FORM 10−Q

POZEN INC /NC − POZN

Filed: August 08, 2006 (period: June 30, 2006)

Quarterly report which provides a continuing view of a company's financial position

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FINANCIAL INFORMATION

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10−Q

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

For the quarterly period ended June 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 000−31719

POZEN Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62−1657552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1414 Raleigh Road

Suite 400

Chapel Hill, North Carolina 27517

(Address of principal executive offices, including zip code)

(919) 913−1030

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant 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 Securities Exchange Act of 1934. (Check one):

☐ Large Accelerated Filer ☒ Accelerated Filer ☐ Non−Accelerated Filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b−2 of the Exchange Act): ☐ Yes ☒ No

The number of shares outstanding of the registrant’s common stock as of July 31, 2006 was 29,176,866.

POZEN Inc.

(A Development Stage Company)

FORM 10−Q

For the Six Months Ended June 30, 2006

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.

(A Development Stage Company)

BALANCE SHEETS

(Unaudited)

	June 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,303,594	$ 27,467,789
Short−term investments	18,559,186	18,370,701
Prepaid expenses and other current assets	296,895	613,682
Total current assets	32,159,675	46,452,172
Equipment, net of accumulated depreciation	220,626	234,839
Total assets	$ 32,380,301	$ 46,687,011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,214,385	$ 1,443,676
Accrued compensation	851,033	2,591,633
Accrued expenses	1,349,663	1,201,023
Deferred revenue	3,428,200	6,552,000
Total current liabilities	6,843,281	11,788,332
Long−term liabilities:		
Deferred revenue	1,000,000	1,000,000
Total liabilities	7,843,281	12,788,332
Common stock, $0.001 par value, 90,000,000 shares authorized; 29,176,866 and 29,002,306 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively	29,177	29,002
Additional paid−in capital	151,904,842	146,399,373
Accumulated other comprehensive loss	(10,290)	(8,551)
Deficit accumulated during the development stage	(127,386,709)	(112,521,145)
Total stockholders' equity	24,537,020	33,898,679
Total liabilities and stockholders' equity	$ 32,380,301	$ 46,687,011

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period From Inception (September 26, 1996) Through June 30,
	2006	2005	2006	2005	2006
Revenue	$ 886,800	$ 1,958,885	$ 3,123,800	$ 4,011,375	$ 58,576,082
Operating expenses:					
General and administrative	3,078,544	2,328,632	6,731,014	4,725,218	56,803,965
Research and development	6,659,465	4,003,467	12,147,643	9,331,252	138,156,843
Total operating expenses	9,738,009	6,332,099	18,878,657	14,056,470	194,960,808
Other income:					
Interest and other income	430,436	285,531	889,293	557,204	9,932,495
Net loss	(8,420,773)	(4,087,683)	(14,865,564)	(9,487,891)	(126,452,231)
Non−cash preferred stock charge	—	—	—	—	27,617,105
Preferred stock dividends	—	—	—	—	934,478
Net loss attributable to common stockholders	$(8,420,773)	$(4,087,683)	$(14,865,564)	$(9,487,891)	$ (155,003,814)
Basic net loss per common share	$ (0.29)	$ (0.14)	$ (0.51)	$ (0.33)	
Shares used in computing basic net loss per common share	29,164,333	28,915,511	29,139,452	28,914,116	
Diluted net loss per common share	$ (0.29)	$ (0.14)	$ (0.51)	$ (0.33)	
Shares used in computing diluted net loss per common share	29,164,333	28,915,511	29,139,452	28,914,116	

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30,		Period from Inception (September 26, 1996) Through June 30,
	2006	2005	2006
Operating activities:			
Net (loss) income	$(14,865,564)	$ (9,487,891)	$ (126,452,231)
Adjustments to reconcile net loss to net cash (used in) operating activities:			
Depreciation	53,570	90,348	894,988
Write−down of impaired asset	—	69,272	155,576
Gain on sale of investments	—	49,717	—
Bond amortization	(508,772)	(219,615)	(1,080,452)
Noncash compensation expense	3,268,149	340,549	15,505,126
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	316,787	618,568	(296,895)
Accounts payable and accrued expenses	(459,556)	(2,135,632)	3,415,080
Deferred revenue	(3,123,800)	(4,007,070)	4,428,200
Net cash used in operating activities	(15,319,186)	(14,681,754)	(102,980,608)
Investment activities:			
Purchase of equipment	(39,357)	(35,639)	(1,271,190)
Purchase of investments	(18,281,452)	(25,655,235)	(65,289,025)
Sale of investments	18,600,000	6,350,283	47,800,000
Net cash provided by (used in) investing activities	279,191	(19,340,591)	(18,760,215)
Financing activities:			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	875,799	4	82,550,551
Proceeds from notes payable	—	—	3,000,000
Proceeds from stockholders' receivables	—	—	1,004,310
Payment of dividends	—	—	(162,295)
Net cash provided by financing activities	875,799	4	135,044,416
Net (decrease) increase in cash and cash equivalents	(14,164,195)	(34,022,341)	13,303,594
Cash and cash equivalents at beginning of period	27,467,789	51,764,129	—
Cash and cash equivalents at end of period	$ 13,303,594	$ 17,741,788	$ 13,303,594
Supplemental schedule of cash flow information:			
Cash paid for interest	$ —	$ —	$ 191,328
Supplemental schedule of noncash investing and financing activities:			
Conversion of notes payable to preferred stock	$ —	$ —	$ 3,000,000
Preferred stock dividend	$ —	$ —	$ 772,183
Forfeiture of common stock options and warrants	$ —	$ —	$ 314,379
Conversion of preferred stock warrants to common stock	$ —	$ —	$ 1,080,001

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. Development Stage Company

POZEN Inc. ("POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain−related conditions. The Company's product development emphasis is on diseases with unmet medical needs where the Company can improve efficacy, safety and/or patient convenience. Since inception, the Company has focused its efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. The Company is also exploring the development of product candidates in other pain−related therapeutic areas. The Company intends to enter into collaboration agreements to commercialize its product candidates, and has entered into, and expects to continue to enter into such collaborations. The Company has not obtained regulatory approval to market any of its product candidates in the United States. The United Kingdom's (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a marketing authorization for the Company's product candidate MT 100 for the acute treatment of migraine in the UK.

Statement of Financial Accounting Standards Board ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. The Company will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of the Company's product candidates. As of June 30, 2006, the Company had $13.3 million in cash and cash equivalents and $18.6 million in short−term investments. If the Company's operating expenses for 2006 and 2007 remain at the level of its operating expenses in 2005, the Company believes it will have sufficient cash reserves to maintain that level of business activities throughout 2007 provided that, under the terms of the Company's August 1, 2006 Collaboration and License Agreement (Agreement) with AstraZeneca AB (AstraZeneca), the Company receives an upfront license fee of $40 million which is payable to the Company following the termination of the waiting period under the Hart−Scott−Rodino Antitrust Improvements Act and provided that certain development expenses are paid by AstraZeneca, as outlined in the Agreement. The Company's expenses might increase in 2006 and 2007 if any regulatory agency requires the Company to conduct additional clinical trials, studies or investigations in connection with their consideration, or reconsideration, of the Company's regulatory filings for any of its product candidates. The Company is not currently obligated to make any milestone payments to third parties and does not currently have any other required material payment obligations during that period. However, regulatory delays, such as the Company is currently experiencing related to the approvable letter the Company received from the U.S. Food and Drug Administration (FDA) in June 2006 related to the Company's New Drug Application (NDA) for Trexima, or unforeseen developments in the development of the Company's existing and future product candidates, may increase the Company's cash requirements beyond its currently assumed needs.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements—The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission ("SEC") regulations for interim financial information. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring accruals) necessary to present fairly the balance sheets, statements of operations and statements of cash flows for the periods presented in accordance with accounting principles generally accepted in the United States. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to SEC rules and regulations. It is presumed that users of this interim financial information have read or have access to the audited financial statements and footnote disclosure for the preceding fiscal year contained in the Company's Annual Report on Form 10−K, filed on March 8, 2006. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2006.

Revenue Recognition—The Company's licensing agreements have terms that include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and royalty payments based on future product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition", as amended by SAB 104, "Revenue Recognition" ("SAB 101"), and Emerging Issues Task Force 00−21 ("EITF 00−21"), "Revenue Arrangements with Multiple Deliverables." The non−refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a straightline basis over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on the part of the Company. For the Company's current agreements, these periods are estimated to be as follows:

- The June 2003 initial licensing and patent−issuance milestone payments totaling $25.0 million for MT 400 received from GSK have been deferred and were originally being amortized over 42 months. During the third quarter of 2005 the amortization period was decreased to 39 months based upon the August 2005 submission to the FDA of the Trexima NDA which was earlier than anticipated. The decrease in the deferred period resulted in a $357,000 increase in amortization in future quarters as compared to the second quarter 2005 amortization. During the second quarter of 2006 the remaining amortization period of 6 months was increased to 15 months based upon the June 2006 receipt of an approvable letter from the FDA related to the Trexima NDA and an estimated extension of 9 months, which represents what the Company believes to be the conclusion of any obligation on its part under the agreement. The increase in the deferred period resulted in a $1.3 million decrease in amortization in future quarters as compared to the first quarter 2006 amortization.

- The September 2003 $1.0 licensing fee for MT 300 ($2.0 million non−refundable upfront licensing fee net of a potential termination fee of $1.0 million) received from Valeant Pharmaceuticals North America (Valeant NA), a subsidiary of Valeant Pharmaceuticals International (formerly Xcel Pharmaceuticals Inc.), has been amortized over 32 months. As the result of the receipt in October 2003 of a not−approvable letter from the FDA relating to the NDA for MT 300, after three months of amortization, this estimated deferral period was increased from an original estimate of 20 months to 32 months ending in April 2006, resulting in a $14,000 decrease in the fourth quarter 2003 amortization from the third quarter 2003 estimate.

Milestone payments are recognized as revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement and (ii) the fees are non−refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Royalty revenue will be recognized when earned with respect to the manufacture, sale or use of the Company's products or technology. For those arrangements where royalties are reasonably estimable, the Company will recognize revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties.

Additionally, the Company's licensing agreements may include payment for services provided by the Company on an hourly rate and direct expense basis. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project.

Investments—Investments consist primarily of United States government and government agency obligations, and corporate fixed income securities. The Company invests in high−credit quality investments in accordance with its investment policy, which minimizes the possibility of loss. Under the Company's investment policy, investments that have a maturity of greater than three months and less than one year are classified as short−term, are considered to be available−for−sale and are carried at fair value with unrealized gains and losses recognized in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis. Generally, investments with maturities beyond twelve months are classified as long−term. Marketable and non−marketable equity investments are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, the investment would be written down to fair value and the write−down would be permanent. For the six month periods ended June 30, 2005 and 2006, the Company had $0.2 million and $0.5 million of bond amortization and $7,485 and $10,290 of unrealized losses on investments included in other income (loss) for each period, respectively.

Accumulated Other Comprehensive Income—Accumulated other comprehensive income is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders' equity. The Company had $7,485 and $10,290 of unrealized losses on its investments that are classified as accumulated other comprehensive loss at June 30, 2005 and 2006, respectively.

Comprehensive income consists of the following components for the six months ended June 30, 2006 and 2005:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net loss	$(8,420,773)	$(4,087,683)	$(14,865,564)	$(9,487,891)
Unrealized gain (loss) on marketable securities	9,934	4,498	(10,290)	(7,485)
Total comprehensive loss	$(8,410,839)	$(4,083,185)	$(14,875,854)	$(9,495,376)

Stock−based Compensation—On January 1, 2006, we adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share−Based Payment," which requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the Accounting Principles Board Opinion No. 25 ("APB 25"),

"Accounting for Stock Issued to Employees," intrinsic value method. Accordingly, prior to January 1, 2006 we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options, as all such options had an exercise price equal to the market value of the underlying common stock on the date of the grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. Under this transition method, our compensation cost recognized includes compensation costs for all share−based payments granted prior to, but not yet vested as of, January 1, 2006 based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and compensation cost for all share−based payments granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Accordingly, we have not restated our financial results for prior periods.

Under the fair value recognition provisions of SFAS No. 123(R), stock−based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure−only purposes under the provisions of SFAS No. 123, we use the Black−Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded−vesting features, we recognize compensation cost on a straight−line basis over the requisite service period. For awards with performance or market conditions granted subsequent to our adoption of SFAS No. 123(R), we intend to recognize compensation cost over the expected period to achieve the performance or market condition.

The adoption of SFAS No. 123(R) had a significant impact on our results of operations. Our consolidated statement of operations for the six months ended June 30, 2006 includes the following stock−based compensation expense:

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Research and development	$ 386,900	$ 1,119,800
General and administrative	960,800	2,148,300
Operating loss	(1,347,700)	(3,268,100)
Tax benefit	—	—
Net loss	$ (1,347,700)	$ (3,268,100)

Unrecognized stock−based compensation expense, including time−based options, performance−based options and restricted stock awards, expected to be recognized over an estimated weighted−average amortization period of 2.20 years was $11.0 million at June 30, 2006. Unrecognized stock−based compensation expense expected to be recognized over the remaining period ending December 31, 2006 was $3.0 million at June 30, 2006.

Stock Plans

On November 20, 1996, the Company established a Stock Option Plan (the "Option Plan") and authorized the issuance of options for up to 1,605,310 shares of common stock to attract and retain quality employees and to allow such employees to participate in the growth of the Company. Awards were permitted to be made under the Option Plan to eligible employees, officers, consultants and non−employee directors in the form of incentive or nonqualified stock options. Eligible participants under the Option Plan include executive and key employees of the Company. The vesting periods for options granted under the Option Plan range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. The exercise price for incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (110% with respect to incentive stock options granted to optionees who are holders of 10% or more of the Company's common stock).

In May 2000, the Board of Directors adopted, and in June 2000 the stockholders approved, the POZEN Inc. 2000 Equity Compensation Plan (the "Plan"). The Plan became effective upon the completion of the Company's initial public offering in October 2000, after which time no further grants were made under the Option Plan. The Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units, and other stock−based awards to employees, non−employee directors, advisors and consultants. At adoption, the Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The vesting periods for awards made under the Plan generally range from immediate vesting at issuance to four years or may vest immediately, as described in and in accordance with the Plan, upon a change of control as defined in the Plan. If options granted under the Plan expire or are terminated for any reason without being exercised, or if stock awards, performance units, or other stock−based awards are forfeited or otherwise terminate, the shares of common stock underlying the grants will again be available for awards granted under the Plan.

In 2004, the Board of Directors adopted and the stockholders approved an amendment to and restatement of the Plan. The amendment to the Plan provided for an increase in the number of shares of common stock authorized for issuance under the Plan, from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. In addition, the amendment to the Plan limited the number of shares that may be issued pursuant to grants other than options under the Plan to 2,000,000 shares and made certain other clarifying changes. These plans are discussed in more detail in Note 7 to our financial statements for the fiscal year ended December 31, 2005 included in our Annual Report on Form 10−K filed on March 8, 2006.

In May 2004 an award of 98,135 restricted stock units was made to the Company's chief executive officer under the Plan. The restricted stock award vests in equal amounts on January 1, 2005, January 1, 2006 and January 1, 2007 and is payable in shares of common stock upon cessation of employment or the provision of service to the Company or, as provided in and in accordance with the plan upon a change of control.

On January 3, 2005, pursuant to an incentive program (the "Trexima incentive program") approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 506,772 shares of common stock. As of June 30, 2006, due to forfeitures resulting from employee terminations, options to purchase an aggregate of 388,593 shares of common stock remain outstanding under the Trexima incentive program. Each performance−based option will vest in full upon the later to occur of (i) January 3, 2007 or (ii) the receipt by the Company of an action letter from the FDA indicating approval of the NDA for the product candidate Trexima, which is being developed pursuant to the Company's collaboration agreement with GSK; provided, however that 25% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur prior to June 30, 2007, and 100% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur on or before December 31, 2007. These performance−based options, which were granted under the Plan, as amended and restated, have a ten−year term and an exercise price of $7.06, which was equal to the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant.

Time−Based Stock Awards

The fair value of each time−based award is estimated on the date of grant using the Black−Scholes option valuation model, which uses the assumptions described below. Our weighted−average assumptions used in the Black−Scholes valuation model for equity awards with time−based vesting provisions granted during the six months ended June 30, 2006 are shown in the following table:

(In thousands)	Three months ended June 30, 2006	Six months ended June 30, 2006
Expected volatility	76.6 – 80.0%	76.0 – 80.0%
Expected dividends	0%	0%
Expected terms	6.25 Years	6.25 Years
Risk−free interest rate	5.0 − 5.1%	4.3 − 5.1%

The expected volatility rate was estimated based on an equal weighting of the historical volatility of POZEN common stock over a four year period. The expected term was estimated based on a simplified method, as allowed under SEC Staff Accounting Bulletin No. 107, averaging the vesting term and original contractual term. The risk−free interest rate for periods within the contractual life of the option is based on seven year U.S. Treasury securities. The pre−vesting forfeiture rate used for the three and six month periods ended June 30, 2006 was based on historical rates. As required under SFAS No. 123(R), we will adjust the estimated forfeiture rate to our actual experience.

A summary of the time−based stock awards as of June 30, 2006, and changes during the six months ended June 30, 2006, is as follows:

	Underlying Shares (000s)	Weighted−Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Stock Awards				
Outstanding at January 1, 2006	3,317	$ 7.67		
Granted	826	10.91		
Exercised	157	5.34		
Forfeited or expired	49	9.28		
Outstanding at March 31, 2006	3,937	8.42	7.6	$ 32,663
Exercisable at March 31, 2006	1,927	$ 7.38	6.2	$ 17,968
Granted	57	12.81		
Exercised	18	2.10		
Forfeited or expired	288	10.41		
Outstanding at June 30, 2006	3,688	8.36	7.3	$ 944
Exercisable at June 30, 2006	1,816	$ 7.31	5.9	$ 2,445

The aggregate intrinsic value represents the pretax value (the period's closing market price, less the exercise price, times the number of in−the−money options) that would have been received by all option holders had they exercised their options at the end of the period. The exercise price of stock options granted during the three and six month periods ended June 30, 2006 was equal to the market price of the underlying common stock on the grant date. The total intrinsic value of stock options exercised during the three and six month periods ended June 30, 2006 was $0.1 million and $0.8 million, respectively.

Restricted Stock

As of June 30, 2006, there was $0.2 million in unrecognized compensation expense related to unvested restricted stock units under the May 2004 award of 98,135 restricted stock units granted to our chief executive officer described above. That cost is expected to be recognized over the period ending December 31, 2006. The grant−date fair value of these restricted stock units was $12.24 per share. There were 32,712 unvested restricted stock units outstanding at June 30, 2006 and no time−based restricted stock was granted nor forfeited during the three and six month periods ended June 30, 2006.

Performance−Based Awards

The fair value of each performance−based option granted under the Trexima incentive program was estimated as of the grant date using the Black−Scholes option valuation model without consideration of the performance measures. The inputs for expected volatility, expected term, expected dividends, and risk−free interest rate used in estimating fair value of performance−based awards in the six months ended June 30, 2006, are the same as those noted above under Time−Based Stock Awards.

Determining the appropriate amount to expense based on the achievement of stated goals in a performance−based award requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

As of June 30, 2006, there was $0.4 million in unrecognized compensation related to performance−based awards granted under the Trexima incentive program. That cost is expected to be recognized over the period ending June 30, 2007. The grant−date fair value of these performance−based options was $3.77 per share. There were 388,593 unvested performance−based options outstanding at June 30, 2006. No performance−based awards were granted nor exercised during the six months ended June 30, 2006; 49,542 and 54,818 awards were forfeited during the three and six month periods ended June 30, 2006. At June 30, 2006 the performance−based options had no intrinsic value and a remaining contractual life of 8.5 years.

2005 Stock−Based Compensation

The following table illustrates the effect on net income (loss) and net income (loss) per share for the three and six months ended June 30, 2005, if we had accounted for all employee stock−based compensation during that period based on the fair value method as prescribed by SFAS No. 123(R).

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Net loss attributable to common stockholders as reported	$ (4,087,683)	$ (9,487,891)
Add: Stock−based employee compensation expense reflected in reported net loss, net of related tax effects	$ 240,451	$ 340,549
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(1,434,949)	(3,043,864)
Pro forma net loss attributable to common stockholders	$ (5,282,181)	$(12,191,206)
Earnings per share		
Basic net income (loss) per common share as reported	$ (0.14)	$ (0.33)
Basic net income (loss) per common share pro forma	$ (0.18)	$ (0.42)
Diluted net income (loss) per common share as reported	$ (0.14)	$ (0.33)
Diluted net income (loss) per common share pro forma	$ (0.18)	$ (0.42)

For the purpose of the above table, the fair value of each option grant was estimated as of the date of grant by using the Black−Scholes option pricing model with the following weighted−average assumptions used for grants in the six month period ended June 30, 2005: a risk−free interest rate of 3.90% to 4.05%; a dividend yield of 0%; a weighted−average expected life of 7.0 years; and a volatility rate of 97% to 98%. The expected volatility was estimated using the historical volatility over a period of four years preceding the applicable period. The weighted−average fair value of options granted in the three month and six month periods ended June 30, 2005 were $7.51 and $7.10 respectively.

Net Loss Per Share—Basic and diluted net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted−average number of shares of common stock outstanding for the six months ended June 30, 2005 and 2006. During the six months ended June 30, 2005 and 2006, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for these periods because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share is the same for the three months ended June 30, 2005 and 2006. In accordance with SFAS 128, the Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the EPS calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

Rights Plan/Series A Junior Participating Preferred Stock—In January 2005, the Company approved a stockholder rights plan (the "Rights Plan"), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Company declared a dividend of a right to acquire one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock, $0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Generally, the Rights only are triggered and become exercisable if a person or group acquires beneficial ownership of 15 percent or more of the Company's common stock or announces a tender offer for 15 percent or more of the Company's common stock. The Rights Plan is similar to plans adopted by many other publicly−traded companies. The effect of the Rights Plan is to discourage any potential acquirer from triggering the Rights without first convincing POZEN's Board of Directors that the proposed acquisition is fair to, and in the best interest of, the shareholders and the Company. The provisions of the Plan will substantially dilute the equity and voting interest of any potential acquirer unless the Board of Directors determines that the proposed acquisition is in the best interest of the shareholders. In connection with the Plan, the Company designated 90,000 shares of its authorized Preferred Stock as Series A Junior Participating Preferred Stock. Each Right, if and when exercisable, will entitle the registered holder to purchase from the Company one one−thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00, subject to adjustment. Each holder of a Right (except for the Acquiring Person (as defined in the Rights Plan), whose Rights will be null and void upon such event) shall thereafter have the right to receive, upon exercise, that number of shares of Common Stock of the Company (or, in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of Common Stock at the date of the occurrence of such event. The Rights can be terminated by POZEN's Board of Directors and are subject to optional redemption by the Company at $0.001 per Right. The Rights Plan has a 10−year term and contains provisions requiring a periodic review and evaluation by the Board of Directors.

New Accounting Pronouncements—In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share−Based Payment," which is a revision of SFAS Statement No. 123, *Accounting for Stock−Based Compensation* ("SFAS No. 123"). SFAS No. 123(R) supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share−based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We adopted SFAS No. 123(R) on January 1, 2006. SFAS No. 123(R) requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the APB 25 intrinsic value method and, therefore we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options as such options had an exercise price equal to the market price of the underlying common stock on the date of grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. We have not restated our financial results from prior periods as a result of our adoption of SFAS No. 123(R).

Under the fair value recognition provisions of SFAS No. 123(R), stock−based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure−only purposes under the provisions of SFAS No. 123, we use the Black−Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded−vesting features, we recognize compensation cost on a straight−line basis over the requisite service period. For awards with performance or market conditions granted subsequent to our adoption of SFAS No. 123(R), we will recognize compensation cost based on the graded−vesting method.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. The expected volatility rates are estimated based on historical and implied volatilities of our common stock. The expected term represents the average time that options that vest are expected to be outstanding based on the vesting provisions and our historical exercise, cancellation and expiration patterns. We estimate pre−vesting forfeitures when recognizing compensation expense based on historical rates.

Determining the appropriate amount to expense for performance−based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

Contingencies—Five purported class action lawsuits were filed during 2004 by holders of the Company's securities against the Company and certain of its current and former officers, in the U. S. District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions were consolidated for pre−trial purposes. A lead plaintiff has been appointed by the court and a consolidated amended complaint was filed on December 20, 2004. The amended complaint alleges, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b−5 and Section 20(a) of the Exchange Act against the Company and the Company's chairman and chief executive officer, arising out of allegedly false and misleading statements made by the Company concerning its product candidates, MT 100 and MT 300, during the class period. On January 27, 2005, the Company filed a motion to dismiss the amended complaint. The motion to dismiss was denied on August 30, 2005 and the case is now in discovery phase. The Company and the defendant believe that the allegations in this action are without merit and intend to defend this case vigorously.

While the Company cannot predict the outcome or reasonably estimate the range of potential loss, if any, from this litigation, it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on the Company's results of operations, financial condition or cash flows.

Under its commercialization collaboration with Valeant NA, related to MT 300, if the Company chooses to withdraw the MT 300 NDA for commercial or financial reasons under the conditions specified in the agreement, it could be required to pay a withdrawal fee of $1.0 million. As a result of this contingency, $1.0 million of the $2.0 million upfront payment received by the Company from Valeant NA pursuant to the agreement has not been recognized as revenue and will not be recognized as revenue until the conditions in the agreement have been satisfied or resolved.

On July 21, 2005, the Company received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. The Company does not believe the withdrawal fee is payable. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. The Company intends to vigorously defend its position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA when the ultimate resolution of this dispute is reached.

While the Company cannot predict the probability that it will be required to pay any withdrawal fee obligations in the future, it is the current judgment of management that no reserve is currently required.

3. Subsequent Event

On August 2, 2006, the Company announced that it had signed an exclusive global collaboration and license agreement with AstraZeneca AB (AstraZeneca) for the co−development and commercialization of proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the non−steroidal anti−inflammatory drug (NSAID) naproxen, in a single tablet. The initial product will be indicated for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID−associated gastric ulcers.

Under the terms of the agreement, AstraZeneca will pay the Company an upfront license fee of $40 million, which is payable following termination of the waiting period under the Hart−Scott−Rodino Antitrust Improvements Act, with potential aggregate milestone payments of up to $160 million for certain development and regulatory milestones and up to $175 million of potential sales performance milestones, if specified thresholds are achieved. Royalties will be paid on net sales under a tiered royalty structure that ranges from mid−single digits to mid−teens. The Company will be responsible for the development and filing of any NDA in the U.S., while AstraZeneca will have full responsibility for development activities outside of the U.S. as well as all aspects of manufacturing, marketing, sales and distribution on a worldwide basis. AstraZeneca will also be responsible for all non−U.S. regulatory filings. The collaboration is subject to clearance under the Hart−Scott−Rodino Antitrust Improvements Act.

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

This discussion of our financial condition and the results of operations should be read together with the financial statements, including the notes contained elsewhere in this Form 10−Q, and the financial statements, including the notes thereto, contained in our Annual Report on Form 10−K for the year ended December 31, 2005, as filed on March 8, 2006.

This report includes "forward−looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward−looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward−looking statements are expressed differently. You should be aware that the forward−looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward−looking statements. The forward−looking statements are subject to a number of risks and uncertainties which are discussed in this Quarterly Report on Form 10−Q, Part II, under the heading "Item 1A. Risk Factors" and elsewhere in this report and in other documents filed by us with the Securities and Exchange Commission. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward−looking statements, other than as is required under the federal securities laws.

Overview

We are a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain−related conditions. Our product development emphasis is on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception, we have focused our efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. We are also exploring the development of product candidates in other pain−related therapeutic areas. We intend to enter into collaboration agreements to commercialize our product candidates, and have entered into, and expect to continue to enter into such collaborations. We have not obtained regulatory approval to market any of our product candidates in the United States (U.S.). The United Kingdom's (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a marketing authorization for our product candidate MT 100 for the acute treatment of migraine in the UK.

Our business activities to date have included:

- product candidate research and development;
- designing and funding clinical trials for our product candidates;
- regulatory and clinical affairs;
- intellectual property prosecution and expansion; and
- business development, including product acquisition and/or licensing and collaboration activities.

We are currently developing Trexima™ in collaboration with GlaxoSmithKline (GSK). Trexima is GSK's proposed brand name for the combination of sumatriptan succinate, formulated with GSK's RT Technology™, and naproxen sodium in a single tablet designed for the acute treatment of migraine. Trexima incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5−HT $_{1B/1D}$ agonist) and a non−steroidal anti−inflammatory drug (NSAID). Under our MT 400 technology, we seek to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed a New Drug Application (NDA) for Trexima with the U.S. Food and Drug Administration (FDA) in August 2005 and on June 8, 2006, we received an approvable letter related to our NDA for Trexima requiring us to provide certain additional safety information relating to Trexima. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. We, along with GSK, met with the FDA on July 26, 2006 to discuss the approvable letter and we expect to submit a full response to the FDA's approvable letter in the fourth quarter of the year. The FDA will then have up to six months to review the information contained in our response.

We are also developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor (PPI), with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone. On August 2, 2006, we announced that we had entered into an exclusive global collaboration and license agreement with AstraZeneca AB (AstraZeneca) to co−develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet using our PN formulation technology. Another candidate under this development program, PA 325, a combination of a PPI and aspirin, is currently in formulation development and is not covered under our agreement with AstraZeneca.

In addition, we are exploring the development of product candidates containing lornoxicam, an NSAID that is currently marketed outside the U.S. (including Europe and Japan). These product candidates, which are being developed under an exclusive license agreement with Nycomed Danmark ApS (Nycomed) granting us certain rights to develop and commercialize products containing lornoxicam, are intended to treat pain or other pain−related indications. We have filed Investigational New Drug Applications (INDs) with the FDA for an oral and an injectable lornoxicam formulation.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of June 30, 2006, our accumulated deficit was approximately $127.4 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented 71% of our total operating expenses. For the six months ended June 30, 2006, our research and development expenses represented approximately 64% of our total operating expenses.

Statement of Financial Accounting Standards Board (“SFAS”) No. 7, “Accounting and Reporting by Development Stage Enterprises,” states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. We will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of our product candidates.

We expect that we may continue to incur operating losses over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of Trexima and our other product candidates in the clinical and regulatory process;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates;
- The acquisition and/or in−licensing, and development, of other therapeutic product candidates; and
- Costs related to the pending class action lawsuit against us and our president and chief executive officer relating to the approvability of MT 100 and MT 300.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and currently plan to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and successfully develop product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products.

Status of Our Product Candidates

There follows a brief discussion of the status of each of our product candidates, as well as the costs relating to our development activities. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We do not maintain records that allocate our employees’ time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total compensation and benefit costs for our personnel involved in our research and development activities during the six month period ended June 30, 2006 were $3.6 million. Other research and development department costs for the six month period ended June 30, 2006 were $0.2 million.

MT 400/Trexima

On June 8, 2006, we received an approvable letter from the FDA related to the NDA for Trexima. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. The approvable letter reflected that the FDA has determined that Trexima is effective as an acute treatment for migraine headaches. The FDA has requested additional safety information on Trexima, some of which require new studies. We, along with GSK, met with the FDA on July 26, 2006 to discuss the approvable letter and we expect to submit a full response to the approvable letter providing additional safety information in the fourth quarter of the year. The FDA will have up to six months to review the information contained in our response. There are no guarantees that FDA will find the submission to be satisfactory, that the FDA will approve the NDA, or that additional testing will not be required for approval.

As part of our Phase 3 clinical program for Trexima, we conducted two Phase 3 pivotal trials using a formulation of Trexima developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Trexima, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours; we believe that this is the current FDA standard for establishing efficacy of migraine products. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Trexima (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination is sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine.

In February 2005, we completed the first Phase 3 pivotal trial, in which Trexima demonstrated superiority over the individual components measured by sustained pain−free response ($p<.001$) and, with the exception of the incidence of nausea−free at two hours, all other regulatory endpoints were met ($p <.001$). Trexima did reach statistical significance for the nausea endpoint compared to placebo by three hours and maintained superiority through twenty−four hours. All of the active treatments (Trexima, sumatriptan and naproxen) had a similar incidence of nausea at two hours compared to placebo. In April 2005, we completed the second Phase 3 pivotal trial, in which Trexima demonstrated superiority over the individual components measured by sustained pain−free response ($p<0.001$ vs. naproxen; $p=0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

We met with the FDA in April 2005 to discuss the results of our two Phase 3 pivotal trials, along with other information required for the submission of the Trexima NDA. The Trexima NDA submission was made in August 2005 and was accepted for review by the FDA in October 2005. In October 2005, we received a $20.0 million payment from GSK, payable under our collaboration agreement with GSK upon the FDA's acceptance for review of the Trexima NDA.

In addition to our Phase 3 pivotal studies, we completed two additional pharmacokinetic Phase 1 studies requested by the FDA and these were submitted to the FDA within the Trexima NDA. We also completed a long−term, twelve−month open label safety study for Trexima. The final results of this study were submitted to the NDA, as previously agreed with FDA, in December 2005 in the 120−day safety update report to the NDA. GSK has funded and continues to conduct pre−approval market support studies for Trexima under our IND. Additional safety data from two of these GSK−sponsored studies were submitted to the FDA within the 120−day safety update report, and the final reports of those studies were filed to the IND during the first quarter of 2006.

We cannot reasonably estimate or know the amount or timing of the costs necessary to complete the development of Trexima or when, if and to what extent we will receive future cash inflows from Trexima. The additional costs that we may incur include expenses relating to clinical trials and other research and development activities and the cost and timing of activities necessary to obtain regulatory approvals.

We incurred $24,000 in direct development costs associated with the development of MT 400/Trexima for the six−month period ended June 30, 2006 and we have incurred $24.5 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 100

In May 2004, we received a not−approvable letter from the FDA with respect to our NDA for MT 100, our proprietary combination of metoclopramide hydrochloride and naproxen sodium. In September 2005, after an FDA advisory committee concluded that the potential but unquantified risk of the occurrence of an involuntary neurological movement disorder known as tardive dyskinesia associated with the use of metoclopramide would outweigh the benefits of the MT 100 combination, we decided to discontinue further development of MT 100 in the U.S. and to reevaluate our MT 100 European strategy. As a part of that reevaluation, in September 2005 we terminated our license agreement with Nycomed for the development and commercialization of MT 100 in Denmark, Norway, Sweden and Finland in exchange for a payment to Nycomed of $250,000. We are exploring the possibility of selling or otherwise disposing of the MT 100 asset to a third party, although there can be no assurance that we will, or will be able to, consummate such a transaction.

In October 2002, we submitted a Market Authorization Application (MAA) for MT 100 for the acute treatment of migraine to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK). In November 2005, we received notification that the MHRA had granted us marketing approval for MT 100 in the UK.

We are not currently conducting and do not plan to conduct any clinical trials for MT 100 and do not expect to incur any additional significant development costs related to MT 100. We incurred $55,000 in direct development costs associated with the development of MT 100 for the six−month period ended June 30, 2006 and we have incurred $39.8 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300

In October 2003, we received a not−approvable letter from the FDA related to our NDA for MT 300, which we had submitted in December 2002. Subsequently, we continued our communications with the FDA relative to the NDA. Based upon our most recent discussions with the FDA, in which the FDA affirmed its previously stated concerns that approval of the NDA was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo, and our understanding of the current FDA standards for approving migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300.

We have, therefore, begun discussions with Valeant NA regarding termination of our MT 300 commercialization agreement. In July, 2005, we received a letter from Valeant NA seeking payment of a $1.0 million withdrawal fee required under certain conditions under the agreement. Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant NA of this situation and Valeant NA elects not to assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a termination fee of $1.0 million. If Valeant NA decides to assume development, it would be credited $1.0 million in development expense. We do not believe that the withdrawal fee is payable under the circumstances of receipt of a not−approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

We are not currently conducting any clinical trials for MT 300 and do not expect to incur any additional significant development costs related to MT 300. Given our current assessment that we do not believe we can reverse the not−approvable status of the NDA for MT 300, we believe that we will not receive any cash inflows from MT 300.

We incurred $14,000 in direct development costs associated with the development of MT 300 for the six−month period ended June 30, 2006 and we have incurred $14.5 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PN/PA Program

Under our PN program, we have completed formulation development and initiated clinical studies for combinations of a PPI and an NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. To date, we have conducted studies with two PN product formulations in this program − PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen. Our future development and commercialization efforts under the PN program will be covered under our exclusive collaboration agreement with AstraZeneca, which we announced on August 2, 2006, using the PPI esomeprazole magnesium and naproxen. Our PA product candidate, PA 325, currently in formulation development, is a combination of a PPI and aspirin and is not covered under the AstraZeneca agreement. We have retained all rights to this PA product candidate.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for use of naproxen in adults would accrue to the PN product, if clinical trials successfully demonstrated improved safety (lower incidence of gastric ulcers) of the PN product compared with naproxen alone and the PN formulation was shown to be bioequivalent to marketed formulations of naproxen. Prior to entering into our collaboration agreement with AstraZeneca, we completed a study designed to demonstrate the bioequivalence of the naproxen component of our PN 200 product candidate development formulation to enteric−coated naproxen. This study demonstrated that the PN formulation was bioequivalent to the reference drug, EC Naprosyn®.

In early 2006, we submitted a Special Protocol Assessment (SPA) to the FDA for our pivotal Phase 3 clinical trials for PN 200. The SPA is a process in which the FDA provides evaluations and guidance on clinical trial protocols for pivotal Phase 3 clinical trials. In April 2006 we announced that we had reached an agreement with the FDA on the Phase 3 pivotal clinical trials for PN 200 for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID−associated gastric ulcers. In light of our collaboration agreement with AstraZeneca, we, along with AstraZeneca, expect to meet with the FDA during the next few months to determine whether, notwithstanding the use of a different PPI, the core development program and the SPA already agreed upon will apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen. We plan to commence certain PN 200 trials in the third quarter of 2006 to test longer−term gastro−protection of the PN product concept. Additional trials with the naproxen/esomeprazole fixed combination will begin once the new product is formulated and clinical supplies manufactured, with Phase 3 clinical trials expected to start in the third quarter of 2007. We do not anticipate any material changes in the design of the overall Phase 3 program.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID−containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX−2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen safety concerns becomes available, long−term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN and PA product candidates.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PN or PA product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PN or PA products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN/PA program of $4.5 million during the six−month period ended June 30, 2006 and we have incurred $13.1 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Lornoxicam Program

In this program, we have begun development work and conducted clinical studies to investigate the development of novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. Our exploratory and development work is being conducted under an exclusive license agreement with Nycomed, pursuant to which Nycomed licensed to us certain rights to develop and commercialize products containing lornoxicam in the U.S. As a part of our agreement with Nycomed, we have also granted certain exclusive rights to Nycomed to supply us, or our commercialization partners, if any, with lornoxicam active drug substance for use in the manufacture of any of our lornoxicam product candidates.

Oral Tablet Formulation. We filed an IND with the FDA in 2003 for an oral lornoxicam tablet formulation and completed our first human study with this formulation in 2004 in patients undergoing dental surgery. The data from this study confirmed the acute safety profile for lornoxicam in these patients and provided preliminary evidence of efficacy in this pain model. As a result of the FDA advisory committee meeting held in February 2005 addressing the safety and cardiovascular risks of NSAIDs, described above, the FDA has indicated that long−term cardiovascular safety studies will be required prior to NDA approval of new NSAID products that may be used on an intermittent or chronic basis, such as our oral tablet lornoxicam product candidate.

Injectable Formulation. We filed an IND with the FDA for an injectable lornoxicam formulation in May 2005, and during 2005 we initiated the first human studies with this formulation under our IND. We have completed a Phase 1 pharmacokinetic study as well as two Phase 2 studies to evaluate lornoxicam for management of acute post−operative bunionectomy pain and for management of migraine pain. In the Phase 2 bunionectomy study, both active doses of lornoxicam were significantly better than placebo in the acute management of pain following bunionectomy. Based on the results of our Phase 2 migraine study, the regulatory environment and commercial opportunities, we currently do not intend to pursue the migraine indications. It is anticipated that the injectable formulation will be studied in the management of moderate to severe acute pain in the clinical setting and as such, we believe, based

on our discussions to date with the FDA, that long term cardiovascular safety studies may not be required for NDA approval of this formulation. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and discuss with the FDA the clinical and non−clinical study requirements for approval of this and our other lornoxicam product candidates.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any lornoxicam product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any lornoxicam products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our lornoxicam program of $3.4 million during the six−month period ended June 30, 2006, and we have incurred $8.6 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Collaborative Arrangements

We have entered into and plan to continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to develop, commercialize and/or manufacture our product candidates. Our existing collaborations are described below.

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5−HT $_{1B/1D}$ agonist) and a long−acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long−acting NSAID. We are responsible for development of the first combination product, while GSK is to provide formulation development and manufacturing. GSK has proposed Trexima as the brand name of the combination of sumatriptan succinate, formulated with GSK's RT Technology™, and naproxen sodium in a single tablet, being developed under the agreement. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart−Scott−Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the Trexima NDA. Additionally, GSK is obligated to make payments to us in an aggregate amount of up to $20.0 million upon FDA approval of the Trexima NDA and upon notification of intent to commercialize Trexima. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017 based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre−determined share of the market for the product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

AstraZeneca AB (AstraZeneca)

On August 1, 2006, we entered into a collaboration and license agreement with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee−bearing license, in all countries of the world except Japan, under our patents and know−how relating to combinations of gastroproductive agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca may, at no additional cost, elect to include Japan in the licensed territory within two years after the effective date of the agreement.

Under the terms of the agreement, AstraZeneca will pay us an upfront license fee of $40 million. In addition, AstraZeneca has agreed to make milestone payments upon the achievement of certain development events and sales events. If all development milestones are achieved, total development milestone payments due us under the agreement will be $160 million. If all sales milestone events are achieved, total sales milestone payments due us under the agreement will be $175 million. We will also receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees under the agreement during the royalty term. The royalty rate varies based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, with percentages ranging from the mid−single digits to the mid−teens. In addition, the agreement provides for certain reductions to the royalty rate based on qualified royalty payments to other third parties and loss of market share due to generic competition. Our right to receive royalties from AstraZeneca for the sale of such products expires on a country−by−country basis upon the later of (a) expiration of the last−to−expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We retain responsibility for the development and filing of the New Drug Application (NDA) for the product in the United States. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We have agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing−related expenses, will be paid by AstraZeneca. The agreement establishes joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees will operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, shall expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement**,** elect to transfer the product and all rights to us.

Nycomed Danmark ApS (Nycomed)

Lornoxicam

In May 2003, we entered into a development, option and license agreement with Nycomed pursuant to which we obtained an exclusive license to certain development rights during the option period and an exclusive option to license certain rights to develop, manufacture and commercialize products containing lornoxicam. In July 2005, we exercised the option and were granted an exclusive license, with the right to sublicense, develop, manufacture and commercialize single−entity products and combination products containing lornoxicam in the U.S. (and its territories) and Canada (the Exclusive Territory). We were granted a non−exclusive license to develop and commercialize combination products containing lornoxicam in Belgium, Germany, Greece, France, Ireland, Luxembourg, The Netherlands, Austria, Finland, Denmark, United Kingdom, Sweden, Armenia, Azerbaijan, Belarus, Estonia, Georgia, Iceland, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Moldova, Norway, Russia, Switzerland, Tajikistan, Turkmenistan, Ukraine and Uzbekistan (the Limited Territory). We were granted a non−exclusive license to manufacture single−entity and combination products containing lornoxicam outside of the Exclusive Territory, excluding certain countries. We granted Nycomed a right of first refusal with respect to the development, manufacturing and commercialization, in Iceland, Denmark, Norway, Finland, Sweden, Lithuania, Latvia, Estonia, Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine, of certain combination lornoxicam products that we may develop under the agreement.

Pursuant to the agreement, we paid Nycomed a total of $500,000 for upfront and milestone payments during the option period. We paid Nycomed a non−refundable $500,000 payment in August 2005 to exercise our option under the agreement. We will be obligated to pay additional milestone payments in an aggregate amount of up to $500,000 upon the occurrence of certain regulatory approvals. In addition, we will be obligated to pay Nycomed specified single digit royalties on all net sales of any licensed single−entity or combination lornoxicam products, with the amount of such royalties subject to reduction upon the occurrences of certain specified events. The obligation to pay such royalties expires on a product−by−product and country−by−country basis ten (10) years from the first commercial sale of a product in a given country. We are also obligated to pay Nycomed a specified single digit percentage of any upfront and milestone payments we may receive from our sublicensees up to a preset maximum amount per sub−licensee.

As a part of the agreement, Nycomed will supply us with all of our required clinical supply of active drug substance, and may also supply some clinical trial materials under certain conditions. Under the agreement, subject to Nycomed's ability to meet a specified percentage of our and each of our sublicensee's requirements, we and each of our sublicensees (each, a buyer) must purchase all of their required commercial supply of active drug substance from Nycomed for a minimum of five years. For each buyer, this exclusive 5−year purchase commitment for each of the Exclusive Territory and the Limited Territory begins with the buyer's first commercial sale of its first licensed lornoxicam product in a particular specified country within the Exclusive Territory and the Limited Territory, respectively, as applicable.

Each party generally has the duty to indemnify the other for damages arising from each party's breach of its representations, warranties and obligations under the agreement, as well as for gross negligence or willful misconduct. In addition, we must indemnify Nycomed for any claim brought by a third party arising from our development, testing, manufacture or sale of any licensed product. Further, each party has a duty to maintain commercially reasonable insurance coverage commensurate with its obligations under the agreement. Nycomed has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If Nycomed does not bring any such action within a certain time frame, we have the right, but not the obligation, at our own expense, to bring the appropriate action. The agreement terminates upon the date of expiration of all royalty obligations unless terminated earlier by either party for material breach or upon the bankruptcy, insolvency or dissolution of either party, or by us if we determine in good faith that it is not commercially or scientifically feasible to continue development and commercialization efforts with respect to products using the licensed technology. Nycomed also may terminate the agreement if we or any sublicensee initiates a lawsuit challenging the validity of any licensed patent.

MT 100

In June 2003, we signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries and received an initial license fee of $500,000. As a result of our decision to discontinue development of MT 100 in the U.S. and to re−evaluate our MT 100 European strategy, we terminated this agreement and the related supply agreement with Nycomed in September 2005 pursuant to the terms of a termination agreement. The termination agreement provided for the immediate termination of the license and supply agreements and all rights and obligations of the parties under those agreements, subject to the survival of certain specified provisions, including under the license agreement, those related to confidentiality and indemnification obligations, ownership rights, and limitation of warranty and liability, and under the supply agreement, those related to confidentiality obligations. Subject to these surviving provisions and the parties' obligations under the termination agreement, the parties also agreed to mutually release each other from any and all present and future claims resulting from events existing as of the date of the termination agreement. As consideration for Nycomed's consent to enter into the termination agreement and the mutual release, we paid Nycomed $250,000.

Valeant Pharmaceuticals North American (Valeant NA) (formerly Xcel Pharmaceuticals Inc.)

In September 2003, we signed an agreement with Valeant NA for the further development and commercialization of MT 300. In March 2005, Valeant Pharmaceuticals International (Valeant International) acquired Valeant NA. Under the terms of the agreement, Valeant NA would have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations. Pursuant to the terms of the agreement, Valeant NA paid us an upfront fee of $2.0 million. Upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300, potential milestone payments of up to $8.0 million would be due. Valeant NA is also obligated to pay us royalties on all combined net sales of MT 300 and Valeant NA's D.H.E. 45® (dihydroergotamine mesylate) Injection, upon commercialization of MT 300, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that Valeant NA pays royalties to one or more third parties to license rights from such third parties to commercialize MT 300. The agreement terminates on the date of expiration of all royalty obligations (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent) unless earlier terminated by either party for a material breach or in the event that either party determines not to pursue approval of MT 300, under the conditions described below. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non−terminating party. Generally, each party must indemnify the other for damages arising from such party's breach of its representations, warranties and obligations under the agreement, as well as for the gross negligence or willful misconduct by either party. Additionally, Valeant NA must indemnify us for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while we must indemnify Valeant NA for any damages arising from such development, manufacture or use prior to the effective date. We must also indemnify Valeant NA for any use by us or any sub licensee of certain technology owned by Valeant NA.

Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may

elect to withdraw the NDA. If we notify Valeant of this situation and Valeant NA does not assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a withdrawal fee of $1.0 million. If Valeant decides to assume development, it would be credited $1.0 million in development expense. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300 and we have begun discussions regarding termination of our commercialization agreement with Valeant NA. In July 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. We do not believe that the withdrawal fee is payable based on our receipt of a not−approvable letter from the FDA with respect to our NDA for MT 300. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. We intend to vigorously defend our position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA upon the ultimate resolution of this dispute.

Based upon the delays related to commercialization of MT 300 due to our receipt of the not−approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Valeant NA had previously agreed to extend the time for certain activities under our agreement with Valeant NA that are dependent on the FDA's actions with respect to MT 300. In the event of termination of the agreement, these obligations will not be relevant.

We can give no assurance that Valeant NA or Valeant International will agree to termination terms acceptable to us or that we will not be required to pay Valeant NA the withdrawal fee of $1.0 million described above.

Critical Accounting Policies and Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States in the preparation of our financial statements. The development and selection of the critical accounting policies, and the related disclosure about these policies, have been reviewed by the audit committee of our board of directors. We evaluate our estimates and judgments on an ongoing basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We have a discussion below of four critical accounting estimates: revenue recognition, accrued expenses, stock−based compensation and income taxes.

Revenue Recognition

Our licensing and other collaborative agreements have terms that include up−front payments upon contract signing, additional payments if and when certain milestones in the product's development are reached, royalty payments based on future product sales and withdrawal fees if certain conditions are met. We recognize revenue under these agreements in accordance with SEC Staff Accounting Bulletin 101, "Revenue Recognition" as amended by SAB 104, "Revenue Recognition" ("SAB 101"), and Emerging Issues Task Force 00−21 ("EITF 00−21"), "Revenue Arrangements with Multiple Deliverables."

Under SAB 101 recognition of revenue from non−refundable up−front payments is deferred by us upon receipt and recognized over the period ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. If regulatory approvals or other events relating to our product candidates are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products would prospectively be accelerated or reduced accordingly.

We recognize milestone payments as revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement and (ii) the fees are non−refundable. Any milestone payments received prior to satisfying these revenue recognition criteria will be recorded as deferred revenue and only recognized as revenue when both criteria are met.

We have not previously received royalty revenue but we anticipate such revenue will be recognized related to the manufacture, sale or use of our products or technology. For those arrangements where royalties are reasonably estimable, we will recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period. Additionally, our licensing agreements may include payment for services provided by us on an hourly rate and direct expenses. We record such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project.

Management believes that its current assumptions and other considerations used to estimate the periods for revenue recognition described above are appropriate, and historical changes in our estimates of these periods have not resulted in material changes in the revenue we recognized. However, we continually review these estimates, which could result in a change in the deferral

period and might impact the timing and amount of revenue recognition. Further, if regulatory approval of Trexima is accelerated, delayed or not ultimately obtained, then the amortization of revenues for this product would prospectively be accelerated or reduced accordingly. For example, as a result of our receipt in June 2006 of an approvable letter from the FDA related to our Trexima NDA, we have extended the amortization period for completion of our obligations under our Trexima collaboration agreement with GSK.

As of June 30, 2006, we had deferred $4.4 million of revenue, of which $1.0 million is refundable under certain termination or cancellation provisions within our licensing agreements. We recognized revenue related to our collaborations of $3.1 million for the six month period ended June 30, 2006, $28.6 million for the fiscal year ended December 31, 2005, $23.1 million for the fiscal year ended December 31, 2004 and $3.7 million for the fiscal year ended December 31, 2003.

Accrued expenses, including contracted costs

Significant management judgments and estimates must be made and used in connection with accrued expenses, including those related to contract costs, such as costs associated with our clinical trials. Specifically, our management must make estimates of costs incurred to date but not yet invoiced in relation to contracted, external costs. Management analyzes the progress of product development, clinical trial and toxicology and related activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. Material differences in the amount and timing of the accrued liability for any period may result if management made different judgments or utilized different estimates.

Management believes that its current assumptions and other considerations used to estimate accrued expenses for the period are appropriate. However, determining the date on which certain contract services commence, the level of services performed on or before a given date and the cost of such services involves subjective judgments and often must be based upon information provided by third parties. In the event that we do not identify certain contract costs which have begun to be incurred or we under− or over−estimate the level of services performed or the costs of such services, our reported accrued expenses for such period would be too low or too high, as the case may be.

We recognized accrued costs related to product development and operating activities, including clinical trials, based upon the progress of these activities covered by the related contracts, invoices received and estimated costs, of $1.0 million for the fiscal year ended December 31, 2005, $1.4 million for the fiscal year ended December 31, 2004 and $0.8 million for the fiscal year ended December 31, 2003. The variance, at each of these ending periods, between the actual expenses incurred and the expenses accrued has been less than $125,000.

Stock−Based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards (“SFAS”) No. 123(R), “Share−Based Payment,” which requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the Accounting Principles Board Opinion No. 25 (“APB 25”), “Accounting for Stock Issued to Employees,” intrinsic value method. Therefore, prior to January 1, 2006 we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options, as all such options had an exercise price equal to the market value of the underlying common stock on the date of the grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. Under this transition method, our compensation cost recognized includes compensation costs for all share−based payments granted prior to, but not yet vested as of, January 1, 2006 based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and compensation cost for all share−based payments granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Accordingly, we have not restated our financial results for prior periods.

Under the fair value recognition provisions of SFAS No. 123(R), stock−based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure−only purposes under the provisions of SFAS No. 123, we use the Black−Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded−vesting features, we recognize compensation cost on a straight−line basis over the requisite service period. For awards with performance or market conditions granted subsequent to our adoption of SFAS No. 123(R), we intend to recognize compensation cost over the expected period to achieve the performance or market condition.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. The expected volatility rate was estimated based on an equal weighting of the historical volatility of our common stock over a four year period. The expected term was estimated based on a simplified method as allowed

under SEC Staff Accounting Bulletin No. 107 averaging the vesting term and original contractual term. The risk−free interest rate for periods within the contractual life of the option is based on seven year U.S. Treasury securities. The pre−vesting forfeiture rate used for the six months ended June 30, 2006 was based on historical rates.

Determining the appropriate amount to expense for performance−based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

Income Taxes

We record deferred tax assets and liabilities based on the net tax effects of tax credits, operating loss carry−forwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we establish an annual valuation allowance. We have not recorded any tax provision or benefit for the years ended December 31, 2005, 2004, or 2003 and have provided a valuation allowance for the full amount of our net deferred tax assets. If results of operations in the future indicate that some or all of the deferred tax assets will be recovered, the reduction of the valuation allowance will be recorded as a tax benefit during one or more periods. Until we record a tax provision or benefit based upon anticipated utilization of the prior operating loss carry−forwards, no estimate of the effect of a change in our estimated effective tax rate will be made.

Results of Operations

Three months ended June 30, 2006 compared to the three months ended June 30, 2005

Net income (loss) per share: Net loss attributable to common stockholders for the quarter ended June 30, 2006 was $(8.4) million or $(0.29) per share as compared to a net loss of $(4.1) million, or $(0.14) per share, for the quarter ended June 30, 2005. The net loss for the quarter ended June 30, 2006 included $1.3 million or ($0.05) per share charge for non−cash stock−based compensation expenses resulting from our adoption of SFAS No. 123(R) on January 1, 2006.

Revenue: We recognized $0.9 million of revenue for the quarter ended June 30, 2006 as compared to $2.0 million for the quarter ended June 30, 2005. The decrease in revenue was primarily due to an extension of the amortization period of upfront payments we received pursuant to our development and commercialization agreement relating to Trexima. During the quarter, the remaining Trexima amortization period was increased from 6 months to 15 months based upon our receipt in June 2006 of an approvable letter from the FDA related to our Trexima NDA and an estimated additional 9 months which we believe represents the period required to conclude any obligations on our part. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non−refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $4.4 million remains in deferred revenue at June 30, 2006. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development total expenses increased by $2.7 million to $6.7 million for the quarter ended June 30, 2006, as compared to the same period of 2005. The increase was due primarily to an increase in direct development costs for the lornoxicam and the PN programs, partially offset by a decrease in direct development costs for Trexima, as compared to the same period of 2005. Direct development costs for the lornoxicam program increased by $1.2 million to $1.4 million, primarily due to Phase I/II clinical trial activities during the second quarter of 2006 as compared to the same period of 2005. Direct development costs for the PN/PA program increased by $1.9 million to $3.1 million, primarily due to product development activities including the formulation and development of clinical trial materials and other clinical trial activities during the second quarter of 2006, as compared to the same period of 2005. Direct development costs for Trexima decreased by $1.0 million primarily due to the completion of clinical trial activities during 2005. Research and development departmental expenses increased by $0.4 million to $1.8 million as compared to the same period of 2005, primarily due to a $0.4 million non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by $0.7 million to $3.1 million for the second quarter of 2006, as compared to the same period of 2005. The increase was due primarily to a $1.0 million non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. Cost associated with our business development activities increased by $0.2 million to $0.6 million, primarily due to increased legal expenses and other

consulting expenses related to our licensing activities. Costs associated with our public company activities decreased by $0.2 million primarily due to a decrease in class action litigation legal fees. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.2 million for the quarters ended June, 2006 and June 30, 2005. Investment income from bond amortization for the period ended June 30, 2006 totaled $0.3 million as compared to $0.1 million from bond amortization during the same period of 2005.

Six months ended June 30, 2006 compared to the six months ended June 30, 2005

Net income (loss) per share: Net loss attributable to common stockholders for the six months ended June 30, 2006 was $(14.9) million, or $(0.51) per share, as compared to a net loss of $(9.5) million, or $(0.33) per share, for the same period of 2005. The net loss for the quarter ended June 30, 2006 included $3.3 million, or $(0.11) per share, charge for non−cash stock−based compensation expenses resulting from our adoption of SFAS No. 123(R) on January 1, 2006.

Revenue: We recognized $3.1 million of revenue for the six months ended June 30, 2006, as compared to $4.0 million for the same period of 2005. The decrease in revenue was primarily due to the extension of the amortization period of the upfront payments we received pursuant to our development and commercialization agreement with GSK related to Trexima. During the quarter, the remaining Trexima amortization period was increased from 6 months to 15 months based upon our receipt in June 2006 of an approvable letter from the FDA related to our Trexima NDA and an estimated additional 9 months which we believe represents the period required to conclude any obligations on our part. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non−refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $4.4 million remains in deferred revenue at June 30, 2006. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development total expenses increased by $2.8 million to $12.1 million for the six months ended June 30, 2006, as compared to the same period of 2005. The increase was due primarily to a $1.1 million non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006 and an increase in direct development costs for the lornoxicam and the PN programs, partially offset by a decrease in direct development costs for Trexima, as compared to the same period of 2005. Direct development costs for the lornoxicam program increased by $2.7 million to $3.4 million, primarily due to Phase I/II clinical trial activities during the first half of 2006 as compared to the same period of 2005. Direct development costs for the PN/PA program increased by $2.9 million to $4.5 million, primarily due to product development activities including the formulation and development of clinical trial materials and other clinical trial activities during the first half of 2006, as compared to the same period of 2005. Direct development costs for Trexima decreased by $4.0 million primarily due to the completion of clinical trial activities during 2005. Research and development departmental expenses increased $1.2 million to $3.8 million as compared to the same period of 2005, primarily due to a $1.1 million non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. We have included in our research and development total expenses the personnel costs associated with our departmental research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by $2.0 million to $6.7 million for the six month ended June 30, 2006, as compared to the same period of 2005. The increase was due primarily to a $2.1 million non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. Costs associated with our business development activities increased by $0.4 million to $1.3 million, primarily due to increased legal expenses and other consulting expenses related to our licensing activities. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.4 million and $0.3 million for the six months ended June, 2006 and June 30, 2005, respectively. Investment income from bond amortization for the period ended June 30, 2006 totaled $0.5 million as compared to $0.2 million from bond amortization during the same period of 2005.

Income Taxes

As of December 31, 2005, we had net operating loss carry−forwards of approximately $86.8 million for federal and state income tax purposes, which expire between 2011 and 2024. We also have research and development tax credit carry−forwards of approximately $7.8 million for federal income tax reporting purposes that expire between 2012 and 2024. We currently estimate net operating income of approximately $10.8 million for the twelve months ending December 31, 2006 and estimate an effective tax rate of 0% for the six month period ended June 30, 2006 and was based upon financial results available at June 30, 2006. Our effective tax rate was 0% for the six month period ended June 30, 2005. The estimated effective rate was based upon estimates of loss for the fiscal year and our ability to use remaining net operating loss carry−forwards and other tax credits. However, the actual effective rate may vary depending upon actual

licensing fees and milestone payments received, specifically the pre−tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with SFAS 109, “Accounting for Income Taxes.” Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986 (the “Act”) provides for a limitation on the annual use of net operating loss and research and development tax credit carry−forwards (following certain ownership changes, as defined by the Act) that could significantly limit our ability to utilize these carry−forwards. We have experienced various ownership changes, as defined by the Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the aforementioned carry−forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry−forwards may be applied against future taxes, we may not be able to take full advantage of these carry−forwards for federal income tax purposes. In July 2006, the FASB issued interpretation No. 48 “Accounting for Uncertainty in Income Taxes”, (“FIN 48”). FIN 48 clarifies SFAS No. 109 “Accounting for Income Taxes” by providing specific guidance in reporting uncertain income taxes recognized in a company’s financial statements, including consistent recognition threshold, classification, interest and penalties and disclosures. FIN No. 48 is effective for us as of January 1, 2007. We have not yet determined the impact of the adoption of FIN No. 48 on our financial position, results of operations or cash flows; however, there is no impact on our current financial statements.

Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in cash inflows of $133.9 million, and since 2003, from upfront and milestone payments from our collaborators, resulting in cash inflows of $63.3 million. At June 30, 2006, cash and cash equivalents, along with short−term investments, totaled $31.9 million, a decrease of $14.0 million compared to December 31, 2005. Our cash and cash equivalents are invested in money market funds that invest primarily in short−term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short−term corporate fixed income obligations and U.S. Government agency obligations.

During the first quarter of 2006, we moved an additional $5.0 million into a managed investment account designed to increase the return on our cash. This account, which is invested as described above, is managed within our Board approved investment policy, which restricts investments to less than twelve months, limits concentration to 5% or less and requires minimum credit ratings of A1/P1, among other requirements. Because certain holdings in the managed account have maturities longer than three months, we have classified these holdings as short−term investments in our balance sheet and accounting principles require reporting such investments at market value. Any difference in market value and cost is reported in the stockholder’s equity section of our financial statements as comprehensive income or loss.

We did not receive any operating cash during the six month period ended June 30, 2006. Pursuant to the terms of our collaboration agreement with AstraZeneca, we expect to receive an upfront license fee of $40 million following termination of the waiting period under the Hart−Scott−Rodino Antitrust Improvement Act’s notification program. Cash received from financing activities during the period totaled $0.9 million reflecting net proceeds from the exercise of stock options.

Based upon the direct method of presenting cash flow, cash used in operating activities totaled $13.4 million for the six−month period ended June 30, 2006. The indirect method for presenting cash flow is used in the Statement of Cash Flows included in our financial statements. Cash used in operating activities was $27.4 million for the fiscal year ended December 31, 2005, $26.4 million for the fiscal year ended December 31, 2004 and $18.4 million for the fiscal year ended December 31, 2003. Net cash provided by investing activities during the six month period ended June 30, 2006 totaled $0.3 million, reflecting investing activities associated with the sale of short−term securities. Cash required for our operating activities during 2006 is projected to approximate our 2005 requirements. During the six month period ended June 30, 2006 we recorded non−cash stock−based compensation expense of $3.3 million as a result of adopting SFAS No. 123(R) on January 1, 2006. We also reclassified, from current liabilities to additional paid−in capital, $1.4 million of prior year accrued compensation related to the expensing of restricted stock units and performance based options granted under the Trexima incentive program. This reclassification also resulted from our adoption of SFAS No. 123(R).

As of June 30, 2006, we had $13.3 million in cash and cash equivalents and $18.6 million in short−term investments. If our operating expenses for 2006 and 2007 remain at the level of our operating expenses in 2005, we believe that we will have sufficient cash reserves to maintain that level of business activities throughout 2007, provided that, under the terms of our collaboration agreement with AstraZeneca, we receive an upfront license fee of $40 million which is payable to us following the termination of the waiting period under the Hart−Scott−Rodino Antitrust Improvements Act and provided that certain development expenses are paid by AstraZeneca, as outlined in the agreement.

As part of our ongoing assessment of our business and liquidity needs, we regularly assess available funding options and will consider available funding opportunities as they arise. We may issue shares of common stock in the future, to fund additional development activities and increase our working capital. We have filed with the Securities and Exchange Commission (SEC), and the SEC has declared effective, a shelf registration statement on Form S−3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Our forecast of the period of time through which we expect that our financial resources will be adequate to support our operations is a forward−looking statement that involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements will depend on many factors, including:

- the number and progress of our clinical trials and other trials and studies;
- our success in obtaining, and any delays in obtaining, regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights;
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies; and
- costs incurred in the defense of the class action lawsuit that is pending against us and our president and chief executive officer relating to MT 100 and MT 300.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from our initial public offering and, private placements and revenue from our collaboration agreements have been invested, in accordance with our investment policy, in money market funds that invest primarily in short−term, highly−rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short−term corporate fixed income obligations and U.S. Government and Government agency obligations. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short−term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were designed and functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

(b) Change in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Five purported class action lawsuits were filed during 2004 by holders of our securities against us and certain of our current and former officers, in the U. S. District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions were filed as a single consolidated amended complaint on December 20, 2004. The amended complaint alleges, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b−5 and Section 20(a) of the Exchange Act against us and Dr. John R. Plachetka, our chairman and chief executive officer, arising out of allegedly false and misleading statements made by us concerning our product candidates, MT 100 and MT 300, during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. On January 27, 2005, we filed a motion to dismiss the amended complaint. On August 30, 2005, our motion to dismiss was denied and the case is now in the discovery phase.

We believe that the allegations in the class action lawsuit are without merit and intend to defend this action vigorously. While we cannot predict the outcome or reasonably estimate the range of potential loss, if any, from this litigation, it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on our results of operation or financial condition.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We depend heavily on the success of our product candidates, which may never be approved for commercial use. If we are unable to develop, gain approval of or commercialize those product candidates, we will never receive revenues from the sale of our product candidates.

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of our current product candidates. Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, in June 2006 we received an approvable letter relating to our NDA for Trexima, in which the FDA requested additional safety information on Trexima which will require some additional studies. We expect to submit a full response to the FDA's approvable letter in the fourth quarter of 2006. However, there can be no guarantee that the FDA will approve our NDA based on the information contained in our response to the approvable letter, or at all. Further, we have decided to discontinue development of MT 100 in the U.S. and to explore the possibility of selling or otherwise disposing of the MT 100 asset, based upon the determination of an FDA Advisory Committee in August 2005. The FDA Advisory Committee determined, following our receipt of a not approvable letter from the FDA in 2004 for our NDA for MT 100, that the potential, but unquantified, risk of tardive dyskinesia, an involuntary movement disorder associated with the use of metoclopramide, one of the components of MT 100, outweighed the benefits, as defined by the FDA, of metoclopramide hydrochloride in combination with naproxen sodium. Further, based upon our understandings from our recent communications with the FDA, in which the FDA restated its concerns that approval of MT 300 was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo, we do not believe it is possible to reverse the not approvable status of MT 300 stated in the not approvable letter we received from the FDA in 2003. In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. We do not have a current source of product revenue.

We have incurred significant losses since our inception. As of June 30, 2006, we had an accumulated deficit of approximately $127.4 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing of payments that we may receive from others. We expect to continue to incur significant operating losses and do not know when, if and to what extent we will generate product revenue.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with GSK and AstraZeneca. Our remaining milestone payments under our collaboration agreement with GSK related to Trexima are payable upon FDA approval of and GSK's intent to commercialize Trexima. As a result of our receipt in June 2006 of an approvable letter relating to our NDA for Trexima requesting certain additional safety information, we cannot guarantee when or if we will receive future payments under that agreement. Further, we may have to pay Valeant NA a $1.0 million withdrawal fee if we do not prevail in our current dispute with them as to whether the withdrawal fee is payable. This amount is currently reflected in our financial statements as deferred revenue and will never be recognized as revenue if repaid.

Changes in regulatory approval policy or statutory or regulatory requirements, or in the regulatory environment, during the development period of any of our product candidates may result in delays in the approval, or rejection, of the application for approval of one or more of our product candidates. If we fail to obtain approval, or are delayed in obtaining approval, of our product candidates, our ability to generate revenue will be severely impaired.

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. Further, changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained in conversations and other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX−2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. On April 7, 2005 the FDA issued a Public Health Advisory (Advisory) based, in part, upon the recommendations of the advisory committee. The Advisory stated that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life−threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005, the FDA has indicated that long−term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. For example, we believe that long−term cardiovascular safety studies will be required for NDA approval of our oral lornoxicam product candidate. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our product candidates which contain NSAIDs.

If we, or our current or future collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates. Further, if we are delayed in obtaining or unable to obtain, any required approvals, our collaborators may be entitled to terminate their agreements with us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the United States. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. None of our product candidates have been approved for sale in the U.S. or any foreign market (except for MT 100, which has been approved for sale in the UK) and they may never be approved. For example, in June 2006, we received an approvable letter relating to our NDA for Trexima, in which the FDA requested additional safety information on Trexima thereby delaying regulatory approval, and any subsequent commercial sales, if at all. We also previously received not−approvable letters from the FDA relating to our NDAs for MT 100 and MT 300.

In the U.S., a separate NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity

studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek in the future outside the U.S.

Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. For example, under our PN collaboration agreement with AstraZeneca, AstraZeneca has the right to terminate the agreement if certain delays occur or specified development and regulatory objectives are not met. Further, under our MT 300 collaboration agreement with Valeant NA, we may elect to withdraw the NDA, if we determine that additional studies or data that are required by the FDA for approval of the NDA would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300. If we notify Valeant NA of this situation and Valeant NA elects not to assume control of efforts to seek approval of the NDA, then upon notice from Valeant, the agreement would terminate and we would be required to pay to Valeant NA a withdrawal fee of $1.0 million. We have begun discussions regarding termination of our commercialization agreement with Valeant NA. On July 21, 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable based on our receipt of a not−approvable letter from the FDA with respect to our NDA for MT 300. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. We can give no assurance that Valeant NA will agree to termination terms acceptable to us or that we will not be required to pay Valeant NA the $1.0 million withdrawal fee.

If we or our contract manufacturers do not maintain required regulatory approvals, we may not be able to commercialize our products. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post−approval studies. These post−approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

We and our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practices ("cGMP") regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation.

Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third−party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, which could result in a delay or an inability to manufacture the products.

Labeling and promotional activities are subject to scrutiny by the FDA and state regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of unapproved products as well as the marketing of approved products for unapproved, or off−label, uses. These regulations and the FDA's interpretation of them may impair our ability to effectively market products for which we gain approval. Failure to comply with these requirements can result in federal and state regulatory enforcement action. Further, we may not obtain the labeling claims we believe are necessary or desirable for the promotion of our product candidates.

Because we do not believe it is possible to convince the FDA to reverse its conclusion as stated in its not−approvable letter for MT 300, we do not expect to receive any revenue from sales of MT 300 in the United States.

In October 2003, we received a not−approvable letter from the FDA related to our NDA for MT 300. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre−defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Further, the FDA noted that the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours. Since our receipt of the not−approvable letter, we have had continuing communications with the FDA regarding the MT 300 NDA. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the MT 300 NDA. Therefore, we do not believe that we will receive any revenue from sales of MT 300 in the U.S.

Our reliance on collaborations with third parties to develop and commercialize our products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

Under our current strategy, and for the foreseeable future, we expect to depend upon collaborations with third parties to develop our product candidates and we expect to depend substantially upon third parties to commercialize our products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and any future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions, such as our license and development agreement with Nycomed pursuant to which we obtained an exclusive license to certain rights to develop, manufacture and commercialize products containing lornoxicam. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology in the U.S., a global collaboration with AstraZeneca for the development and commercialization of proprietary combinations of the PPI esomeprozole magnesium and naproxen, and a collaboration with Valeant NA in the U.S. for the development and commercialization of MT 300. In these collaboration agreements, as well as under our lornoxicam license agreement with Nycomed described above, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK and AstraZeneca are entitled to terminate their agreements upon 90 days' notice for any reason. Substantial delays in obtaining regulatory approval to market Trexima, such as may result from our receipt in June 2006 of an approvable letter relating to our NDA for Trexima in which the FDA requested additional safety information, could increase this risk of termination of the GSK agreement. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under the respective agreements if generic competitors attain a pre−determined share of the market for products marketed under the agreements, or if either GSK or AstraZeneca must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca is also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives are not met. Valeant NA is entitled to terminate its agreement with us and a $1.0 million withdrawal fee payable by us in the event we choose to withdraw the NDA if we determine that additional studies or data that are required by the FDA for approval of the NDA would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300. Due to our belief that the FDA will not approve the NDA for MT 300, we have begun discussions with Valeant NA regarding termination of our agreement. Valeant NA has demanded payment of the $1.0 million withdrawal fee, which POZEN is disputing.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with our collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determined, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Trexima clinical trials. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre−clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in commercialization we are currently experiencing as a result of the approvable letter we received from the FDA in June 2006 related to our Trexima NDA, would delay or eliminate our potential product revenues. Further, our collaborators may be able to exercise control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under the respective agreements and would have exclusive control over such enforcement litigation.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day−to−day control over the activities of our contractors or collaborators;

- third parties may not fulfill their regulatory or other obligations;

- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and

- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive from our collaborators, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time−consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

A collaborator may withdraw support or cease to perform work on our product candidates if the collaborator determines to develop its own competing product candidate instead.

We have entered into collaboration and license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. For example, our development and commercialization agreement with GSK is subject to this risk. GSK has publicly disclosed that it is exploring the development of several early−stage compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to work with us on Trexima or any other product candidates that may be developed under the agreement, it has the ability to terminate our agreement upon 90 days' written notice. Any substantial delays in obtaining, or failure to obtain, regulatory approval from the FDA to market Trexima, including as a result of our receipt in June 2006 from the FDA of an approvable letter requesting additional safety information for Trexima, would exacerbate this risk. In such a case, we would need to enter into a new development and commercialization agreement and would need to start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our MT 400 technology, which is not certain, we would face delays and redundant expenses in that development.

We need to maintain current agreements and enter into additional agreements with third parties that possess sales, marketing and distribution capabilities, or establish internally the capability to perform these functions, in order to successfully market and sell our future drug products.

We have no sales or distribution personnel or capabilities. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively, we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that, should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, and clinical trials for our product candidates. Any negative or unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could cause us to discontinue development of a product candidate or reduce, delay or eliminate our receipt of revenues for one or more of our product candidates and adversely affect our ability to achieve profitability.

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the type of product candidate and the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and

trials can be very costly and time−consuming. For example, long−term cardiovascular safety studies, such as those the FDA has indicated will be required for approval of certain product candidates containing NSAIDs, typically take approximately three years. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of Trexima differed from the results of our second Phase 3 clinical trial and from the Phase 2 proof−of−concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the first Phase 3 study Trexima failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, Trexima demonstrated superiority over the individual components measured by sustained pain−free response ($p<0.001$ vs. naproxen; $p=0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

The successful completion of clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. For example, even though we are entitled to submit an NDA for Trexima as a 505(b)(2) application, the FDA may require us to conduct more studies or trials than we now believe are necessary or required.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of a marketing application, we may be required to conduct additional clinical trials, studies or investigations to support our marketing applications. In addition, we and/or our marketing or development partners may determine that pre−approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could a have material impact on the approval of filed or planned market applications or could result in limits placed on the marketing of the product. We may also determine from time to time that it would be necessary to seek to provide justification to the FDA or other regulatory agency that would result in evaluation of the results of a study or clinical trial in a manner that differs from the way the regulatory agency initially or customarily evaluated the results. In addition, we may have unexpected results in our preclinical or clinical trials or other studies that require us to reconsider the need for certain studies or trials or cause us to discontinue development of a product candidate. For example, results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies for Trexima or other MT 400 product candidates we may develop.

Once submitted, an NDA requires FDA approval before we can distribute or commercialize the product described in the application. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA has requested additional safety information on Trexima in the approvable letter we received in June 2006 relating to our NDA for Trexima, which will require some additional studies. There is no guarantee that such studies will be successful or that the FDA will approve the NDA based on the additional information and study results contained in our submission in response to the FDA's approvable letter, or at all. Further, although we believe that we provided the necessary data to support approval of the NDAs for MT 100 and MT 300, the FDA issued not−approvable letters for the MT 100 and MT 300 NDAs on May 28, 2004 and October 17, 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 in the U.S.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long−term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement. We face similar regulatory hurdles in other countries to those that we face in the U.S.

Our costs associated with our human clinical trials vary based on a number of factors, including:

- the order and timing of clinical indications pursued;

- the extent of development and financial support from collaborative parties, if any;
- the need to conduct additional clinical trials or studies;
- the number of patients required for enrollment;
- the difficulty of obtaining sufficient patient populations and clinicians;
- the difficulty of obtaining clinical supplies of our product candidates; and
- governmental and regulatory delays.

We currently depend and will in the future depend on third parties to manufacture our product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our product candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture either clinical trial or commercial quantities of products that we may develop or have under development. We rely upon third−party manufacturers to supply us with our product candidates. We also need supply contracts to sell our products commercially. There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if our current manufacturer is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

If our competitors develop and commercialize products faster than we do or if their products are superior to ours, our commercial opportunities will be reduced or eliminated.

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non−competitive. For example, our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals), biotechnology companies, universities and public and private research institutions. The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non−selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX−2 inhibitor, Celebrex ®.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

- developing product candidates;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates; and

- manufacturing and marketing products.

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products where we cannot or before we do. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we are currently experiencing as a result of the approvable letter we received from the FDA in June 2006 relating to the Trexima NDA, and as we previously experienced as a result of the not−approvable letters we received from the FDA on MT 100 and MT 300, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non−competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If there is an adverse outcome in the securities class action lawsuits that have been filed against us or our current or former directors and officers, our business may be materially harmed. Further, defending against these lawsuits may be expensive and will divert the attention of our management.

Four purported class action lawsuits claiming violations of securities laws were filed between June 4 and July 28, 2004 in the U.S. District Court for the Middle District of North Carolina by holders of our securities against us and certain of our current and former officers. These actions have been consolidated for pre−trial purposes. A fifth case filed on August 6, 2004 has also been consolidated with those actions for pre−trial purposes. By order dated November 4, 2004, the court appointed a lead plaintiff, who filed a consolidated amended complaint (amended complaint) on December 20, 2004. The defendants named in the amended complaint are POZEN and John R. Plachetka, our chairman and chief executive officer. The complaint alleges violations of federal securities laws, including violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b−5, and violations of Section 20(a) of the Exchange Act against Dr. Plachetka. The amended complaint alleges that we made false and misleading statements concerning our product candidates MT 100 and MT 300 during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. In January 2005, we moved to dismiss the amended complaint. On August 30, 2005, our motion to dismiss the complaint was denied and the case is now in the discovery phase.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above. Furthermore, we will have to incur expenses in connection with this lawsuit, which may be substantial. In the event of an adverse outcome, our business could be materially harmed. Moreover, responding to and defending the pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

If we are unable to protect our patents or proprietary rights, or if we are unable to operate our business without infringing the patents and proprietary rights of others, we may be unable to develop our product candidates or compete effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions. Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured**.** If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. In addition, due to the extensive time needed to develop and test our products, any patents that we obtain may expire in a short time after commercialization. This would reduce or eliminate any advantages that such patents may give us. In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. For example, in October 2005 oppositions were filed against our issued European patent for MT 400 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. Such opposition proceedings may not be resolved for several years, and may result in the revocation of the issued patent.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such a risk exists with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued.

We may need to license rights to third party patents and intellectual property to continue the development and marketing of our product candidates. If we are unable to acquire such rights on acceptable terms, our development activities may be blocked and we may be unable to bring our product candidates to market.

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know−how, or determine the scope and validity of others' patent or proprietary rights. As a result of such litigation, our patent claims may be found to be invalid, unenforceable or not of sufficient scope to cover the activities of an alleged infringement. With respect to some of our product candidates, under certain circumstances, our development or commercialization collaborators have the first right to enforce our patents and would have exclusive control over such enforcement litigation. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each have the first right to enforce our patents under their respective agreements.

If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Additionally, if we or our development or commercialization collaborator seek to enforce our patents and are unsuccessful, we may be subject to claims for bringing a failed enforcement action, including claims alleging various forms of antitrust violations (both state and federal) and unfair competition. If we are found to be liable for such claims, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and commercialization activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and know−how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know−how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

If we fail to acquire, develop and commercialize additional products or product candidates, or fail to successfully promote or market approved products, we may never achieve profitability.

As part of our business strategy, we plan to identify, self−invent and/or acquire product candidates or approved products in areas in which we possess particular knowledge. Because we do not directly engage in basic research or drug discovery, we may rely upon third parties to sell or license product opportunities to us. Other companies, including some with substantially greater financial, marketing and sales resources, are competing with us to acquire such products and product candidates. We may not be able to acquire rights to additional products or product candidates on acceptable terms, if at all. In addition, if we acquire new products or product candidates with different marketing strategies, distribution channels and bases of competition than those of our current product candidates, we may not be able to compete favorably in those product categories.

None of our future products may be accepted by the market.

Even if our product candidates perform successfully in clinical trials and are approved by the FDA and other regulatory authorities, our future products may not achieve market acceptance and may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the receipt and timing of regulatory approvals;
- the availability of third−party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;
- the price of the product relative to alternative therapies;
- the availability of alternative therapies;

- the extent and effectiveness of marketing efforts by us and third−party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

If we do not receive adequate third−party reimbursements for our future products, our revenues and profitability will be reduced.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved healthcare product. Adequate third−party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third−party payors for use of our products, our products may fail to achieve market acceptance.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third−party payors to contain or reduce the costs of healthcare through various means. We expect that a number of federal, state and foreign proposals will seek to control the cost of drugs through governmental regulation. We are unsure of the form that any healthcare reform legislation may take or what actions federal, state, foreign and private payors may take in response to any proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The testing and marketing of pharmaceutical products entails an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our human clinical trials in an amount equal to up to $10.0 million annual aggregate limit with a $0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our products and commercial sales of the product begin. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

We may need additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development or commercialization efforts.

We may need to raise additional funds to execute our business strategy. We have incurred losses from operations since inception and we may continue to incur additional operating losses. Our actual capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing or the need conduct additional trials, studies or other testing;
- the time and cost involved in obtaining any regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;

- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

Our operating expenses for the six−month period ended June 30, 2006 totaled $18.9 million, including non−cash compensation expense of $3.9 million related to stock options and other stock−based awards, associated with our adoption of SFAS No. 123(R) on January 1, 2006. For fiscal years 2003 through 2005, our average annual operating expenses (including average non−cash deferred compensation of $0.6 million) were $25.4 million. We are currently expecting operating expenses for the 2006 fiscal year to be between $33.0 million and $36.0 million, including non−cash compensation expenses, related to stock options and other stock−based awards expected to be $6.5 million, resulting from our adoption of SFAS 123(R) on January 1, 2006. As of June 30, 2006, we had an aggregate of $31.9 million in cash and cash equivalents and short−term investments. If our operating expenses for 2006 and 2007 are at the level of our operating expenses in 2005, and if we do not receive any payments under any of our collaboration agreements, including the upfront payment of $40 million and payments to reimburse us for certain development expenses, which are payable to us under our collaboration agreement with AstraZeneca, we will not have sufficient cash reserves to maintain our level of business activities through 2007. Further, our expenses might increase in 2006 and 2007 beyond currently expected levels if any regulatory agency requires us to conduct additional clinical trials, studies or investigations, including in connection with their consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of $1.0 million if we do not prevail in our current dispute with them as to whether the withdrawal fee is payable under our MT 300 collaboration agreement.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy. Further, to the extent that we obtain additional funding through collaboration and licensing arrangements, it may be necessary for us to give up valuable rights to our development programs or technologies or grant licenses on terms that may not be favorable to us.

The sale by us of additional equity securities or the expectation that we will sell additional equity securities may have an adverse effect on the price of our common stock.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our research and development efforts.

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, for a three−year term with automatic one−year renewal terms. We have also entered into employment agreements with certain of our other key management personnel, which provide for one or two−year terms with automatic one−year renewal terms. If we should lose the services of Dr. Plachetka, or are unable to replace the services of our other key personnel who may leave the Company, such as Dr. Marshall E. Reese, Executive Vice President, Product Development, William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer, or Kristina M. Adomonis, Senior Vice President, Business Development or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific personnel. Since our business is very science−oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

Our stock price is volatile, which may result in significant losses to stockholders.

There has been significant volatility in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include:

- fluctuations in our operating results;

- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- developments in new or pending litigation;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. From October 16, 2000, when our common stock began trading on the Nasdaq National Market, through June 30, 2006, the high and low closing prices of our common stock ranged from $2.25 to $21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market could depress our stock price.

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and four of our stockholders and their affiliates beneficially hold approximately 34% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, as we recently announced, beginning in September 2006 our chief executive officer and one of our directors may sell up to an aggregate of 1,010,000 shares pursuant to Rule 10b5−1 trading plans. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We have filed with the SEC, and the SEC has declared effective, a shelf registration statement on Form S−3 under which we may register up to 8,540,000 shares of our common stock for sale to the public in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to 540,000 of such shares, and we would not receive any of the proceeds from sales of those shares.

Anti−takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.

Provisions of our charter and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of POZEN. For example, these provisions:

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three−year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;

- eliminate the ability of stockholders to call special meetings of stockholders;

- prohibit stockholder action by written consent; and

- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Further, in January 2005 our board of directors adopted a stockholder rights plan, similar to plans adopted by many other publicly−traded companies. The stockholder rights plan is intended to deter an attempt to acquire us in a manner or on terms not approved by our board of directors.

Item 4. Submission of Matters to Vote of Security Holders

Our annual meeting of stockholders was held on May 16, 2006. There were present at the annual meeting of stockholders in person or by proxy stockholders holding an aggregate of 27,378,173 shares of our common stock out of a total number of 29,160,448 shares of common stock issued and outstanding and entitled to vote at the meeting. Our stockholders voted on two matters, as follows:

1. The stockholders elected three Class III directors to each serve for a three year term (until our 2009 annual meeting of stockholders and until their successors have been duly elected and qualified) by the following votes (there were no abstentions or broker non−votes in connection with the election of the Class III directors):

	Number of Shares of Common Stock	
	For:	Withheld:
John R. Plachetka	27,235,752	142,421
Peter J. Wise	26,855,551	522,622
James J. Mauzey	27,115,541	262,632

The other directors whose terms of office as director continued after the meeting are as follows: Arthur S. Kirsch, Kenneth B. Lee, Jr., Paul J. Rizzo, Bruce A. Tomason and Donald H. Namm. As we reported on a Current Report on Form 8−K filed on June 28, 2006, Dr. Namm notified us on June 27, 2006 of his resignation as a director, for personal reasons. Dr. Namm has no disagreements with the Company on any matter relating to the Company's operations, policies or practices.

2. The stockholders ratified the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2006 by the following votes (there were no broker non−votes in connection with the ratification of our independent auditor):

Number of Shares of Common Stock		
For:	Against:	Abstain:
27,245,112	132,359	702

Item 6. Exhibits

Exhibit Number	Description
10.1*	Confidential Separation Agreement and General Release dated June 15, 2006 between the Registrant and W. James Alexander, M.D.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a−14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes−Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a−14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes−Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes−Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes−Oxley Act of 2002.

* Management contract or compensatory plan

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.

POZEN Inc.

(Registrant)

August 8, 2006

By: /s/ JOHN R. PLACHETKA
John R. Plachetka
President and Chief Executive Officer

August 8, 2006

By: /s/ WILLIAM L. HODGES
William L. Hodges
Chief Financial Officer

August 8, 2006

By: /s/ JOHN E. BARNHARDT
John E. Barnhardt
Principal Accounting Officer

EXHIBIT INDEX

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CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE

WHEREAS, W. James Alexander, MD, MPH, ("Employee") has been employed by POZEN Inc. ("POZEN" or "the Company") (collectively, the "Parties");

WHEREAS, the Parties have mutually agreed that Employee will separate from his employment with the Company, effective June 15, 2005; and

WHEREAS, in conjunction with the termination of Employee's employment, as set forth below, the parties have agreed to a separation package and the resolution of any and all disputes between them;

IT IS HEREBY AGREED, by and between Employee and POZEN, as follows:

1. In consideration of Employee's execution and non−revocation of this Confidential Separation Agreement and General Release ("Agreement and Release"), Employee's agreement to be legally bound by its terms, and Employee's undertakings as set forth herein, POZEN agrees to continue Employee's semi−monthly salary of $12,361.53 paid on the 15th and end of each month, minus all applicable federal, state and local taxes, through December 31, 2006, in accordance with the Company's ordinary payroll practice. These payments will commence on the first regularly scheduled payroll date occurring at least eight (8) days after Employee returns this Agreement and Release fully executed, and the Agreement and Release is effective, no longer subject to rescission under any applicable law.

2. In consideration of this Agreement and Release, Employee expressly agrees to make himself available, upon reasonable notice, to consult with POZEN on matters related to POZEN's legitimate business activities. Employee's obligation to so consult will extend through December 31, 2006. The Parties agree that Marshall Reese shall be Employee's primary contact at POZEN for consulting purposes. The Parties further agree that Paul Ossi shall be Employee's secondary contact. The Parties agree and understand that Employee's obligations under this paragraph shall not interfere with any obligations Employee owes to any subsequent

employer, which obligations should take priority, provided further, however, that Employee shall use his best efforts to complete the requested consultative services in a timely manner.

3. POZEN shall prepare a mutually agreed−upon, neutral letter of reference in the form attached hereto as Exhibit A.

4. POZEN agrees to indemnify Employee to the maximum extent permitted by law as to matters arising out of his performance of his responsibilities as an employee and officer of the Company.

5. Employee, on behalf of himself, his heirs, executors, administrators, and/or assigns, does hereby **RELEASE AND FOREVER DISCHARGE** POZEN, together with its parents and subsidiaries, and affiliated, predecessor and successor corporations and business entities, past, present and future, and its and their agents, directors, officers, employees, executives, shareholders, investors, insurers and reinsurers, representatives, and attorneys, past, present and future (collectively, the "Releasees"), of and from any and all legally waivable causes of action, suits, debts, complaints, claims and demands whatsoever in law or in equity, whether known or unknown, which Employee, or his heirs, executors, administrators, and assigns, ever had or now has against each or any of the Releasees, from the beginning of time to the date of execution of this Agreement and Release, including, without limitation, any and all claims relating to Employee's employment with POZEN or the termination of that employment, including, without limitation, claims under the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Older Workers Benefit Protection Act, 29 U.S.C. § 626(f), Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., Section 1981 of the Civil Rights Act of 1870, 42 U.S.C. § 1981 et seq., the Americans with Disabilities Act, 42 U.S.C. § 12101 et seq., the Employee Retirement Income Security Act, 29 U.S.C. § 1001 et seq., the Family Medical Leave Act, 29 U.S.C. § 2601 et seq., the Sarbanes−Oxley Act, 18 U.S.C. § 1514A, the North Carolina Equal Employment Practices Act, N.C. Gen. Stat. §§ 143−422.1 et seq., the North

Carolina Persons with Disabilities Protection Act, N.C. Gen. Stat. §§ 168A−1 to 168A−12, the North Carolina Whistleblower Protection Law, N.C. Gen. Stat. §§ 95−28.1, 95−28.1A, and 95−240 to 95−245, the North Carolina Family Leave Law, N.C. Gen. Stat. §§ 95−28.3, the North Carolina Wage and Hour Act, N.C. Gen. Stat. §§ 95−25.1, and any and all other federal, state or local statutory or common law claims, now or hereafter recognized, including but not limited to, any claims for economic loss, compensatory damages, punitive damages, liquidated damages, attorneys' fees, expenses and costs.

6. POZEN, on behalf of its parents and subsidiaries, and affiliated, predecessor and successor corporations and business entities, past, present and future, and its and their agents, directors, officers, employees, executives, shareholders, investors, insurers and reinsurers, representatives, and attorneys, past, present and future, does hereby **RELEASE AND FOREVER DISCHARGE** Employee, his heirs, executors, administrators, and/or assigns, of and from any and all legally waivable causes of action, suits, debts, complaints, claims and demands whatsoever in law or in equity, which are known to POZEN at the time of execution of this Agreement and Release.

7. Employee hereby agrees and recognizes that his employment relationship with POZEN has been completely severed as of June 15, 2006 and that POZEN has no obligation, contractual or otherwise, to hire, rehire or re−employ Employee in the future.

8. Employee represents that he does not have any lawsuits, claims, or charges pending against any of the Releasees.

9. Employee agrees and acknowledges that this Agreement and Release is not, and shall not be construed to be, an admission of any violation of any federal, state or local statute, ordinance or regulation, or of any duty owed by Releasees to Employee, or of any wrongdoing to Employee by Releasees.

10. This Agreement and Release constitutes the entire agreement between Employee and POZEN with respect to the subject matter hereof and supersedes all prior negotiations and agreements, whether written or oral, relating to the subject matter hereof, with the sole exception of the "Non−Disclosure, Invention and Non−Competition Agreement" between POZEN and Employee, effective November 7, 2003 (the "Non−Disclosure Agreement"). The Non−Disclosure Agreement is attached as Exhibit B. Employee acknowledges that neither POZEN, the Releasees, nor their agents or attorneys have made any promise, representation or warranty whatsoever, either express or implied, written or oral, other than the express written representations contained in the Non−Disclosure Agreement and herein. Employee agrees that this Agreement and Release may not be altered, amended, modified, or otherwise changed in any respect except by another written agreement signed by both Employee and POZEN.

11. Employee agrees that this Agreement and Release and its terms and conditions shall remain confidential to the Parties and its terms shall not be disclosed except to Employee's accountants, lawyers, or immediate family members.

12. This Agreement and Release has been made and executed in the State of North Carolina, and all disputes or questions of interpretation arising from or relating to this Agreement and Release shall be resolved under North Carolina law, regardless of the application of conflicts of laws principles.

13. This Agreement and Release shall be interpreted in accordance with the plain meaning of its terms and not strictly for or against any of the Parties. This Agreement and Release shall be deemed to have been mutually negotiated and shall not be construed against any party solely by reason of authorship.

14. Employee further certifies and acknowledges that:

a. Employee has read the terms of this Agreement and Release and understands its terms and effects, including the fact that he has agreed to RELEASE AND

FOREVER DISCHARGE the RELEASEES from any legal action arising out of his employment relationship with POZEN, the terms and conditions of that employment relationship, and the termination of that relationship;

b. Employee has signed this Agreement and Release voluntarily and knowingly in exchange for the consideration described herein, which Employee acknowledges is adequate and satisfactory to him;

c. The payments, benefits, promises and undertakings performed, and to be performed, as set forth herein exceed and are greater than the payments and benefits, if any, to which Employee would have been entitled had he not executed this Agreement and Release;

d. Releasees have advised Employee to consult with an attorney concerning this Agreement and Release prior to signing this Agreement and Release, and he has done so;

e. Employee has been informed that he has the right to consider this Agreement and Release for a period of twenty−one (21) days from receipt prior to entering into this Agreement and Release and Employee has signed on the date indicated below after concluding that the Agreement and Release is satisfactory; and

f. Employee has been informed that he has the right to revoke this Agreement and Release for a period of seven (7) days following his execution of this Agreement and Release by giving written notice to POZEN to the attention of Richard G. Rosenblatt, Esquire, 502 Carnegie Center, Princeton, New Jersey 08540, and that this Agreement and Release will not be effective or enforceable until this seven (7) day period has expired.

IN WITNESS WHEREOF, and intending to be legally bound hereby, Employee and POZEN hereby execute the foregoing Confidential Separation Agreement and General Release on this 13th day of June, 2006.

/s/ W. James Alexander
W. James Alexander

By: /s/ William L. Hodges
William L. Hodges

Senior Vice President, Finance and Administration and Chief Financial Officer

Exhibit A

Dear Sir or Madam:

This letter will confirm that POZEN, Inc. employed W. James Alexander, MD, MPH, as its Senior Vice President, Product Development, and Chief Medical Officer from November 24, 2003 to June 15, 2006. Pursuant to company policy, we are unable to disclose additional information. Nonetheless, we appreciate his service to our company and wish him the best in his future endeavors.

Sincerely,

EXHIBIT 31.1

Section 302 Certification

I, John R. Plachetka**,** certify that:

1. I have reviewed this Form 10−Q of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a−15(e) and 15d−15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a−15(f) and 15d−15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
President and Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

Section 302 Certification

I, William L. Hodges, certify that:

1. I have reviewed this Form 10−Q of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a−15(e) and 15d−15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a−15(f) and 15d−15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006

/s/ William L. Hodges
William L. Hodges
Senior Vice President, Finance and Administration and
Chief Financial Officer

EXHIBIT 32.1

CEO CERTIFICATION PURSUANT TO

SECTION 906 OF THE SARBANES−OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

In connection with Form 10−Q of POZEN Inc. (the "Company"), as filed with the Securities and Exchange Commission (the "Report"), I, John R. Plachetka, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes−Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2006

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CFO CERTIFICATION PURSUANT TO

SECTION 906 OF THE SARBANES−OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

In connection with Form 10−Q of POZEN Inc. (the "Company"), as filed with the Securities and Exchange Commission (the "Report"), I, William L. Hodges, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes−Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2006

/s/ William L. Hodges
William L. Hodges
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.