3. Acquisitions and Divestitures

Abraxis BioScience, Inc.

On October 15, 2010, or the Acquisition Date, the Company acquired all of the outstanding common stock of Abraxis in exchange for consideration valued at the Acquisition Date at approximately \$3.205 billion, consisting of cash, stock and contingent value rights, or CVRs. The transaction, referred to as the Merger, resulted in Abraxis becoming a wholly owned subsidiary of the Company.

As discussed further under **Contingent Value Rights** below, a holder of a CVR is entitled to receive a *pro rata* portion of cash payments that the Company is obligated to pay to all holders of CVRs, which is determined by achievement of certain net sales and U.S. regulatory approval milestones. Potential cash payments to CVR holders range from no payment, if no regulatory milestones or net sales thresholds are met, to a maximum of \$650.0 million in milestone payments plus payments based on annual net sales levels if all milestones are met at the earliest target dates and annual net sales exceed threshold amounts.

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The Merger has been accounted for using the acquisition method of accounting which requires that most assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date and requires the fair value of acquired in-process research and development, or IPR&D, to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. A preliminary purchase price allocation has been made and amounts for certain income tax attributes are subject to change pending the filing of Abraxis pre-acquisition tax returns. The Company does not expect any material adjustments.

No adjustments were made during the nine-month period ended September 30, 2011 to the amounts initially recorded for the assets acquired and liabilities assumed as of the Acquisition Date. The amounts recognized will be finalized as the information necessary to complete the analyses is obtained, but no later than one year from the Acquisition Date.

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Sale of Non-core Assets

The purchase of Abraxis included a number of assets that are not associated with nab® technology or ABRAXANE®. These assets, or non-core assets, consisted of a number of subsidiaries, tangible assets, equity investments, joint venture partnerships and assets that supported research and sales of products not directly related to the nab® technology or ABRAXANE®. At the time of acquisition, the Company committed to a plan to divest certain non-core assets and they were classified on the Consolidated Balance Sheets as of December 31, 2010 as assets held for sale and the associated liabilities were classified as liabilities of disposal group. In April 2011, the Company sold these non-core assets to various entities that are owned or controlled by Dr. Patrick Soon-Shiong, the former majority shareholder and executive chairman of Abraxis.

The Company received cash consideration of \$110.0 million, 10% equity ownership in Active Biomaterials, LLC, which is an entity that was formed with certain of the non-core assets with revenue-producing potential, and a future royalty stream based on net sales of certain products of Active Biomaterials, LLC. The royalties, which commence in 2014 at the earliest and are not to exceed an annual amount of \$128.0 million, will be calculated based on a range of between 10% and 12.5% of net sales of certain future products. Dr. Patrick Soon-Shiong holds an option to purchase the 10% equity ownership in Active Biomaterials, LLC from the Company for a price of \$15.0 million at any time prior to April 2013. The Company recorded the equity ownership at its fair market value of \$14.0 million based on the present value of the amount likely to be received upon exercise of the purchase option. The Company recorded the future royalty stream as an asset and assigned a value of \$170.0 million based on its fair market value calculated as the present value of estimated future net cash flows. The sale of the non-core assets resulted in a gain of \$2.9 million which was included in the Consolidated Statements of Income, in other income (expense), net. The Company's policy is to present gains and losses from sales of businesses as other income or expense.

Assets Held For Sale

The remaining balances in the assets held for sale and liabilities of disposal group line items on the Consolidated Balance Sheets at September 30, 2011 relate to two facilities that were acquired in the purchase of Abraxis. The Company intends to sell these assets as it rationalizes certain manufacturing facilities. No material gain or loss is expected to result from the sale.

Contingent Value Rights

In connection with the Merger on October 15, 2010, CVRs were issued under a Contingent Value Rights Agreement, or CVR Agreement, entered into between Celgene and American Stock Transfer & Trust Company, LLC, as trustee. The CVRs are registered for trading on the NASDAQ Global Select Market under the symbol CELGZ. The fair value of the CVRs and the liability of the Company related to payments under the CVR Agreement are subject to fluctuation based on trading prices for the publicly traded CVRs. Subsequent to the Acquisition Date, the Company has measured the contingent consideration represented by the CVRs at fair value with changes in fair value recognized in operating earnings.

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

- *Milestone Payment #1.* \$250.0 million upon U.S. Food and Drug Administration, or FDA, approval of ABRAXANE® for use in the treatment of non-small cell lung cancer, or NSCLC, if such approval permits the Company to market ABRAXANE® with FDA approval that includes a progression-free survival, or PFS, claim, but only if this milestone is achieved no later than the fifth anniversary of the Merger.

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- *Milestone Payment #2.* \$400.0 million (if achieved no later than April 1, 2013) or \$300.0 million (if achieved after April 1, 2013 and before the fifth anniversary of the Merger) upon FDA approval of ABRAXANE® for use in the treatment of pancreatic cancer, if such approval permits the Company to market ABRAXANE® with FDA approval that includes an overall survival claim.
- *Net Sales Payments.* For each full one-year period ending December 31 during the term of the CVR Agreement, which we refer to as a net sales measuring period (with the first net sales measuring period beginning January 1, 2011 and ending December 31, 2011):
 - 2.5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$1.0 billion but are less than or equal to \$2.0 billion for such period, plus
 - an additional amount equal to 5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$2.0 billion but are less than or equal to \$3.0 billion for such period, plus
 - an additional amount equal to 10% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$3.0 billion for such period.

No payments will be due under the CVR Agreement with respect to net sales of ABRAXANE® and the Abraxis pipeline products after December 31, 2025, which we refer to as the net sales payment termination date, unless net sales for the net sales measuring period ending on December 31, 2025 are equal to or greater than \$1.0 billion, in which case the net sales payment termination date will be extended until the last day of the net sales measuring period subsequent to December 31, 2025 during which net sales of ABRAXANE® and the Abraxis pipeline products are less than \$1.0 billion or, if earlier, December 31, 2030.

The final results for the ongoing ABRAXANE® Phase III study in NSCLC, or the NSCLC study, were presented at a major scientific congress in June 2010. These results showed that the primary endpoint of the study, response rate, was met and was statistically significant. An interim analysis for the secondary endpoint of PFS was announced in January 2011 and, although not statistically significant, did not show a negative trend against the comparator. On June 4, 2011, the Company announced that the final analysis for both PFS and Overall Survival, or OS, was completed during the second quarter of 2011 and the PFS remained consistent with the interim analysis. In addition, the final OS, similar to the final PFS analysis, did not show a negative trend against the comparator. The Special Protocol Assessment, or SPA, as agreed with the FDA, states that the NSCLC study must reach the primary endpoint of response rate, which has been met, as well as showing that the secondary endpoints of both PFS and OS are not negative, *i.e.* no detrimental effect on PFS or OS for the ABRAXANE® group of the NSCLC study. Accordingly, because the final PFS results were not statistically significant, this reduced the probability that a payment will be made for Milestone Payment #1 under the CVR Agreement that the Company entered into with the former shareholders of Abraxis. Milestone Payment #1 relates to FDA approval of ABRAXANE® for the treatment of NSCLC that permits the Company to market ABRAXANE® with FDA approval that includes a PFS claim, which the Company believes is now unlikely to be achieved based on the foregoing data. The market value

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of the publicly traded CVRs, which represents the fair value of the Company's liability for all potential payments under the CVR Agreement, decreased from \$212.0 million at December 31, 2010 to \$75.3 million at September 30, 2011. The reduction in the fair value of the Company's liability was recognized as a gain of \$136.7 million in acquisition-related (gains) charges and restructuring, net on the Consolidated Statements of Income for the nine-month period ended September 30, 2011, including a gain of \$13.4 million for the three-month period ended September 30, 2011.

In the first quarter of 2011, the Company evaluated the value assigned to the IPR&D from Abraxis and determined that, based on a lower level of probable sales than that estimated at the time of the Merger for sales of ABRAXANE® for NSCLC with FDA approval that includes a PFS claim, the fair value of the

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CELGENE CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

IPR&D acquired from Abraxis has fallen below the \$1.290 billion recorded at the time of acquisition. An impairment charge included in research and development on the accompanying Consolidated Statements of Income in the amount of \$118.0 million was recorded in the three-month period ended March 31, 2011 to reduce the value of the IPR&D asset acquired from Abraxis to its revised current fair value of \$1.172 billion at September 30, 2011.

Gloucester Pharmaceuticals, Inc.

On January 15, 2010, the Company acquired all of the outstanding common stock and stock options of Gloucester Pharmaceuticals, Inc., or Gloucester. The assets acquired and liabilities assumed of Gloucester were recorded as of the acquisition date, at their respective fair values, and consolidated with those of the Company. Gloucester's results of operations are included in the Company's consolidated financial statements from the date of acquisition.

The Company paid \$338.9 million in cash before milestone payments with potential additional future payments of up to \$300.0 million in contingent regulatory milestone payments. As part of the consideration for the Gloucester acquisition, the Company is contractually obligated to pay certain consideration resulting from the outcome of future events. The Company updates its assumptions each reporting period based on new developments and records such amounts at fair value until such consideration is satisfied.

In June 2011, the FDA granted accelerated approval of the Supplemental New Drug Application for ISTODAX® for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. This FDA approval was the triggering event for the payment of one of the two contingent regulatory milestone payments associated with the Gloucester acquisition. The Company made a payment of \$180.0 million to the former shareholders of Gloucester in July 2011 in satisfaction of this milestone payment requirement. The single remaining contingent milestone payment is for a \$120.0 million cash payment upon the marketing approval for the European Union PTCL.

Subsequent to the acquisition date, the Company has measured the contingent consideration arrangement at fair value for each period with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the IPR&D assets and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses, and will be accrued based on an accretion schedule. At September 30, 2011, the balance of the contingent consideration, which reflects the fair value of the single remaining contingent milestone payment, was \$87.1 million, and is included in other non-current liabilities.

4. Restructuring

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The Company has incurred costs from restructuring activities related to the October 15, 2010 acquisition of Abraxis. Restructuring costs include employee termination costs, contract termination fees and facility closing costs. Employee termination costs are generally recorded when the actions are probable and estimable and include accrued severance benefits and health insurance continuation, many of which may be paid out during periods after termination of employment.

The following tables summarize the restructuring expenses and changes in the restructuring liability related to the Abraxis acquisition during the three- and nine-month periods ended September 30, 2011:

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

| | Three-Month Periods Ended September 30, | | Nine-Month Periods Ended September 30, | |
|-------------------------------|--|------|---|------|
| | 2011 | 2010 | 2011 | 2010 |
| Employee termination benefits | \$ 86 | \$ | \$ 2,312 | \$ |
| Contract termination fees | | | 1,304 | |
| Facility closing costs | 113 | | 1,858 | |
| Total restructuring expense | \$ 199 | \$ | \$ 5,474 | \$ |

| | Balance December 31, 2010 | Expense Recognized | Payments | Balance September 30, 2011 | Cumulative Payments |
|-------------------------------|------------------------------|-----------------------|-----------|-------------------------------|------------------------|
| Employee termination benefits | \$ 14,881 | \$ 2,312 | \$ 12,047 | \$ 5,146 | \$ 13,280 |
| Contract termination fees | | 1,304 | 1,304 | | 1,304 |
| Facility closing costs | | 1,858 | 1,066 | 792 | 1,066 |
| Total restructuring costs | \$ 14,881 | \$ 5,474 | \$ 14,417 | \$ 5,938 | \$ 15,650 |

The Company does not expect to incur material additional restructuring expenses related to the acquisition of Abraxis. Future cash payments related to the restructuring activity are estimated to be approximately \$1.3 million in 2011, \$4.3 million in 2012 and \$0.3 million in 2013.

5. Earnings Per Share

| | Three-Month Periods Ended September 30, | | Nine-Month Periods Ended September 30, | |
|--|--|------------|---|------------|
| | 2011 | 2010 | 2011 | 2010 |
| Net income attributable to Celgene | \$ 372,984 | \$ 281,151 | \$ 907,972 | \$ 670,945 |
| Weighted-average shares (in thousands): | | | | |
| Basic | 452,019 | 459,653 | 460,161 | 459,957 |
| Effect of dilutive securities: | | | | |
| Options, restricted stock units, warrants and other incentives | 7,511 | 6,679 | 6,891 | 7,180 |
| Diluted | 459,530 | 466,332 | 467,052 | 467,137 |
| Net income per share: | | | | |
| Basic | \$ 0.83 | \$ 0.61 | \$ 1.97 | \$ 1.46 |
| Diluted | \$ 0.81 | \$ 0.60 | \$ 1.94 | \$ 1.44 |

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The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 21,682,141 and 24,472,208 shares for the three-month periods ended September 30, 2011 and 2010, respectively. The total number of potential common shares excluded for the nine-month periods ended September 30, 2011 and 2010 was 26,846,063 and 23,624,432, respectively.

The Company's Board of Directors has approved an open-ended common share repurchase program up to an aggregate of \$4.0 billion of the Company's common stock. As of September 30, 2011, an aggregate of 35,676,097 shares of common stock were repurchased under the program, including 15,549,400 shares of common stock repurchased during the three-month period ended September 30, 2011.

Table of Contents**CELGENE CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Comprehensive Income**

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

| | Three-Month Periods Ended September 30, | | Nine-Month Periods Ended September 30, | |
|--|--|------------|---|------------|
| | 2011 | 2010 | 2011 | 2010 |
| Net income | \$ 372,984 | \$ 281,151 | \$ 907,972 | \$ 670,945 |
| Other comprehensive income: | | | | |
| Marketable securities: | | | | |
| Net unrealized gains on marketable securities available for sale, net of tax | 124 | 4,682 | 4,928 | 17,681 |
| Reclassification adjustment for (gains) and losses included in net income | (3,072) | (6,560) | (1,783) | (12,432) |
| Total other comprehensive (gains) losses related to marketable securities available for sale, net of tax | (2,948) | (1,878) | 3,145 | 5,249 |
| Net unrealized gains (losses) related to cash flow hedges, net of tax | 52,789 | (118,501) | (1,356) | 1,663 |
| Currency translation adjustments | (12,713) | 11,709 | 6,108 | 32,769 |
| Total other comprehensive income (loss) items | 37,128 | (108,670) | 7,897 | 39,681 |
| Comprehensive income | 410,112 | 172,481 | 915,869 | 710,626 |

7. Financial Instruments and Fair Value Measurement

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2011 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 and global corporate debt securities. 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 non-publicly traded companies. The Company's Level 1 liability relates to the Company's publicly traded CVRs. The Level 2 liability relates to forward currency contracts and the Level 3 liability consists of contingent consideration related to undeveloped product rights resulting from the Gloucester acquisition.

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

| | Balance at September 30, 2011 | Quoted Price in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|--|----------------------------------|--|--|--|
| Assets: | | | | |
| Cash equivalents | \$ | \$ | \$ | \$ |
| Available-for-sale securities | 784,160 | 424 | 783,736 | |
| Forward currency contracts | 9,824 | | 9,824 | |
| Warrants | 2,077 | | | 2,077 |
| Total assets | \$ 796,061 | \$ 424 | \$ 793,560 | \$ 2,077 |
| Liabilities: | | | | |
| Acquisition related contingent consideration | \$ (162,390) | \$ (75,297) | \$ | \$ (87,093) |

| | Balance at December 31, 2010 | Quoted Price in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|--|---------------------------------|--|--|--|
| Assets: | | | | |
| Cash equivalents | \$ 5,000 | \$ | \$ 5,000 | \$ |
| Available-for-sale securities | 1,250,173 | 4,268 | 1,242,402 | 3,503 |
| Warrants | 1,757 | | | 1,757 |
| Warrants classified as held for sale | 1,904 | | | 1,904 |
| Securities classified as held for sale | 19,863 | 3,655 | | 16,208 |
| Total assets | \$ 1,278,697 | \$ 7,923 | \$ 1,247,402 | \$ 23,372 |
| Liabilities: | | | | |
| Forward currency contracts | \$ (18,436) | \$ | \$ (18,436) | \$ |
| Acquisition related contingent consideration | (464,937) | (212,042) | | (252,895) |
| Total liabilities | \$ (483,373) | \$ (212,042) | \$ (18,436) | \$ (252,895) |

There were no security transfers between Levels 1 and 2 in the nine-month period ended September 30, 2011. The following tables represent a roll-forward of the fair value of Level 3 instruments (significant unobservable inputs):

| | Nine-Month Periods Ended September 30, | |
|--------------------------------|--|----------|
| | 2011 | 2010 |
| Assets: | | |
| Balance at beginning of period | \$ 23,372 | \$ 1,598 |

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| | | | | |
|--|----|----------|----|-------|
| Amounts acquired or issued | | | | |
| Net realized and unrealized gains (losses) | | 1,182 | | (10) |
| Settlements | | (22,477) | | 169 |
| Transfers in and/or out of Level 3 | | | | |
| Balance at end of period | \$ | 2,077 | \$ | 1,757 |

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

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

| | Nine-Month Periods Ended September 30, | |
|------------------------------------|--|--------------|
| | 2011 | 2010 |
| Liabilities: | | |
| Balance at beginning of period | \$ (252,895) | \$ (230,201) |
| Amounts acquired or issued | | (230,201) |
| Net accretion | (14,198) | (16,697) |
| Settlements | | |
| Transfers in and/or out of Level 3 | 180,000 | |
| Balance at end of period | \$ (87,093) | \$ (246,898) |

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

8. Derivative Instruments and Hedging Activities

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

The Company enters into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at September 30, 2011 and December 31, 2010 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at September 30, 2011 and December 31, 2010:

| Foreign Currency | Notional Amount | |
|------------------|--------------------|-------------------|
| | September 30, 2011 | December 31, 2010 |
| | | |

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| | | | | |
|-------------------|----|-----------|----|-----------|
| Australian Dollar | \$ | 14,280 | \$ | 51,809 |
| British Pound | | | | 58,440 |
| Canadian Dollar | | 93,768 | | 133,128 |
| Euro | | 794,766 | | 675,438 |
| Japanese Yen | | 647,960 | | 632,962 |
| Swiss Franc | | 56,376 | | 77,669 |
| Others | | | | 2,835 |
| Total | \$ | 1,607,150 | \$ | 1,632,281 |

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.

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Celgene CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2011, credit risk did not materially change the fair value of the Company's foreign currency forward contracts.

The Company also enters into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2011 and December 31, 2010 were \$1,023.2 million and \$848.6 million, respectively.

From time to time the Company hedges the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amount of the swap match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swaps are recorded on the Consolidated Balance Sheets with no net impact recorded in the Consolidated Statements of Income.

Additionally, any net interest payments made or received are recognized as interest expense. At June 30, 2011, the Company was a party to three pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts matched the amount of the hedged fixed-rate notes. In August 2011, the Company settled the swap contracts resulting in the receipt of \$34.3 million. The proceeds from the swap settlement are being accounted for as a reduction of current and future interest expense. There were no interest rate swap contracts outstanding at September 30, 2011.

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

The following table summarizes the fair value and presentation in the consolidated balance sheets for derivative instruments as of September 30, 2011 and December 31, 2010:

| Instrument | September 30, 2011 | | | |
|---|-------------------------------|------------------|-------------------------------|------------------|
| | Asset Derivatives | | Liability Derivatives | |
| | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Foreign currency forward contracts designated as hedging instruments* | Other current assets | \$ 22,556 | Other current assets | \$ 1,448 |
| | Other current liabilities | 23,764 | Other current liabilities | 34,665 |
| | Other non-current assets | 3,231 | Other non-current assets | 213 |
| | Other non-current liabilities | 6,533 | Other non-current liabilities | 34,722 |
| Foreign currency forward contracts not designated as hedging instruments* | Other current assets | 34,870 | Other current assets | 3,877 |
| | Other current liabilities | 2,499 | Other current liabilities | 8,813 |
| | Other non-current assets | 1,450 | Other non-current assets | |
| | Other non-current liabilities | | Other non-current liabilities | 1,341 |
| Total | | \$ 94,903 | | \$ 85,079 |
| Instrument | December 31, 2010 | | | |
| | Asset Derivatives | | Liability Derivatives | |
| | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Foreign currency forward contracts designated as hedging instruments* | Other current assets | \$ 23,536 | Other current assets | \$ 1,177 |
| | Other current liabilities | 16,656 | Other current liabilities | 21,645 |
| | Other non-current liabilities | | Other non-current liabilities | 33,824 |
| Foreign currency forward contracts not designated as hedging instruments* | Other current assets | 8,127 | Other current assets | 1,976 |
| | Other current liabilities | 2,444 | Other current liabilities | 10,577 |
| Total | | \$ 50,763 | | \$ 69,199 |

* 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.

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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 Income for the three- and nine-month periods ended September 30, 2011 and 2010, respectively:

| Instrument | For the Three-Month Period Ended September 30, 2011 | | | | |
|------------------------------------|---|---|---|---|---|
| | Amount of Gain/(Loss) Recognized in OCI on Derivative <i>(Effective Portion)</i> | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Location of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> | Amount of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> |
| Foreign currency forward contracts | \$ 47,987(1) | Net product sales | \$ (4,802) | Other income, net | \$ (6,256)(2) |
| Interest rate swaps | | Interest expense | \$ 1,724 | | |

(1) Gains of \$10,675 are expected to be reclassified from Accumulated OCI into operations in the next 12 months.

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

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

forward
contracts

| | | |
|-----------------------------|----|-----|
| Research and development | \$ | (1) |
|-----------------------------|----|-----|

(1) The amount of net gains recognized in income represents \$394 in gains related to the ineffective portion of the hedging relationships, and \$5,581 of gains related to amounts excluded from the assessment of hedge effectiveness.

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

| For the Nine-Month Period Ended September 30, 2011 | | | | | |
|--|---|---|---|---|---|
| Instrument | Amount of Gain/(Loss) Recognized in OCI on Derivative <i>(Effective Portion)</i> | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Location of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> | Amount of Gain/(Loss) Recognized in Income on Derivative <i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> |
| Foreign currency forward contracts | \$ (9,190)(1) | Net product sales | \$ (7,833) | Other income, net | \$ (6,021)(2) |
| Interest rate swaps | | Interest expense | \$ 5,460 | | |

(1) Gains of \$10,675 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 \$566 in losses related to the ineffective portion of the hedging relationships and \$5,455 of losses related to amounts excluded from the assessment of hedge effectiveness.

| For the Nine-Month Period Ended September 30, 2010 | | | | | |
|--|---|---|---|---|---|
| Instrument | Amount of Gain/(Loss) Recognized in OCI on Derivative <i>(Effective Portion)</i> | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income <i>(Effective Portion)</i> | Location of Gain/(Loss) Recognized in Income on Derivative <i>(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 | \$ 43,377 | Net product sales | \$ 41,718 | Other income, net | \$ 3,019(1) |
| | | Research and development | \$ (4) | | |

(1) The amount of net gain recognized in income represents \$415 in losses related to the ineffective portion of the hedging relationships and \$3,434 of gains related to amounts excluded from the assessment of hedge effectiveness.

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 Income for the three- and nine-month periods ended September 30, 2011 and 2010:

| Instrument | Location of Gain/(Loss) Recognized in Income on Derivative | Amount of Gain/(Loss) Recognized in Income on Derivative | | | |
|---|--|--|-------------|--|------------|
| | | Three-Month Periods Ended September 30, 2011 | | Nine-Month Periods Ended September 30, 2010 | |
| Foreign currency forward contracts | Other income, net | \$ (46,586) | \$ (49,661) | \$ (11,666) | \$ (4,177) |

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

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

Money market funds of \$0.603 billion and \$1.050 billion at September 30, 2011 and December 31, 2010, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security at September 30, 2011 and December 31, 2010 were as follows:

| September 30, 2011 | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Estimated Fair Value |
|--|-------------------|-----------------------------|-----------------------------|----------------------------|
| U.S. Treasury securities | \$ 222,678 | \$ 401 | \$ (236) | \$ 222,843 |
| U.S. government-sponsored agency securities | 137,312 | 575 | (79) | 137,808 |
| U.S. government-sponsored agency MBS | 303,028 | 2,343 | (2,056) | 303,315 |
| Non-U.S. government, agency and Supranational securities | 11,182 | 198 | | 11,380 |
| Corporate debt - global | 107,470 | 1,151 | (231) | 108,390 |
| Marketable equity securities | 407 | 17 | | 424 |
| Total available-for-sale marketable securities | \$ 782,077 | \$ 4,685 | \$ (2,602) | \$ 784,160 |

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| December 31, 2010 | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Estimated Fair Value |
|--|-------------------|-----------------------------|-----------------------------|----------------------------|
| U.S. Treasury securities | \$ 431,913 | \$ 921 | \$ (378) | \$ 432,456 |
| U.S. government-sponsored agency securities | 359,060 | 1,055 | (267) | 359,848 |
| U.S. government-sponsored agency MBS | 250,618 | 1,230 | (1,332) | 250,516 |
| Non-U.S. government, agency and Supranational securities | 35,382 | 182 | (18) | 35,546 |
| Corporate debt - global | 167,876 | 1,002 | (1,340) | 167,538 |
| Marketable equity securities | 4,050 | 368 | (149) | 4,269 |
| Total available-for-sale marketable securities | \$ 1,248,899 | \$ 4,758 | \$ (3,484) | \$ 1,250,173 |

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 U.S. Government Sponsored Enterprises. U.S. government-sponsored agency mortgage-backed securities, or MBS, include mortgage-backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and Supranational securities consist of direct obligations of highly rated governments of nations other than the United States and obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. Corporate debt global includes obligations issued by investment-grade corporations, including some issues that have been guaranteed by governments and government agencies. Net unrealized gains in the marketable debt securities primarily reflect the impact of decreased interest rates at September 30, 2011 and December 31, 2010.

Duration periods of available-for-sale debt securities at September 30, 2011 were as follows:

| | Amortized Cost | Fair Value |
|--------------------------------------|-------------------|---------------|
| Duration of one year or less | \$ 171,765 | \$ 171,428 |
| Duration of one through three years | 514,872 | 516,676 |
| Duration of three through five years | 95,033 | 95,632 |
| Total | \$ 781,670 | \$ 783,736 |

10. Inventory

A summary of inventories by major category at September 30, 2011 and December 31, 2010 follows:

| | September 30, 2011 | December 31, 2010 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$ 51,609 | \$ 37,458 |
| Work in process | 100,429 | 95,822 |
| Finished goods | 35,487 | 126,850 |
| Total | \$ 187,525 | \$ 260,130 |

The finished goods inventory balance at December 31, 2010 includes the unamortized acquisition accounting step-up to fair value resulting from the acquisition of Abraxis in the amount of \$90.3 million which has been fully amortized as of September 30, 2011.

Table of Contents**Celgene CORPORATION AND SUBSIDIARIES****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Investment in Affiliated Companies**

As of September 30, 2011, the Company maintained three equity method investments, including two limited partnership investment funds. Additional equity method investment contributions, net of investment returns totaled \$2.9 million during the nine-month period ended September 30, 2011. A summary of the Company's equity investments in affiliated companies follows:

| Investment in Affiliated Companies | September 2011 | December 31, 2010 |
|---|-------------------|----------------------|
| Investment in affiliated companies (1) | \$ 26,358 | \$ 21,419 |
| Excess of investment over share of equity (2) | 1,112 | 1,654 |
| Investment in affiliated companies | \$ 27,470 | \$ 23,073 |

| Equity in Losses of Affiliated Companies | Three-Month Periods Ended September 30, | | Nine-Month Periods Ended September 30, | |
|--|--|----------|---|--------|
| | 2011 | 2010 | 2011 | 2010 |
| Affiliated companies losses (1) (3) | \$ 1,661 | \$ 1,384 | \$ 966 | \$ 746 |

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

(2) Consists of goodwill.

(3) Affiliated companies losses for the nine-month period of 2011 includes certain losses related to non-core former Abraxis equity method investments which were divested in the second quarter of 2011.

12. Intangible Assets and Goodwill

Intangible Assets: The Company's intangible assets consist of developed product rights from the Pharmion, Gloucester and Abraxis acquisitions, IPR&D product rights from the Gloucester and Abraxis acquisitions, contract-based licenses, technology and other. The amortization periods related to non-IPR&D intangible assets range from one to 17 years. The following summary of intangible assets by

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category includes intangibles currently being amortized and intangibles not yet subject to amortization:

| September 30, 2011 | Gross Carrying Value | Accumulated Amortization | Intangible Assets, Net | Weighted Average Life (Years) |
|--|----------------------------|-----------------------------|------------------------------|-------------------------------------|
| Amortizable intangible assets: | | | | |
| Acquired developed product rights | \$ 2,186,000 | \$ (592,844) | \$ 1,593,156 | 11.9 |
| Licenses | 64,250 | (5,149) | 59,101 | 16.8 |
| Technology and other | 43,148 | (9,393) | 33,755 | 8.9 |
| | 2,293,398 | (607,386) | 1,686,012 | 11.9 |
| Nonamortized intangible assets: | | | | |
| Acquired IPR&D product rights | 1,234,000 | | 1,234,000 | |
| Total intangible assets | \$ 3,527,398 | \$ (607,386) | \$ 2,920,012 | |

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Celgene CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

| December 31, 2010 | Gross Carrying Value | Accumulated Amortization | Intangible Assets, Net | Weighted Average Life (Years) |
|--|----------------------------|-----------------------------|------------------------------|-------------------------------------|
| Amortizable intangible assets: | | | | |
| Acquired developed product rights | \$ 1,897,000 | \$ (384,891) | \$ 1,512,109 | 12.3 |
| Licenses | 64,250 | (2,271) | 61,979 | 16.8 |
| Technology and other | 40,601 | (5,191) | 35,410 | 8.8 |
| | 2,001,851 | (392,353) | 1,609,498 | 12.4 |
| Nonamortized intangible assets: | | | | |
| Acquired IPR&D product rights | 1,639,000 | | 1,639,000 | |
| Total intangible assets | \$ 3,640,851 | \$ (392,353) | \$ 3,248,498 | |

In June 2011, ISTODAX® was approved by the FDA for the treatment of PTCL in patients who have received at least one prior therapy. Accordingly, the related \$287.0 million intangible asset obtained from the Gloucester acquisition was reclassified from an acquired IPR&D intangible to an acquired developed product rights intangible and amortization commenced with an 8.8 year expected useful life. The \$113.5 million decrease in gross carrying value of intangible assets at September 30, 2011 compared to December 31, 2010 was primarily due to a \$118.0 million impairment charge related to a change in the probability of obtaining PFS labeling for the treatment of NSCLC with ABRIXANE® in the United States, which was partly offset by the addition of two intangible assets with a combined value of approximately \$4.5 million.

Amortization expense was \$75.3 million and \$46.8 million for the three-month periods ended September 30, 2011 and 2010, respectively. Amortization expense in 2011 included \$22.2 million from the amortization of intangible assets obtained in the October 2010 Abraxis acquisition. Amortization expense for the nine-month periods ended September 30, 2011 and 2010 was \$214.9 million and \$136.0 million, respectively. Amortization expense for the nine-month period ended September 30, 2011 included \$67.0 million from the amortization of intangible assets obtained in the Abraxis acquisition. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for the next five years is estimated to be approximately \$289.2 million for 2011, \$139.9 million for 2012, \$138.2 million for 2013, \$134.1 million for 2014 and \$129.9 million for 2015.

Goodwill: At September 30, 2011, the Company's goodwill related to the October 2010 acquisition of Abraxis, the January 2010 acquisition of Gloucester, the March 2008 acquisition of Pharmion and the October 2004 acquisition of Penn T Limited.

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

| | |
|---|--------------|
| Balance at December 31, 2010 | \$ 1,896,344 |
| Tax benefit on the exercise of Pharmion converted stock options | (61) |

| | | |
|-------------------------------|----|-----------|
| Balance at September 30, 2011 | \$ | 1,896,283 |
|-------------------------------|----|-----------|

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Senior Notes: Summarized below are the carrying values of the Company's senior notes at September 30, 2011 and December 31, 2010:

| | September 30, 2011 | December 31, 2010 |
|------------------------------|--------------------|-------------------|
| 2.450% senior notes due 2015 | \$ 528,951 | \$ 499,301 |
| 3.950% senior notes due 2020 | 498,827 | 498,749 |
| 5.700% senior notes due 2040 | 249,538 | 249,534 |
| Total long-term debt | \$ 1,277,316 | \$ 1,247,584 |

On October 7, 2010, the Company issued a total of \$1.25 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes due 2015 (the "2015 notes"), \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 (the "2020 notes") and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040 (the "2040 notes" and, together with the 2015 notes and the 2020 notes, referred to herein as the "notes"). The notes were issued at 99.854%, 99.745% and 99.813% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$10.5 million have been recorded as debt issuance costs on the Company's Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on April 15 and October 15 each year beginning April 15, 2011 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal. If a change of control of the Company occurs accompanied by a downgrade of the debt to below investment grade, the Company will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. The Company is subject to covenants which limit the ability of the Company to pledge properties as security under borrowing arrangements and limit the ability of the Company to perform sale and leaseback transactions involving the property of the Company. At September 30, 2011, the fair value of the Company's Senior Notes outstanding was \$1.316 billion.

The Company entered into interest rate swap contracts in February and March 2011 to convert a portion of its interest rate exposure from fixed rate to floating rate to more closely align interest expense with interest income received on its cash equivalent and investment balances. In August 2011, the Company settled the swap contracts resulting in the receipt of \$34.3 million. The proceeds from the swap settlement are being accounted for as a reduction of current and future interest expense associated with the Company's \$500.0 million, 2.45% fixed-rate notes due in 2015. There were no interest rate swap contracts outstanding at September 30, 2011.

Commercial Paper: In September 2011, the Company entered into a commercial paper program, or the "Program," under which the Company issues unsecured commercial paper notes, or "Commercial Paper," on a private placement basis up to a maximum aggregate amount outstanding at any time of \$1.0 billion, the proceeds of which will be used for general corporate purposes. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis.

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Borrowings under the Program are accounted for as short-term borrowings. As of September 30, 2011, the carrying value of Commercial Paper

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Celgene CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was \$269.1 million and approximated its fair value. The effective interest rate on the outstanding Commercial Paper balance at September 30, 2011 was 0.4%.

Senior Unsecured Credit Facility: In September 2011, the Company, entered into a senior unsecured revolving credit facility, or the Credit Facility, providing for revolving credit to the Company in the aggregate amount of \$1.0 billion. Subject to certain conditions, the Company has the right to increase the amount of the Credit Facility (but in no event more than once per annum) up to a maximum aggregate amount of \$1.250 billion.

The Credit Facility has a five-year term and amounts may be borrowed in U.S. dollars for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for the Company's Commercial Paper borrowings. Costs of \$3.5 million associated with securing the Credit Facility have been recorded as other non-current assets on the balance sheet and are being amortized to income over the five-year term of the Credit Facility. As of September 30, 2011 there was no outstanding borrowing against the Credit Facility.

Borrowings under the Credit Facility will bear interest at a rate per annum equal to (i) the Base Rate, a fluctuating rate equal to the Applicable Margin plus the highest of (x) Citibank, N.A.'s Base Rate, (y) the Federal Funds Rate plus 0.50% and (z) one-month LIBOR plus 1.00% or (ii) the Eurodollar Rate, a periodic fixed rate equal to LIBOR plus the Applicable Margin. The Applicable Margin is determined based on a pricing grid and is dependent on the Company's public debt ratings.

The Credit Facility contains affirmative and negative covenants including certain customary financial covenants. The Company was in compliance with all financial debt covenants as of September 30, 2011.

14. Share-Based Compensation

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the three- and nine-month periods ended September 30, 2011 and 2010:

| | Three-Month Periods Ended | | Nine-Month Periods Ended | |
|--------------------------|---------------------------|----------|--------------------------|----------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Cost of good sold | \$ 2,627 | \$ 1,788 | \$ 7,054 | \$ 4,909 |
| Research and development | 24,527 | 21,220 | 79,998 | 60,373 |

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| | | | | |
|---|-----------|-----------|------------|------------|
| Selling, general and administrative | 27,198 | 24,160 | 75,906 | 66,276 |
| Total share-based compensation expense | 54,352 | 47,168 | 162,958 | 131,558 |
| Tax benefit related to share-based compensation expense | 13,728 | 10,740 | 41,598 | 29,908 |
| Reduction in income | \$ 40,624 | \$ 36,428 | \$ 121,360 | \$ 101,650 |

Share-based compensation cost included in inventory was \$2.3 million and \$2.4 million at September 30, 2011 and December 31, 2010, respectively.

Stock Options: The weighted-average grant date fair value of the stock options granted during the three-month periods ended September 30, 2011 and 2010 was \$15.46 per share and \$18.16 per share, respectively. The weighted-average grant date fair value of the stock options issued during the nine-month periods ended September 30, 2011 and 2010 was \$16.13 per share and \$18.91 per share, respectively. There have been no significant changes to the assumptions used to estimate the fair value of options granted during the nine-month

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period ended September 30, 2011 compared to those granted in 2010 disclosed in Note 15 to the Consolidated Financial Statements included in the Company's 2010 Annual Report on Form 10-K.

The following table summarizes all stock option activity for the nine-month period ended September 30, 2011:

| | Options | Weighted Average Exercise Price Per Option | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (In Thousands) |
|--|-------------|--|--|--|
| Outstanding at December 31, 2010 | 41,137,686 | \$ 48.56 | 6.7 | \$ 501,663 |
| Changes during the Year: | | | | |
| Granted | 7,459,292 | | | |
| Exercised | (2,905,809) | | | |
| Forfeited | (1,069,868) | | | |
| Expired | (376,639) | | | |
| Outstanding at September 30, 2011 | 44,244,662 | \$ 50.87 | 6.6 | \$ 527,518 |
| Vested at September 30, 2011 or expected to vest in the future | 43,309,232 | \$ 50.75 | 6.6 | \$ 522,236 |
| Vested at September 30, 2011 | 22,887,020 | \$ 45.80 | 4.9 | \$ 398,652 |

The total fair value of shares vested during the nine-month periods ended September 30, 2011 and 2010 was \$116.2 million and \$100.2 million, respectively. The total intrinsic value of stock options exercised during the nine-month periods ended September 30, 2011 and 2010 was \$79.9 million and \$75.7 million, respectively. The Company primarily utilizes newly issued shares to satisfy the exercise of stock options.

As of September 30, 2011, there was \$271.6 million of total unrecognized compensation cost related to stock options granted under the plans. That cost will be recognized over an expected remaining weighted-average period of 2.3 years.

Restricted Stock Units: At the option of employee participants, equity awards may be divided between stock options and restricted stock units, or RSUs. The employee has three choices: (1) 100% stock options; (2) a mix of stock options and RSUs based on a two-thirds and one-third mix, using a three-to-one ratio of stock options to RSUs in calculating the number of RSUs to be granted; or (3) a mix of stock options and RSUs based on a one-half mix, using a three-to-one ratio of stock options to RSUs in calculating the number of RSUs to be granted. The fair value of RSUs is determined based on the closing price of the Company's common stock on the grant dates. Information regarding the Company's RSUs for the nine-month period ended September 30, 2011 is as follows:

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| Nonvested RSUs | Share Equivalent | | Weighted Average Grant Date Fair Value |
|----------------------------------|---------------------|----|---|
| Nonvested at December 31, 2010 | 1,510,384 | \$ | 54.84 |
| Changes during the period: | | | |
| Granted | 1,351,726 | | 58.50 |
| Vested | (9,072) | | 49.97 |
| Forfeited | (64,440) | | 55.03 |
| Non-vested at September 30, 2011 | 2,788,598 | \$ | 56.63 |

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

As of September 30, 2011, there was \$97.9 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 1.9 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. The Company primarily utilizes newly issued shares to satisfy the vesting of RSUs.

Performance-Based Restricted Stock Units: The Company's performance-based restricted stock units vest contingent upon the achievement of pre-determined performance-based milestones typically related to product development. If these performance-based milestones are not met, the RSUs will not vest, in which case, any compensation expense the Company has recognized to date associated with awards that will not vest will be reversed. The weighted-average grant date fair value of performance-based restricted stock units is based on the quoted market price of the Company's common stock on the date of grant. The following table summarizes the Company's performance-based restricted stock unit activity for the nine-month period ended September 30, 2011:

| Nonvested Performance-Based RSUs | Share Equivalent | Weighted Average Grant Date Fair Value |
|----------------------------------|---------------------|---|
| Nonvested at December 31, 2010 | | \$ |
| Changes during the period: | | |
| Granted | 28,500 | 60.88 |
| Vested | | |
| Forfeited | | |
| Non-vested at September 30, 2011 | 28,500 | \$ 60.88 |

As of September 30, 2011, there was \$1.5 million of total unrecognized compensation cost related to non-vested awards of performance-based RSUs that is expected to be recognized over a period of 2.3 years.

15. Income Taxes

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

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The Company's U.S. federal income tax returns have been audited by the U.S. 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 and scheduled to be completed within the next 12 months. 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 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

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Celgene CORPORATION AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as the Company's industry experience. These evaluations are based on estimates and assumptions that have been deemed reasonable by management. However, if management's estimates are not representative of actual outcomes, the Company's results of operations could be materially impacted.

Unrecognized tax benefits, generally represented by liabilities on the consolidated balance sheet and all subject to tax examinations, arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. These unrecognized tax benefits relate primarily to issues common among multinational corporations. Virtually all of these unrecognized tax benefits, if recognized, would impact the effective income tax rate. The Company accounts for interest and potential penalties related to uncertain tax positions as part of its provision for income taxes. Increases to the amount of unrecognized tax benefits from January 1, 2011 of approximately \$79.5 million relate primarily to current year operations. The Company's tax returns are under routine examination in many taxing jurisdictions. The scope of these examinations includes, but is not limited to, the review of the Company's taxable presence in a jurisdiction, deduction of certain items, the claims for research and development credits, compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from tax returns as filed. Settlements of examinations with taxing authorities or statute of limitations expirations may result in significant changes in the Company's unrecognized tax benefits. Certain examinations are scheduled to conclude within the next 12 months. It is reasonably possible that the amount of the liability for unrecognized tax benefits could change by a significant amount during the next 12-month period as a result of settlements or statute of limitations expirations. Finalizing examinations with the relevant taxing authorities can include formal administrative and legal proceedings and, as a result, it is difficult to estimate the timing and range of possible change related to the Company's unrecognized tax benefits. An estimate of the range of the possible change cannot be made until issues are further developed or examinations close.

16. Collaboration Agreements

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

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

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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:

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- a. either party if the other party materially breaches any of its material obligations under the agreement,

- b. the Company if Novartis fails to pay amounts due under the agreement two or more times in a 12-month period,

- c. either party, on a product-by-product and country-by-country basis, in the event of withdrawal of the d-MPH product or Ritalin® product from the market because of regulatory mandate,

- d. either party if the other party files for bankruptcy.

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

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

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

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

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

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are achieved as well as royalties on net sales. In December 2010, the Company made a \$10.0 million discovery milestone payment as required by the collaboration agreement upon the filing and clearance of an investigational new drug application with the FDA.

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

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

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

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

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, as amended, combines both companies' resources and commitment to developing products for the treatment of cancer and cancer-related bone loss and expands the joint development, manufacturing and commercialization of Acceleron's products to include anemia exclusivity. The ACE-011 agreement also includes an option for certain discovery stage programs. Under the terms of the ACE-011 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. The Company has agreed to pay all development costs incurred after January 1, 2013. Until January 1, 2013, Acceleron will continue to pay its share of these development expenses.

Under the ACE-011 agreement, 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, as amended on August 2, 2011, of up to \$367.0

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million for the ACE-011 program and up to an additional \$348.0 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, upon the commercialization of a development compound. The Company made a \$7.0 million development milestone payment to Acceleron in April 2011 for the initiation of enrollment into a Phase II study for chemotherapy-induced anemia.

On August 2, 2011, the Company also entered into a collaboration, license and option agreement with Acceleron, for the joint development and commercialization of ACE-536 for the treatment of anemia. The ACE-536 agreement also includes an option for future Acceleron anemia programs. The ACE-536 agreement provides the Company with an exclusive, worldwide, royalty-bearing license to the ACE-536 program and future Acceleron programs for the treatment of anemia. The parties also agreed to co-promote the products in the United States, Canada and Mexico.

Under the ACE-536 agreement, Acceleron will be responsible for initial activities, including research and development, and for conducting the Phase I and initial Phase II clinical trials, as well as manufacturing the clinical supplies for these studies. In turn, the Company will conduct subsequent Phase II and Phase III clinical studies and will oversee the manufacture of Phase III and commercial supplies.

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In August 2011, the Company made an upfront payment, under the ACE-536 agreement, to Acceleron in the amount of \$25.0 million. The Company has also agreed to pay all development costs incurred after January 1, 2013. Until January 1, 2013, Acceleron will pay its portion of the development expenses. Acceleron is eligible to receive development, regulatory approval and sales-based milestones of up to \$217.5 million for the ACE-536 program and up to an additional \$170.8 million for the first discovery stage program, \$148.8 million for the second discovery stage program and \$125.4 million for each additional discovery stage program thereafter. In September 2011, the Company recorded an expense of \$7.5 million, which was paid in October 2011, for a milestone payment for the initiation of a Phase I clinical study of ACE-536. Acceleron will receive tiered royalties on worldwide net sales, upon the commercialization of a development compound. Pursuant to the ACE-011 agreement, the Company has an option to buy down the royalty rate, for both ACE-011, as described above, and ACE-536, until and including January 1, 2013 at the Company's sole discretion for a one-time payment of \$25.0 million.

The agreements for ACE-011 and ACE-536 will each 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 such agreement. Upon the Company's full satisfaction of its royalty payment obligations to Acceleron under each such 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. Each 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, each agreement may be terminated by:

(i) the Company at its sole discretion, at any time for the ACE-011 agreement and with respect to the ACE-536 agreement after completion of the initial Phase II clinical trials, 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 ACE-011 or ACE-536 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 such 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 under such agreement. If the ACE-011 or ACE-536 agreement is terminated by the Company for a material breach by Acceleron, then, among other things, (A) the licenses granted to Acceleron under such agreement will terminate, (B) the licenses granted to the Company under such agreement will continue in

perpetuity, (C) all future royalties payable by the Company under such agreement will be reduced by 50% and (D) the Company's obligation to make any future milestone payments will terminate under such agreement.

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.,

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

The amrubicin license expires on a country-by-country basis and on a product-by-product basis upon the later of the (i) 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) first day of the first quarter for which the total number of generic product units sold in a given country exceeds 20% of the total number of generic product units sold plus licensed product units sold in the relevant country during the same calendar quarter.

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

- (i) the Company at its sole discretion,

- (ii) either party if the other party:
 - a. materially breaches any of its material obligations under the agreement, or

 - b. files for bankruptcy,

- (iii) DSP if the Company takes any action to challenge the title or validity of the patents owned by DSP, or

- (iv) DSP in the event of a change in control of the Company.

If the agreement is terminated by the Company at its sole discretion or by DSP under circumstances described in clauses (ii)(a) or (iii) above, respectively, 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. In June 2011, the collaboration and option agreement was amended, for no additional upfront consideration, to remove collaboration compound GI-10000 and replace it with collaboration compound GI-6300. 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 and GI-3000 programs and \$161.0 million for each of the GI-6300 program and 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-6300 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

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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-6300 oncology drug candidate programs terminates. Upon exercise of a Company option, the agreement will continue until the Company has satisfied all royalty payment obligations to GlobeImmune. Upon the expiration of the agreement, on a product-by-product, country-by-country basis, GlobeImmune will grant the Company an exclusive, fully paid-up, royalty-free, perpetual license to use certain intellectual property of GlobeImmune to market and sell the compounds and products developed under the agreement. The agreement may expire on a product-by-product and country-by-country basis as the Company satisfies its royalty payment obligation with respect to each product in each country.

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

- (i) the Company at its sole discretion, or

- (ii) either party if the other party:
 - a. materially breaches any of its material obligations under the agreement, or

 - b. files for bankruptcy.

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

Agios Pharmaceuticals, Inc.: On April 14, 2010, the Company entered into a discovery and development collaboration and license agreement with Agios Pharmaceuticals, Inc., or Agios, which focuses on cancer metabolism targets and the discovery, development and commercialization of associated therapeutics. As part of the agreement, the Company paid Agios a \$121.2 million non-refundable, upfront payment, which was expensed by the Company as research and development in the second quarter of 2010. The Company also made an \$8.8 million equity investment in Agios Series B Convertible Preferred Stock, representing approximately a 10.94% ownership interest in Agios and is included in other non-current assets in the Company's Consolidated Balance Sheets. The Company receives an initial period of exclusivity during which it has the option to develop any drugs resulting from the Agios cancer metabolism research platform and may extend this exclusivity period by providing Agios additional funding. The Company has an exclusive option to license any resulting clinical candidates developed during this

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period and will lead and fund global development and commercialization of certain licensed programs. With respect to each product in a program that the Company chooses to license, Agios could receive up to \$120.0 million upon achievement of certain milestones plus royalties on sales, and Agios may also participate in the development and commercialization of certain products in the United States. Agios may also receive a one-time milestone payment of \$25.0 million upon dosing of the final human subject in a Phase II study, such payment to be made only once with respect to only one program.

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

In October 2011, the Company and Agios agreed to extend the initial period of exclusivity by one year to April 14, 2014 in exchange for payment by the Company of \$20.0 million. The agreement was also amended to grant Agios the right to develop certain compounds covered by the collaboration agreement for indications not related to oncology and outside of the collaboration agreement. The amendment provides the Company with the right of first negotiation to license eventual products developed from these compounds.

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

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 the agreement and fails to cure such breach within the specified period, or

b. files for bankruptcy.

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

The Company has determined that Agios is a variable interest entity; however, the Company is not the primary beneficiary of Agios. Although the Company would have the right to receive the benefits from the collaboration and license agreement and it is probable that this agreement incorporates the activities that most significantly impact the economic performance of Agios for up to six years, the Company does not have the power to direct the activities under the collaboration and license agreement as Agios has the decision-making authority for the Joint Steering Committee and Joint Research Committee until the Company exercises its option to license a product. The Company's interest in Agios is limited

to its 10.94% equity ownership and it does not have any obligations or rights to the future losses or returns of Agios beyond this ownership. The collaboration agreement, including the upfront payment and series B convertible preferred stock investment, does not entitle the Company to participate in future returns beyond the 10.94% ownership and it does not obligate the Company to absorb future losses beyond the \$8.8 million investment in Agios Series B Convertible Preferred Stock. In addition, there are no other agreements other than the collaboration agreement that entitle the Company to receive returns beyond the 10.94% ownership or obligate the Company to absorb additional losses.

The Institute for Advanced Health: In April 2011, the Company entered into an agreement with the Institute for Advanced Health, or the Institute, that included an upfront contribution, future contingent matching contributions and an additional milestone-based contingent payment. The Institute is a non-profit organization dedicated to research and technology development in personalized molecular medicine of which Dr. Patrick Soon-Shiong is the Chairman and Chief Executive Officer. Under the terms of the agreement, the Company made an initial contribution with a value of \$41.0 million. The agreement provides for additional contributions of up to \$50.0 million to be made by the Company based on the level of other third-party contributions received by the Institute. No contributions have been made as of September 30, 2011. A final additional \$25.0 million milestone-based payment is contingent upon the Institute achieving specified results

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related to the collection of DNA data and genomic sequences and the initiation of research and development alliances to be achieved before December 31, 2015. Contributions made under this agreement will be recognized on the Company's Statements of Income as research and development expense.

As part of the contribution agreement, the Company will receive a right of first offer and matching rights with respect to all oncology products developed, funded, acquired or licensed by the Institute, the right to designate one of its employees to the Institute's Scientific Advisory Board and will be the exclusive oncology therapeutics sponsor of the Institute. These rights will continue for as long as the Company continues to make payments under a preexisting agreement.

17. Commitments and Contingencies

Collaboration Arrangements: The Company has entered into certain research and development collaboration agreements, as identified in Note 16, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. The Company's obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded in the Company's accompanying Consolidated Balance Sheets at September 30, 2011 and December 31, 2010.

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.

On January 20, 2011, the Supreme Court of Canada ruled that the jurisdiction of the Patented Medicine Prices Review Board, or the PMPRB, extends to sales of drugs to Canadian patients even if the locus of sale is within the United States. As a result of this ruling, the Company's U.S. sales of THALOMID® brand drug to Canadian patients under the special access program are subject to PMPRB jurisdiction on and after January 12, 1995. In accordance with the ruling of the Supreme Court of Canada, we have provided to-date data regarding these special access program sales to the PMPRB. In light of the approval of THALOMID® brand drug for multiple myeloma by Health Canada on August 4, 2010, this drug is currently sold through the Company's Canadian entity and is no longer sold to Canadian patients in the United States. The PMPRB's proposed pricing arrangement has not been determined. Depending on the calculation, the Company may be requested to return certain revenues associated with these sales and to pay fines. Should this occur, the Company would have to consider various legal options to address whether the pricing determination was reasonable.

18. Legal Proceedings

The Company and certain of its subsidiaries are involved in various patent, commercial and other claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of business. These legal proceedings and other matters are complex in nature and have outcomes that are difficult to predict and could have a material adverse effect on the Company.

Patent proceedings include challenges to scope, validity or enforceability of our patents relating to the Company's various products or processes. Although the Company believes it has substantial defenses to these challenges with respect to all its material patents, there can be no assurance as to the outcome of these

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matters, and a loss in any of these cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that drug and could materially affect future results of operations.

Among the principal matters pending to which the Company is a party are the following:

In the fourth quarter of 2009, the Company received a Civil Investigative Demand, or CID, from the U.S. Federal Trade Commission, or the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase the Company's patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that the Company has engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, the Company received a second CID from the FTC relating to this matter. The Company continues to respond to requests for information.

REVLIMID®: The Company has publicly announced that it has received a notice letter dated August 30, 2010, sent from Natco Pharma Limited of India (Natco) notifying it of a Paragraph IV certification alleging that patents listed for REVLIMID® in the Orange Book are invalid, and/or not infringed (the Notice Letter). The Notice Letter was sent pursuant to Natco having filed an abbreviated new drug application, or ANDA, seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg capsules of REVLIMID®. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book) four years after the pioneer company obtains approval of its New Drug Application, or an NDA. On October 8, 2010, we filed an infringement action in the United States District Court of New Jersey against Natco in response to the Notice Letter with respect to United States Patent Nos. 5,635,517 (the 517 patent), 6,045,501 (the 501 patent), 6,281,230 (the 230 patent), 6,315,720 (the 720 patent), 6,555,554 (the 554 patent), 6,561,976 (the 976 patent), 6,561,977 (the 977 patent), 6,755,784 (the 784 patent), 7,119,106 (the 106 patent), and 7,465,800 (the 800 patent). If Natco is successful in challenging the Company's patents listed in the Orange Book, and the FDA were to approve the ANDA with a comprehensive education and risk management program for a generic version of lenalidomide, sales of REVLIMID® could be significantly reduced in the United States by the entrance of a generic lenalidomide product, potentially reducing the Company's revenue.

Natco responded to the Company's infringement action on November 18, 2010, with its Answer, Affirmative Defenses and Counterclaims. Natco has alleged (through Affirmative Defenses and Counterclaims) that the patents are invalid, unenforceable and/or not infringed by Natco's proposed generic productions. After filing the infringement action, the Company learned the identity of Natco's U.S. partner, Arrow International Limited, or Arrow, and filed an amended complaint on January 7, 2011, adding Arrow as a defendant.

The Company believes that Natco's counterclaims are likely to be unsustainable and intends to vigorously defend its patent rights. The Company believes it unlikely that Natco will prevail on each and every patent and patent claim subject to the lawsuit and that all of the patents would be deemed to be invalidated, unenforceable and/or non-infringed. In addition the Company believes that it is unlikely that the FDA will approve an appropriate, non-infringing comprehensive education and risk management program for a generic version of lenalidomide. Accordingly, the Company believes that the ultimate outcome will not have a material adverse effect on its financial condition or results of operations.

In the first quarter of 2011, the Company received a letter from the United States Attorney for the Central District of California informing the Company that it was under investigation relating to its promotion of the drugs THALOMID® and REVLIMID® regarding off-label marketing and improper payments to physicians. The Company is cooperating with the United States Attorney in connection with this investigation.

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

Forward-Looking Information

This report contains forward-looking statements that reflect the current views of our management with respect to future events, results of operations, economic performance and/or financial condition. Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words expects, anticipates, believes, intends, estimates, aims, plans, may, could, will, will continue, seeks, should, predicts, potential, outlook, guidance, possible or the negative of such terms and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions and projections, which are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws. We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements, and therefore you should not place too much reliance on them. These factors include, among others, those described in the sections Forward-Looking Statements and Risk Factors contained in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or the SEC, and in this report and our other public reports filed with the SEC. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

Executive Summary

Celgene Corporation and its subsidiaries (collectively we, our or us) is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development which is designed to bring new therapies to market and are involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmunity and placental cell, including stem and progenitor cell, research.

Our primary commercial stage products include REVLIMID®, VIDAZA®, THALOMID® (inclusive of Thalidomide Celgene® and Thalidomide Pharmion®), ABRAXANE® and ISTODAX®.

- REVLIMID® is an oral immunomodulatory drug primarily marketed in the United States and select international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy and for the treatment of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes, or MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
- VIDAZA®, which is licensed from Pfizer, is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA® is a Category 1 recommended treatment for patients with

intermediate-2 and high-risk MDS according to the National Comprehensive Cancer Network, or NCCN, and is marketed in the United States for the treatment of all subtypes of MDS. The U.S. regulatory exclusivity for

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VIDAZA® expired on May 19, 2011. If a generic version of VIDAZA® is successfully launched, we may quickly lose a significant portion of our sales for this product in the United States. In Europe, VIDAZA® is marketed for the treatment of intermediate-2 and high-risk MDS as well as acute myeloid leukemia, or AML, with 30% blasts and has been granted orphan drug designation for the treatment of MDS and AML. We have regulatory exclusivity for VIDAZA® in Europe until 2018 and Japan until January 2021.

- THALOMID® is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.
- ABRAXANE®, which was obtained in the 2010 acquisition of Abraxis BioScience Inc., or Abraxis, is a nanoparticle, albumin-bound paclitaxel that was approved by the U.S. Food and Drug Administration, or FDA, in January 2005 for the treatment of metastatic breast cancer. ABRAXANE® is based on a tumor-targeting platform known as nab® technology.
- ISTODAX®, which was obtained in the 2010 acquisition of Gloucester Pharmaceuticals, Inc., or Gloucester, was approved in November 2009 by the FDA for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy and in June 2011 for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. ISTODAX® has received orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, which includes CTCL and PTCL. The European Agency for the Evaluation of Medicinal Products, or EMA, has granted orphan status designation for ISTODAX® for the treatment of both CTCL and PTCL.

Additional sources of revenue include a licensing agreement with Novartis, which entitles us to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Cellular Therapeutics subsidiary and other 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 have certain immunomodulatory and other biologically important properties, our leading oral anti-inflammatory agents, our cell products and our nanoparticle, albumin-bound compounds. We believe that continued acceptance of our primary commercial stage products, participation in research and development collaboration arrangements, depth of our product pipeline, regulatory approvals of both new products and expanded use of existing products will provide the catalysts for future growth.

The following table summarizes total revenue and earnings for the three- and nine-month periods ended September 30, 2011 and 2010:

| <i>(In thousands \$, except earnings per share)</i> | Three-Month Periods Ended | | Increase | Percent Change |
|---|---------------------------|--------------------|------------|----------------|
| | 2011 | September 30, 2010 | | |
| Total revenue | \$ 1,249,737 | \$ 910,111 | \$ 339,626 | 37.3% |

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| | | | | | | | |
|--|----|---------|----|---------|----|--------|-------|
| Net income attributable to Celgene | \$ | 372,984 | \$ | 281,151 | \$ | 91,833 | 32.7% |
| Diluted earnings per share attributable to Celgene | \$ | 0.81 | \$ | 0.60 | \$ | 0.21 | 35.0% |

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| <i>(In thousands \$, except earnings per share)</i> | Nine-Month Periods Ended September 30, | | | Increase | Percent Change |
|---|---|--------------|--------------|----------|-------------------|
| | 2011 | 2010 | | | |
| Total revenue | \$ 3,558,173 | \$ 2,554,057 | \$ 1,004,116 | 39.3% | |
| Net income attributable to Celgene | \$ 907,972 | \$ 670,945 | \$ 237,027 | 35.3% | |
| Diluted earnings per share attributable to Celgene | \$ 1.94 | \$ 1.44 | \$ 0.50 | 34.7% | |

The increase in revenue for the three- and nine-month periods ended September 30, 2011 compared to the three- and nine-month periods ended September 30, 2010 was primarily due to the continued growth of REVLIMID® and VIDAZA® in both U.S. and international markets, in addition to sales of ABRAXANE® subsequent to the acquisition of Abraxis in October 2010. Net income and diluted earnings per share for the three- and nine-month periods ended September 30, 2011 reflect the higher level of revenue, partly offset by additional costs incurred resulting from the acquisition of Abraxis in October 2010, in addition to increased spending for new product launches and research and development activities.

Sale of Non-core Assets: The purchase of Abraxis included a number of assets that were not associated with nab® technology or ABRAXANE®. These assets, or non-core assets, consisted of a number of subsidiaries, tangible assets, equity investments, joint venture partnerships and assets that supported research and sales of products not related to nab® technology. At the time of acquisition, we were committed to a plan to divest the non-core assets and they were classified on the Consolidated Balance Sheets as of December 31, 2010 as assets held for sale and the associated liabilities were classified as liabilities of disposal group. In April 2011, we sold the non-core assets to various entities that are owned or controlled by Dr. Patrick Soon-Shiong, the former majority shareholder and executive chairman of Abraxis.

We received cash consideration of \$110.0 million, 10% equity ownership in an entity, Active Biomaterials, LLC, formed with certain of the non-core assets with revenue-producing potential and a future royalty stream based on net sales of certain products of Active Biomaterials, LLC. The royalties, which commence in 2014 at the earliest and are not to exceed an annual amount of \$128.0 million, will be calculated based on a range of between 10% and 12.5% of net sales of certain future products. Dr. Patrick Soon-Shiong holds an option to purchase the 10% equity ownership in Active Biomaterials, LLC from us for a price of \$15.0 million at any time prior to April 2013. The equity ownership was recorded at its fair market value of \$14.0 million based on the present value of the amount likely to be received upon exercise of the purchase option. We recorded the future royalty stream as an asset and assigned a value of \$170.0 million based on its fair market value calculated as the present value of estimated future net cash flows. The sale of the non-core assets resulted in a gain of \$2.9 million which was included in the Consolidated Statements of Income in other income (expense), net. Our policy is to present gains and losses from sales of businesses as other income or expense.

Assets Held For Sale: In June 2011, management made the decision that certain additional assets associated with facilities acquired from Abraxis are intended to be sold as we rationalize certain manufacturing facilities. These additional assets are classified on the Consolidated Balance Sheets as of September 30, 2011 as assets held for sale and the associated liabilities are classified as liabilities of disposal group.

Gloucester Acquisition Milestone Achievement: In June 2011, the FDA granted accelerated approval of the Supplemental New Drug Application for ISTODAX® for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. This FDA approval was the triggering event for the payment of one of the two contingent regulatory milestone payments associated with the Gloucester acquisition. We made a payment of \$180.0 million to the former shareholders of Gloucester in July 2011 in satisfaction of this milestone payment requirement. The single remaining contingent milestone payment is for a \$120.0 million cash payment upon the marketing approval for the European Union PTCL.

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We measure this contingent consideration arrangement at fair value for each period with changes in fair value recognized in operating earnings. Changes in fair value reflect new information about the IPR&D assets and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses, and will be accrued based on an accretion schedule. At September 30, 2011, the balance of the contingent consideration was \$87.1 million and is included in other non-current liabilities.

Results of Operations:**Three-Month Periods Ended September 30, 2011 and 2010**

Total Revenue: Total revenue and related percentages for the three-month periods ended September 30, 2011 and 2010 were as follows:

| <i>(In thousands \$)</i> | Three-Month Periods Ended | | Increase (Decrease) | Percent Change |
|--|---------------------------|-----------------------|------------------------|-------------------|
| | 2011 | September 30, 2010 | | |
| Net product sales: | | | | |
| REVLIMID ® | \$ 820,019 | \$ 641,272 | \$ 178,747 | 27.9% |
| VIDAZA ® | 191,162 | 141,422 | 49,740 | 35.2% |
| THALOMID ® | 83,305 | 94,179 | (10,874) | -11.5% |
| ABRAXANE ® | 113,549 | | 113,549 | N/A |
| ISTODAX ® | 8,252 | 5,414 | 2,838 | 52.4% |
| Other | 2,831 | 3,369 | (538) | -16.0% |
| Total net product sales | \$ 1,219,118 | \$ 885,656 | \$ 333,462 | 37.7% |
| Collaborative agreements and other revenue | 3,766 | 2,241 | 1,525 | 68.0% |
| Royalty revenue | 26,853 | 22,214 | 4,639 | 20.9% |
| Total revenue | \$ 1,249,737 | \$ 910,111 | \$ 339,626 | 37.3% |

Total revenue increased by \$339.6 million, or 37.3%, to \$1.250 billion for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, reflecting increases of \$190.9 million, or 35.5%, in the United States, and \$148.7 million, or 39.9%, in international markets.

Net Product Sales:

Total net product sales for the three-month period ended September 30, 2011 increased by \$333.5 million, or 37.7%, to \$1.219 billion compared to the three-month period ended September 30, 2010. The increase was comprised of net volume increases of \$300.8 million, price increases of \$11.7 million and a favorable impact from foreign exchange of \$21.0 million. The increase in price was primarily due to price increases on THALOMID®, a decreased accrual rate for invoices related to Medicaid Managed Care Organizations in 2011 and a refinement of prior period Medicare Part D Coverage Gap charges.

REVLIMID® net sales increased by \$178.7 million, or 27.9%, to \$820.0 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, primarily due to increased unit sales in both U.S. and international markets. Increased market penetration and the increase in treatment duration of patients using REVLIMID® in multiple myeloma contributed to U.S. growth. The growth in international markets reflects the expansion of our commercial activities in addition to product reimbursement approvals and the launch of REVLIMID® in Japan in the latter part of 2010.

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VIDAZA® net sales increased by \$49.7 million, or 35.2%, to \$191.2 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, with sales increases in both the U.S. and international markets. The growth in international markets was primarily due to the increase in treatment duration of patients using VIDAZA® and product launches in additional countries. VIDAZA® retains orphan drug exclusivity in Europe through the end of 2018 and in Japan until January 2021.

THALOMID® net sales decreased by \$10.9 million, or 11.5%, to \$83.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, primarily due to lower unit volumes in the United States.

ABRAXANE® was obtained in the acquisition of Abraxis in October 2010 and was approved by the FDA in January 2005 for the treatment of metastatic breast cancer.

ISTODAX® net sales increased by \$2.8 million, or 52.4%, to \$8.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010. ISTODAX® was obtained in the acquisition of Gloucester in January 2010 and was approved by the FDA for the treatment of CTCL in November 2009 and PTCL in June 2011 in patients who have received at least one prior therapy. ISTODAX® was launched for the treatment of CTCL in March 2010.

The other net product sales category for the three-month period ended September 30, 2011 primarily included \$0.9 million in sales of FOCALIN® and \$1.5 million in sales of Pharmion products to be divested. The other net product sales category for the three-month period ended September 30, 2010 primarily included \$0.9 million in sales of FOCALIN® and \$2.0 million in sales of Pharmion products to be divested.

Collaborative Agreements and Other Revenue: Revenues from collaborative agreements and other sources increased by \$1.5 million to \$3.8 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010. The increase was primarily due to an increase in licensing fees and sale of services through our Cellular Therapeutics subsidiary in the current year quarter.

Royalty Revenue: Royalty revenue increased by \$4.6 million to \$26.9 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010 primarily due to an increase in royalties earned from Novartis on its sales of FOCALIN XR® and the entire RITALIN® family of drugs.

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

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

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THALOMID® is distributed in the United States under our proprietary *System for Thalidomide Education and Prescribing Safety*, or S.T.E.P.S.®, program which is a comprehensive education and risk-management distribution program with the objective of providing for the safe and appropriate distribution and use of THALOMID®. Internationally, THALOMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to help ensure the safe and appropriate distribution and use of THALOMID®. These programs may vary by country and, depending upon the country and the design of the

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risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA®, ISTODAX® and ABRAXANE® are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as THALOMID® and REVLIMID®.

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

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

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. Net revenues for the period ended September 30, 2011 were negatively impacted by a component of the U.S. Health Care Reform Act of 2010, or Health Care Reform Act, which became effective January 1, 2011 and required manufacturers of pharmaceutical products to be responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products. This expense is recognized throughout the year as incurred. In addition, certain international markets have government-sponsored programs that require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales. The Health Care Reform Act mandated an annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs. The fee, which is not material, is included in selling, general and administrative on the Consolidated Statements of Income.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We provide a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense

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Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

See Critical Accounting Estimates and Significant Accounting Policies in Note 1 of the Notes to the Consolidated Financial Statements included in our 2010 Annual Report on Form 10-K for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the three-month periods ended September 30, 2011 and 2010 were as follows:

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

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

A comparison of provisions for allowances for sales within each of the four categories noted above for the three-month periods ended September 30, 2011 and 2010 follows:

Returns and allowances increased by \$0.5 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, primarily due to higher returns for THALOMID®, partly offset by lower returns from divested products.

Discounts increased by \$5.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, primarily due to revenue increases in the United States and international markets, both of which offer different discount programs, and expansion into new international markets.

Government rebates increased by \$6.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, primarily due to an increase of approximately \$13.8 million in reimbursement rates in certain international markets. This increase was partially offset by a decrease in rebates related to various U.S. governmental agencies of \$7.5 million, primarily attributable to the refinement of estimates for Medicaid Managed Care Organizations and Medicare Part D Coverage Gap.

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Chargebacks and distributor service fees increased by \$18.0 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010. Chargebacks increased by \$9.2 million primarily due to \$6.9 million in chargebacks related to the inclusion of ABRAXANE® sales in the current year three-month period and increased U.S. sales of both REVLIMID® and VIDAZA®. Distributor service fees increased by approximately \$8.8 million primarily due to the inclusion of \$7.1 million in service fees associated with sales of ABRAXANE®.

Operating Costs and Expenses: Operating costs, expenses and related percentages for the three-month periods ended September 30, 2011 and 2010 were as follows:

| (In thousands \$) | Three-Month Periods Ended | | Increase (Decrease) | Percent Change |
|---|---------------------------|-----------------------|------------------------|-------------------|
| | 2011 | September 30, 2010 | | |
| Cost of goods sold (excluding amortization of acquired intangible assets) | \$ 94,645 | \$ 63,542 | \$ 31,103 | 48.9% |
| Percent of net product sales | 7.8% | 7.2% | | |
| Research and development | \$ 356,839 | \$ 253,547 | \$ 103,292 | 40.7% |
| Percent of total revenue | 28.6% | 27.9% | | |
| Selling, general and administrative | \$ 303,303 | \$ 228,281 | \$ 75,022 | 32.9% |
| Percent of total revenue | 24.3% | 25.1% | | |
| Amortization of acquired intangible assets | \$ 75,044 | \$ 46,540 | \$ 28,504 | 61.2% |
| Acquisition related (gains) charges and restructuring, net | \$ (11,209) | \$ 7,495 | \$ (18,704) | N/A |

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$31.1 million to \$94.6 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010. The increase was primarily due to increased sales activity and \$6.9 million of inventory step-up amortization adjustment related to sales of ABRAXANE® subsequent to the acquisition of Abraxis. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) increased to 7.8% in the three-month period ended September 30, 2011 compared to 7.2% for the three-month period ended September 30, 2010, primarily due to the inventory step-up amortization for ABRAXANE®. Excluding the step-up adjustment, the cost of goods sold ratio for 2011 was 7.2%.

Research and Development: Research and development expenses increased by \$103.3 million to \$356.8 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, partly due to a \$25.0 million upfront payment to Acceleron Pharma, or Acceleron, for a research and development collaboration arrangement related to ACE-536, a \$7.5 million milestone payment to Acceleron for the initiation of a Phase I clinical study of ACE-536, increase in research and development project spending in support of multiple programs across a broad range of diseases and the inclusion of \$23.5 million of expenses related to the Abraxis business acquired in October 2010.

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

| <i>(In thousands \$)</i> | Three-Month Periods Ended | | | Increase |
|--|---------------------------|---------------|------------|----------|
| | 2011 | September 30, | 2010 | |
| Human pharmaceutical clinical programs | \$ 185,768 | \$ 124,288 | \$ 61,480 | |
| Other pharmaceutical programs | 98,493 | 93,211 | 5,282 | |
| Drug discovery and development | 34,371 | 30,534 | 3,837 | |
| Placental stem cell | 5,707 | 5,514 | 193 | |
| Collaboration arrangements | 32,500 | | 32,500 | |
| Total | \$ 356,839 | \$ 253,547 | \$ 103,292 | |

Research and development expenditures support multiple ongoing clinical proprietary development programs for REVLIMID® and other IMiDs® compounds; VIDAZA®; ABRAXANE® in melanoma, non-small cell lung and pancreatic cancers; ISTODAX® for treatment of CTCL and PTCL; ABI compounds, which are targeted nanoparticle, albumin-bound compounds for treatment of solid tumor cancers; amrubicin, our lead compound for small cell lung cancer; apremilast (CC-10004), our lead anti-inflammatory compound that inhibits multiple proinflammatory mediators and which is currently being evaluated in Phase III clinical trials for the treatment of psoriasis and psoriatic arthritis; pomalidomide, which is currently being evaluated in Phase I, II and III clinical trials; CC-11050, for which Phase II clinical trials are planned; our kinase inhibitor programs; as well as our cell therapy programs.

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

The following table presents significant developments in our population of Phase III clinical trials that occurred during the three-month period ended September 30, 2011 and developments that are expected to occur if the future occurrence is material and reasonably certain:

Regulatory approval requests in major markets

| Product | Disease Indication | Major Market | Regulatory Agency | Date of Submission |
|-----------|--------------------|--------------|-------------------|-------------------------------------|
| ABRAXANE® | NSCLC2 | U.S. | FDA | Fourth quarter of 2011 ¹ |
| REVLIMID® | RRMM3 | China | sFDA | Fourth quarter of 2011 ¹ |
| REVLIMID® | Del 5q MDS | E.U. | EMA | First quarter of 2012 ¹ |
| REVLIMID® | NDMM4 | U.S. | FDA | 2012 ¹ |

¹ Current estimated submission timeframes

2 Non Small Cell Lung Cancer

3 Relapsed & Refractory Multiple Myeloma

4 Newly Diagnosed Multiple Myeloma

Selling, General and Administrative: Selling, general and administrative expenses increased by \$75.0 million to \$303.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, partly due to higher marketing and sales related expenses due to ongoing product launch activities, including REVLIMID® in Japan, VIDAZA® in Europe and ISTODAX® in the United

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States. In addition, the three-month period ended September 30, 2011 included \$39.6 million in expenses related to the Abraxis business acquired in October 2010.

Amortization of Acquired Intangible Assets: Amortization of acquired intangible assets is summarized below for the three-month periods ended September 30, 2011 and 2010:

| (In thousands \$) | Three-Month Periods Ended | | Increase (Decrease) |
|------------------------|---------------------------|-----------------------|------------------------|
| | 2011 | September 30, 2010 | |
| Abraxis acquisition | \$ 22,232 | \$ | \$ 22,232 |
| Gloucester acquisition | 12,875 | 6,550 | 6,325 |
| Pharmion acquisition | 39,937 | 39,990 | (53) |
| Total amortization | \$ 75,044 | \$ 46,540 | \$ 28,504 |

Amortization of acquired intangible assets increased by \$28.5 million to \$75.0 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010 primarily due to the October 2010 acquisition of Abraxis. In addition, in June 2011, the FDA approved ISTODAX®, which was obtained in the January 2010 acquisition of Gloucester, for treatment of PTCL in patients who have received at least one prior therapy. As a result of the FDA approval, amortization of the intangible asset commenced with an 8.8 year expected useful life.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition related (gains) charges and restructuring, net was a net gain of \$11.2 million for the three-month period ended September 30, 2011 and a charge of \$7.5 million for the three-month period ended September 30, 2010. The three-month period ended September 30, 2011 included a \$13.4 million favorable adjustment to the fair value of our liability related to publicly traded contingent value rights, or CVRs, that were issued as part of the acquisition of Abraxis, partly offset by \$2.0 million of accretion of a contingent liability related to the acquisition of Gloucester.

Interest and Investment Income, Net: Interest and investment income, net decreased by \$4.3 million to \$8.5 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010. The decrease was primarily due to a \$0.8 million reduction in interest income due to lower overall yields and a \$3.5 million net reduction in gains on sales of marketable securities.

Equity in Losses of Affiliated Companies: Under the equity method of accounting, we recorded losses of \$1.7 million and \$1.4 million for the three-month periods ended September 30, 2011 and 2010, respectively.

Interest Expense: Interest expense increased by \$9.9 million to \$10.3 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010, reflecting the interest on \$1.25 billion in senior notes issued in October 2010, net of the benefit from interest rate swaps and certain Commercial Paper issuances in September 2011.

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Other income (expense), net: Other income (expense), net was a net expense of \$15.0 million for the three-month period ended September 30, 2011 and a net income of \$8.5 million for the three-month period ended September 30, 2010. Other income (expense), net for the three-month period ended September 30, 2011 included net foreign exchange losses of \$7.9 million.

Income Tax Provision: The income tax provision decreased by \$9.4 million to \$39.7 million for the three-month period ended September 30, 2011 compared to the three-month period ended September 30, 2010.

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The full year 2011 underlying effective tax rate of 12.3% reflects the impact from our low tax Swiss manufacturing operations, the favorable impact of a shift in projected earnings between the U.S. and lower tax foreign jurisdictions, and tax deductions related to our acquisitions. The underlying effective tax rate also reflects benefits related to a non-taxable gain from a decrease in the fair value of our liability under the CVR Agreement related to the acquisition of Abraxis and a benefit from an IPR&D asset impairment charge. Tax benefits of \$18.2 million relating to a foreign tax credit and \$4.6 million, resulting from the filing of our 2010 income tax returns with certain items being more favorable than originally estimated, were recorded as discrete items in the three-month period ended September 30, 2011. The income tax provision for the three-month period ended September 30, 2010 included a full year underlying effective tax rate of 17.7% and a discrete tax benefit of \$8.0 million which was primarily the result of filing our 2009 income tax returns with certain items being more favorable than originally estimated.

Nine-Month Periods Ended September 30, 2011 and 2010

Total Revenue: Total revenue and related percentages for the nine-month periods ended September 30, 2011 and 2010 were as follows:

| <i>(In thousands \$)</i> | Nine-Month Periods Ended | | Increase (Decrease) | Percent Change |
|--|--------------------------|-----------------------|------------------------|-------------------|
| | 2011 | September 30, 2010 | | |
| Net product sales: | | | | |
| REVLIMID ® | \$ 2,353,334 | \$ 1,758,881 | \$ 594,453 | 33.8% |
| VIDAZA ® | 516,142 | 393,561 | 122,581 | 31.1% |
| THALOMID ® | 256,894 | 296,017 | (39,123) | -13.2% |
| ABRAXANE ® | 282,206 | | 282,206 | N/A |
| ISTODAX ® | 20,957 | 9,553 | 11,404 | 119.4% |
| Other | 27,522 | 10,152 | 17,370 | 171.1% |
| Total net product sales | \$ 3,457,055 | \$ 2,468,164 | \$ 988,891 | 40.1% |
| Collaborative agreements and other revenue | 16,468 | 7,165 | 9,303 | 129.8% |
| Royalty revenue | 84,650 | 78,728 | 5,922 | 7.5% |
| Total revenue | \$ 3,558,173 | \$ 2,554,057 | \$ 1,004,116 | 39.3% |

Total revenue increased by \$1.004 billion, or 39.3%, to \$3.558 billion for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, reflecting increases of \$569.2 million, or 37.2%, in the United States, and \$434.8 million, or 43.1%, in international markets.

Net Product Sales:

Total net product sales for the nine-month period ended September 30, 2011 increased by \$988.9 million, or 40.1%, to \$3.457 billion compared to the nine-month period ended September 30, 2010. The increase was comprised of net volume increases of \$990.9 million, price decreases of \$33.6 million and the favorable impact from foreign exchange of \$31.6 million. The decrease in prices was primarily due to increased Medicare Part D Coverage Gap rebates resulting from the Health Care Reform Act and an increase in rebates to U.S. and international governments resulting from their attempts to reduce health care costs, partly offset by product price increases.

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REVLIMID® net sales increased by \$594.5 million, or 33.8%, to \$2.353 billion for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily due to increased unit sales in both U.S. and international markets. Increased market penetration and the increase in treatment duration of patients using REVLIMID® in multiple myeloma contributed to U.S. growth. The

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growth in international markets reflects the expansion of our commercial activities in addition to product reimbursement approvals and the launch of REVLIMID® in Japan in the latter part of 2010.

VIDAZA® net sales increased by \$122.6 million, or 31.1%, to \$516.1 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, with sales increases in both the U.S. and international markets. The growth in international markets was primarily due to the increase in treatment duration of patients using VIDAZA® and product launches in additional countries.

THALOMID® net sales decreased by \$39.1 million, or 13.2%, to \$256.9 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily due to lower unit volumes in the United States.

ABRAXANE® was obtained in the acquisition of Abraxis in October 2010 and was approved by the FDA in January 2005 for the treatment of metastatic breast cancer.

ISTODAX® net sales increased by \$11.4 million, or 119.4%, to \$21.0 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. ISTODAX® was obtained in the acquisition of Gloucester in January 2010 and was approved by the FDA for the treatment of CTCL in November 2009 and PTCL in June 2011 in patients who have received at least one prior therapy. ISTODAX® was launched for the treatment of CTCL in March of 2010.

The other net product sales category for the nine-month period ended September 30, 2011 primarily included \$21.3 million in sales of non-core products obtained from the acquisition of Abraxis, which were divested in April 2011, \$3.7 million in sales of non-core Pharmion products to be divested and \$1.3 million in sales of FOCALIN®. The other net product sales category for the nine-month period ended September 30, 2010 primarily included \$6.7 million in sales of Pharmion products to be divested and \$3.2 million in sales of FOCALIN®.

Collaborative Agreements and Other Revenue: Revenue from collaborative agreements and other sources increased by \$9.3 million to \$16.5 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. The increase was primarily due to receipt of a \$6.3 million milestone payment in February 2011 related to the approval of VIDAZA® in Japan and the inclusion of certain manufacturing and management fees in the current year.

Royalty Revenue: Royalty revenue increased by \$5.9 million to \$84.7 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010 primarily due to an increase in royalties earned from Novartis on its sales of FOCALIN XR® and the entire RITALIN® family of drugs, which was partly offset by a decrease in residual payments earned by us based upon GSK's ALKERAN® revenues subsequent to the conclusion of the ALKERAN® license with GSK which ended in March 2011.

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Gross to Net Sales Accruals: Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2011 and 2010 were as follows:

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

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

A comparison of allowances for sales within each of the four categories noted above for the nine-month periods ended September 30, 2011 and 2010 follows:

Returns and allowances decreased by \$1.7 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily due to reduced U.S. provisions resulting from decreased revenue from products with higher return rates.

Discounts increased by \$17.5 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily due to revenue increases in the U.S. and international markets, both of which offer discount programs, and expansion into new international markets.

Government rebates increased by \$75.8 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily due to an increase of \$59.0 million in reimbursement rates in certain international markets, product approvals in new markets and \$16.8 million in increased costs associated with Medicaid Managed Care Organizations and Medicare Part D Coverage Gap. The nine month period ended September 30, 2011 included a benefit of \$4.3 million related to a refinement of prior year estimates for Medicaid Managed Care Organizations and the Medicare Part D Coverage Gap.

Chargebacks and distributor service fees increased by \$49.7 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. Chargebacks increased by \$27.2 million primarily due to \$16.8 million related to the inclusion of ABRAXANE® sales in the current year nine-month period and \$6.5 million related to sales of VIDAZA®, including \$2.1 million related to disputed claims from 2010. Distributor service fees increased by \$22.5 million due to the inclusion of \$17.6 million of service fees primarily attributable to sales of ABRAXANE® and a \$3.9 million increase in rebates related to TRICARE.

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Operating Costs and Expenses: Operating costs, expenses and related percentages for the nine-month periods ended September 30, 2011 and 2010 were as follows:

| <i>(In thousands \$)</i> | Nine-Month Periods Ended | | Increase (Decrease) | Percent Change |
|---|--------------------------|-----------------------|------------------------|-------------------|
| | 2011 | September 30, 2010 | | |
| Cost of goods sold (excluding amortization of acquired intangible assets) | \$ 348,356 | \$ 193,450 | \$ 154,906 | 80.1% |
| Percent of net product sales | 10.1% | 7.8% | | |
| Research and development | \$ 1,163,837 | \$ 800,965 | \$ 362,872 | 45.3% |
| Percent of total revenue | 32.7% | 31.4% | | |
| Selling, general and administrative | \$ 911,207 | \$ 655,522 | \$ 255,685 | 39.0% |
| Percent of total revenue | 25.6% | 25.7% | | |
| Amortization of acquired intangible assets | \$ 214,181 | \$ 135,201 | \$ 78,980 | 58.4% |
| Acquisition related (gains) charges | \$ (117,430) | \$ 20,193 | \$ (137,623) | N/A |

Cost of goods sold (excluding amortization of acquired intangible assets): Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$154.9 million to \$348.4 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. The increase was primarily due to the inclusion of a \$90.3 million inventory step-up amortization adjustment related to sales of ABRAXANE® subsequent to the acquisition of Abraxis, in addition to increased sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) increased to 10.1% in the nine-month period ended September 30, 2011 compared to 7.8% for the nine-month period ended September 30, 2010 primarily due to the inventory step-up amortization for ABRAXANE®. Excluding the step-up adjustment, the cost of goods sold ratio for the nine-month period ended September 30, 2011 was 7.5%.

Research and Development: Research and development expenses increased by \$362.9 million to \$1.164 billion for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. The nine-month period ended September 30, 2011 included \$232.0 million of research and development expenses related to the Abraxis business acquired in October 2010. These expenses included a \$118.0 million impairment charge related to the in-process research and development, or IPR&D, acquired intangible asset as a result of a change in the probability of obtaining progression-free survival labeling for the treatment of non-small cell lung cancer for ABRAXANE® in the United States. Expenses for the 2011 nine-month period also included a \$25.0 million upfront payment to Acceleron for expansion of a research and development collaboration arrangement to include ACE-536, milestone payments to Acceleron of \$7.0 million for the initiation of enrollment into a phase II study for chemotherapy-induced anemia and \$7.5 million for the initiation of a Phase I clinical study of ACE-536, a \$41.0 million upfront payment to the Institute for Advanced Health and an increase in research and development project spending in support of multiple programs across a broad range of diseases. The nine-month period ended September 30, 2010 included a \$121.2 million upfront payment to Agios Pharmaceuticals, Inc.

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

| <i>(In thousands \$)</i> | Nine-Month Periods Ended | | | Increase |
|--|--------------------------|---------------|---------|------------|
| | 2011 | September 30, | 2010 | |
| Human pharmaceutical clinical programs | \$ 542,736 | \$ | 326,141 | \$ 216,595 |
| Other pharmaceutical programs | 296,787 | | 257,669 | 39,118 |
| Drug discovery and development | 111,127 | | 80,413 | 30,714 |
| Placental stem cell | 14,705 | | 15,566 | (861) |
| Collaboration arrangements | 80,482 | | 121,176 | (40,694) |
| Asset impairment charge | 118,000 | | | 118,000 |
| Total | \$ 1,163,837 | \$ | 800,965 | \$ 362,872 |

Research and development expenditures support multiple ongoing clinical proprietary development programs for REVLIMID® and other IMiDs® compounds; VIDAZA®; ABRAXANE® in melanoma, non-small cell lung and pancreatic cancers; ISTODAX® for treatment of CTCL and PTCL; ABI compounds, which are targeted nanoparticle, albumin-bound compounds for treatment of solid tumor cancers; amrubicin, our lead compound for small cell lung cancer; apremilast (CC-10004), our lead anti-inflammatory compound that inhibits multiple proinflammatory mediators and which is currently being evaluated in Phase III clinical trials for the treatment of psoriasis and psoriatic arthritis; pomalidomide, which is currently being evaluated in Phase I, II and III clinical trials; CC-11050, for which Phase II clinical trials are planned; our kinase inhibitor programs; as well as our cell therapy programs.

Selling, General and Administrative: Selling, general and administrative expenses increased by \$255.7 million to \$911.2 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, partly due to a \$13.3 million increase in donations to non-profit foundations and higher marketing and sales-related expenses resulting from ongoing product launch activities, including REVLIMID® in Japan, VIDAZA® in Europe and ISTODAX® in the United States. In addition, the nine-month period ended September 30, 2011 included \$96.1 million in expenses related to the Abraxis business acquired in October 2010.

Amortization of Acquired Intangible Assets: Amortization of acquired intangible assets is summarized below for the nine-month periods ended September 30, 2011 and 2010:

| <i>(In thousands \$)</i> | Nine-Month Periods Ended | | | Increase (Decrease) |
|--------------------------|--------------------------|---------------|---------|------------------------|
| | 2011 | September 30, | 2010 | |
| Abraxis acquisition | \$ 67,027 | \$ | | \$ 67,027 |
| Gloucester acquisition | 27,342 | | 15,283 | 12,059 |
| Pharmion acquisition | 119,812 | | 119,918 | (106) |
| Total amortization | \$ 214,181 | \$ | 135,201 | \$ 78,980 |

Amortization of acquired intangible assets increased by \$79.0 million to \$214.2 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010 primarily due to the October 2010 acquisition of Abraxis. In addition, in June 2011, the FDA approved ISTODAX®, which was obtained in the January 2010 acquisition of Gloucester, for treatment of PTCL in patients

who

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have received at least one prior therapy. As a result of the FDA approval, amortization of the intangible asset commenced with an 8.8 year expected useful life.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition-related (gains) charges and restructuring, net was a net gain of \$117.4 million for the nine-month period ended September 30, 2011 and a charge of \$20.2 million for the nine-month period ended September 30, 2010. The \$137.6 million favorable variance was primarily due to a \$136.7 million favorable adjustment to the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis.

Interest and Investment Income, Net: Interest and investment income, net decreased by \$18.1 million to \$18.9 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. The decrease was primarily due to a \$10.1 million reduction in interest income due to lower overall yields, liquidation of securities to fund the Abraxis acquisition and a \$10.6 million net reduction in gains on sales of marketable securities, partly offset by a \$2.5 million net decrease in the amortization of premiums and discounts related to the purchase of marketable securities.

Equity in (Gains) Losses of Affiliated Companies: Under the equity method of accounting, we recorded losses of \$1.0 million and \$0.7 million for the nine-month periods ended September 30, 2011 and 2010. The loss for the nine-month period ended September 30, 2011 included losses from non-core former Abraxis equity method investments which were divested in April 2011.

Interest Expense: Interest expense increased by \$30.1 million to \$31.5 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010, primarily reflecting the \$30.3 million interest on \$1.25 billion in senior notes issued in October 2010, net of the benefit from interest rate swaps.

Other Income (Expense), Net: Other income (expense), net was a net expense of \$6.7 million for the nine-month period ended September 30, 2011 and a net income of \$7.1 million for the nine-month period ended September 30, 2010. The \$13.8 million decrease in other income (expense), net was primarily due to a decrease in net gains on foreign currency forward contracts that have not been designated as hedges entered into in order to offset net foreign exchange gains and losses, partly offset by a \$2.9 million gain on the sale of non-core assets and a \$3.6 million economic development grant received from the State of New Jersey.

Income Tax Provision: The income tax provision decreased by \$9.3 million to \$110.6 million for the nine-month period ended September 30, 2011 compared to the nine-month period ended September 30, 2010. The full year 2011 underlying effective tax rate of 12.3% reflects the impact from our low tax Swiss manufacturing operations, the favorable impact of a shift in projected earnings between the United States and lower tax foreign jurisdictions, and tax deductions related to our acquisitions. The decrease in the underlying effective tax rate also reflects benefits from an increase in acquisition-related charges, including an IPR&D asset impairment charge of \$118.0 million and a non-taxable gain from a decrease in the fair value of our liability under the CVR Agreement related to the acquisition of Abraxis of \$136.7 million. Tax expense of \$8.3 million related to a change in state tax law was recorded as a discrete item. In addition, tax benefits of \$18.2 million relating to a foreign tax credit and \$4.6 million, resulting from the filing of our 2010 income tax returns with certain items being more favorable than originally estimated, were also recorded as discrete items in the nine-month period ended September 30, 2011. The income tax provision for the nine-month period ended September 30, 2010 included a full year underlying effective tax rate of 17.7% and discrete tax benefits of \$12.5 million related to the settlement of a tax examination and \$8.0 million which was primarily the result of filing our 2009 income tax returns with certain items being more favorable than originally estimated.

Table of Contents**Financial Condition, Liquidity and Capital Resources**

The following table summarizes the components of our financial condition:

| <i>(In thousands \$)</i> | September 30, 2011 | December 31, 2010 | Increase (Decrease) |
|--|-----------------------|----------------------|------------------------|
| Financial assets: | | | |
| Cash, cash equivalents | \$ 1,794,927 | \$ 1,351,128 | \$ 443,799 |
| Marketable securities available for sale | 784,160 | 1,250,173 | \$ (466,013) |
| Total financial assets | \$ 2,579,087 | \$ 2,601,301 | \$ (22,214) |
| Debt: | | | |
| Short-term borrowings | \$ 269,125 | \$ | \$ 269,125 |
| Long-term debt | \$ 1,277,316 | \$ 1,247,584 | \$ 29,732 |
| Total debt | \$ 1,546,441 | \$ 1,247,584 | \$ 298,857 |
| Working capital (1) | \$ 2,746,916 | \$ 2,835,427 | \$ (88,511) |

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

We rely primarily on positive cash flows from operating activities, proceeds from sales of available-for-sale marketable securities, and borrowings in the form of long-term notes payable and, beginning in September 2011, short-term Commercial Paper to provide for our liquidity requirements. We expect continued growth in our expenditures, particularly those related to research and development, clinical trials, commercialization of new products, international expansion and capital investments. However, we anticipate that existing cash and cash equivalent balances, marketable securities available for sale, cash generated from operations and existing sources of and access to financing are adequate to fund our operating needs, capital expenditures, debt service requirements and our plans to repurchase stock or pursue other strategic business initiatives for the foreseeable future.

We consider the unrepatriated cumulative earnings of our foreign subsidiaries to be invested indefinitely outside the United States. In providing for our liquidity requirements in the U.S. we do not rely on these unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings.

Share Repurchase Program: In August 2011, our Board of Directors approved additional purchases of up to \$2.0 billion of our common stock. We have approximately \$2.034 billion remaining for future share repurchases, including all previous authorizations. During the nine-month-period ended September 30, 2011 we have used \$1.574 billion for share repurchases.

Components of Working Capital

Cash, Cash Equivalents and Marketable Securities Available for Sale: We invest our excess cash primarily in money market funds, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities and global corporate debt securities. All liquid investments with maturities of three months or

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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 \$22.2 million decrease in cash, cash equivalents and marketable securities available for sale at September 30, 2011 compared to December 31, 2010 was primarily due to the \$1.574 billion cash paid out under our share repurchase program, partly offset by cash generated from operations and short-term borrowings.

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Marketable securities available for sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges, is included in interest and investment income, net. For more information related to the fair value and valuation of our marketable securities, see Note 7 to the Notes to the Consolidated Financial Statements included elsewhere in this report.

Accounts Receivable, Net: Accounts receivable, net increased by \$181.7 million to \$888.2 million as of September 30, 2011 compared to December 31, 2010, primarily due to increased U.S. and international sales of REVLIMID®, VIDAZA® and ABRAXANE®, resulting in an increase in amounts due primarily from certain European countries. Days of sales outstanding at September 30, 2011 increased to 66 days compared to 59 days at December 31, 2010. The increase in days of sales outstanding was primarily due to increased international sales in countries where payment terms are typically greater than 60 days, thereby extending collection periods beyond those in the United States. We expect this trend to continue as our international sales continue to expand.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt crisis in certain European countries and associated impacts on the financial markets and our business. Our total net receivables in Spain, Italy and Portugal amounted to \$366.1 million at September 30, 2011 compared to \$231.6 million at December 31, 2010. We have not experienced significant losses or write-offs with respect to the collection of our accounts receivable in these countries. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of receivables in Greece.

Inventory: Inventory balances decreased by \$72.6 million to \$187.5 million at September 30, 2011 compared to December 31, 2010, primarily due to a \$90.3 million reduction in ABRAXANE® inventory related to the inventory step-up adjustment to fair value resulting from the acquisition of Abraxis, which flowed through cost of goods sold during the nine-month period ended September 30, 2011, partly offset by an increase in REVLIMID® and VIDAZA® inventories, attributable to higher sales levels.

Other Current Assets: Other current assets decreased by \$32.1 million to \$242.9 million as of September 30, 2011 compared to December 31, 2010 primarily due to decreases in prepaid taxes and prepaid royalties related to VIDAZA® sales, which were partly offset by an increase in the fair value of foreign currency forward contracts.

Commercial Paper: In September 2011, we entered into a commercial paper program, or the Program, under which we issues unsecured commercial paper notes, or Commercial Paper, on a private placement basis up to a maximum aggregate amount outstanding at any time of \$1.0 billion, the proceeds of which will be used for general corporate purposes. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis. Borrowings under the Program are accounted for as short-term borrowings. As of September 30, 2011, \$269.1 million of Commercial Paper was outstanding bearing an effective interest rate of 0.4%.

Senior Unsecured Credit Facility: In September 2011, we entered into a senior unsecured revolving credit facility, or the Credit Facility, providing for revolving credit in the aggregate amount of \$1.0 billion. Subject to certain conditions, we have the right to increase the amount of the Credit Facility (but in no event more than one time per annum), up to a maximum aggregate amount of \$1.250 billion.

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The Credit Facility has a five-year term and amounts may be borrowed for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of September 30, 2011 there was no outstanding borrowing against the Credit Facility.

The Credit Facility contains affirmative and negative covenants including certain customary financial covenants. We were in compliance with all debt covenants as of September 30, 2011.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities decreased by \$124.4 million to \$871.6 million as of September 30, 2011 compared to December 31, 2010. The decrease was primarily due to the payment of \$180.0 million of contingent consideration related to the purchase of Gloucester, which had a fair value of \$171.9 million on December 31, 2010. This decrease was partly offset by increases in governmental rebates and Medicaid reimbursements, clinical trial accruals and accrued interest expense.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by \$78.1 million to \$641.5 million as of September 30, 2011 compared to December 31, 2010, primarily from the current provision for income taxes of \$212.1 million, mostly offset by tax payments of \$79.2 million, a reduction of prepaid income taxes of \$32.1 million and a tax benefit of stock options of \$19.4 million.

Analysis of Cash Flows

Cash flows from operating, investing and financing activities for the nine-month periods ended September 30, 2011 and 2010 were as follows:

| (In thousands \$) | Nine-Month Periods Ended | | Change |
|---|--------------------------|-------------|----------------|
| | 2011 | 2010 | |
| Net cash provided by operating activities | \$ 1,338,473 | \$ 976,711 | \$ 361,762 |
| Net cash provided by (used in) investing activities | \$ 312,004 | \$ 797,167 | \$ (485,163) |
| Net cash provided by (used in) financing activities | \$ (1,197,330) | \$ (40,322) | \$ (1,157,008) |

Operating Activities: Net cash provided by operating activities for the nine-month period ended September 30, 2011 increased by \$361.8 million to \$1.338 billion as compared to the nine-month period ended September 30, 2010. The increase in net cash provided by operating activities was primarily attributable to the continued expansion of our operations and related increase in net earnings.

Investing Activities: Net cash provided by investing activities for the nine-month period ended September 30, 2011 decreased by \$485.2 million to \$312.0 million as compared to the nine-month period ended September 30, 2010. The decrease in net cash provided by investing activities was principally related to a reduced level of proceeds from the net sales of marketable securities and a cash use of \$180.0 million for the payment of a contingent consideration milestone related to the purchase of Gloucester, partially offset by \$93.2 million of net proceeds from the sale of non-core assets in April 2011. Net sales of marketable securities available for sale amounted to \$487.7 million during the nine-month period ended September 30, 2011 compared to net sales of \$1.210 billion in the nine-month period ended September 30, 2010.

Financing Activities: Net cash used in financing activities for the nine-month period ended September 30, 2011 was \$1.197 billion compared to \$40.3 million for the nine-month period ended September 30, 2010. The \$1.157 billion increase in net cash used in financing activities in 2011 was primarily attributable to \$1.574 billion of cash used for the repurchase of our common stock during the nine-month period ended September 30, 2011 compared to \$105.4 million of cash used during the nine-month period ended September

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30, 2010. The Commercial Paper program initiated in September 2011 resulted in net borrowings of \$269.1 million during the nine-month period ended September 30, 2011.

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 2010 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2010 aside from those disclosed in Notes 16 and 17 to the Notes to the Consolidated Financial Statements included elsewhere in this report.

Critical Accounting Estimates and Significant Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our significant accounting policies are more fully described in Note 1 of the Notes to the Consolidated Financial Statements included in our 2010 Annual Report on Form 10-K and Note 2 to Notes to Unaudited Consolidated Financial Statements included elsewhere in this report. Our critical accounting estimates are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our 2010 Annual Report on Form 10-K. There have not been any material changes to such significant accounting policies and critical accounting estimates since December 31, 2010.

Table of Contents**Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

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

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At September 30, 2011, our market risk sensitive instruments consisted of marketable securities available for sale, our long-term debt, our note payable and certain foreign currency forward contracts.

Marketable Securities Available for Sale: At September 30, 2011, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities, global corporate debt securities and a marketable equity security. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. Government Sponsored Enterprises. U.S. government-sponsored agency MBS include mortgage backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and Supranational securities consist of direct obligations of highly rated governments of nations other than the United States, obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. Corporate debt global includes obligations issued by investment-grade corporations including some issues that have been guaranteed by governments and government agencies.

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

As of September 30, 2011, 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>(In thousands \$)</i> | Duration | | | Total |
|--------------------------------|---------------------|--------------|--------------|------------|
| | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | |
| Principal amount | \$ 164,898 | \$ 506,567 | \$ 91,375 | \$ 762,840 |
| Fair value | \$ 171,428 | \$ 516,676 | \$ 95,632 | \$ 783,736 |
| Weighted average interest rate | 1.4% | 0.7% | 1.6% | 1.0% |

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Long-Term Debt: On October 7, 2010, we issued a total of \$1.25 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes due 2015, \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040. The notes were issued at 99.854%, 99.745% and 99.813% of par, respectively, and the discount amortized as additional interest expense over the period from issuance through

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maturity. Offering costs of approximately \$10.5 million have been recorded as debt issuance costs on our consolidated balance sheet and are amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on April 15 and October 15 of each year beginning April 15, 2011 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property. At September 30, 2011, the fair value of our senior notes outstanding was \$1.316 billion.

Note Payable: In December 2006, we purchased an active pharmaceutical ingredient, or API, manufacturing facility and certain other assets and liabilities from Siegfried. At September 30, 2011, the fair value of our note payable to Siegfried approximated its carrying value of \$22.6 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.

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

We enter into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at September 30, 2011 and December 31, 2010 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges under ASC 815 and, accordingly, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows:

| <i>(In thousands \$)</i> | Notional Amount | |
|--------------------------|--------------------|-------------------|
| | September 30, 2011 | December 31, 2010 |
| Foreign Currency | | |
| Australian Dollar | \$ 14,280 | \$ 51,809 |
| British Pound | | 58,440 |
| Canadian Dollar | 93,768 | 133,128 |
| Euro | 794,766 | 675,438 |
| Japanese Yen | 647,960 | 632,962 |
| Swiss Franc | 56,376 | 77,669 |
| Others | | 2,835 |
| Total | \$ 1,607,150 | \$ 1,632,281 |

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

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We recognized decreases in net product sales for certain effective cash flow hedge instruments of \$4.8 million and \$7.8 million for the three- and nine-month periods ended September 30, 2011, respectively, and increases of \$20.6 million and \$41.7 million for the three- and nine-month periods ended September 30, 2010, respectively. These settlements were recorded in the same period as the related forecasted sales occurred. Changes in time value, which we excluded from the hedge effectiveness assessment, were included in other income (expense), 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 (expense), net in the current period. Changes in the fair value of these currency forward contracts that have not been designated as hedges resulted in losses of \$46.6 million and \$11.7 million for the three- and nine-month periods ended September 30, 2011, respectively, compared to losses of \$49.7 million and \$4.2 million for the three- and nine-month periods ended September 30, 2010, respectively. The aggregate notional amounts of the foreign currency forward non-designated hedging contracts outstanding at September 30, 2011 and December 31, 2010 were \$1.023 billion and \$848.6 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the September 30, 2011 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$254.2 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.

We enter into interest rate swap contracts to convert a portion of our interest rate exposure from fixed rate to floating rate to more closely align interest expense with interest income received on our cash equivalent and investment balances. There were no interest rate swap contracts outstanding at September 30, 2011.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

The information called for by this item is incorporated herein by reference to Note 18 included in Part I, Item 1, Unaudited Financial Statements - Notes to Unaudited Consolidated Financial Statements.

Item 1A. Risk Factors.

The following statements describe the major risks to our business and should be considered carefully. Any of these factors could significantly and negatively affect our business, prospects, financial condition, operating results or credit ratings, which could cause the trading price of our common stock to decline. The risks described below are not the only risks we may face. Additional risks and uncertainties not presently known to us, or risks that we currently consider immaterial, could also negatively affect our business, financial results and operations.

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

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

- demand or lack of demand for our products, including demand that adversely affects our ability to optimize the use of our manufacturing facilities;
- the introduction and pricing of products competitive with ours, including generic competition;

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- developments regarding the safety or efficacy of our products;
- regulatory approvals for our products and pricing determinations with respect to our products;
- regulatory approvals for our and our competitor s manufacturing facilities;
- timing and levels of spending for research and development, sales and marketing;
- timing and levels of reimbursement from third-party payers for our products;
- development or expansion of business infrastructure in new clinical and geographic markets;
- the acquisition of new products and companies;
- tax rates in the jurisdictions in which we operate;
- timing and recognition of certain research and development milestones and license fees;
- ability to control our costs;
- fluctuations in foreign currency exchange rates; and
- economic and market instability.

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

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

Further, if unexpected adverse experiences are reported in connection with the use of our products, physician and patient comfort with the product could be undermined, the commercial success of such products could be adversely affected and the acceptance of our other products could be negatively impacted. We are subject to adverse event reporting regulations that require us to report to the FDA or similar bodies in other countries if our products are associated with a death or serious injury. These adverse events, among others, could result in additional regulatory controls, such as the performance of costly post-approval clinical studies or revisions to our approved labeling, which could limit the indications or patient population for our products or could even lead to the withdrawal of a product from the market. Similarly, the occurrence of serious adverse events known or suspected to be related to the products could negatively impact product sales. For example, THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities in the baby. REVLIMID® is also considered fetal toxic and there are warnings against use of VIDAZA® in pregnant women as well. While we have restricted distribution systems for both THALOMID® and REVLIMID® and we endeavor to educate patients regarding the potential known adverse events including pregnancy risks, we cannot ensure that all such warnings and

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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®, FOCALIN XR® and the RITALIN® family of drugs. A number of factors may adversely impact the degree of market acceptance of our products, including the products' efficacy, safety and advantages, if any, over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans, patent disputes and claims about adverse side effects.

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

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

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

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

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

- In general, preclinical tests and clinical trials can take many years, and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretation that could delay, limit or prevent regulatory approval;
- Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality or, in

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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;

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- The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and reimbursed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the drug;
- Approved products, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their manufacture, sale or use or in their withdrawal from the market;
- Regulatory authorities and agencies of the United States or foreign governments may promulgate additional regulations restricting the sale of our existing and proposed products, including specifically tailored risk evaluation and mitigation strategies;
- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our products;
- Once a product receives marketing approval, we may not market that product for broader or different applications, and the FDA may not grant us approval with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing approvals in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products. The FDA may also request that we perform additional clinical trials or change the labeling of our existing or proposed products if we or others identify side effects after our products are on the market;
- Products, such as REVLIMID®, that are subject to accelerated approval can be subject to an expedited withdrawal if the post-marketing 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;

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- 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. Currently, we are required to be, and are, licensed to operate in New York, New Jersey, Maryland and California. If other states adopt similar licensing requirements, we would need to obtain such licenses to continue operating our stem cell banking businesses. If we are delayed in receiving, or are unable to obtain at all, necessary licenses, we will be unable to provide services in those states and this could impact negatively on our revenue.

Sales of our products will be significantly reduced if access to and reimbursement for our products by governmental and other third-party payers is reduced or terminated.

Sales of our products will depend, in part, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of healthcare costs of patients. These health care management organizations and third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the newly enacted Health Care Reform Act has provided sweeping health care reform, which may impact the prices of drugs. In addition to the newly enacted federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures, including the impact of the Health Care Reform Act, could adversely impact our business and future results. If these organizations and third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

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

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

Our long-term success depends, in part, on intellectual property protection.

Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions including those related to our risk evaluation and mitigation strategies (such as our S.T.E.P.S.[®] and RevAssist[®] programs). In addition, the coverage sought in a patent application can be significantly reduced before the patent is issued.

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

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

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

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We may in the future have to prove that we are not infringing patents or we may be required to obtain licenses to such patents. However, we do not know whether such licenses will be available on commercially reasonable terms, or at all. Prosecution of patent applications and litigation to establish the validity and scope of patents, to assert patent infringement claims against others and to defend against patent infringement claims by others can be expensive and time-consuming. There can be no assurance that, in the event that claims of any of our owned or licensed patents are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity relating to the subject matter delineated by such patent claims and may have a material adverse effect on our business. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the products or processes covered by the disputed rights, be subject to significant liabilities to such third party and/or be required to license technologies from such third party. Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention or that any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Competitors have chosen and in the future may choose to file oppositions to patent applications, which have been deemed allowable by foreign patent examiners. Furthermore, even if our owned or licensed patents are determined to be valid and enforceable, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. Additionally, for these same reasons, we cannot be sure that patents of a broader scope than ours may be issued and thereby create freedom to operate issues. If this occurs we may need to reevaluate pursuing such technology, which is dominated by others' patent rights, or alternatively, seek a license to practice our own invention, whether or not patented.

We also rely upon unpatented, proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach or that our trade secrets, proprietary know-how and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology or that such technology will not be found to be non-proprietary or not a trade secret.

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

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

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

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

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

We have received a Paragraph IV Certification Letter dated August 30, 2010, advising us that Natco Pharma Limited of Hyderabad, India, or Natco, submitted an ANDA to the FDA. See Part I, Item 1, Note 18 to Notes to Unaudited Consolidated Financial Statements included elsewhere in this report for further information.

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

The pharmaceutical and biotech industry in which we operate is highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms, including, but not limited to:

- Takeda and Johnson & Johnson, which compete with REVLIMID® and THALOMID® in the treatment of multiple myeloma and in clinical trials with our compounds;
- Eisai Co., Ltd., SuperGen, Inc. and Johnson & Johnson, which compete or may potentially compete with VIDAZA®, in addition Eisai Co., Ltd. potentially competes with ABRAXANE®, and in other oncology products in general;
- Amgen, which potentially competes with our TNF- and kinase inhibitors;

- AstraZeneca plc, which potentially competes in clinical trials with our compounds and TNF- inhibitors;
- Biogen Idec Inc. is generally developing drugs that address the oncology and immunology markets;

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- Bristol Myers Squibb Co., which potentially competes with ABRAXANE®, and in clinical trials with our compounds and TNF- inhibitors, in addition to other oncology products in general;
- F. Hoffman-La Roche Ltd., which potentially competes in clinical trials with our IMiDs® compounds and TNF- inhibitors, in addition to other oncology products in general;
- Johnson & Johnson, which potentially competes with certain of our proprietary programs, including our oral anti-inflammatory programs;
- Abbott Laboratories, which potentially competes with our oral anti-inflammatory programs;
- Novartis, which potentially competes with our compounds and kinase programs;
- Pfizer, which potentially competes in clinical trials with our kinase inhibitors; and
- SANOFI, which competes with ABRAXANE®, in addition to other oncology products in general.

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

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

From time to time, we may be subject to litigation or governmental investigation on a variety of matters, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, whistleblower, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business as currently conducted or as conducted in the future.

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In particular, we are subject to significant product liability risks as a result of the testing of our products in human clinical trials and for products that we sell after regulatory approval.

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

In the fourth quarter of 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission, or the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, we received a second CID from the FTC relating to this matter. We continue to respond to requests for information.

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In the first quarter of 2011, we received a letter from the United States Attorney for the Central District of California informing us that we were under investigation relating to our promotion of the drugs THALOMID® and REVLIMID® regarding off-label marketing and improper payments to physicians. We are cooperating with the United States Attorney in connection with this investigation.

On January 20, 2011, the Supreme Court of Canada ruled that the jurisdiction of the Patented Medicine Prices Review Board, or the PMPRB, extends to sales of drugs to Canadian patients even if the locus of sale is within the United States. This means that our U.S. sales of THALOMID® brand drug to Canadian patients under the special access program are subject to PMPRB jurisdiction from and after January 12, 1995. In accordance with the ruling of the Supreme Court of Canada, we have provided to-date data regarding these special access program sales to the PMPRB. In light of the approval of THALOMID® brand drug for multiple myeloma by Health Canada on August 4, 2010, this drug is now sold through our Canadian entity and is no longer sold to Canadian patients in the United States. The PMPRB's proposed pricing arrangement has not been determined. Depending on the calculation, we may be requested to return certain revenues associated with these sales and to pay fines. Should this occur, we would have to consider various legal options to address whether the pricing determination was reasonable.

Litigation and governmental investigations are inherently unpredictable and may:

- result in rulings that are materially unfavorable to us, including claims for significant damages, fines or penalties, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that prevent us from operating our business in a certain manner;
- cause us to change our business operations to avoid perceived risks associated with such litigation or investigations;
- have an adverse affect on our reputation and the demand for our products; and
- require the expenditure of significant time and resources, which may divert the attention of our management and interfere with the pursuit of our strategic objectives.

While we maintain insurance for certain risks, the amount of our insurance coverage may not be adequate to cover the total amount of all insured claims and liabilities. It also is not possible to obtain insurance to protect against all potential risks and liabilities. If any litigation or governmental investigation were to have a material adverse result, there could be a material impact on our results of operations, cash flows or financial position. See also "Legal Proceedings" contained in Part II, Item 1 of this report.

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

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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

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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.

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

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

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

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

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

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

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

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors and pharmacy chains control a significant share of the market. We expect that consolidation of drug wholesalers and pharmacy chains will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements, and their purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

Risks from the improper conduct of employees, agents or contractors or collaborators could adversely affect our business or reputation.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including without limitation, employment, foreign corrupt practices, environmental, competition and privacy laws. Such improper actions could subject us to civil or criminal investigations, monetary and injunctive penalties and could adversely impact our ability to conduct business, results of operations and reputation.

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

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

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

- the diversion of management's attention from the management of daily operations to the integration of operations;
- higher integration costs than anticipated;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;

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- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, controls, including internal control over financial reporting required by the Sarbanes-Oxley Act of 2002 and related procedures and policies.

If we cannot successfully integrate Abraxis or other acquired businesses we may experience material negative consequences to our business, financial condition or results of operations. Successful integration of Abraxis and other acquired businesses will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by offerings and expanded geographic market coverage and, to some degree, to eliminate redundant and excess costs. Because of difficulties in combining geographically distant operations, we may not be able to achieve the benefits that we hope to achieve as a result of the acquisition of Abraxis or other acquired businesses.

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

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

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

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options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other jurisdictions, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets, and changes in overall levels of pre-tax earnings. The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have an impact on our results of operations.

Currency fluctuations and changes in exchange rates could increase our costs and may cause our profitability to decline.

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results.

We utilize foreign currency forward contracts 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 is intended to mitigate the exposure of these risks with the intent to reduce our risk or cost, but may not fully offset any change in operating results as a consequence of fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations.

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.

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

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

Due to tightened global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including portions of our product manufacturing, royalty revenue, clinical development of future collaboration products, conduct of clinical trials and raw materials. If such third parties are unable to satisfy their commitments to us, our business could be adversely affected.

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

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

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- results of our clinical trials or adverse events associated with our marketed products;
- fluctuations in our commercial and operating results;
- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- stock market conditions generally;
- changes in governmental regulations and laws, including, without limitation, changes in tax laws, health care legislation, environmental laws, competition laws, and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- patent or proprietary rights developments;
- changes in pricing and third-party reimbursement policies for our products;
- the outcome of litigation involving our products or processes related to production and formulation of those products or uses of those products;
- other litigation or governmental investigations;

- competition; and

- investor reaction to announcements regarding business or product acquisitions.

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

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

On October 7, 2010, we issued a total of \$1.25 billion principal amount of senior notes, consisting of the 2015 notes, the 2020 notes and the 2040 notes, collectively referred to as the notes. Our ability to pay interest on the notes, to repay the principal amount of the notes when due at maturity, to comply with the covenants of the notes or to repurchase the notes if a change of control occurs will depend upon, among other things, continued commercial success of our products and other factors that affect our future financial and operating performance, including, without limitation, prevailing economic conditions and financial, business, and regulatory factors, many of which are beyond our control.

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

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

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

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

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy breaches by employees and others who access our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to protect our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

We have certain charter and by-law provisions that may deter a third-party from acquiring us and may impede the stockholders' ability to remove and replace our management or board of directors.

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5,000,000 shares of preferred stock, and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third-party from acquiring a majority of our outstanding voting stock. Additionally, our board of directors has adopted certain amendments to our by-laws intended to strengthen the board's position in the event of a hostile takeover attempt. These provisions could impede the stockholders' ability to remove and replace our management and/or board of directors. Furthermore, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

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

On October 15, 2010, we acquired all of the outstanding common stock of Abraxis BioScience, Inc. and in connection with our acquisition, contingent value rights, or CVRs, were issued under a CVR Agreement entered into between us and American Stock Transfer & Trust Company, LLC, as trustee. A copy of the CVR Agreement was filed on Form 8-A with the Securities and Exchange Commission on October 15, 2010. Pursuant to the CVR Agreement, each holder of a CVR is entitled to receive a *pro rata* portion, based on the number of CVRs then outstanding, of certain milestone and net sales payments if certain specified conditions are satisfied. For more information, see Note 3 of Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

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In addition to the risks relating to our common stock, CVR holders are subject to additional risks, including:

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

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(c) Issuer Purchases of Equity Securities

The following table presents the total number of shares purchased during the three-month period ended September 30, 2011, the average price paid per share, the number of shares that were purchased and the approximate dollar value of shares that still could have been purchased, pursuant to our publicly announced repurchase program:

| Period | Total Number of Shares (or Units) Purchased | Average Price Paid per Share (or Unit) | Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares (or Units) that may yet be Purchased Under the Plans or Programs |
|----------------------------|---|--|---|---|
| July 1 - July 31 | 2,335,000 | \$ 60.49 | 2,335,000 | \$ 777,405,462 |
| August 1 - August 31 | 11,014,200 | \$ 55.25 | 11,014,200 | \$ 2,168,902,615 |
| September 1 - September 30 | 2,200,200 | \$ 61.46 | 2,200,200 | \$ 2,033,677,841 |

In April 2009, our Board of Directors approved a \$0.5 billion common share repurchase program, which was subsequently increased by \$3.5 billion to an aggregate of up to \$4.0 billion of our common shares that may be repurchased under this program. Approved amounts exclude share repurchase transaction fees.

As of September 30, 2011 an aggregate 35,676,097 common shares were repurchased under the program at an average price of \$55.12 per common share and total cost of \$1.967 billion, including share repurchase transaction fees.

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

None.

Item 6. Exhibits.

- 31.1 Certification by the Company's Chief Executive Officer.
- 31.2 Certification by the Company's Chief Financial Officer.
- 32.1 Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
- 32.2 Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
- 101 The following materials from Celgene Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.

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SIGNATURES

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

CELGENE CORPORATION

DATE: November 2, 2011

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

DATE: November 2, 2011

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