FORM 10−Q

POZEN INC /NC − POZN

Filed: November 09, 2005 (period: September 30, 2005)

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

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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 September 30, 2005

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 an accelerated filer (as defined in Rule 12b−2 of the Securities Exchange Act of 1934). ☒ Yes ☐ No

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 October 24, 2005 was 29,001,265.

POZEN Inc.

(A Development Stage Company)

FORM 10−Q

For the Three and Nine Months Ended September 30, 2005

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.

(A Development Stage Company)

BALANCE SHEETS

(Unaudited)

	September 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,545,728	$ 51,764,129
Short−term investments	19,778,456	—
Prepaid expenses and other current assets	74,773	1,064,032
Total current assets	31,398,957	52,828,161
Equipment, net of accumulated depreciation	267,656	467,688
Total assets	$ 31,666,613	$ 53,295,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 580,580	$ 2,330,349
Accrued compensation	2,432,372	1,182,848
Accrued expenses	1,119,001	1,626,829
Deferred revenue	8,789,000	8,680,092
Total current liabilities	12,920,953	13,820,118
Long−term liabilities:		
Deferred revenue	1,000,000	7,764,978
Total liabilities	13,920,953	21,585,096
Preferred stock, $0.001 par value; 10,000,000 shares authorized, issuable in series, of which 90,000 shares are designated Series A Junior Participating Preferred Stock, none outstanding	—	—
Common stock, $0.001 par value, 90,000,000 shares authorized; 28,991,265 and 28,852,743 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	28,991	28,853
Additional paid−in capital	146,379,192	146,161,655
Accumulated other comprehensive loss	(9,099)	—
Deficit accumulated during the development stage	(128,653,424)	(114,479,755)
Total stockholders' equity	17,745,660	31,710,753
Total liabilities and stockholders' equity	$ 31,666,613	$ 53,295,849

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period From Inception (September 26, 1996) Through September 30, 2005
	2005	2004	2005	2004	
Revenue	$ 2,399,000	$ 1,891,499	$ 6,410,374	$ 20,670,499	$ 33,215,282
Operating expenses:					
General and administrative	2,473,439	2,065,869	7,198,656	6,071,475	48,086,356
Research and development	4,900,642	5,859,319	14,231,894	11,903,282	121,471,871
Total operating expenses	7,374,081	7,925,188	21,430,550	17,974,757	169,558,227
Other income:					
Interest and other income	289,303	202,369	846,507	463,342	8,623,999
Net income (loss)	(4,685,778)	(5,831,320)	(14,173,669)	3,159,084	(127,718,946)
Non−cash preferred stock charge	—	—	—	—	27,617,105
Preferred stock dividends	—	—	—	—	934,478
Net income (loss) attributable to common stockholders	$ (4,685,778)	$ (5,831,320)	$ (14,173,669)	$ 3,159,084	$(156,270,529)
Basic net income (loss) per common share	$ (0.16)	$ (0.20)	$ (0.49)	$ 0.11	
Shares used in computing basic net income (loss) per common share	28,929,503	28,799,277	28,919,245	28,713,806	
Diluted net income (loss) per common share	$ (0.16)	$ (0.20)	$ (0.49)	$ 0.11	
Shares used in computing diluted net income (loss) per common share	28,929,503	28,799,277	28,919,245	29,666,989	

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,		Period from Inception (September 26, 1996) Through September 30,
	2005	2004	2005
Operating activities:			
Net (loss) income	$(14,173,669)	$(13,245,416)	$(127,718,946)
Adjustments to reconcile net (loss) income to net cash (used in) operating activities:			
Depreciation	121,304	102,602	809,762
Write−down of impaired asset	69,272	—	102,839
Gain on sale of investments	224,058	—	224,058
Bond amortization	(386,047)	—	(386,047)
Noncash compensation expense	1,046,974	448,443	12,322,643
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	989,259	473,632	(74,773)
Accounts payable and accrued expenses	(1,914,738)	1,155,438	2,824,900
Deferred revenue	(6,656,070)	25,612,980	9,789,000
Net cash provided by (used in) operating activities	(20,679,656)	14,587,679	(101,656,563)
Investment activities:			
Purchase of equipment	(37,626)	(32,224)	(1,227,339)
Purchase of investments	(38,201,508)	—	(38,201,508)
Sale of investments	18,575,942	—	18,575,942
Net cash used in investing activities	(19,663,192)	(32,224)	(20,852,905)
Financing activities:			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	124,447	750,569	81,561,331
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	124,447	750,569	134,055,196
Net increase (decrease) in cash and cash equivalents	(40,218,401)	15,306,024	11,545,728
Cash and cash equivalents at beginning of period	51,764,129	50,056,251	—
Cash and cash equivalents at end of period	$ 11,545,728	$ 65,362,275	$ 11,545,728
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

We are a pharmaceutical company focused primarily on products for the treatment of migraine, acute and chronic pain and other pain−related indications. Our product development emphasis is on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception in 1996, we have focused our efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. Our portfolio currently contains product candidates in the migraine area and other acute and chronic pain and pain−related therapeutic areas. We have not obtained regulatory approval to market any of our product candidates. Statement of Financial Accounting Standards Board No. ("SFAS") 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 believe that 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.

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 9, 2005. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2005.

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 $500,000 licensing fee for MT 100 received from Nycomed Danamark ApS ("Nycomed") has been amortized over 30 months. (Note: The Nycomed agreement was terminated in September 2005 and any deferred revenue which the Company is entitled to recognize as income will no longer be deferred, but is being recognized in the third quarter of 2005.)

- The June 2003 initial licensing and patent−issuance milestone payments totaling $25.0 million for MT 400 received from GlaxoSmithKline ("GSK") have been deferred and was 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 U.S. Food and Drug Administration ("FDA") of the Trexima New Drug Application ("NDA") which was earlier than anticipated. The decrease in the deferred period resulted in a $357,000 increase in the third quarter amortization from the second quarter 2005 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 expenses. 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 current, 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 nine months period ended September 30, 2004 and 2005, the Company had $0.0 million and $0.4 million of bond amortization, $0.0 million and $0.2 million of realized gains and $0.0 million and $9,099 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 $9,099 of unrealized losses on its investments that are classified as accumulated other comprehensive loss at September 30, 2005.

Comprehensive income consists of the following components for the nine months ended September 30, 2005 and 2004:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income (loss)	$ (4,685,778)	$ (5,831,320)	$ (14,173,669)	$ 3,159,084
Unrealized gain (loss) on marketable securities	(1,614)	—	(9,099)	—
Total comprehensive loss	$ (4,687,392)	$ (5,831,320)	$ (14,182,768)	$ 3,159,084

Stock−based Compensation—The Company accounts for non−cash stock−based compensation in accordance with the provisions of Accounting Principles Board Opinion No. ("APB") 25, "Accounting for Stock Issued to Employees and Statement of Financial Accounting Standards ("SFAS") No. 123 Share Based Payments. Accounting Principles Board Opinion No. ("APB") 25, "Accounting for Stock Issued to Employees," states that no compensation expense is recognized for stock options or other stock−based awards that are granted to employees with an exercise price equal to or above the estimated fair value of the Company's common stock on the grant date. In the event that stock options are granted with an exercise price below the estimated fair market value of the Company's common stock at the grant date, the difference between the fair market value of the Company's common stock and the exercise price of the stock option is recorded as deferred compensation and amortized as compensation expense over the vesting period of the options.

On January 3, 2005, pursuant to an incentive program approved by the Compensation Committee of the Board of Directors of the Company, stock options (the "Trexima grants") were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 506,772 shares of common stock. Each 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. The options, which were granted under the Company's Equity Compensation Plan, as amended and restated, have a ten−year term and an exercise price of $7.06, the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant.

As a result, the Company is required to apply variable stock−based compensation accounting for the Trexima grants until the underlying options are vested or forfeited. The Company is only subject to compensation expense for such options when the Company's stock price is greater than the exercise price of the options. Regarding the Trexima grants, for the three and nine month periods ended September 30, 2005, the Company recorded $515,000 and $655,000, respectively, in variable stock−based compensation expense because its common stock price on September 30, 2005 exceeded the options' exercise price of $7.06.

Because the determination of variable stock−based compensation expense associated with the Trexima grants is significantly dependent upon the market price of the common stock at the end of the applicable reporting period, it is not possible to determine its future impact, either favorable or unfavorable, on the Company's financial statements for prospective reporting periods.

In connection with the grant of stock awards to employees, consisting of the January 2005 Trexima grants and a restricted stock unit award made in May 2004 to our Chief Executive Officer, the Company recorded $100,000 and $300,000 in stock based compensation expense in the three and nine month periods ended September 30, 2005, respectively, and $515,000 and $655,000 in amortized deferred compensation for the three and nine month periods ended September 30, 2005. Vesting periods of the options are generally three or four years except as noted above regarding the Trexima grants, and the restricted stock unit award vests in equal amounts on January 1, 2005, January 1, 2006 and January 1, 2007.

The following table illustrates the effect on net income (loss) and net income (loss) per share as if the Company had applied the fair value recognition provisions of SFAS 123, "Accounting for Stock−Based Compensation," to stock−based employee compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income (loss) attributable to common stockholders as reported	$ (4,685,778)	$ (5,831,320)	$ (14,173,669)	$ 3,159,084
Add: Stock−based employee compensation expense reflected in reported net income (loss), net of related tax effects	$ 615,197	$ 94,698	$ 955,746	$ 189,396
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(1,305,369)	(1,119,966)	(4,349,233)	(3,090,456)
Pro forma net income (loss) attributable to common stockholders	$ (5,375,950)	$ (6,856,588)	$ (17,567,156)	$ 258,024
Earnings per share				
Basic net income (loss) per common share as reported	$ (0.16)	$ (0.20)	$ (0.49)	$ 0.11
Basic net income (loss) per common share pro forma	$ (0.19)	$ (0.24)	$ (0.61)	$ 0.01
Diluted net income (loss) per common share as reported	$ (0.16)	$ (0.20)	$ (0.49)	$ 0.11
Diluted net income (loss) per common share pro forma	$ (0.19)	$ (0.24)	$ (0.61)	$ 0.01

Net Loss Per Share—Basic and diluted net (loss) income 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) income per common share amounts have been computed using the weighted−average number of shares of common stock outstanding for the three and nine month periods ended September 30, 2004 and 2005. During the three and nine months ended September 30, 2004 and 2005, 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 the three and nine month periods ended September 30, 2005, or the three months ended September 30, 2004, because the effect would be anti−dilutive. 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. The following table illustrates the calculation of dilutive shares outstanding:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Weighted−average shares used in computing basic net income (loss) per share	28,929,503	28,799,277	28,919,245	28,713,806
Effect of dilutive securities	—	—	—	953,183
Weighted−average shares used in computing diluted net income (loss)	28,929,503	28,799,277	28,919,245	29,666,989

per share

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 determine 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 for each one one−thousandth of a share, 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—On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004) ("Statement 123(R)"), Share−Based Payment, which is a revision of FASB Statement No. 123, *Accounting for Stock−Based Compensation* ("FASB123"). Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in FASB 123. However, Statement 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.

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

- A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share−based payments granted after the effective date and (b) based on the requirements of FASB 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.

- A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under FASB 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

Statement 123(R) must be adopted no later than January 1, 2006. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company is reviewing Statement 123(R) and the additional guidance regarding assumptions and option−pricing models and currently anticipates adoption of Statement 123(R) on January 1, 2006 using the modified prospective method.

As permitted by FASB 123, we currently account for share−based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of the adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share−based payments granted in the future. However, had we adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of FASB 123 as described in the disclosure of pro forma net (loss) income and earnings (loss) per share in Note 2 above. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the decrease in operating cash flows which would have been recognized for such excess tax deductions was $0.9 million and $0.7 million in 2004 and 2003, respectively.

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.

In September 2004, two derivative actions were also filed against certain of the Company's current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina, alleging violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning the Company's product candidates, MT 100 and MT 300, that are referenced in the purported class action lawsuits. The two cases have been consolidated and assigned to the North Carolina Business Court.

The plaintiffs in the derivative actions have filed a consolidated amended complaint asserting the same claims as were asserted in the original complaints. On May 31, 2005, the Company filed a motion to dismiss the consolidated amended complaint. Oral arguments were made before the North Carolina Business Court on August 9, 2005. The Court has not yet ruled the motion to dismiss.

The Company and the other defendants believe that the allegations in these actions are without merit and intend to defend these cases 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.

Additionally, 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 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

The Company's Trexima NDA submission was made in August of 2005 and accepted for review by the FDA in October 2005. Under the Company's collaboration agreement with GSK, upon the FDA's acceptance for review of the Trexima NDA, GSK became obligated to pay the Company a milestone payment in the amount of $20.0 million. The $20.0 milestone payment was received by the Company on October 18, 2005.

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, 2004, as filed on March 9, 2005.

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 below under "Factors That May Affect Our Results." 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 migraine, acute and chronic pain and other pain−related indications. 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 acute and chronic pain and 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.

Our business activities 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.

Under 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"), 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. In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long−acting NSAID for the U.S. market. The combinations covered by the agreement are among the combinations of our MT 400 technology. Trexima is the proposed brand name for the combination of GSK's sumatriptan succinate, formulated with GSK's RT Technology™, and naproxen sodium in a single tablet being developed pursuant to our agreement with GSK. We commenced a Phase 3 clinical program for Trexima in the second half of 2004. We filed the Trexima NDA with the U.S. Food and Drug Administration (FDA) in August 2005 and received confirmation from the FDA in October 2005 that the NDA had been accepted for review. Under our collaboration agreement with GSK, upon the FDA's acceptance for review of the Trexima NDA, GSK becomes obligated to pay us a milestone payment in the amount of $20 million. We received this payment in October 2005.

We currently have two exploratory programs in pain−related therapeutic areas. In one such program, we are seeking to identify potential product candidates, designated our PN and PA product candidates, that combine acid inhibitor with an NSAID. We have begun exploratory formulation development and clinical studies for combinations of a proton pump inhibitor ("PPI") and an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone. We have two PN product candidates and one PA product candidate in development. Our other exploratory program involves the development of novel product candidates containing lornoxicam, an NSAID, alone or in combination with other active ingredients, as potential treatments for pain or other indications. This exploratory work is being conducted under an exclusive license agreement with Nycomed granting us certain rights to develop and commercialize products containing lornoxicam. 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.

We have discontinued further development of our product candidate MT 100 in the United States and are reevaluating our European strategy for MT 100. 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, as well as a related supply agreement with Nycomed. We are continuing to seek marketing approval of MT 100 in the United Kingdom ("UK"). Further, based on our understandings from our recent communications with the FDA 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 our product candidate MT 300. We have, therefore, begun discussions with Valeant NA regarding termination of our commercialization agreement for MT 300.

We have financed our operations and internal growth primarily through private placements of preferred stock, our initial public offering and, beginning in 2003, payments received under our collaborations. Beginning in the third quarter of 2003, we began recognizing revenue from initial payments received under our collaboration agreements.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of September 30, 2005, our accumulated deficit was approximately $128.7 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 72% of our total operating expenses. In the nine−month period ended September 30, 2005, our research and development expenses represented approximately 68% of our total operating expenses.

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
- our costs related to the lawsuits that have been filed against us and our current or former directors and officers relating to the approvability of MT 100 and MT 300. The status of these proceedings is discussed in this Form 10−Q under "PART II. Item 1. Legal Proceedings".

Our ability to generate revenue is dependent upon our ability, alone or with others, to achieve the milestones set forth in our collaboration agreements and successfully develop our migraine and other 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 nine month period ended September 30, 2005 were $3.6 million. Other research and development department costs for the nine month period ended September 30, 2005 were $0.7 million.

MT 400/Trexima. As part of our Phase 3 program for Trexima, we conducted two Phase 3 pivotal trials designed to determine the effectiveness and safety of Trexima for the acute treatment of migraine as well as to satisfy the requirements of the FDA's combination drug rule.

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 after two 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 both Phase 3 trials and other information required for the submission of the Trexima NDA. The Trexima NDA submission was made in August of 2005 and accepted for review by the FDA in October 2005. Based upon discussions at the April 2005 pre−NDA meeting, we believe that no additional pre−clinical or clinical trials are necessary; however, we cannot guarantee that additional studies will not be necessary following the FDA's review of the NDA. Under our collaboration agreement with GSK, upon the FDA's acceptance for review of the Trexima NDA, GSK became obligated to pay us a milestone payment in the amount of $20 million. We received this payment in October 2005.

In addition to the Phase 3 studies, we have completed a long−term, open label safety study for Trexima, the results of which we believe to be consistent with the six−month safety data we submitted in the Trexima NDA. Further, GSK has funded and is conducting two Phase 3b/4 studies. The additional safety data from the open label study and the Phase 3b/4 studies will be submitted to the FDA in December 2005 in a 120−day safety update report to the NDA.

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

We have incurred direct development costs associated with the development of Trexima during the nine months ended September 30, 2005 and from inception to date of $5.2 million and $24.3 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PN (PPI / NSAID) Program. This exploratory development program is intended to identify potential product candidates that combine a proton pump inhibitor (PPI) with an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone. We have designated these potential product candidates as our PN and PA product candidates. We currently have two PN product candidates in development – PN 100, a combination of lansoprazole and naproxen, and PN 200, a combination of omeprazole and naproxen. A third product candidate under this exploratory program, PA 325, a combination of a PPI and aspirin, is currently in formulation development. In August 2005, a patent was issued covering combinations of acid inhibitors and NSAIDs, including naproxen and aspirin. Our PN/PA suite of product candidates are among the compositions covered by this patent.

In late 2004, we requested a pre−IND meeting with the FDA to discuss our exploratory proprietary tablet formulations containing a traditional non−selective NSAID and a PPI. Our studies in human volunteers have suggested that such fixed combinations could provide a degree of protection against the development of gastric and/or duodenal ulcers in patients who require the daily use of an NSAID drug for arthritis or other chronic inflammatory conditions.

We met with the FDA in January 2005 and discussed our proposals for studies to obtain approval of PN 100. At a second meeting with the FDA in September 2005, we reaffirmed our understandings and discussed our development plans for studies to pursue FDA approval of PN 200. Based on those discussions, we believe we should be able to initiate Phase 3 studies of one of our PN product candidates in the first half of 2006. At the September meeting, we also discussed 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 that addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX−2 selective NSAIDs. Based on these discussions, we believe that long−term cardiovascular safety studies may not be required at this time for FDA approval of our PN product candidates containing naproxen. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements necessary to support approval of NDAs for our PN and PA product candidates.

We have incurred direct development costs associated with the development of our PN/PA program, for the nine month period ended September 30, 2005 and from inception to date, of $2.5 million and $6.8 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Lornoxicam Program. We are exploring the development of novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. We are conducting our exploratory work under an exclusive license agreement with Nycomed granting to us certain rights to develop and commercialize products containing lornoxicam.

In December 2003, we submitted an IND to the FDA for lornoxicam oral tablets and, in January 2004, received FDA approval to conduct the first human study with this formulation in the United States. This single−site trial evaluated the efficacy and safety of single doses of lornoxicam (at three different dose strengths), ibuprofen and placebo in 125 patients undergoing dental surgery for impacted third molars. 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. In September 2004, we met with the FDA to review the results of this study, to discuss information provided in the IND and to discuss non−clinical issues and potential additional clinical studies. We provided additional analyses and information requested by the FDA following that meeting. As a result of the FDA advisory committee meeting held in February 2005 addressing the potential cardiovascular risk of COX−2 selective NSAIDs and related drugs, 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 lornoxicam oral tablet product candidate.

In May 2005, we submitted an IND to the FDA for an injectable lornoxicam formulation and, in June 2005, received FDA approval to conduct the first human study with this formulation under our IND. Phase 1 studies have been initiated for this injectable formulation, and we expect to commence Phase 2 studies in two pain models, bunionectomy and migraine, by the end of 2005. 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 with the FDA, that long term cardiovascular safety studies may not be required for NDA approval of this formulation.

We will continue to evaluate and discuss with the FDA the clinical and non−clinical study requirements, including safety study requirements, anticipated for approval of our 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 have incurred direct development costs associated with the development of our lornoxicam program, for the nine month period ended September 30, 2005 and from inception to date, of $1.3 million and $3.9 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

MT 100. In July 2003, we submitted an NDA to the FDA for our product candidate MT 100, our combination of metoplopamide hydrochloride and naproxen sodium. In May 2004, we received a not−approvable letter from the FDA with respect to our NDA. In August 2005, the FDA's Peripheral and Central Nervous System Drugs Advisory Committee ("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, one of the components of POZEN's product candidate MT 100, would outweigh the benefits, as defined by the FDA, of metoclopramide hydrochloride in combination with naproxen sodium. Based on the outcome of the FDA advisory committee, we have discontinued further development of our product candidate MT 100 in the United States and are reevaluating our European strategy for MT 100. 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, as well as a related supply agreement with Nycomed. We have begun to explore 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 be successful in consummating such a transaction, should we elect to do so.

We are continuing to seek marketing approval in the U.K. In October 2002, we submitted a Market Authorization Application ("MAA") for MT 100 to the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the UK. In September 2003, we received a letter of comments relating to our MAA from an MHRA advisory committee to which we subsequently responded. In January 2005, we were notified that the MHRA Advisory Committee was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided that we supply certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. In February 2005, we provided information to the MHRA advisory committee which we believe addresses all the conditions set forth by the MHRA advisory committee.

We are not currently conducting and do no 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 have incurred direct development costs associated with the development of MT 100, during the nine months ended September 30, 2005 and from inception to date, of $0.8 million and $39.7 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300. In December 2002, we submitted to the FDA an NDA for approval of MT 300. In October 2003, we received a not−approvable letter from the FDA with respect to our NDA for MT 300. Based upon our understandings from our most recent communications with the FDA, in which the FDA reaffirmed its previously stated 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, and our understanding of the FDA's current standards of 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 with Valeant NA regarding termination of our commercialization agreement. On July 21, 2005, POZEN received a letter from Valeant NA seeking payment of a $1 million withdrawal fee required if we withdraw the NDA for MT 300 for financial or commercial reasons under the conditions specified in the agreement with Valeant NA. 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 or to give assurance that Valeant NA will agree to termination terms acceptable to us.

We are not currently conducting any clinical trials for 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 future cash inflows from MT 300.

We have incurred direct development costs associated with the development of MT 300, during the nine months ended September 30, 2005 and from inception to date of $0.1 and $14.5 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of 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 commercialize and manufacture our product candidates. Our existing commercialization collaborations are described below.

GlaxoSmithKline

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 United States 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. 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. Additionally, GSK is obligated to make payments to us in an amount up to $40.0 million upon the achievement of specified development and regulatory milestones relating to an NDA and commercialization progress for the first product. In addition, GSK will pay us sales performance milestones of up to $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 POZEN 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.

Nycomed Danmark ApS

MT 100

In June 2003, we signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries. 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.

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. (& 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 POZEN's and each of its sublicensee's requirements, POZEN and each of its sublicensees (each, a buyer) must purchase all of their required commercial supply of active drug substance from Nycomed for a minimum of 5 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.

Valeant Pharmaceuticals North American (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. On July 21, 2005, POZEN 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.

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 historically discussed three critical accounting estimates: revenue recognition, accrued expenses 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 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.

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.

In the years ended December 31, 2004, 2003 and 2002, we recognized $1.4 million, $0.8 million and $0.6 million respectively, for 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 budgeted costs. The variance, at each of these ending periods, between the actual expenses incurred and the expenses accrued has been less than $125,000.

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, 2004, 2003, or 2002 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 September 30, 2005 compared to the three months ended September 30, 2004

Net income (loss) per share: Net loss attributable to common stockholders for the quarter ended September 30, 2005 was $(4.7) million or $(0.16) per share, as compared to a net loss of $5.8 million, or $0.20 per share, for the quarter ended September 30, 2004.

Revenue: We recognized $2.4 million of revenue for the quarter ended September 30, 2005 as compared to $1.9 million for the quarter ended September 30, 2004. Revenue for the period resulted from amortization of upfront payments and other payments we received pursuant to development and commercialization agreements relating to MT 100, MT 300 and Trexima. Revenue for the quarter ended September 30, 2005 increased by $0.3 million due to the acceleration of the amortization of licensing fees for Trexima as a result of the NDA submission and $0.2 million due to the recognition of upfront fees for MT 100 as a result of the termination of our licensing agreement with Nycomed Danmark ApS. 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 $9.8 million remains in deferred revenue at September 30, 2005. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses decreased by $1.0 million to $4.9 million for the third quarter of 2005, as compared to the same period of 2004. The decrease was due primarily to a decrease in direct development costs for Trexima offset by an increase in direct development costs for MT 100 and personnel related expenses as compared to the same period of 2004. Direct development costs for Trexima decreased by $1.9 million to $1.2 million, primarily due to Phase 3 clinical trial activities during the third quarter of 2004 as compared to the same period of 2005. Direct development costs for MT 100 increased by $0.3 million to $0.4 million primarily due to consulting costs incurred in preparation for the FDA's Peripheral and Central Nervous Systems Drugs Advisory Committee meeting held in August 2005. Research and development personnel costs increased $0.6 million to $1.4 million as compared to the same period of 2004 primarily due to a $0.2 million non−cash compensation expense for the January 2005 grants of Trexima stock options to employees and an increase in personnel. We have included in our research and development expenses the personnel costs associated with our research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by $0.4 million to $2.5 million for the third quarter of 2005, as compared to the same period of 2004. The increase was due primarily to a $0.3 million non−cash compensation expense for the January 2005 grants of Trexima stock options to employees and increases in the costs associated with our public company activities. Costs associated with our public company activities increased by $0.1 million to $0.8 million primarily due to increases in directors' and officers' insurance. 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 for the quarter ended September 30, 2005 and the quarter ended September 30, 2004 were $0.1 and $0.1 million, respectively. Investment income from bond amortization for the period ended September 30, 2005 totaled $0.2 million as compared to no investment income from bond amortization during the same period of 2004.

Nine months ended September 30, 2005 compared to the Nine months ended September 30, 2004

Net income (loss) per share: Net loss attributable to common stockholders for the nine months ended September 30, 2005 was $(14.1) million or $(0.49) per share, as compared to net income of $3.2 million, or $0.11 per share, for the nine months ended September 30, 2004.

Revenue: We recognized $6.4 million of revenue for the nine months ended September 30, 2005 as compared to $20.7 million for the nine month period ended September 30, 2004. Revenue for the period resulted from amortization of upfront payments and other payments we received pursuant to development and commercialization agreements relating to MT 100, MT 300 and Trexima. Revenue for the nine month period ended September 30, 2004 included a milestone payment of $15.0 million from GSK for commencement of Phase 3 clinical trial activities for Trexima. 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 $9.8 million remains in deferred revenue at September 30, 2005. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by $2.6 million to $14.5 million for the nine months ended September 30, 2005, as compared to the same period of 2004. The increase was due primarily to an increase in direct development costs for the PN exploratory development program and increases in personnel costs. Direct development costs for the PN exploratory program increased by $0.9 million to $2.5 million primarily due to product development activities during the nine months ended September 30, 2005, as compared to the same period of 2004. Research and development personnel costs increased $1.3 million to $3.6 million as compared to the same period of 2004, primarily due to a $0.3 million non−cash compensation expense for the January 2005 grants of Trexima stock options to employees and an increase in personnel. We have included in our research and development expenses the personnel costs associated with our research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by $1.1 million to $7.2 million for the nine months ended September 30, 2005, as compared to the same period of 2004. The increase was due primarily to a $0.4 million non−cash compensation expense for the January 2005 grants of Trexima stock options to employees and an increase in the cost associated with our public company activities. Costs associated with our public company activities increased by $0.6 million to $2.7 million, primarily due to increases in directors' and officers' insurance. 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 for the nine month periods ended September 30, 2005 and September 30, 2004 was $0.4 million and $0.3 million, respectively. Investment income from bond amortization for the period ended September 30, 2005 totaled $0.4 million as compared to no investment income from bond amortization during the same period of 2004.

Income Taxes

As of December 31, 2004, we had net operating loss carry−forwards of approximately $80.8 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, which expire between 2013 and 2024. We also have research and development tax credit carry−forwards of approximately $6.5 million for federal income tax reporting purposes that expire between 2012 and 2024. We currently estimate a cumulative net operating loss carry−forward of approximately $4.2 million for the twelve months ending December 31, 2005 and estimate an effective tax rate of 0% for the three and nine month periods ended September 30, 2005. Our effective tax rate was 0% for the three and nine month periods ended September 30, 2004. The estimated effective rate was based upon estimates of income 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.

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 $43.3 million. Our cash and cash equivalents are invested primarily in short−term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks.

During the first quarter of 2005, we moved $20 million into a managed investment account designed to increase the return on our cash. This account is managed within our Board approved investment policy, which restricts investments to less than 12 months, limits concentration to 5% or less and requires credit ratings of A1/P1, among other requirements. Because certain holdings in the managed account have maturities longer than 3 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.

No operating cash was received during the nine−month period ended September 30, 2005. We expect milestone payments from GSK over the next several years in an aggregate amount of up to $40.0 million upon the satisfaction of specified regulatory and commercialization events for Trexima. These milestone payments include a $20 million payment payable upon the FDA’s acceptance for review of the Trexima NDA. The FDA’s acceptance occurred, and we received this payment, in October 2005.

Based upon the direct method of presenting cash flow, cash paid for operating activities totaled $21.4 million for the nine−month period ended September 30, 2005. The indirect method for presenting cash flow is used in the Statement of Cash Flows. Cash paid for operating activities in the fiscal years ended December 31, 2004, 2003, and 2002 was $26.4, $17.8 million and $23.7 million, respectively. Net cash paid for investing activities during the period totaled $19.7 million, reflecting investing activities associated with the purchase of short−term securities. Cash required for our operating activities during 2005 is projected to be slightly higher than our 2004 requirements due to the expected cash required to complete Phase 3 clinical trial activities for Trexima and to continue development of our exploratory programs.

As of September 30, 2005, we had $11.5 million in cash and cash equivalents and $19.8 million in short−term investments. If our operating expenses for the remainder of 2005 and 2006 are at the level of our currently expected operating expenses in 2005, and if we do not receive any additional milestone payments under any of our collaboration agreements during 2005 and 2006, including in particular $20.0 million in remaining milestone payments payable by GSK related to the Trexima NDA and the commercialization of Trexima, we will not have sufficient cash reserves to maintain our level of business activities throughout 2007. Further, our expenses might increase in 2006 and 2007 if any regulatory agency requires us to conduct additional clinical trials, studies or investigations in connection with their consideration, or reconsideration of our regulatory filings for our product candidates. We are not currently obligated to make any milestone payments to third parties and do not currently have any other required material payment obligations during that period. However, regulatory delays or unforeseen developments in the development of our existing and future product candidates may increase our cash requirements beyond our currently assumed needs. 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. If any of the foregoing occurs, we may seek to raise additional funds. Sources of such funds may not be available on terms favorable to us. 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, including to fund additional unplanned development activities. In February 2004, we filed with the Securities and Exchange Commission (SEC) 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. Such registration statement has not yet been declared effective. 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

sales of those shares made by the selling stockholders. The shares of our common stock covered by the registration statement can not be sold until the registration statement is declared effective by the SEC. 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 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 class action and shareholder derivative lawsuits that have been filed against us or our current or former directors and officers relating to MT 100 and MT 300.

Factors That May Affect Our Results

Our business is subject to certain risks and uncertainties, each of which could materially adversely affect our business, financial condition, cash flows and results of operations.

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. 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 also 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 Advisory Committee determined, following our receipt of a not approvable letter from the FDA in 2004, 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.

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 losses in each year since our inception. As of June 30, 2005, we had an accumulated deficit of approximately $124.0 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 agreement with GSK for Trexima. 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 regulations 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 United States or any foreign market and they may never be approved.

In the United States, 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 outside the United States. For example, as described in the risk factor that follows, we are currently seeking to resolve issues raised by the MHRA related to our MAA for MT 100 in the UK.

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 current 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 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 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.

If we are unable to address satisfactorily the comments we received on our Marketing Authorization Application (MAA) for MT 100 in the UK and do not receive marketing approval of MT 100 in the UK, it would not be possible to market MT 100 in the UK or to use the mutual recognition procedure in the European Union. Further, our ability to sell MT 100 to a third party may be adversely affected.

In September 2003, we received a letter of comments relating to the MAA we submitted for MT 100 from an MHRA Advisory Committee. The most significant comment in the MHRA Advisory Committee's letter of comments was that we provide additional data to support the benefits of the combination of metoclopramide hydrochloride and naproxen sodium in MT 100. We provided additional data and supplemental information to the MHRA Advisory Committee in 2004 to address the MHRA Advisory Committee's questions and, in January 2005, the MHRA Advisory Committee advised us in a letter that it was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided we supply certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. These conditions and the additional information requested generally relate to minor modifications to the Summary of Product Characteristics and to the patient leaflet and labeling information, and an update of certain areas of the pharmaceutical data. The MHRA is not bound by the MHRA Advisory Committee's comments, and, although we believe we have addressed the requests of the MHRA Advisory Committee as set forth in its letter to us, we can give no assurance that the MHRA Advisory Committee will accept the supplemental information we supplied or that the MHRA will follow the MHRA Advisory Committee's recommendations. Without approval of our MAA in the UK by the MHRA, MT 100 could not be marketed in the UK. Further, it would not be possible to use the mutual recognition process to obtain approval of MT 100 in other European Union countries without first obtaining approval in another country in the European Union, which would result in increased expenses and time delays. As a part of our reevaluation of our European strategy for MT 100 following our decision to discontinue further development of MT 100 in the United States, we have begun to explore the possibility of selling or otherwise disposing of the MT 100 asset to a third party. Our inability to obtain market approval of MT 100 in the UK may adversely affect our ability to consummate such a transaction, or the value we may be able to realize in such a transaction should it be consummated. There can be no assurance that we will be successful in consummating such a transaction should we elect to do so.

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 US.

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. Collaborative agreements for the acquisition of new compounds or product candidates may 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 United States and a collaboration with Valeant NA in the United States for the development and commercialization of MT 300. In these collaboration agreements, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK is entitled to terminate its agreement upon 90 days' notice for any reason. Additionally, GSK may reduce the royalties on net sales of products payable to us under the agreement if generic competitors attain a pre−determined share of the market for products marketed under the agreement, or if GSK owes a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreement. Valeant NA is entitled to terminate its agreement with us and a $1.0 million withdrawal fee payable by us if we choose to withdraw the NDA for MT 300 for commercial or financial reasons under the conditions specified in the agreement. 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 and Valeant NA has demanded payment of the $1.0 million withdrawal fee.

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 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 determines, 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 would delay or eliminate our potential product revenues.

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. 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. 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 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 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 our clinical trials are not necessarily predictive of results we will obtain in subsequent clinical trials. 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 trial of Trexima differed from the results of our second Phase 3 clinical trial and 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 planned clinical trials for a product candidate and submitted an NDA for such product candidate, the FDA may require us to conduct additional clinical trials, studies or investigations to support our NDAs. We may also determine from time to time that it would be necessary to seek to persuade the FDA to evaluate the results of a study or trial in a manner that differs from the way the FDA initially evaluated the results, or customarily evaluates results. In addition, we may have unexpected results that require us to reconsider the need for certain studies or trials. 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, 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 United States. For example, no assurance can be given that the MHRA will follow the MHRA Advisory Committee's recommendation, of which we received notice in January 2005, that marketing authorization be granted in the UK for MT 100, subject to our providing additional information and addressing certain matters set forth in our notice from the MHRA Advisory Committee, or that we will be able to satisfactorily answer and/or address such matters.

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. Our primary competitors will likely include large

pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., Astra Zeneca, Johnson & Johnson and Pfizer, Inc.), biotechnology companies, universities and public and private research institutions. Based upon their migraine 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 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 not−approvable letters we have 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 or shareholder derivative 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. On January 27, 2005, we moved to dismiss the amended complaint. On August 30, 2005, our motion to dismiss the complaint was denied.

In September 2004, two derivative actions were filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina. These actions allege violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning the same product candidates MT 100 and MT 300 that are referenced in the various purported class action lawsuits. The cases have been consolidated and assigned to the North Carolina Business Court. The plaintiffs in the derivative actions have filed a consolidated amended complaint asserting the same claims as were asserted in the original complaints. On May 31, 2005, we filed a motion to dismiss the consolidated and amended complaint. On August 9, 2005, oral arguments were made before the North Carolina Business Court. The Court has not yet ruled on the motion to dismiss.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of these pending lawsuits. Furthermore, we will have to incur expenses in connection with these lawsuits, 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.

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. 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. 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 United States, 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. 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.

In addition, collaborative arrangements may require us to grant product development programs or licenses to third parties for products that we might otherwise seek to develop or commercialize ourselves which may increase our capital requirements.

For fiscal years 2002 through 2004, our average annual operating expenses (including average non−cash deferred compensation of $2.2 million) were $24.6 million. We are currently expecting operating expenses for the 2005 fiscal year to be between $28.0 million and $30.0 million, excluding any non−cash compensation expense that would result from the award of stock options upon the adoption of SFAS 123(R). As of September 30, 2005, we had $31.3 million in cash and cash equivalents and short−term investments. If our operating expenses in 2005 and 2006 are at the level of our currently expected operating expenses for 2005 and if we do not receive any additional milestone payments under any of our collaboration agreements, in particular $20.0 million in remaining milestone payments payable by GSK related to the Trexima NDA and the commercialization of Trexima, we will not have sufficient cash reserves to maintain our level of business activities throughout 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 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.

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 employment agreement with us on April 1, 1999, as amended and restated on July 25, 2001, for a three−year term with automatic one−year renewal terms. We 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, Kristina M. Adomonis, Senior Vice President, Business Development, or Dr. W. James Alexander, Senior Vice President, Product 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 September 15, 2005, 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 standing 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. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We have filed with the Securities and Exchange Commission, and are seeking effectiveness of, 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. These shares will not be registered until the registration statement is declared effective by the Securities and Exchange Commission. 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 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 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.

On September 13, 2004, two derivative actions were also filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina, alleging violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning our product candidates, MT 100 and MT 300, that are referenced in the various purported class action lawsuits. The two cases have been consolidated and assigned to the North Carolina Business Court.

The plaintiffs in the derivative actions have filed a consolidated amended complaint asserting the same claims as were asserted in the original complaints. On May 31, 2005, we filed a motion to dismiss the consolidated amended complaint. Oral arguments were made to the North Carolina Business Court on August 9, 2005. The Court has not yet ruled on the motion to dismiss.

We and the other defendants believe that the allegations in these actions are without merit and intend to defend these cases 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 6. Exhibits

Exhibit Number	Description
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.

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)

November 9, 2005 By: /s/ JOHN R. PLACHETKA

John R. Plachetka
President and Chief Executive Officer

November 9, 2005 By: /s/ WILLIAM L. HODGES

William L. Hodges
Chief Financial Officer

November 9, 2005 By: /s/ JOHN E. BARNHARDT

John E. Barnhardt
Principal Accounting Officer

EXHIBIT INDEX

Exhibit Number	Description
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.

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: November 9, 2005

/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: November 9, 2005

/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: November 9, 2005

/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.

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: November 9, 2005

/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.