CELGENE CORP /DE/
Form 10-Q
November 08, 2006

FORM 10-Q
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

(Mark one)

[x] QUARTERLY REPORT UNDER SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2006

OR

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

For the transition period from _____to _____

Commission File Number 0-16132

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

| Delaware | 22-2711928 |
|---|---|
| (State or other jurisdiction of incorporatio or organization) | (I.R.S. Employer Identification Number) |

| 86 Morris Avenue, Summit, NJ | 07901 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (908) 673-9000.

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

Yes X No
--- ---

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated X Accelerated Non-accelerated
--- --- ---

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

Yes No X

--- ---

At November 1, 2006, 352,441,666 shares of Common Stock par value $.01 per share, were outstanding.

CELGENE CORPORATION

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Item 1. Unaudited Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(Dollars in thousands, except per share amounts)

| | Three-Month Period Ended September 30, | | Nine-Mont Septe |
|---|---|---|---|
| | 2006 | 2005 | 2006 |
| Revenues: | | | |
| Net product sales | $ 223,105 | $ 113,900 | $ 559,749 |
| Collaborative agreements and other revenue | 4,186 | 4,879 | 12,032 |
| Royalty revenue | 17,548 | 10,727 | 52,138 |
| Total revenues | 244,839 | 129,506 | 623,919 |
| Expenses: | | | |
| Cost of goods sold | 34,205 | 23,199 | 91,148 |
| Research and development | 66,756 | 49,348 | 178,298 |
| Selling, general and administrative | 89,597 | 46,941 | 239,318 |
| Total expenses | 190,558 | 119,488 | 508,764 |
| Operating income | 54,281 | 10,018 | 115,155 |
| Other income and expense: | | | |
| Interest and other income, net | 10,392 | 6,979 | 26,118 |
| Equity in losses of affiliated company | 736 | 980 | 5,202 |
| Interest expense | 2,361 | 2,374 | 7,086 |
| Income before income taxes | 61,576 | 13,643 | 128,985 |
| Income tax provision | 41,139 | 12,975 | 82,916 |
| Net income | $ 20,437 | $ 668 | $ 46,069 |
| Net income per common share: | | | |
| Basic | $0.06 | $0.00 | $0.13 |
| Diluted | $0.05 | $0.00 | $0.12 |

See accompanying Notes to Consolidated Financial Statements



CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(DOLLARS IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

| | SEPTEMBER 30, 2006 (UNAUDITED) |
|---|---|
| ASSETS | |
| Current assets: | |
| Cash and cash equivalents | $ 243,665 |
| Marketable securities available for sale | 628,809 |
| Accounts receivable, net of allowance of $6,495 and $3,739 at September 30, 2006 and December 31, 2005, respectively | 109,856 |
| Inventory | 36,058 |
| Deferred income taxes | 111,180 |
| Other current assets | 85,002 |
| Total current assets | 1,214,570 |
| Property, plant and equipment, net | 97,760 |
| Investment in affiliated company | 13,514 |
| Intangible assets, net | 98,261 |
| Goodwill | 36,792 |
| Deferred income taxes | 49,204 |
| Other assets | 16,718 |
| Total assets | $ 1,526,819 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current liabilities: | |
| Accounts payable | $ 35,158 |
| Accrued expenses | 92,833 |
| Income taxes payable | 64,896 |
| Current portion of deferred revenue | 7,064 |
| Other current liabilities | 4,346 |
| Total current liabilities | 204,297 |
| Long-term convertible notes | 399,962 |
| Deferred revenue, net of current portion | 61,367 |
| Other non-current liabilities | 22,915 |
| Total liabilities | 688,541 |
| COMMITMENTS AND CONTINGENCIES | |

| | |
|---|---|
| STOCKHOLDERS' EQUITY: | |
| Preferred stock, $.01 par value per share, 5,000,000 shares authorized; none outstanding at September 30, 2006 and December 31, 2005 | -- |
| Common stock, $.01 par value per share, 575,000,000 shares authorized; issued 355,877,715 and 344,125,158 shares at September 30, 2006 and December 31, 2005, respectively | 3,559 |
| Common stock in treasury, at cost; 3,743,797 and 1,953,282 shares at September 30, 2006 and December 31, 2005, respectively | (129,789) |
| Additional paid-in capital | 1,083,844 |
| Accumulated deficit | (124,684) |
| Accumulated other comprehensive income | 5,348 |
| Total stockholders' equity | 838,278 |
| Total liabilities and stockholders' equity | $ 1,526,819 |

See accompanying Notes to Consolidated Financial Statements



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

| | NINE-S |
|---|---|
| | 2006 |
| Net income | $ 46,0 |
| Adjustments to reconcile net income to net cash provided by operating activities: | |
| Depreciation and amortization of long-term assets | 18,6 |
| Provision for accounts receivable allowances | 15,5 |
| Unrealized loss (gain) on marketable securities available for sale and cash equivalents | 3,9 |
| Unrealized gain on foreign exchange forward contracts | (3,5 |
| Unrealized loss on value of EntreMed warrants | 2 |
| Equity losses of affiliated company | 4,8 |
| Non-cash share-based compensation expense | 58,8 |
| Amortization of premium/discount on marketable securities available for sale, net | (2,3 |
| Loss on asset disposals | 1 |
| Amortization of debt issuance cost | 1,8 |
| Deferred income taxes | (23,3 |
| Shares issued for employee benefit plans | 6,5 |
| Other | 7 |

| | |
|---|---|
| Change in operating assets and liabilities, excluding the impact of acquisition: | |
| Increase in accounts receivable | (51,3 |
| Increase in inventory | (13,6 |
| Increase in other operating assets | (45,4 |
| Increase (decrease) in accounts payable, accrued expenses and other liabilities | (28,9 |
| Increase in income tax payable | 56,1 |
| Decrease in deferred revenue | (2,1 |
| Net cash provided by operating activities | 42,8 |
| Cash flows from investing activities: | |
| Capital expenditures | (31,9 |
| Business acquisition | |
| Proceeds from sales and maturities of marketable securities available for sale | 563,5 |
| Purchases of marketable securities available for sale | (581,0 |
| Investment in affiliated company | (2,0 |
| Other investments | (6 |
| Net cash used in investing activities | (52,0 |
| Cash flows from financing activities: | |
| Net proceeds from exercise of common stock options and warrants | 67,9 |
| Excess tax benefit from share-based compensation arrangements | 57,7 |
| Repayment of capital lease and note obligations | |
| Net cash provided by financing activities | 125,7 |
| Effect of currency rate changes on cash and cash equivalents | 3,7 |
| Net increase (decrease) in cash and cash equivalents | 120,3 |
| Cash and cash equivalents at beginning of period | 123,3 |
| Cash and cash equivalents at end of period | $ 243,6 |

See accompanying Notes to Consolidated Financial Statements



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

NINE-MONTH PERIOD EN
SEPTEMBER 30,

| | 2006 | 2 |
|---|---|---|
| Supplemental schedule of non-cash investing and financing activity: | | |
| Change in net unrealized loss on marketable securities available for sale | $ 7,986 | $ |
| Matured shares tendered for stock option exercises and employee tax withholdings | $ (85,876) | $ |
| Conversion of convertible notes | $ 22 | $ |
| Supplemental disclosure of cash flow information: | | |
| Interest paid | $ 5,250 | $ |
| Income taxes paid | $ 24,071 | $ |

See accompanying Notes to Consolidated Financial Statements



NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2006
(THOUSANDS OF DOLLARS, EXCEPT PER SHARE AMOUNTS, UNLESS OTHERWISE INDICATED)

1. ORGANIZATION AND BASIS OF PRESENTATION

Celgene Corporation and its subsidiaries (collectively "Celgene" or the "Company") is an integrated biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory diseases. The Company's revenues include pharmaceutical sales of REVLIMID(R), THALOMID(R), and ALKERAN(R) and sales of FOCALIN(R) to Novartis Pharma AG, or Novartis; a licensing agreement with Novartis which entitles the Company to royalties on FOCALIN(R) XR and the entire RITALIN(R) family of drugs; a licensing and product supply agreement with Pharmion for its sales of thalidomide; and sales of bio-therapeutic products and services through Celgene Cellular Therapeutics.

The accompanying unaudited consolidated financial statements have been prepared from the books and records of the Company pursuant to the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Certain reclassifications have been made to the prior period's consolidated financial statements in order to conform to the current period's presentation. The interim consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's current report on Form 8-K filed with the Securities and Exchange Commission on November 3, 2006 to update its previously issued

financial statements for all years shown in the Company's 2005 Annual Report on Form 10-K to reflect the realignment of our organizational and reportable business segments into a single segment.

The Company is changing the presentation of how it reflects deferred income taxes and changes in income tax payable within the cash flows from the operations section of the consolidated statement of cash flows. The change in presentation will better align the deferred income tax amount with the deferred tax amount reflected in the consolidated statement of operations and the change in income taxes payable with the amount of current expense. The consolidated statement of cash flows for the nine-months ended September 30, 2006 and 2005 was prepared on this basis. Additionally our 2006 Form 10-K will include reclassifications of certain amounts in 2005 and 2004 within the operating activities section of cash flows to conform to this presentation. This change in presentation does not impact previously reported cash flows from operations, financing or investing activities for those years.

Interim results may not be indicative of the results that may be expected for the full year. In the opinion of management, these financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim statements.

In December 2005, the Company's Board of Directors approved a two-for-one stock split payable in the form of a 100 percent stock dividend. Stockholders received one additional share for every share they owned as of the close of business on February 17, 2006. The additional shares were distributed on February 24, 2006. As a result, the total number of authorized shares of capital stock increased from 280,000,000 to 580,000,000 (575,000,000 shares of common stock and 5,000,000 shares of preferred stock). All share and per share amounts in the consolidated financial statements have been restated to reflect the two-for-one stock split effective February 17, 2006.

2. NEW ACCOUNTING PRINCIPLES

In June 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes--an interpretation of FASB Statement No. 109. This





Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB No. 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. This Interpretation is effective for the Company beginning January 1, 2007. We are in the process of analyzing the impact that this Interpretation may have on the Company's consolidated financial statements. Therefore, we are not in a position to conclude whether the adoption of this Interpretation will have a material impact on the Company's consolidated financial statements.

In February 2006, the FASB, issued Financial Accounting Standard No. 155,

"Accounting for Certain Hybrid Financial Instruments - an amendment of FASB Statements No. 133 and 140," which permits a fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that would otherwise require bifurcation. This accounting standard is effective for the Company beginning January 1, 2007. We have not yet determined the effect, if any, the adoption of FAS 155 may have on our financial position and results of operations.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 ("SAB 108"), which provides guidance on the consideration of the effects of prior period misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 provides for the quantification of the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements. If a misstatement is material to the current year financial statements, the prior year financial statements should also be corrected, even though such revision was, and continues to be, immaterial to the prior year financial statements. Correcting prior year financial statements for immaterial errors would not require previously filed reports to be amended. Such correction should be made in the current period filings. SAB 108 is effective for fiscal years ending on or after November 15, 2006. We are currently evaluating the impact that the adoption of SAB 108 will have on our consolidated financial statements.

3. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income adjusted to add back the after-tax amount of interest recognized in the period associated with any convertible debt issuance that may be dilutive by the weighted-average number of common shares outstanding during the period increased to include all additional common shares that would have been outstanding assuming potentially dilutive common shares had been issued and any proceeds thereof used to repurchase common stock at the average market price during the period. The proceeds used to repurchase common stock are assumed to be the sum of the amount to be paid to the Company upon exercise of options, the amount of compensation cost attributed to future services and not yet recognized and, if applicable, the amount of income taxes that would be credited to or deducted from paid-in capital upon exercise.

The total number of potential common shares excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 1,872,512 and 35,071,174 shares for the three-month periods ended September 30, 2006 and 2005, respectively. The total number of potential common shares excluded for the nine-month periods ended September 30, 2006 and 2005 was 2,893,814 and 3,547,470 shares, respectively.





The following represents the reconciliation of the basic and diluted earnings per share computations for the three and nine months ended September 30, 2006 and 2005:

| | Three-Month Period Ended September 30, | | |
|---|---|---|---|
| | 2006 | 2005 | 2 |
| Income available to common stockholders: | | | |
| Net income for basic EPS | $ 20,437 | $ 668 | $ |
| Interest expense on convertible debt, net of tax | 1,393 | -- | |
| Net income for diluted EPS | $ 21,830 | $ 668 | $ |
| Weighted average number of common shares outstanding (IN THOUSANDS): | | | |
| Basic | 351,200 | 336,596 | 3 |
| Effect of dilutive securities: | | | |
| Options, warrants and other incentives | 20,637 | 23,128 | |
| Convertible debt | 33,021 | -- | |
| Diluted | 404,858 | 359,724 | 4 |
| Earnings per share: | | | |
| Basic | $ 0.06 | $ 0.00 | $ |
| Diluted | $ 0.05 | $ 0.00 | $ |

4. CONVERTIBLE DEBT

In June 2003, the Company issued an aggregate principal amount of $400.0 million of unsecured convertible notes. The notes have a five-year term and a coupon rate of 1.75% payable semi-annually on June 1 and December 1. Each $1,000 principal amount of convertible notes is convertible into 82.5592 shares of common stock, or a conversion rate of $12.1125 per share, which represented a 50% premium to the closing price on May 28, 2003 of the Company's common stock of $8.075, after adjusting prices for the two-for-one stock splits which became effective on February 17, 2006 and October 22, 2004. The debt issuance costs related to these convertible notes, which totaled approximately $12.2 million, are classified under "Other Assets" on the consolidated balance sheet and are being amortized over five years, assuming no conversion. Under the terms of the purchase agreement, the noteholders can convert the outstanding notes at any time into an aggregate 33,020,545 shares of common stock at the conversion price. In addition, the noteholders have the right to require the Company to redeem the notes in cash at a price equal to 100% of the principal amount to be redeemed, plus accrued interest, prior to maturity in the event of a change of control and certain other transactions defined as a "fundamental change," in the indenture governing the notes. Subsequent to the June 2003 issuance date, an immaterial amount of principal has been converted into common stock.





5. MARKETABLE SECURITIES AVAILABLE FOR SALE

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, 2006 and December 31, 2005 were as follows:

| September 30, 2006 | Amortized Cost | Gross Unrealized Gain | Unr |
|---|---|---|---|
| CASH EQUIVALENTS (1) | | | |
| Government sponsored enterprises | $151,343 | $ 24 | |
| AVAILABLE-FOR-SALE MARKETABLE SECURITIES | | | |
| Mortgage-backed obligations | 83,397 | 252 | |
| U.S. treasury securities | 53,767 | -- | |
| Government sponsored enterprises | 273,666 | -- | |
| Corporate debt securities | 13,489 | 16 | |
| Other asset backed securities | 21,149 | 1,594 | |
| Auction rate notes | 145,500 | -- | |
| Marketable equity securities | 20,212 | 21,586 | |
| Total available-for-sale marketable securities | 611,180 | 23,448 | |
| Total marketable securities | $762,523 | $ 23,472 | |

(1) Marketable debt securities with maturities of three months or less at time of purchase are classified as cash equivalents.

| December 31, 2005 | Amortized Cost | Gross Unrealized Gain | Unr |
|---|---|---|---|
| AVAILABLE-FOR-SALE MARKETABLE SECURITIES | | | |
| Mortgage-backed obligations | $ 86,478 | $ 365 | $ |
| U.S. treasury securities | 24,391 | 14 | |
| Government sponsored enterprises | 183,315 | 25 | |
| Corporate debt securities | 18,526 | 29 | |
| Other asset backed securities | 29,765 | 164 | |
| Auction rate notes | 232,575 | -- | |
| Marketable equity securities | 20,212 | 14,255 | |
| Total available-for-sale marketable securities | $595,262 | $ 14,852 | $ |

Government sponsored enterprises include fixed asset-backed securities issued by the Federal National Mortgage Association and the Federal Home Loan Bank. Other asset-backed securities are securities backed by collateral other than mortgage obligations. Unrealized losses for mortgage-backed obligations, U.S. treasury securities and government sponsored enterprises were primarily due to increases in interest rates. Unrealized losses for corporate debt and other asset-backed securities were primarily due to increases in interest rates as well as widening credit spreads. The Company has sufficient liquidity and the intent to hold these securities until the market value recovers. Moreover, the Company does not believe it is probable that it will be unable to collect all amounts due according to the contractual terms of the individual investments. In the nine months ended September 30, 2006, the Company determined that certain securities had sustained an other-than-temporary impairment and recognized a $3.8 million

impairment loss related to these securities due to reductions in their future estimated cash flows.





As of September 30, 2006, the duration of the Company's debt securities classified as cash equivalents and marketable securities available for sale were as follows:

| | Amortized Cost | Fair Value |
|---|---|---|
| Duration of one year or less | $449,108 | $448,928 |
| Duration of one through three years | 79,428 | 78,755 |
| Duration of three through five years | 191,343 | 188,269 |
| Duration of five through seven years | 19,967 | 19,961 |
| Duration greater than seven years | 2,465 | 2,465 |
| Total | $742,311 | $738,378 |

6. INVENTORY

Inventory at September 30, 2006 and December 31, 2005 consisted of the following:

| | September 30, 2006 | December 31, 2005 |
|---|---|---|
| Raw materials | $ 9,045 | $ 5,044 |
| Work in process | 3,783 | 1,644 |
| Finished goods | 23,230 | 13,554 |
| Total | $36,058 | $20,242 |

7. SHARE-BASED COMPENSATION

The Company has a shareholder approved 1998 equity incentive plan, or the 1998 Incentive Plan, that provides for the granting of options, restricted stock awards, stock appreciation rights, performance awards and other share-based awards to employees and officers of the Company. On June 14, 2006, the stockholders of the Company approved an amendment to the 1998 Incentive Plan to increase the aggregate number of shares of Common Stock that may be subject to awards thereunder from 62,000,000 to 84,000,000 shares, subject to adjustment under certain circumstances. The Management Compensation and Development Committee of the Board of Directors, or the Compensation Committee, determines the type, amount and terms, including vesting, of any awards made under the Incentive Plan. The 1998 Incentive Plan will terminate in 2008.

With respect to options granted under the 1998 Incentive Plan, the exercise price may not be less than the market price of the common stock on the date of grant. In general, options granted under the 1998 Incentive Plan vest over

periods ranging from immediate vesting to four-year vesting and expire ten years from the date of grant, subject to earlier expiration in case of termination of employment. The vesting period for options and restricted stock awards granted under the 1998 Incentive Plan is subject to certain acceleration provisions if a change in control, as defined in the 1998 Incentive Plan, occurs. Plan participants may elect to exercise options at any time during the option term. However, any shares so purchased which have not vested as of the date of exercise shall be subject to forfeiture, which will lapse in accordance with the established vesting time period.

In June 1995, the stockholders of the Company approved the 1995 Non-Employee Directors' Incentive Plan, which, as amended, provides for the granting of non-qualified stock options to purchase an aggregate of not





more than 7,700,000 shares of common stock (subject to adjustment under certain circumstances) to directors of the Company who are not officers or employees of the Company, or Non-Employee Directors. Each new Non-Employee Director, upon the date of election or appointment, receives an option to purchase 20,000 shares of common stock, which vest in four equal annual installments commencing on the first anniversary of the date of grant. As amended in 2003, continuing Non-Employee Directors receive quarterly grants of 3,750 options aggregating 15,000 options annually, which vest in full one year from the date of grant. The 1995 Non-Employee Directors' Incentive Plan also provides for a discretionary grant upon the date of each annual meeting of an additional option to purchase up to 5,000 shares to a Non-Employee Director who serves as a member (but not a chairman) of a committee of the Board of Directors and an option to purchase up to 10,000 shares to a Non-Employee Director who serves as the chairman of a committee of the Board of Directors. All options are granted at an exercise price that equals the market value of the Company's common stock at the grant date and expire ten years after the date of grant. This plan terminates on June 30, 2015. In December 2005, in recognition of the significance of the REVLIMID(R) regulatory approval, continuing Non-Employee Directors received the 2006 annual stock option award of 15,000 shares, which were granted at an exercise price equal to the fair value of the Company's common stock on December 29, 2005 and vest pursuant to the standard terms of the plan.

Stock options available for future grants under all plans were 22,696,267 at September 30, 2006.

Historically, the Company applied the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees," or APB 25, and related interpretations. As such, compensation expense for grants of stock options to employees or members of the Board of Directors would be recorded on the date of grant only if the current market price of the Company's stock exceeded the exercise price. Statement of Financial Accounting Standards, or SFAS, No. 123 "Accounting For Stock-Based Compensation," or SFAS 123, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of APB 25 described above, and adopted only the disclosure requirements of SFAS 123, as amended by SFAS No. 148, "Accounting For Stock-Based Compensation - Transition and Disclosure."

The following table illustrates the effect on net income and net income per common share applicable to common stockholders for the three and nine-month periods ended September 30, 2005, as if the Company had applied the fair value recognition provisions for stock-based compensation of SFAS 123, as amended:





| | Three Months Ended September 30, 2005 |
|---|---|
| Net income as reported | $ 668 |
| Add: stock-based employee compensation expense included in reported income, net of tax | 32 |
| Add: stock-based employee compensation expense determined under fair-value-based method (1) | (6,407) |
| Basic pro forma net income | $(5,707) |
| Interest expense on convertible debt, net of tax | -- |
| Diluted, pro forma net income | $(5,707) |
| Net income per common share: | |
| Basic, as reported | $ -- |
| Basic, pro forma | $ (0.02) |
| Diluted, as reported | $ -- |
| Diluted, pro forma | $ (0.02) |

(1) Nine months ended September 30, 2005 reflects an adjustment recorded in the first quarter of 2005 to eliminate related valuation allowances of $17.7 million based on the Company's determination that it was more likely than not that certain benefits of its deferred tax assets would be realized.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, "Share-Based Payment", or SFAS 123R. SFAS 123R, which replaces SFAS 123, and supersedes APB 25, requires that compensation cost relating to share-based payment transactions be recognized in financial statements based on the fair value for all awards granted after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method as prescribed by SFAS 123R does not require restatement of prior periods to reflect the impact of adopting SFAS 123R.

The Company adopted SFAS 123R effective January 1, 2006 and has selected the Black-Scholes method of valuation for share-based compensation. The Company has adopted the modified prospective application method under which the provisions of SFAS 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award's original estimate of fair value. SFAS 123R requires compensation costs to be recognized based on the estimated number of awards

expected to vest. Changes in the estimated forfeiture rates are reflected prospectively.





The following table summarizes the impact of adopting SFAS 123R effective January 1, 2006:

| | Three Months Ended September 30, 2006 |
|---|---|
| Cost of good sold | $ 413 |
| Research and development | 2,689 |
| Selling, general and administrative | 20,091 |
| Total share-based compensation expense | 23,193 |
| Tax benefit related to share-based compensation expense | (7,783) |
| Effect on net income | $ 15,410 |
| Effect on earnings per share: | |
| Basic | $ 0.04 |
| Diluted | $ 0.04 |

Included in stock-based compensation expense for the three and nine-month periods ended September 30, 2006 was compensation expense related to non-qualified stock options of $19.0 million and $44.0 million, respectively.

No amounts of share-based compensation cost were capitalized as inventory or other assets during the three and nine months ended September 30, 2006. As of September 30, 2006, there was $81.2 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 1.1 years.

In November 2005, the FASB issued FASB Staff Position 123(R)-3, "Transition Election Related to Accounting for the Tax Effects of Share-based Payment Awards," or FSP 123R- 3, which provides an elective alternative transition method of calculating the additional paid-in capital pool, or APIC Pool, of excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123R to the method otherwise required by paragraph 81 of SFAS 123R. The Company may take up to one year from the effective date of FSP 123R-3 to evaluate its available alternatives and make its one-time election. The Company is evaluating the impact of the adoption of this FSP in connection with its adoption of SFAS 123R.

Prior to the adoption of SFAS 123R, the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Consolidated Statement of Cash Flows. SFAS 123R requires excess tax

benefits (i.e., the tax benefit recognized upon exercise of stock options in excess of the benefit recognized from recognizing compensation cost for those options) to be classified as financing cash flows in the Consolidated Statement of Cash Flows. Cash received from stock option exercises for the nine-month period ended September 30, 2006 was $68.0 million and the excess tax benefit recognized was $57.8 million. Cash received from stock option exercises for the nine-month period ended September 30, 2005 was $37.9 million. Pursuant to SFAS 123R, tax benefits resulting from the exercise of stock options, which have been presented as operating cash flows prior to the adoption of SFAS 123R are not reclassified to financing activities, but rather shall continue to be presented as operating cash flows.

The weighted-average grant-date fair value of the stock options granted during the three and nine-month periods ended September 30, 2006 was $20.03 per share and $16.82 per share, respectively. The weighted-average grant-date fair value of the stock options granted during the three and nine-month periods ended September 30, 2005 was $8.14 per share and $7.12 per share adjusted for the February 17, 2006 two-for-one stock split. The Company estimated the fair value of options granted using a Black-Scholes option pricing model with the following assumptions:





| | Three Months Ended September 30, 2006 | 2005 | Nine Mon 2006 |
|---|---|---|---|
| Risk-free interest rate | 4.63% - 4.92% | 3.56% - 4.34% | 4.50% - |
| Expected volatility | 46% - 51% | 41% | 40% - |
| Weighted average expected volatility | 48% | 41% | 49 |
| Expected term (years) | 4.1 - 4.9 | 3.5 | 3.1- |
| Expected dividend yield | 0% | 0% | 0% |

The fair value of stock options granted is estimated using the Black-Scholes option pricing model. The fair value of stock options granted after January 1, 2006 is amortized on a straight-line basis. The fair value of stock options granted before January 1, 2006 is amortized using the graded vesting attribution approach. Compensation cost is amortized over the requisite service periods of the awards, which are generally the vesting periods.

For grants during the three and nine-month periods ended September 30, 2006, the risk-free interest rate is based on the U.S. Treasury zero-coupon curve. Expected volatility of stock option awards is estimated based on the implied volatility of greater than one-year publicly traded options. The use of implied volatility was based upon the availability of actively traded options on the Company's common stock and the assessment that implied volatility is more representative of future stock price trends than historical volatility. Prior to the adoption of SFAS 123R, the Company calculated expected volatility using only historical stock price volatility. The expected term of an employee share option is the period of time for which the option is expected to be outstanding. The Company has made a determination of expected term by analyzing employees' historical exercise experience from its history of grants and exercises in the

Company's option database and management estimates. Forfeiture rates are estimated based on historical data.

In December 2005, in recognition of the significance of the REVLIMID(R) regulatory approval, the Board of Directors approved a resolution to grant the 2006 annual stock option awards under the 1998 Incentive Plan in 2005. All stock options awarded were granted fully vested. Half of the options granted had an exercise price of $34.05 per option, which was at a 5% premium to the closing price of the Company's common stock of $32.43 per share on the grant date of December 29, 2005; the remaining options granted had an exercise price of $35.67 per option, which was at a 10% premium to the closing price of the Company's common stock of $32.43 per share on the grant date of December 29, 2005. The Board's decision to grant these options was in recognition of the REVLIMID(R) regulatory approval and in response to a review of the Company's long-term incentive compensation programs in light of changes in market practices and recently issued changes in accounting rules resulting from the issuance of SFAS 123R, which the Company adopted effective in the first quarter of 2006. Management believes that granting these options prior to the adoption of FASB No. 123R will result in the Company not being required to recognize cumulative compensation expense of approximately $70.8 million for the four-year period ending December 31, 2009.





Stock option transactions for the nine months ended September 30, 2006 under all plans are as follows:

| | Options | Weighted Average Exercise Price Per Share | Weight Avera Remain Contrac Term (y |
|---|---|---|---|
| Outstanding at December 31, 2005 | 50,594,378 | $ 13.70 | 6.9 |
| Changes during the year: | | | |
| Granted | 2,899,614 | 41.40 | -- |
| Exercised | (11,690,742) | 9.20 | -- |
| Forfeited | (1,119,977) | 14.11 | -- |
| Expired | (97,281) | 11.71 | -- |
| Outstanding at September 30, 2006 | 40,585,992 | $ 16.93 | 6.3 |
| Vested or expected to vest at September 30, 2006 | 40,026,077 | $ 16.87 | 6.3 |
| Vested at September 30, 2006 | 27,886,806 | $ 14.68 | 5.7 |

The total intrinsic value of stock options exercised during the nine months ended September 30, 2006 and 2005 was $370.2 million and $163.3 million,

respectively. The Company primarily utilizes newly issued shares to satisfy the exercise of stock options.

The following table summarizes information concerning options outstanding under the 1998 and 1995 Incentive Plans at September 30, 2006:

| | Options Outstanding | | | | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding | Weighted Average Exercise Price Per Share | Weighted Average Remaining Term (yrs.) | Number Vested | W A E Pric |
| $ 0.04 - $ 5.00 | 6,327,512 | $ 2.05 | 3.1 | 6,318,512 | $ |
| 5.01 - 10.00 | 8,334,634 | 6.78 | 4.9 | 7,310,085 | |
| 10.01 - 15.00 | 8,120,025 | 12.84 | 7.1 | 4,063,590 | |
| 15.01 - 20.00 | 4,271,223 | 16.52 | 6.9 | 1,996,794 | |
| 20.01 - 30.00 | 4,784,135 | 25.15 | 7.5 | 2,542,375 | |
| 30.01 - 48.59 | 8,748,463 | 36.86 | 8.2 | 5,655,450 | |
| | 40,585,992 | $ 16.93 | 6.3 | 27,886,806 | $ |

Stock options granted to executives at the vice-president level and above under the 1998 Incentive Plan, after September 18, 2000, contained a reload feature which provided that if (1) the optionee exercises all or any portion of the stock option (a) at least six months prior to the expiration of the stock option, (b) while employed by the Company and (c) prior to the expiration date of the 1998 Incentive Plan and (2) the optionee pays the exercise price for the portion of the stock option exercised or pays minimum statutory applicable withholding taxes by using common stock owned by the optionee for at least six months prior to the date of exercise, the optionee shall be granted a new stock option under the 1998 Incentive Plan on the date all or any portion of the stock option is exercised to purchase the number of shares of common stock equal to the number of shares of common stock exchanged by the optionee to exercise the stock option or to pay withholding taxes thereon. The reload stock option will be exercisable on the same terms and conditions as apply to the original stock option except that (x) the reload stock option will become exercisable in full on the day which is six months after the





date the original stock option is exercised, (y) the exercise price shall be the fair value (as defined in the 1998 Incentive Plan) of the common stock on the date the reload stock option is granted and (z) the expiration of the reload stock option will be the date of expiration of the original stock option. As of September 30, 2006, the Company has issued 10,876,300 stock options to

executives that contain the reload features noted above, of which 2,127,063 options are still outstanding. The 1998 Incentive Plan was amended to eliminate the reload feature for all stock options granted on or after October 1, 2004.

8. INVESTMENT IN AFFILIATED COMPANY

On February 2, 2006 the Company, along with a group of investors, entered into a private placement transaction to invest $30.0 million in EntreMed in return for newly issued EntreMed common stock and warrants to purchase additional shares of EntreMed common stock at a conversion price of $2.3125 per warrant. The Company's portion of the investment was $2.0 million for which it received 864,864 shares of EntreMed common stock and 432,432 warrants. The fair value of the warrants computed using the Black-Scholes model was $0.6 million and, the remaining value of $1.4 million was ascribed to the equity investment. The warrants are being accounted for at fair value with changes in fair value recorded through earnings. The value of the EntreMed warrants was $0.3 million at September 30, 2006.

Including the February 2, 2006 investment, the Company holds a total of 7,864,864 shares of EntreMed, Inc. common stock and 432,432 warrants to purchase additional shares of EntreMed common stock at September 30, 2006. Since the Company also holds 3,350,000 shares of EntreMed voting preferred shares that are convertible into 16,750,000 shares of common stock, the Company determined that it has significant influence over its investee and applies the equity method of accounting to its common stock investment.

The Company recorded equity in losses of affiliated company of $0.7 million and $1.0 million for the three-month periods ended September 30, 2006 and 2005, respectively. The Company's equity in losses of affiliated company for the nine-month period ended September 30, 2006 was $5.2 million and included $3.1 million related to the Company's share of EntreMed's in-process research and development write-down related to its acquisition of Miikana Therapeutics Inc. on January 10, 2006. The loss for the nine-month period ended September 30, 2005 was $6.0 million and included $4.4 million related to a write-down of a portion of the Company's investment ascribed to in-process research and development at the time of the initial investment. At September 30, 2006, the investment in EntreMed had a carrying value of approximately $13.5 million and a fair value of $14.6 million.

A summary of the Company's investment and equity in losses of affiliates follows:

| | As of September 30, 2006 |
|---|---|
| Interest in EntreMed equity (1) | $ 3,853 |
| Excess of investment over share of EntreMed equity (2) | 9,661 |
| Total investment | $ 13,514 |





| | Three-Month | Nine-Month |
|---|---|---|

| | Period Ended September 30, 2006 | Period Ended September 30, 2006 |
|---|---|---|
| Celgene share of EntreMed, Inc. losses (1)(3) | $ 661 | $4,976 |
| Amortization of intangibles | 75 | 226 |
| Equity in losses of affiliated company | $ 736 | $5,202 |

(1) The Company records its share of losses based on its common stock ownership, which as of September 30, 2006 was 10.73%.

(2) Consists of intangible assets and goodwill of $377 and $9,284, respectively.

(3) Year-to-date September 30, 2006 includes $3.1 million related to the Company's share of EntreMed's in-process research and development write-down related to its acquisition of Miikana Therapeutics Inc. on January 10, 2006.

9. GOODWILL AND INTANGIBLE ASSETS

At September 30, 2006, the Company's intangible assets primarily related to the October 21, 2004 acquisition of Penn T and are being amortized over their estimated useful lives. In December 2005, the Company recognized a $4.3 million intangible for a licensing agreement with Children's Medical Center Corporation, which is being amortized over the patent life of the related product. The gross carrying value and accumulated amortization by major intangible asset class at September 30, 2006 and December 31, 2005 were as follows:

| September 30, 2006 | Gross Carrying Value | Accumulated Amortization | Intangible Assets, Net | Weig Aver Life ( |
|---|---|---|---|---|
| Penn T supply agreements | $103,667 | $ (9,538) | $ 94,129 | |
| License | 4,250 | (230) | 4,020 | |
| Technology | 122 | (10) | 112 | |
| Total | $108,039 | $ (9,778) | $ 98,261 | |

| December 31, 2005 | Gross Carrying Value | Accumulated Amortization | Intangible Assets, Net | Weig Aver Life ( |
|---|---|---|---|---|
| Penn T supply agreements | $ 95,278 | $ (2,659) | $ 92,619 | |
| License | 4,250 | -- | 4,250 | |
| Technology | 122 | (3) | 119 | |
| Total | $ 99,650 | $ (2,662) | $ 96,988 | |

The $8.4 million increase in gross carrying value of intangible assets from

December 31, 2005 to September 30, 2006 represents the impact of foreign currency translation.

Amortization of acquired intangible assets was approximately $2.3 million and $0.2 million for the three-month periods ended September 30, 2006 and 2005, respectively, and $6.7 million and $0.6 million for the nine-month periods ended September 30, 2006 and 2005, respectively. Assuming no changes in the gross carrying amount of intangible assets and holding exchange rates constant, the amortization of intangible assets for the next five fiscal years is estimated to be $9.0 million for 2006, and $8.8 million for each of the years 2007 through 2010.

The Company's reported goodwill of $36.8 million and $33.8 million at September 30, 2006 and December 31, 2005, respectively, relates to the acquisition of Penn T on October 21, 2004. The $3.0 million increase from December 31, 2005 to September 30, 2006 represents the impact of foreign currency translation.





10. COMPREHENSIVE INCOME

The components of comprehensive income, which represents the change in equity from non-owner sources, consists of net income (losses), changes in currency translation adjustments and the after tax effects of changes in net unrealized gains (losses) on marketable securities classified as available for sale.

A summary of comprehensive income for the three and nine-month periods ended September 30, 2006 and 2005 follows:

| | Three-Month Period Ended September 30, | | Ni |
|---|---|---|---|
| | 2006 | 2005 | 20 |
| Net income | $ 20,437 | $ 668 | $ 4 |
| Other comprehensive income (loss): | | | |
| Unrealized losses on marketable securities available for sale, net of tax | 7,936 | (3,971) | |
| Deferred income tax (1) | -- | -- | |
| Less: reclassification adjustment for (gains) losses included in net income | 319 | 82 | |
| Total unrealized gains (losses) on marketable securities available for sale, net of tax | 8,255 | (3,889) | |
| Currency translation adjustments | 4,710 | (1,677) | |
| Total other comprehensive income (loss) | 12,965 | (5,566) | |
| Comprehensive income (loss) | $ 33,402 | $ (4,898) | $ 5 |

(1) Reflects the adjustment recorded in the first quarter of 2005 to eliminate related valuation allowances based on the Company's determination that it was more likely than not that certain benefits of its deferred tax assets would be realized.

The unrealized gains and on marketable securities available for sale for the three and nine-month periods ended September 30, 2006 included an increase in fair value related to the Company's investment in Pharmion common stock of $8.8 million and $7.3 million respectively. The unrealized losses on marketable securities available for sale for the three and nine-month periods ended September 30, 2005 included a decrease in fair value related to Pharmion common stock of $2.7 million and $39.6 million, respectively.

11. INCOME TAXES

The Company periodically evaluates the likelihood of the realization of deferred tax assets, and reduces the carrying amount of these 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.

In the first quarter of 2006, the Company recorded a tax benefit of approximately $6.1 million primarily related to the resolution of certain tax positions taken on the Company's income tax returns in tax years 2000-2002 with the completion of an audit for this period.





At March 31, 2005, the Company determined it was more likely than not that certain benefits of its deferred tax assets would be realized based on favorable clinical data related to REVLIMID(R) (lenalidomide) during the quarter in concert with the Company's nine consecutive quarters of profitability. This led to the conclusion that it was more likely than not that the Company will generate sufficient taxable income to realize the benefits of its deferred tax assets. As a result of eliminating the related valuation allowances, the Company recorded an income tax benefit in 2005 of $42.6 million and an increase to additional paid-in capital of $30.2 million.

12. SEGMENTS

Effective January 1, 2006, the Company has combined the Human Pharmaceuticals and Stem Cell Therapies segments into a single segment. The decision to combine the segments was based on how the Company's chief operating decision makers use internal financial information for evaluating performance and deciding how to allocate resources among the Company's various functions.

The Stem Cell Therapies segment originated in December 2002, with the Company's acquisition of Anthrogenesis Corp. Anthrogenesis, which operates as Celgene Cellular Therapeutics, or CCT, was organized into three main units: (1) stem cells banking for transplantation, (2) private stem cell banking and (3) the

development of biomaterials for organ and tissue repair. Effective January 1, 2006, CCT financial reporting has been combined with the Human Pharmaceuticals research organization as the strategic intent of the business has evolved to focus on discovery, development and commercialization of stem cells in pharmaceutical use.

13. AGREEMENTS

In October 2006, the Company became a limited partner of Burrill Life Sciences Capital Fund III, L.P. and agreed to invest $20.0 million over a 10-year period, of which $1.4 million was invested on October 4, 2006. The fund will invest in start-up companies conducting business in life sciences such as biotechnology, pharmaceuticals, medical technology, devices, diagnostics plus health and wellness.

In October 2006, the Company invested $4.4 million in Royalty Pharma Strategic Partners, LP to participate in a rights offering for an additional interest.

In connection with the Company's acquisition of Penn T, the Company entered into a Technical Services Agreement with Penn Pharmaceutical Services Limited, or PPSL, and Penn Pharmaceutical Holding Limited pursuant to which PPSL provides the services and facilities necessary for the manufacture of THALOMID(R) and other thalidomide formulations. The total cost to be incurred over the five-year minimum agreement period is $11.0 million. At September 30, 2006, the remaining cost to be incurred was $6.9 million.

In December 2004, following the Company's acquisition of Penn T Limited, its wholly-owned subsidiary Celgene UK Manufacturing II Limited, or CUK II, (formerly known as "Penn T Limited") entered into an amended thalidomide supply agreement with Pharmion whereby, in exchange for a reduction in Pharmion's purchase price of thalidomide to 15.5% of its net sales of thalidomide, CUK II received a one-time payment of 39.6 million British pounds sterling, or U.S. dollar equivalency of $77.0 million. The Company also received a one-time payment of $3.0 million in return for granting license rights to Pharmion to develop and market thalidomide in additional territories and eliminating certain of its license termination rights. Under a separate letter agreement simultaneously entered into by the parties, Pharmion also agreed to provide the Company with research and development funding totaling $8.0 million over a three-year period commencing January 1, 2005 and ending December 31, 2007 to support the two companies' existing thalidomide research and development efforts.





Pursuant to EITF 00-21, the Company has determined that the agreements with Pharmion constitute a single unit of accounting and pursuant to SAB No. 101, as amended by SAB No. 104, the Company has recorded the payments received as deferred revenue and is amortizing such payments on a straight line basis over an estimated useful life of 13 years, which is the estimated life of the supply agreement. The remaining payments to be received under the thalidomide research and development letter agreement (i.e., $3.3 million at September 30, 2006, which consists of $0.6 million in 2006 and $2.7 million in 2007) will be recorded as deferred revenue as such payments are received and amortized over

the remaining useful life.

In March 2003, we entered into a supply and distribution agreement with GlaxoSmithKline to distribute, promote and sell ALKERAN(R) (melphalan), a therapy approved by the FDA for the palliative treatment of multiple myeloma and carcinoma of the ovary. Under the terms of the agreement, we purchase ALKERAN(R) tablets and ALKERAN(R) for infusion from GSK and distribute the products in the United States under the Celgene label. The agreement requires us to purchase certain minimum quantities each year under a take-or-pay arrangement. The agreement has been extended through March 31, 2009. On September 30, 2006, the remaining minimum purchase requirements under the agreement totaled $67.3 million, consisting of the following subsequent extensions:

| | | |
|---|---|---|
| o January 1, 2007 - December 31, 2007 | | $ 29,050 |
| o January 1, 2008 - December 31, 2008 | | 30,525 |
| o January 1, 2009 - March 31, 2009 | | 7,725 |
| | | $ 67,300 |

14. SUBSEQUENT EVENTS

In November 2006, the Company issued 20,000,000 shares of its common stock at a public offering price of $51.60 per share with gross proceeds of $1.032 billion and proceeds, net of the Underwriters' discount of $1.007 billion.



PART I - FINANCIAL INFORMATION

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

INTRODUCTION

We are a global integrated biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. Our lead products are: REVLIMID(R), which was approved by the U.S. Food and Drug Administration, or FDA, in December 2005 for treatment of patients with 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 and in June 2006 for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy; and, THALOMID(R) (thalidomide), which is approved in erythema nodosum leprosum, an inflammatory complication of leprosy, and which gained FDA approval in May 2006 for treatment in combination with dexamethasone of newly diagnosed multiple myeloma patients. Over the past several years, THALOMID(R) net sales have grown steadily driven mainly by its use for treating multiple myeloma and other cancers. The sales growth of REVLIMID(R) and THALOMID(R) has enabled us to make substantial investments in research and development, which has advanced our broad portfolio of drug candidates in our product pipeline, including a pipeline of IMiDs(R) compounds, which are a class of compounds proprietary to us and having certain immunomodulatory and other biologically important properties. We believe that the commercial potential of REVLIMID(R) and THALOMID(R), the depth of our product pipeline, near-term regulatory activities and clinical data reported both at major medical conferences and in peer-reviewed publications provide the catalysts for our future growth.

FACTORS AFFECTING FUTURE RESULTS

Future operating results will depend on many factors, including demand for our products, regulatory approvals of our products, the timing and market acceptance of new products launched by us or competing companies, the timing of research and development milestones, challenges to our intellectual property and our ability to control costs. See also the Risk Factors discussion in Part I, Item 1A of our 2005 Annual Report on Form 10-K. Some of the more salient factors that we are focused on are: the ability of REVLIMID(R) to successfully penetrate relevant markets; competitive risks; and our ability to advance clinical and regulatory programs.

THE ABILITY OF REVLIMID(R) TO SUCCESSFULLY PENETRATE RELEVANT MARKETS: Our REVLIMID(R) launch strategy has included among other things: registering physicians in the RevAssistsm program, which is a proprietary risk-management distribution program tailored specifically to help ensure the safe use of REVLIMID(R); partnering with contracted pharmacies to ensure, to the maximum extent possible, safe and rapid distribution of REVLIMID(R); and, transitioning previously treated multiple myeloma patients from our expanded access program that provided many previously treated multiple myeloma patients with free access to REVLIMID(R) to commercial paying patients as a result of the June 2006 Supplemental New Drug Application, or sNDA, approval of REVLIMID for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy. While these initiatives appear to be resulting in a highly visible and successful product launch, our near-term focus continues to be on ensuring REVLIMID's rapid market penetration in both multiple myeloma and MDS. We do not, however, have long-term data on the use of the product and cannot predict whether REVLIMID(R) will gain widespread acceptance, which will mostly depend on the



acceptance of regulators, physicians, patients, payors and opinion leaders. The success of REVLIMID(R) will also depend, in part, on prescription drug coverage by government health agencies, commercial and employer health plans, and other third-party payors. As an oral cancer agent, REVLIMID(R) qualifies as a Medicare, Part D drug. Each Part D plan will review REVLIMID(R) for addition to their formulary. As with all new products introduced into the market, there may be some lag time before being added to each plan's formulary, which may impact our commercial performance.

THE ABILITY TO ADVANCE CLINICAL AND REGULATORY PROGRAMS: Our continued growth will depend, in part, on international regulatory approvals and the progress of our clinical programs across a broad range of hematological malignancies and other cancers. Currently, our Marketing Authorization Applications, or MAA's, for REVLIMID(R) in both multiple myeloma and MDS with the 5q chromosomal deletion are under review by the European Medicines Agency, or EMEA. Future international commercial opportunities are dependent on unpredictable regulatory timelines. In addition, a major objective of our on-going clinical programs is to broaden our knowledge about the full potential of REVLIMID(R) and our other proprietary IMiDs(R) compounds and to continue to evaluate them in a broad range of hematological malignancies and other cancers. Our near-term focus is on evaluating REVLIMID(R) as a treatment of chronic lymphocytic leukemia and aggressive non-Hodgkin's lymphomas.

COMPETITIVE RISKS: While competition could limit REVLIMID(R) launch results and reduce THALOMID(R) sales, we do not believe that competing products will eliminate REVLIMID(R) and THALOMID(R) use entirely. In addition, generic competition could reduce THALOMID(R) sales. However, we own intellectual

property which includes, for example, U.S. patents covering our S.T.E.P.S.(R) distribution program for the safe distribution and appropriate use of thalidomide, which all physicians, patients and pharmacies prescribing, receiving or dispensing thalidomide in the United States must follow. We also have exclusive rights to several issued patents covering the use of THALOMID(R) in oncology and other therapeutic areas.

RESULTS OF OPERATIONS-
THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2006 VS.
THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2005

TOTAL REVENUE: Total revenue and related percentages for the three-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Three-Month Period Ended September 30, 2006 | 2005 | % Change |
|---|---|---|---|
| Net product sales: | | | |
| REVLIMID(R) | $101,314 | $ -- | N/A |
| THALOMID(R) | 108,370 | 99,134 | 9.3% |
| ALKERAN(R) | 12,171 | 13,945 | (12.7%) |
| Focalin(R) | 1,178 | 326 | 261.3% |
| Other | 72 | 495 | (85.5%) |
| Total net product sales | 223,105 | 113,900 | 95.9% |
| Collaborative agreements and other revenue | 4,186 | 4,879 | (14.2%) |
| Royalty revenue | 17,548 | 10,727 | 63.6% |
| Total revenue | $244,839 | $129,506 | 89.1% |



NET PRODUCT SALES:

REVLIMID(R) was approved by the FDA in December 2005 for treatment of patients with transfusion-dependent anemia due to Low- or Intermediate-1-risk MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities and in June 2006 for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy. As a result, sales for this product are reflected only in the 2006 period. REVLIMID(R) net sales increased sequentially from $63.0 million in the three-month period ended June 30, 2006 to $101.3 million in the three-month period ended September 30, 2006. This increase was primarily due to new patient prescriptions aided slightly by transitioning patients from our expanded access program, which provided patients with free access to REVLIMID(R), to commercial paying patients and, to a much lesser extent, the impact of one-time inventory stocking related to the introduction of 15 and 25 milligram capsules, slightly offset by a decrease resulting from patients switching from multiple capsule dosing regimens to the single 15 and 25 milligram capsule regimen. Multiple myeloma accounted for approximately 60% of dispenses during the three-month period ended September 30, 2006, followed by MDS, which accounted for approximately 35% of dispenses and a broad range of cancer indications accounted for the remainder of dispenses. Named patient sales outside of the United States totaled 8.7% of REVLIMID(R) net sales during the three month period ended September 30, 2006. We expect continued incremental benefit from the named

patient sales leading up to a potential European approval in 2007.

Supported by the FDA's approval of newly diagnosed multiple myeloma and newly presented data, THALOMID(R) net sales were higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005. Price increases implemented as we move towards a cost of therapy pricing structure as opposed to a price per milligram basis also contributed to the increase. Sales volumes decreased due to continued average daily dose declines as well as a slight decrease in the total number of prescriptions. Partially offsetting the increase in THALOMID(R) sales were higher gross to net sales accruals for sales returns and distributor chargebacks, largely offset by lower Medicaid rebate accruals. Included in both the three-month periods ended September 30, 2006 and 2005 were sales of approximately $2.8 million from our U.K. subsidiary to Pharmion Corporation under a manufacturing supply agreement as amended December 3, 2004.

ALKERAN(R) net sales were lower in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, due to a decrease in sales volumes and higher gross to net sales accruals for sales returns, partially offset by price increases. We believe the decrease in sales volumes stems largely from supply disruptions, which has lead to inconsistent supplies of ALKERAN(R) IV and consequently inconsistent end-market buying patterns. These factors may continue to contribute to variability in revenues, for the near-term.

Sales of Focalin(R), which is sold exclusively to Novartis and is dependent on the timing of orders from Novartis for their commercial distribution, were higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, due to increased end-market demand.

GROSS TO NET SALES ACCRUALS: Gross to net sales accruals are recorded for sales returns, sales discounts, Medicaid rebates and distributor charge-backs and service fees. Allowance for sales returns are based on the actual returns history for consumed lots and the trend experience for lots where product is still being returned. Sales discounts accruals are based on payment terms extended to customers. Medicaid rebate accruals are based on historical payment data and estimates of future Medicaid beneficiary utilization. Distributor charge-back 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 services accruals are based on actual fees paid to wholesale distributors for services provided. See Critical Accounting Policies for further discussion.



Gross to net sales accruals and the balance in the related allowance accounts for the three-month period ended September 30, 2006 and 2005 were as follows:

| 2006 | Sales Returns | Discounts | Medicaid rebates |
|---|---|---|---|
| Balance at June 30, 2006 | $11,637 | $ 1,752 | $ 7,225 |
| Allowances for sales made during the quarter | 6,346 | 5,015 | 4,289 |

| | | | |
|---|---|---|---|
| Allowances for sales made during prior periods | 2,479 | -- | -- |
| Credits issued for prior year sales | (5,454) | -- | (86) |
| Credits issued for sales during 2006 | (3,513) | (4,708) | (4,458) |
| Balance at September 30, 2006 | $11,495 | $ 2,059 | $ 6,970 |

| 2005 | Sales Returns | Discounts | Medicaid rebates |
|---|---|---|---|
| Balance at June 30, 2005 | $ 7,270 | $ 1,053 | $ 12,155 |
| Allowances for sales made during the quarter | 5,252 | 2,811 | 9,448 |
| Allowances for sales made during prior periods | -- | -- | -- |
| Credits issued for prior year sales | (2,088) | -- | (191) |
| Credits issued for sales during 2005 | (4,174) | (2,744) | (9,966) |
| Balance at September 30, 2005 | $6,260 | $ 1,120 | $11,446 |

Sales returns and discounts allowances increased in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to higher gross sales. Also contributing to the increase in sales returns allowances were higher returns of expired ALKERAN(R) IV product.

Medicaid rebate allowances decreased in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to the impact of the new Medicare, Part D legislation, which became effective January 1, 2006. As a result of the new legislation many patients who had been eligible to receive THALOMID(R) through Medicaid coverage during the prior year period are now covered under Medicare, Part D. Partially offsetting the THALOMID(R) decrease are Medicaid rebate allowances included in the current year period for REVLIMID(R) sales.

Distributor chargebacks increased in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to THALOMID(R) price increases, which reduces the federal ceiling price, or FCP, available to federally funded healthcare providers and thus, increases the distributor chargeback amount. Also contributing to the increase in allowances for distributor chargeback are accruals for REVLIMID(R) sales.

OTHER REVENUES: Revenues from collaborative agreements and other sources totaled $4.2 million for the three-month period ended September 30, 2006, compared to $4.9 million for the three-month period ended September 30, 2005. The decrease was primarily due to lower Pharmion collaboration related revenues.

Royalty revenue for the three-month period ended September 30, 2006 totaled $17.5 million and primarily included $16.7 million received from Novartis on sales of their entire family of Ritalin(R) drugs and Focalin(TM) XR. Royalty revenue for the three-month period ended September 30, 2005 totaled $10.7



million and included $10.4 million from Novartis. Novartis royalty revenue

increased due to higher Focalin(TM) XR product sales.

COST OF GOODS SOLD: Cost of goods sold and related percentages for the three-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Three-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Cost of goods sold | $34,205 | $23,199 |
| Increase from prior year | $11,006 | $ 8,033 |
| Percentage increase from prior year | 47.4% | 53.0% |
| Percentage of net product sales | 15.3% | 20.4% |

Cost of goods sold were higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to higher royalties on THALOMID(R) as a result of higher net sales, higher ALKERAN(R) costs and inclusion of costs associated with REVLIMID(R) sales. ALKERAN(R) costs tend to experience variability depending on the purchase price of the specific units sold during a given period. Cost of goods sold as a percentage of net product sales were lower in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005 primarily due to the impact of REVLIMID(R) sales, which have a lower per unit cost than THALOMID(R), partially offset by higher ALKERAN(R) costs and higher royalties on THALOMID(R).

RESEARCH AND DEVELOPMENT: Research and development expenses consist primarily of salaries and benefits, contractor fees (paid principally to contract research organizations to assist in our clinical development programs), costs of drug supplies for our clinical and preclinical programs, costs of other consumable research supplies, regulatory and quality expenditures and allocated facilities charges such as depreciation, utilities and property taxes.

Research and development expenses and related percentages for the three-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Three-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Research and development expenses | $66,756 | $49,348 |
| Increase from prior year | $17,408 | $ 9,194 |
| Percentage increase from prior year | 35.3% | 22.9% |
| Percentage of total revenue | 27.3% | 38.1% |

Research and development expenses were higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to higher clinical research and development expenses, which among other things support multiple Phase II and Phase III programs evaluating REVLIMID(R) across a broad range of hematological cancers, including multiple myeloma, MDS, chronic lymphocytic leukemia and non-Hodgkin's lymphoma; higher medical information and education expenses, which support educating and training the medical community on hematological cancers such as multiple myeloma and MDS; and higher expenses to support ongoing development of other compounds such as CC-10004, CC-11050, CC-4047, CC-11006, CC-11050 and CC-401. Included in the three-month period ended September 30, 2006 was share-based compensation expense of $2.7 million resulting from the application of Statement of

Financial Accounting Standards, or SFAS, No. 123R, "Share-Based Payments," or SFAS 123R, which became effective January 1, 2006.

Research and development expenses in the three-month period ended September 30, 2006 consisted of approximately $24.9 million spent on human pharmaceutical clinical programs; $28.5 million spent on other pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; $9.9 million spent on biopharmaceutical discovery and development programs; and $3.5 million spent on placental stem cell and biomaterials programs. These expenditures support ongoing clinical progress in multiple proprietary development programs for REVLIMID(R) and THALOMID(R), and for other compounds such as: CC-10004, our lead anti-inflammatory compound that inhibits PDE-4, which results in the inhibition of multiple proinflammatory mediators such as TNF-alpha and, which is currently being evaluated in Phase II clinical trials in the treatment of psoriasis; CC-4047, CC-11006 and CC-11050 which are currently being evaluated in healthy volunteer Phase I clinical trials; and our kinase and ligase inhibitor programs as well as the placental stem cell program. In the three-month period ended September 30, 2005, approximately $18.9 million was spent on human pharmaceutical clinical programs; $18.4 million was spent on other human pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; $9.4 million was spent on biopharmaceutical discovery and development programs; and $2.6 million was spent on placental stem cell and biomaterials programs.

As total revenue increases, research and development expense may continue to decrease as a percentage of total revenue, however the actual dollar amount may continue to increase as earlier stage compounds are moved through the preclinical and clinical stages. Generally, the time to completion of each phase is estimated as follows for oncology indications and can be longer for non-oncology indications:

Phase I ----- 1-2 years
Phase II ---- 2-3 years
Phase III --- 2-5 years

Due to the significant risk factors and uncertainties inherent in preclinical tests and clinical trials associated with each of our research and development projects, the cost to complete such projects is not reasonably estimable. The data obtained from these tests and trials may be susceptible to varying interpretation that could delay, limit or prevent a project's advancement through the various stages of clinical development, which would significantly impact the costs incurred to bring a project to completion.

SELLING, GENERAL AND ADMINISTRATIVE: Selling expenses consist primarily of salaries and benefits for sales and marketing and customer service personnel and other commercial expenses to support our sales force. General and administrative expenses consist primarily of salaries and benefits, outside services for legal, audit, tax and investor activities and allocations of facilities costs, principally for depreciation, utilities and property taxes.

Selling, general and administrative expenses and related percentages for the three-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Three-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Selling, general and administrative expenses | $ 89,597 | $ 46,941 |
| Increase from prior year | $ 42,656 | $ 19,191 |
| Percentage increase from prior year | 90.9% | 69.2% |
| Percentage of total revenue | 36.6% | 36.2% |

Selling, general and administrative expenses were higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005 due to $20.1 million of share-based compensation expense resulting from the application of SFAS 123R beginning in 2006, higher commercial expenses primarily related to sales and marketing for REVLIMID(R) in the United States and higher general administrative expenses primarily related to personnel and professional and other outside service costs incurred in connection with our international expansion in Europe, Japan, Australia and Canada.

INTEREST AND OTHER INCOME, NET: Interest and other income, net was $10.4 million for the three-month period ended September 30, 2006 and primarily consisted of interest income and net realized gains on our cash and marketable securities portfolio of $9.5 million and foreign exchange gains of $1.1 million partially offset by an other-than-temporary impairment loss on marketable securities available for sale of $0.3 million. Interest and other income, net was $7.0 million for the three-month period ended September 30, 2005 and primarily consists of interest and net realized gains on our cash and marketable securities portfolio.

EQUITY IN LOSSES OF AFFILIATED COMPANY: On March 31, 2005, we exercised warrants to purchase 7,000,000 shares of EntreMed, Inc. common stock and, since we also hold 3,350,000 shares of EntreMed voting preferred shares convertible into 16,750,000 shares of common stock, we determined that we have significant influence over EntreMed and began applying the equity method of accounting to our common stock investment effective March 31, 2005.

On February 2, 2006 the Company invested an additional $2.0 million in EntreMed in a private-placement transaction for which it received an additional 864,864 shares of EntreMed common stock and 432,432 warrants. The fair value of the warrants computed using the Black-Scholes model was $0.6 million and, the remaining value of $1.4 million was ascribed to the equity investment. The warrants are being accounted for at fair value with changes in fair value recorded through interest and other income, net.

Under the equity method of accounting, we recorded equity losses of $0.7 million and $1.0 million for the three-month periods ended September 30, 2006 and 2005, respectively.

INTEREST EXPENSE: Interest expense was $2.4 million for each of the three-month periods ended September 30, 2006 and 2005 and primarily reflects three months of interest expense and amortization of debt issuance costs on the $400 million convertible notes issued on June 3, 2003.

INCOME TAX PROVISION (BENEFIT): The income tax provision for the three-month period ended September 30, 2006 was $41.1 million and reflects an effective tax rate for the quarter of 67%. The income tax provision for the three-month period ended September 30, 2005 was $13.0 million based on an effective tax rate for

the nine-month period ended September 30, 2005 of 75%. Our underlying tax rate will continue to exceed the statutory rate for



the near term as a result of certain expenses being incurred outside the United States for which no tax benefit can be recorded.

NET INCOME: Net income and per common share amounts for the three-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Three-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Net income | $ 20,437 | $ 668 |
| Per common share amounts: | | |
| Basic | $ 0.06 | $ 0.00 |
| Diluted | $ 0.05(1) | $ 0.00 |
| Weighted average number of shares of common stock utilized to calculate per common share amounts: | | |
| Basic | 351,200 | 336,596 |
| Diluted | 404,858 | 359,724 |

(1) In computing diluted earnings per share, the numerator has been adjusted to add-back the after-tax amount of interest recognized in the period associated with our convertible debt.

Net income was higher in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005 due to higher net product sales, primarily due to the approval of REVLIMID(R) by the FDA in December 2005 for treatment of transfusion dependent MDS in patients with the 5q chromosomal deletion and in June 2006 for treatment in combination with dexamethasone of previously treated patients with multiple myeloma, partially offset by $23.2 million of share-based compensation expense resulting from the application of SFAS 123R, which became effective January 1, 2006, and increased operating expenses required to support the Company's on-going expansion.

RESULTS OF OPERATIONS-
NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2006 VS.
NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2005

TOTAL REVENUE: Total revenue and related percentages for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Nine-Month Period Ended September 30, 2006 |
|---|---|

| | | |
|---|---|---|
| Net product sales: | | |
| REVLIMID(R) | $196,777 | $ |
| THALOMID(R) | 322,774 | 2 |
| ALKERAN(R) | 34,918 | |
| Focalin(R) | 4,945 | |
| Other | 335 | |
| Total net product sales | 559,749 | 3 |
| Collaborative agreements and other revenue | 12,032 | |
| Royalty revenue | 52,138 | |
| Total revenue | $623,919 | $3 |



NET PRODUCT SALES:

REVLIMID(R) was approved by the FDA in December 2005 for treatment of patients with transfusion-dependent anemia due to Low- or Intermediate-1-risk MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities and in June 2006 for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy. As a result, sales for this product are reflected only in the 2006 period. During the nine-month period ended September 30, 2006, multiple myeloma and MDS indications accounted for approximately 94% of the commercial dispenses (with the percentage of multiple myeloma and MDS prescriptions being about equal) and a broad range of other cancer indications accounted for the remaining dispenses. Named patient sales outside of the United States totaled 7.2% of REVLIMID(R) net sales during the nine-month period ended September 30, 2006. We expect continued incremental benefit from the named patient sales leading up to a potential Europen approval in 2007.

Supported by the FDA's approval of newly diagnosed multiple myeloma and newly presented data, THALOMID(R) net sales were higher in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005. Price increases implemented as we move towards a cost of therapy pricing structure as opposed to a price per milligram basis also contributed to the increase. Sales volumes decreased due to continued average daily dose declines as well as a slight decrease in the total number of prescriptions. Partially offsetting the increase in THALOMID(R) sales were higher gross to net sales accruals for sales returns and distributor chargebacks, partially offset by lower Medicaid rebate accruals. Included in the nine-month period ended September 30, 2006 were sales of approximately $8.3 million from our U.K. subsidiary to Pharmion Corporation under a manufacturing supply agreement as amended December 3, 2004, compared to sales of $5.8 million for the nine-month period ended September 30, 2005.

ALKERAN(R) net sales were higher in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, due to an increase in sales volumes as well as price increases implemented since September 30, 2005. Partially offsetting the increase in ALKERAN(R) sales were higher gross to net sales accruals for sales returns and distributor chargebacks. While ALKERAN(R) use in combination therapies for the treatment of hematological diseases continues to grow driven by clinical data reported at major medical conferences around the world, supply disruptions have lead to inconsistent supplies of ALKERAN(R) IV and consequently have resulted in inconsistent

end-market buying patterns. These factors may continue to contribute to variability in revenues for the near-term.

Sales of Focalin(R), which is sold exclusively to Novartis and is dependent on the timing of orders from Novartis for their commercial distribution, were higher in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, due to increased end-market demand.

GROSS TO NET SALES ACCRUALS: Gross to net sales accruals are recorded for sales returns, sales discounts, Medicaid rebates and distributor charge-backs and service fees. Allowance for sales returns are based on the actual returns history for consumed lots and the trend experience for lots where product is still being returned. Sales discounts accruals are based on payment terms extended to customers. Medicaid rebate accruals are based on historical payment data and estimates of future Medicaid beneficiary utilization. Distributor charge-back 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 services accruals are based on actual fees paid to wholesale distributors for services provided. See Critical Accounting Policies for further discussion.



Gross to net sales accruals and the balance in the related allowance accounts for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| 2006 | Returns and allowances | Discounts | Med re |
|---|---|---|---|
| Balance at December 31, 2005 | $ 5,017 | $ 1,447 | $ 20 |
| Allowances for sales made during 2006 | 23,805 | 13,502 | 16 |
| Allowances for sales made during prior periods | 25,457 | -- | |
| Credits issued for prior year sales | (30,475) | (1,479) | (20 |
| Credits issued for sales during 2006 | (12,309) | (11,411) | (9 |
| Balance at September 30, 2006 | $ 11,495 | $ 2,059 | $ 6 |

| 2005 | Returns and allowances | Discounts | Med re |
|---|---|---|---|
| Balance at December 31, 2004 | $ 9,600 | $ 837 | $ |
| Allowances for sales made during 2005 | 15,026 | 7,712 | 2 |
| Allowances for sales made during prior periods | -- | -- | |
| Credits issued for prior year sales | (9,191) | (831) | ( |
| Credits issued for sales during 2005 | (9,175) | (6,598) | (1 |
| Balance at September 30, 2005 | $ 6,260 | $ 1,120 | $ 1 |

Sales returns allowances increased in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to unusually high THALOMID(R) returns from one large retail pharmacy chain during the first half of the year. The returns from this customer were the result of efforts to more aggressively manage inventory at its pharmacies, the Company's requirement for the pharmacy to purchase full cartons of up to ten sleeves of THALOMID(R) capsules with each order and, S.T.E.P.S. (R) related restrictions, which limited the customer's ability to transfer inventories between its locations. For the past several years, we have experienced sales returns of approximately 4% of sales. As a result of the higher returns activity, we recorded additional allowances, during the three-month period ended June 30, 2006, to increase our reserve to approximately 9% of all estimated THALOMID(R) pharmacy inventories. In addition, we introduced single sleeve units, beginning June 7, 2006 (rather than requiring full carton purchases) and we amended our product returns policy to include a product returns handling fee. These measures have been designed to allow customers to more effectively manage their inventories, since they can now order smaller quantities, as well as limit our product returns exposure. At September 30, 2006, our sales returns reserve was about 9% of all estimated THALOMID(R) pharmacy inventories. Third quarter 2006 sales returns activity suggests that the first half of 2006 activity was an isolated event. We will however, continue to monitor the situation and will adjust our sales returns accrual accordingly. Also, contributing to the increase in sales returns allowances, to a lesser extent, were higher returns of expired ALKERAN(R) IV product.

Sales discounts increased in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, due to higher net sales.

Medicaid rebate allowances decreased in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to the impact of the new Medicare, Part D legislation, which became effective January 1, 2006. As a result of the new legislation many patients who had been eligible to receive THALOMID(R) through Medicaid coverage during the prior year period



are now covered under Medicare, Part D. Partially offsetting the THALOMID(R) decrease are Medicaid rebate allowances included in the current year period for REVLIMID(R) sales.

Distributor chargebacks increased in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to THALOMID(R) price increases, which reduces the federal ceiling price, or FCP, available to federally funded healthcare providers and thus, increases the distributor chargeback amount and an increase in ALKERAN(R) IV sales to certain public health services, or PHS, pricing eligible customers. Also contributing to increase in allowances for distributor chargeback are accruals for REVLIMID(R) sales.

OTHER REVENUES: Revenues from collaborative agreements and other sources totaled $12.0 million for the nine-month period ended September 30, 2006, compared to $35.8 million for the nine-month period ended September 30, 2005. The decrease was primarily due to inclusion in the nine-month period ended September 30, 2005 of a $20.0 million milestone payment from Novartis for the NDA approval of

Focalin(TM) XR and $1.4 million of other license fee payments. Also contributing to the decrease were lower Pharmion collaboration related revenues in the nine-month period ended September 30, 2006.

Royalty revenue for the nine-month period ended September 30, 2006 totaled $52.1 million and primarily included $50.0 million received from Novartis on sales of their entire family of Ritalin(R) drugs and Focalin(TM) XR. Royalty revenue for the nine-month period ended September 30, 2005 totaled $34.8 million and included $33.9 million from Novartis. Novartis royalty revenue increased primarily due to higher Focalin(TM) XR product sales.

COST OF GOODS SOLD: Cost of goods sold and related percentages for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| | Nine-Month Period Ended September 30, | |
|---|---|---|
| (IN THOUSANDS $) | 2006 | 2005 |
| Cost of goods sold | $ 91,148 | $ 53,999 |
| Increase from prior year | $ 37,149 | $ 10,344 |
| Percentage increase from prior year | 68.8% | 23.7% |
| Percentage of net product sales | 16.3% | 17.0% |

Cost of goods sold were higher in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to higher ALKERAN(R) costs. ALKERAN(R) costs tend to experience variability depending on the purchase price of the specific units sold during a given period. Also contributing to the increase in cost of goods sold were higher royalties on THALOMID(R) as a result of higher net sales and inclusion of costs associated with REVLIMID(R) sales. Cost of goods sold as a percentage of net product sales were lower in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005 primarily due to the impact of REVLIMID(R) sales, which have a lower per unit cost than THALOMID(R), partially offset by higher ALKERAN(R) costs and higher royalties on THALOMID(R).

RESEARCH AND DEVELOPMENT: Research and development expenses consist primarily of salaries and benefits, contractor fees (paid principally to contract research organizations to assist in our clinical development programs), costs of drug supplies for our clinical and preclinical programs, costs of other consumable research supplies, regulatory and quality expenditures and allocated facilities charges such as depreciation, utilities and property taxes.



Research and development expenses and related percentages for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| | Nine-Month Period Ended September 30, | |
|---|---|---|
| (IN THOUSANDS $) | 2006 | 2005 |
| Research and development expenses | $ 178,298 | $ 138,413 |
| Increase from prior year | $ 39,885 | $ 21,893 |
| Percentage increase from prior year | 28.8% | 18.8% |
| Percentage of total revenue | 28.6% | 35.7% |

Research and development expenses were higher in the nine-month period ended

September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to higher clinical research and development expenses, which among other things support multiple Phase II and Phase III programs evaluating REVLIMID(R) across a broad range of hematological cancers, including multiple myeloma, MDS, chronic lymphocytic leukemia and non-Hodgkin's lymphoma; higher medical information and education expenses, which support educating and training the medical community on hematological cancers such as multiple myeloma and MDS; and higher expenses to support ongoing development of other compounds such as CC-10004, CC-4047, CC-11006, CC-11050 and CC-401. Included in the nine-month period ended September 30, 2006 was share-based compensation expense of $10.0 million resulting from the application of SFAS 123R, which became effective January 1, 2006.

Research and development expenses in the nine-month period ended September 30, 2006 consisted of $66.7 million spent on human pharmaceutical clinical programs; $73.8 million spent on other pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; $28.8 million spent on biopharmaceutical discovery and development programs; and $9.0 million spent on placental stem cell and biomaterials programs. These expenditures support ongoing clinical progress in multiple proprietary development programs for REVLIMID(R) and THALOMID(R), and for other compounds such as: CC-10004, our lead anti-inflammatory compound that inhibits PDE-4, which results in the inhibition of multiple proinflammatory mediators such as TNF-alpha and, which is currently being evaluated in Phase II clinical trials in the treatment of psoriasis; CC-4047, CC-11006 and CC-11050 which are currently being evaluated in healthy volunteer Phase I clinical trials; and our kinase and ligase inhibitor programs as well as the placental stem cell program. In the nine-month period ended September 30, 2005, $55.0 million was spent on human pharmaceutical clinical programs; $48.1 million was spent on other human pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; $27.5 million was spent on biopharmaceutical discovery and development programs; and $7.8 million was spent on placental stem cell and biomaterials programs.

SELLING, GENERAL AND ADMINISTRATIVE: Selling expenses consist primarily of salaries and benefits for sales and marketing and customer service personnel and other commercial expenses to support our sales force. General and administrative expenses consist primarily of salaries and benefits, outside services for legal, audit, tax and investor activities and allocations of facilities costs, principally for depreciation, utilities and property taxes.



Selling, general and administrative expenses and related percentages for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Nine-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Selling, general and administrative expenses | $ 239,318 | $ 126,114 |

| | | |
|---|---|---|
| Increase from prior year | 113,204 | $ 46,706 |
| Percentage increase from prior year | 89.8% | 58.8% |
| Percentage of total revenue | 38.4% | 32.5% |

Selling, general and administrative expenses were higher in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005 due to $47.3 million of share-based compensation expense resulting from the application of SFAS 123R beginning in 2006, higher commercial expenses primarily related to sales and marketing for REVLIMID(R) in the United States and higher general administrative expenses primarily related to personnel and professional and other outside service costs incurred in connection with our international expansion in Europe, Japan, Australia and Canada.

INTEREST AND OTHER INCOME, NET: Interest and other income, net was $26.1 million for the nine-month period ended September 30, 2006 and included interest income and net realized gains on our cash and marketable securities portfolio of $25.9 million, foreign exchange gains of $4.2 million and other miscellaneous income of $0.1 million, partially offset by losses recorded for changes in the estimated value of our investment in EntreMed, Inc. warrants of $0.3 million and an other-than-temporary impairment loss on marketable securities available for sale of $3.8 million. Interest and other income, net was $12.5 million for the nine-month period ended September 30, 2005 and included interest income and net realized gains on our cash and marketable securities portfolio of $19.6 million, partially offset by losses recorded for changes in the estimated value of our investment in EntreMed, Inc. warrants of $6.9 million and foreign exchange losses of approximately $0.2 million.

EQUITY IN LOSSES OF AFFILIATED COMPANY: On March 31, 2005, we exercised warrants to purchase 7,000,000 shares of EntreMed, Inc. common stock and, since we also hold 3,350,000 shares of EntreMed voting preferred shares convertible into 16,750,000 shares of common stock, we determined that we have significant influence over EntreMed and began applying the equity method of accounting to our common stock investment effective March 31, 2005.

On February 2, 2006 the Company invested an additional $2.0 million in EntreMed in a private-placement transaction for which it received an additional 864,864 shares of EntreMed common stock and 432,432 warrants. The fair value of the warrants computed using the Black-Scholes model was $0.6 million and, the remaining value of $1.4 million was ascribed to the equity investment. The warrants are being accounted for at fair value with changes in fair value recorded through interest and other income, net.

Under the equity method of accounting, we recorded equity losses of $5.2 million and $6.0 million for the nine-month periods ended September 30, 2006 and 2005, respectively. Equity losses recorded for the nine-month period ended September 30, 2005, included $4.4 million for the value of our investment ascribed to in-process research and development and written-off as of March 31, 2005 (the initial date of the investment).



INTEREST EXPENSE: Interest expense was $7.1 million for each of the nine-month periods ended September 30, 2006 and 2005 and primarily reflects nine months of interest expense and amortization of debt issuance costs on the $400 million convertible notes issued on June 3, 2003.

INCOME TAX PROVISION (BENEFIT): The income tax provision for the nine-month period ended September 30, 2006 was $82.9 million and reflects an effective tax

rate of 64%. The tax provision has been adjusted for tax benefits of approximately $6.1 million primarily related to the resolution of certain tax positions taken on our income tax returns for the tax years 2000 through 2002. The income tax provision for the nine-month period ended September 30, 2005 was $8.8 million and included the one-time benefit from eliminating deferred tax asset valuation allowances totaling $42.6 million as of March 31, 2005. Excluding this benefit, the income tax provision for the nine-month period ended September 30, 2005 would have been $51.4 million, which reflects an underlying effective tax rate of 75%. Our underlying tax rate will continue to exceed the statutory rate for the near term as a result of certain expenses being incurred outside the United States for which no tax benefit can be recorded.

NET INCOME: Net income and per common share amounts for the nine-month periods ended September 30, 2006 and 2005 were as follows:

| (IN THOUSANDS $) | Nine-Month Period Ended September 30, 2006 | 2005 |
|---|---|---|
| Net income | $ 46,069 | $ 59,728 |
| Per common share amounts: | | |
| Basic | $ 0.13 | $ 0.18 |
| Diluted | $ 0.12(1) | $ 0.16(1 |
| Weighted average number of shares of common stock utilized to calculate per common share amounts: | | |
| Basic | 347,687 | 334,054 |
| Diluted | 403,092 | 390,004 |

(1) In computing diluted earnings per share, the numerator has been adjusted to add-back the after-tax amount of interest recognized in the period associated with our convertible debt.

Net income and per common share amounts were lower in the nine-month period ended September 30, 2006, compared to the nine-month period ended September 30, 2005, primarily due to inclusion in the 2006 period of $58.7 million of share-based compensation expense resulting from the application of SFAS 123R, which became effective January 1, 2006, and inclusion in the 2005 period of the one-time benefit of $42.6 million recognized from the elimination of deferred tax asset valuation allowances. Offsetting the decrease in net income were higher revenues in the nine-month period ended September 30, 2006, partially offset by higher operating expenses.

LIQUIDITY AND CAPITAL RESOURCES

OPERATING ACTIVITIES: Net cash provided by operating activities was $42.8 million for the nine-month period ended September 30, 2006, compared to net cash provided by operating activities of $54.6 million for the nine-month period ended September 30, 2005. The decrease was primarily due to higher working capital levels as described below and SFAS 123R requirements to classify excess tax benefits (i.e., the tax benefit recognized upon exercise of stock options in excess of the benefit recognized from recognizing compensation cost for those options) as financing cash flows in the Consolidated Statement of Cash Flows in 2006, partially offset by higher earnings excluding the effects of certain non-cash items including share-based compensation expense totaling $58.7 million recorded in the nine-month period ended September 30, 2006 in connection with our

application of SFAS 123(R) beginning January 1, 2006 and the deferred tax benefit recognized in the 2005 period in connection with the reversal of certain deferred tax asset valuation allowances.

CHANGES IN WORKING CAPITAL ITEMS

ACCOUNTS RECEIVABLE: Accounts receivable, net increased $31.9 million during the nine-month period ended September 30, 2006 as a result of higher net sales. Our days of sales outstanding, or DSO, at September 30, 2006 improved by approximately 9 days compared to the DSO at December 31, 2005. The decrease in our DSO was primarily due to the timing of collections at certain large customers.

INVENTORY: Inventory increased $15.8 million during the nine-month period ended September 30, 2006. ALKERAN(R) inventories increased $9.2 million due to the timing of our purchases from GSK. ALKERAN(R) inventories tend to fluctuate depending on the purchase price of the specific units purchased during a given period. REVLIMID(R) inventories increased $4.4 million related to initial stocking in connection with the product launch and the introduction of the 15 milligram and 25 milligram strength capsules. THALOMID(R) and Focalin(R) inventories also increased, but to a lesser extent. The increase in THALOMID(R) inventories was related to the introduction of single sleeve selling units so that customers can more effectively manage their inventory levels.

OTHER OPERATING ASSETS: Other operating assets increased $47.6 million during the nine-month period ended September 30, 2006 primarily due to an increase in prepaid expenses and in the amounts due from Novartis under the FOCALIN(R) license agreement. Prepaid expenses increased primarily due to higher prepaid insurance amounts and inclusion of $31.7 million of prepaid taxes.

ACCOUNTS PAYABLE, ACCRUED EXPENSES AND OTHER LIABILITIES: Accounts payable, accrued expenses and other liabilities increased $17.9 million for the nine-month period ended September 30, 2006 primarily due to accounts payable timing differences.

INCOME TAXES PAYABLE: Income taxes payable increased $50.2 million during the nine-month period ended September 30, 2006 and reflects a current provision for income taxes of $106.3 million and the reclassification of approximately $7.6 million of prepaid taxes to other current assets, offset by the excess tax benefit on stock option exercises of $63.9 million.

INVESTING ACTIVITIES: Net cash used in investing activities was $52.1 million for the nine-month period ended September 30, 2006, compared to net cash used in investing activities of $162.5 million for the nine-month period ended September 30, 2005. Included in the nine-month period ended September 30, 2006 were cash outflows of $31.9 million for capital expenditures, $17.5 million for net purchases of marketable securities available for sale, $2.0 million for an additional investment made in EntreMed, Inc. ($1.4 million investment in EntreMed common stock and $0.6 million investment in EntreMed warrants) and $0.6 million for the purchase of other non-marketable investment securities. Included in the nine-month period ended September 30, 2005 were cash outflows of $22.6 million for capital expenditures, $8.4 million for working capital adjustments and acquisition costs related to our October 2004 acquisition of Penn T Limited, $120.8 million for net purchases of marketable securities available for sale and $10.5 million for the exercise of warrants to purchase 7,000,000 shares of EntreMed common stock. The increase in capital expenditures is due to our on-going international expansion, particularly the construction of a

manufacturing facility in Neuchatel, Switzerland as well as, on-going expansion at our corporate headquarters in Summit, New Jersey.

FINANCING ACTIVITIES: Net cash provided by financing activities was $125.8 million for the nine-month period ended September 30, 2006, compared to net cash provided by financing activities of $37.9 million for the nine-month period ended September 30, 2005. Prior to the adoption of SFAS 123R, we presented



all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Consolidated Statement of Cash Flows. SFAS 123R requires excess tax benefits (i.e., the tax benefit recognized upon exercise of stock options in excess of the benefit recognized from recognizing compensation cost for those options) to be classified as financing cash flows in the Consolidated Statement of Cash Flows. Cash received from stock option exercises for the nine-month period ended September 30, 2006 was $68.0 million and the excess tax benefit recognized was $57.8 million. Cash received from stock option exercises for the nine-month period September 30, 2005 was $37.9 million. Pursuant to SFAS 123R tax benefits resulting from the exercise of stock options, which have been presented as operating cash flows prior to the adoption of SFAS 123R are not reclassified to financing activities, but rather continue to be presented as operating cash flows.

In November 2006, we issued 20,000,000 shares of our common stock at a public offering price of $51.60 per share with gross proceeds of $1.032 billion and proceeds, net of the Underwriters' discount of $1.007 billion.

We expect increased research and product development costs, clinical trial costs, expenses associated with the regulatory approval process, international expansion costs and commercialization of products and capital investments. However, existing cash, cash equivalents and marketable securities available for sale, combined with cash received from expected net product sales and revenues from various research, collaboration and royalties agreements are expected to provide sufficient capital resources to fund our operations for the foreseeable future.

CONTRACTUAL OBLIGATIONS

Our major outstanding contractual obligations relate primarily to our convertible note obligation, operating leases, ALKERAN(R) supply and distribution agreement, Penn Pharmaceutical Services Limited technical services agreement and certain other contractual commitments. For more information on these contractual obligations see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Notes 9 and 18 of the Notes to the Consolidated Financial Statements for the year ended December 31, 2005 contained in our Current Report on Form 8-K filed with the SEC on November 3, 2006.

In October 2006, the Company became a limited partner of Burrill Life Sciences Capital Fund III, L.P. and agreed to invest $20.0 million over a 10-year period, of which $1.4 million was paid as of October 4, 2006. The partnership agreement does not specify future contribution dates; therefore we have included the remaining contributions in 'less than 1 year' for presentation purposes. The fund will invest in start-up companies conducting business in life sciences such as biotechnology, pharmaceuticals, medical technology, devices, diagnostics plus health and wellness.

In October 2006, the Company invested $4.4 million in Royalty Pharma Strategic Partners, LP to participate in a rights offering for an additional interest.

The following table sets forth our contractual obligations as of September 30, 2006 by contractual due dates:

| | Contractual Due Dates | | | |
|---|---|---|---|---|
| (IN MILLIONS $) | Less Than 1 Year | 1-3 Years | 3-5 Years | More 5 Ye |
| Convertible notes obligation | $ - | $ 400.0 | $ - | $ |
| Operating leases | 4.6 | 6.0 | 5.3 | 2 |
| ALKERAN(R) agreements | - | 67.3 | - | |
| Other contract commitments (1) | 28.1 | 5.5 | 0.5 | |
| Total | $ 32.7 | $ 478.8 | $ 5.8 | $ 2 |

(1) Includes our recent commitments with respect to Burrill Life Sciences and Royalty Pharma

CRITICAL 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 fully described in Note 1 of the Notes to the Consolidated Financial Statements for the year ended December 31, 2005 included in our Current Report on Form 8-K filed on November 3, 2006. Our critical accounting policies are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operation in our Current Report on Form 8-K filed on November 3, 2006. The significant changes and or expanded discussion of such critical accounting policies are contained herein:

REVENUE RECOGNITION ON COLLABORATION AGREEMENTS: We have formed collaborative research and development agreements and alliances with other pharmaceutical and biotechnology companies. These agreements are in the form of research and development and license agreements. The agreements are for both early-and late-stage compounds and are focused on specific disease areas. For the early-stage compounds, the agreements are relatively short-term agreements that are renewable depending on the success of the compounds as they move through preclinical development. The agreements call for nonrefundable upfront payments, milestone payments on achieving significant milestone events, and in some cases ongoing research funding. The agreements also contemplate royalty payments on sales if and when the compound receives FDA marketing approval.

Our revenue recognition policies for all nonrefundable upfront license fees and milestone arrangements are in accordance with the guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletin, or SAB, No. 101, "Revenue Recognition in Financial Statements," as amended by SAB No. 104, "Revenue Recognition," or SAB 104. In addition, we follow the provisions of Emerging Issues Task Force, or EITF, Issue 00-21, "Revenue Arrangements with Multiple Deliverables," or EITF 00-21, for multiple element revenue arrangements entered into or materially amended after June 30, 2003. EITF 00-21 provides

guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF's separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue-recognition policy must be determined for the entire arrangement.

Under arrangements where the license fees and research and development activities can be accounted for as a separate unit of accounting, nonrefundable upfront license fees are deferred and recognized as



revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and, (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone. If any of these conditions are not met, we would recognize a proportionate amount of the milestone payment upon receipt as revenue that correlates to work already performed and the remaining portion of the milestone payment will be deferred and recognized as revenue as we complete our performance obligations.

GROSS TO NET SALES ACCRUALS FOR SALES RETURNS, MEDICAID REBATES AND CHARGEBACKS: Our gross to net sales accruals have been primarily driven by sales of THALOMID(R). THALOMID(R) is distributed under our S.T.E.P.S. (R), or System for Thalidomide Education and Prescribing Safety, distribution program. Among other things, S.T.E.P.S. (R), which is a proprietary comprehensive education and risk-management distribution program, requires prescribers, patients and dispensing pharmacies to participate in a registry and an order cannot be filled unless the physician, patient and pharmacy have all obtained an appropriate registration number. Automatic refills are not permitted under the program. Each prescription may not exceed a 28-day supply and a new prescription is required with each order.

Although we invoice through traditional pharmaceutical wholesalers, all THALOMID(R) orders are drop-shipped directly to the prescribing pharmacy overnight. Wholesaler stocking of this product is prohibited. In addition, we do not offer commercial discounts on our products to pharmacies or hospitals and, therefore, have no commercial distributor chargebacks. Our chargebacks result from the difference between the wholesaler price and the lower federal ceiling price available to federally funded healthcare providers, such as Veterans Affairs and the U.S. Department of Defense.

SALES RETURNS: We base our sales returns accrual, which primarily relates to THALOMID(R) sales returns, on actual returns history and the trend experience for lots where product is still being returned. 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 current sales return accruals. We do not use information from external sources in estimating our product returns. The requirements under our S.T.E.P.S. (R) distribution process make factors other than the historical experience less significant when estimating our sales returns accruals for THALOMID(R). As indicated above, THALOMID(R) is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product. In addition, since THALOMID(R) has a relatively long shelf life, typically two years, short-dated inventory has not historically been an issue. The impact that external factors such as price changes from competitors and introductions of new and generic competing products could have on our sales returns accruals is highly judgmental and difficult to quantify. Our sales returns have not been impacted thus far by such external factors; however we continue to monitor such factors. Our sales returns and allowances accruals were $49.3 million and $15.0 million for the nine-month period ended September 30, 2006 and 2005, respectively, which equates to an accrual rate of 7.2% and 3.9% of gross product sales in each of the respective periods. A 10% increase in our returns rate would have resulted in a $4.9 million decrease in our 2005 reported revenue.

MEDICAID REBATES: The Medicaid rebate formula, which is established by the Center for Medicare and Medicaid Services, provides for price increases based on increases in the Consumer Price Index-All Urban Consumers, or CPI-U. Price increases in excess of the allowable increase results in a higher unit



rebate amount, or URA. Our Medicaid rebate accruals are computed using the Medicaid URA, as determined under the Medicaid rebate formula, applied to the estimated Medicaid dispense quantities. Actual Medicaid dispense quantities are reported by individual states on a 45-60 day quarter-end lag. Differences in Medicaid rebate accruals resulting from differences in the estimated Medicaid dispense quantities and actual Medicaid dispense quantities are adjusted in the following period. Medicaid rebate allowances decreased in the three-month period ended September 30, 2006, compared to the three-month period ended September 30, 2005, primarily due to the impact of the new Medicare, Part D legislation, which became effective January 1, 2006. As a result of the new legislation many patients who had been eligible to receive THALOMID(R) through Medicaid coverage during the prior year period are now covered under Medicare, Part D. Partially offsetting the THALOMID(R) decrease are Medicaid rebate allowances included in the current year period for REVLIMID(R) sales.

DISTRIBUTOR CHARGEBACKS: As indicated above, we do not offer commercial discounts on our products to pharmacies or hospitals and, therefore, have no commercial distributor chargebacks. Our distributor chargebacks result from the difference between the wholesaler price and the lower federal ceiling price, or FCP, available to federally funded healthcare providers, such as Veteran Affairs and the U.S. Department of Defense. Under our S.T.E.P.S. (R) distribution program, we can determine which pharmacies are eligible for the lower FCP pricing and, therefore, we record the actual chargeback allowance amount at the time of sale. Like the Medicaid URA calculation, which is impacted by price increases in excess of the allowable amount, the FCP is further reduced for price increases in excess of allowable CPI-U increases and, as in the case of Medicaid rebate accruals, the THALOMID(R) price increases in excess of allowable amounts has resulted in higher distributor chargeback accruals in 2006, as compared to 2005.

OTHER GROSS TO NET SALES ACCRUALS: We record sales discounts accruals based on payment terms extended to customers and we record distributor services accruals based on actual fees paid to wholesale distributors for services provided.

SHARE-BASED COMPENSATION: We adopted the provisions of SFAS 123R effective January 1, 2006, which requires that the cost resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS 123R using the modified prospective application method under which the provisions of SFAS 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. We use the Black-Scholes option pricing model to estimate the fair value of options on the date of grant which requires certain estimates by management including the expected forfeiture rate and expected term of the options. Management also makes decisions regarding the method of calculating the expected volatilities and the risk free interest rate used in the model. Fluctuations in the market that affect these estimates could have an impact on the resulting compensation cost. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized over the remaining service period after the adoption date (see Note 7 to the Consolidated Financial Statements included in this quarterly report for additional information).

OTHER-THAN-TEMPORARY IMPAIRMENTS OF AVAILABLE-FOR-SALE MARKETABLE SECURITIES: A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment on our part and requires consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Our marketable securities consist primarily of debt securities whose fair value is affected by interest rate and credit rating changes. The fair value of certain debt securities were negatively impacted by interest rate increases during 2006. If the cost of an investment exceeds its fair value, factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, asset quality, business prospects of the issuer, adverse changes in the general market conditions in which the issuer operates, length of time that the fair value has been below our cost, our expected future cash flows from the security and our intent and ability to



retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2006, we determined that certain securities had sustained an other-than-temporary impairment and, as a result, we recognized an impairment loss of $3.8 million for the nine-month period ended September 30, 2006 which was recorded in interest and other income, net.

INVESTMENT IN AFFILIATED COMPANY: We hold 7,864,864 shares of EntreMed, Inc. common stock and 432,432 warrants to purchase additional shares of EntreMed common stock at a conversion price of $2.3125 per warrant. Since we also hold 3,350,000 shares of EntreMed voting preferred shares that are convertible into 16,750,000 shares of common stock, we determined that we have significant influence over the investee and are applying the equity method of accounting to our common stock investment. The warrants are being accounted for at fair value using the Black-Scholes model with changes in fair value recorded through interest and other income (expense), net.

The investment in EntreMed had a carrying value of approximately $13.5 million and a fair value of $14.6 million at September 30, 2006.

If the carrying value of our investment were to exceed its fair value, we would review it to determine whether an other-than-temporary decline in value of the investment has been sustained. If the investment is determined to have sustained an other-than-temporary decline in value, the investment will be written-down to its fair value. Such an evaluation is judgmental and dependent on the specific facts and circumstances. Factors that we considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis, the period of time that the market value is below cost, the financial condition of the investee and our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. We evaluate information that we are aware of in addition to quoted market prices, if any, in determining whether an other-than-temporary decline in value exists.

ACCOUNTING FOR LONG-TERM INCENTIVE PLANS: In 2003, we established a Long-Term Incentive Plan, or LTIP, designed to provide key officers and executives with performance-based incentive opportunities contingent upon achievement of pre-established corporate performance objectives, and payable only if employed at the end of the performance cycle. The 2004 performance cycle, or the 2006 Plan, began on January 1, 2004 and will end on December 31, 2006; the 2005 performance cycle, or the 2007 Plan, began on January 1, 2005 and will end on December 31, 2007; and the 2006 performance cycle, or the 2008 Plan, which will end on December 31, 2008.

Performance measures for all Plans are based on the following components: 25% on earnings per share, 25% on net income and 50% on revenue. Payouts for the 2007 and 2008 Plans may be in the range of 0% to 200% of a certain percent of a participant's salary, while the payout range for the 2006 plan is 0% to 150%. Upon a change in control, participants will be entitled to an immediate payment equal to their target award, or, if higher, an award based on actual performance through the date of the change in control.

Assuming achievement of 100% of the established targets, the aggregate payout under the Plans would be $8.1 million and the maximum aggregate payout under the Plans is $18.7 million. We accrue the long-term incentive liability over each three-year cycle. At September 30, 2006, the recorded liability for the long-term incentive plans was $6.5 million.

Accruals recorded for the LTIP entail making certain assumptions concerning future earnings per share, net income and revenues, the actual results of which could be materially different than the assumptions used. Accruals for the LTIP are reviewed on a regular basis and revised accordingly so that the liability recorded reflects updated estimates of future payouts. In estimating the accruals management considers



actual results to date for the performance period, expected results for the remainder of the performance period, operating trends, product development, pricing and competition.

EFFECTIVE TAX RATE: The Company's underlying effective tax rate is approximately 69% for the nine months ended September 30, 2006. The effective tax rate exceeds the statutory tax rate primarily due to share based compensation expense related to incentive stock options (ISO's) for which tax benefits may not be realized and certain expenses being incurred in taxing jurisdictions outside the United States for which the Company does not presently receive a tax benefit. The Company operates under an incentive tax holiday in Switzerland that expires in 2015 and exempts the Company from certain Swiss taxes. Likewise, expenses currently being incurred there do not provide a tax benefit. To the extent we

receive approvals in markets outside the United States and, manufacture and generate taxable income subject to our Swiss tax holiday, we would expect our effective tax rate to be lower in the future.

At March 31, 2005, the Company determined it was more likely than not that the Company will generate sufficient taxable income to realize the benefits of its deferred tax assets and as a result, eliminated certain deferred tax valuation allowances, which resulted in the Company recording an income tax benefit in 2005 of $42.6 million and an increase to additional paid-in capital of $30.2 million. The decision to eliminate the deferred tax valuation allowances was based on an external Independent Data Monitoring Committee's, or IDMC, analyses of two Phase III Special Protocol Assessment multiple myeloma trials and the conclusion that these trials exceeded the pre-specified stopping rule. The IDMC found a statistically significant improvement in time to disease progression -- the primary endpoint of these Phase III trials -- in patients receiving REVLIMID(R) plus dexamethasone compared to patients receiving dexamethasone alone. This, in concert with our nine consecutive quarters of profitability, led to the conclusion that it was more likely than not that we will generate sufficient taxable income to realize the benefits of our deferred tax assets.

The Company periodically evaluates the likelihood of the realization of deferred tax assets, and reduces the carrying amount of these 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 deferred tax assets, including its 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 and, to the extent future expectations change, we would have to assess the recoverability of our deferred tax assets at that time. At September 30, 2006, it was more likely than not that the Company would realize its deferred tax assets, net of valuation allowances.

CAUTIONARY STATEMENTS FOR FORWARD-LOOKING INFORMATION

The Management's Discussion and Analysis of Financial Condition and Results of Operations provided above contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under our control which may cause actual results, performance and achievements to be materially different from the results, performance or other expectations implied by these forward-looking statements. These factors include the results of current or pending clinical trials, our products' failure to demonstrate efficacy or an acceptable safety profile, actions by the FDA, the financial condition of suppliers including their solvency and ability to supply product and other factors detailed herein and in our other filings with the Securities and Exchange Commission.



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. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. We do not use derivative instruments for trading purposes. At September 30, 2006, our market risk sensitive instruments consisted of a foreign currency denominated forward contract, marketable securities available-for-sale, other equity investments and unsecured convertible notes issued by us.

FOREIGN CURRENCY DENOMINATED FORWARD CONTRACT: We may periodically utilize foreign currency denominated forward contracts to hedge currency fluctuations of transactions denominated in currencies other than the functional currency. At September 30, 2006, we were party to a foreign currency forward contract to buy U.S. dollars and sell Swiss francs for a notional amount of $128.5 million. The forward contract expires on October 11, 2006 and is an economic hedge of a U.S. dollar payable of a Swiss foreign entity, which is re-measured through earnings each period based on changes in the spot rate. The fair value of the forward contract at September 30, 2006 was a net gain of approximately $3.3 million and was recorded in other current assets with the change in fair value recorded in current year's earnings. Assuming that the September 30, 2006 exchange rates between U.S. dollar and Swiss franc were to adversely change by a hypothetical ten percent, the change in the fair value of the contract would decrease by approximately $13.9 million. However, since the contract hedges foreign currency payables, any change in the fair value of the contracts would be offset by a change in the underlying value of the hedged item.

MARKETABLE SECURITIES AVAILABLE FOR SALE: At September 30, 2006, our marketable securities available for sale consisted of U.S. treasury securities, government-sponsored agency securities, auction rate notes, mortgage-backed obligations, corporate debt securities, other asset-backed securities and 1,939,600 shares of Pharmion Corporation common stock. Marketable securities available for sale are carried at fair value, are held for an indefinite period of time and are intended for use in meeting our ongoing liquidity needs. Marketable securities with original maturities of three months or less when purchased are classified as cash equivalents. 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 all debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses, is included in interest and other income, net. During 2006, we determined that certain securities had sustained an other-than-temporary impairment due to a reduction in their future estimated cash flows and as a result, we recognized an impairment loss of $3.8 million for the nine-month period ended September 30, 2006.



As of September 30, 2006, 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:

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| | Duration | | | | |
|---|---|---|---|---|---|
| (IN THOUSANDS $) | Less Than 1 Year | 1 to 3 Years | 3 to 5 Years | 5 to 7 Years | Ov Y |
| Principal amount | $ 450,489 | $ 78,828 | $ 201,563 | $ 20,500 | $ |
| Fair value | $ 448,928 | $ 78,755 | $ 188,269 | $ 19,961 | $ |
| Average interest rate | 4.6% | 4.6% | 4.3% | N/A | |

PHARMION COMMON STOCK: At September 30, 2006, we held a total of 1,939,600 shares of Pharmion Corporation common stock, which had an estimated fair value of approximately $41.8 million (based on the closing price reported by the National Association of Securities Dealers Automated Quotations, or NASDAQ system) and, which exceeded the cost by approximately $21.6 million. The amount by which the fair value exceeded the cost (i.e., the unrealized gain) was included in Accumulated Other Comprehensive Income in the Stockholders' Equity section of the Consolidated Balance Sheet. The fair value of the Pharmion common stock investment is subject to market price volatility and any increase or decrease in Pharmion's common stock quoted market price will have a similar percentage increase or decrease in the fair value of our investment.

INVESTMENT IN AFFILIATED COMPANIES: At September 30, 2006, we held 7,864,864 shares of EntreMed, Inc. common stock to which we are applying the equity method of accounting. The investment in EntreMed had a carrying value of approximately $13.5 million and a fair value of $14.6 million at September 30, 2006. Under the equity method, the investment is reviewed to determine whether an other-than-temporary decline in value of the investment has been sustained. If it is determined that the investment has sustained an other-than-temporary decline in its value, the investment will be written down to its fair value. Such an evaluation is judgmental and dependent on the specific facts and circumstances. See our discussion of Critical Accounting Policy contained in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operation for factors that are considered in determining whether an other-than-temporary decline in value has occurred.

We also hold warrants to purchase an additional 432,432 shares of EntreMed common stock at a conversion price of $2.3125 per warrant. The warrants are being accounted for at fair value with changes in fair value recorded through earnings. At September 30, 2006, the warrants had a fair value of $0.3 million and are classified in other non-current assets. Since the warrants give us the right, but not an obligation, to purchase the shares of EntreMed common stock, the fair value of the warrants can never fall below zero and, the maximum cumulative charge is $0.6 million, which is fair value of the warrants, computed using the Black-Scholes model, on February 2, 2006, or the date of the investment.

CONVERTIBLE DEBT: In June 2003, we issued an aggregate principal amount of $400.0 million of unsecured convertible notes. The notes have a five-year term and a coupon rate of 1.75% payable semi-annually on June 1 and December 1. Each $1,000 principal amount of convertible notes is convertible into 82.5592 shares of common stock, or a conversion rate of $12.1125 per share, which represented a 50% premium to the closing price on May 28, 2003 of our common stock of $8.075 per share, after adjusting prices for the two-for-one stock splits affected on February 17, 2006 and October 22, 2004. Under the terms of the purchase agreement, the noteholders can convert the outstanding notes at any time into an aggregate 33,020,545 shares of common stock at the conversion price. In addition, the noteholders have the right to require us to redeem the notes in cash at a price equal to 100% of the principal amount to be redeemed, plus accrued interest, prior to maturity in the event of a change of control and certain other transactions defined as a "fundamental change," in the indenture governing the notes.

At September 30, 2006, the fair value of our convertible notes exceeded the carrying value of $400.0 million by approximately $1.0 billion, which we believe reflects the increase in the market price of our common stock to $43.30 per share as of September 30, 2006. Assuming other factors are held constant, an increase in interest rates generally results in a decrease in the fair value of fixed-rate convertible debt, but does not impact the carrying value, and an increase in our stock price generally results in an increase in the fair value of convertible debt, but does not impact the carrying value.

ITEM 4 - CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this quarterly report, we carried out an evaluation, under the supervision and with the participation of the Company's 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)). 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 the Company in the reports that it files or submits 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.

(b) Changes in Internal Control Over Financial Reporting. There have not been any changes in our internal control over financial reporting during the fiscal quarter to which this report relates 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

We are not engaged in any material legal proceedings.

Item 1A. Risk Factors

The risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 have not materially changed.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds - None

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|---|---|---|
| Item 3. | Defaults Upon Senior Securities | - None |
| Item 4. | Submission of Matters to a Vote of Security Holders | - None |
| Item 5. | Other Information | - None |

Item 6. Exhibits

| | |
|---|---|
| 31.1 | Certification by the Company's Chief Executive Officer dated November 8, 2006. |
| 31.2 | Certification by the Company's Chief Financial Officer dated November 8, 2006. |
| 32.1 | Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350 dated November 8, 2006. |
| 32.2 | Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350 dated November 8, 2006. |



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 8, 2006 | By: | /s/Robert J. Hugin<br>Robert J. Hugin<br>President, Chief Operating Officer and Chief Financial Officer |
| DATE | November 8, 2006 | By: | /s/James R. Swenson<br>James R. Swenson<br>Controller |

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