FORM 10−Q

POZEN INC /NC − POZN

Filed: April 29, 2005 (period: March 31, 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 March 31, 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

The number of shares outstanding of the registrant's common stock as of April 20, 2005 was 28,915,511.

POZEN Inc.

(A Development Stage Company)

FORM 10−Q

For the Three Months Ended March 31, 2005

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.

(A Development Stage Company)

BALANCE SHEETS

(Unaudited)

	March 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,448,405	$ 51,764,129
Short−term investments	18,650,411	—
Prepaid expenses and other current assets	805,182	1,064,032
Total current assets	43,903,998	52,828,161
Equipment, net of accumulated depreciation	454,748	467,688
Total assets	$ 44,358,746	$ 53,295,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 812,845	$ 2,330,349
Accrued compensation	832,379	1,182,848
Accrued expenses	2,022,376	1,626,829
Deferred revenue	8,754,580	8,680,092
Total current liabilities	12,422,180	13,820,118
Long−term liabilities:		
Deferred revenue	5,638,000	7,764,978
Total liabilities	18,060,180	21,585,096
Common stock, $0.001 par value, 90,000,000 shares authorized; 28,915,511 and 28,852,743 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	28,916	28,853
Additional paid−in capital	146,161,596	146,161,655
Accumulated other comprehensive loss	(11,983)	—
Deficit accumulated during the development stage	(119,879,963)	(114,479,755)
Total stockholders' equity	26,298,566	31,710,753
Total liabilities and stockholders' equity	$ 44,358,746	$ 53,295,849

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,		Period From Inception (September 26,1996) Through March 31,
	2005	2004	2005
Revenue:	$ 2,052,490	$ 1,889,500	$ 28,857,398
Operating expenses:			
General and administrative	2,396,586	1,998,049	43,284,286
Research and development	5,327,785	2,371,967	112,567,762
Total operating expenses	7,724,371	4,370,016	155,852,048
Other income:			
Interest and other income	271,673	126,150	8,049,165
Net loss:	(5,400,208)	(2,354,366)	(118,945,485)
Non−cash preferred stock charge	—	—	27,617,105
Preferred stock dividends	—	—	934,478
Net loss attributable to common stockholders	$ (5,400,208)	$ (2,354,366)	$ (147,497,068)
Basic and diluted net loss per common share	$ (0.19)	$ (0.08)	
Shares used in computing basic and diluted net loss per common share	28,912,721	28,555,654	

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,		Period from Inception (September 26, 1996) Through March 31,
	2005	2004	2005
Operating activities:			
Net loss	$ (5,400,208)	$(2,354,366)	$ (118,945,485)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	44,995	25,643	733,453
Loss on disposal of equipment	—	—	33,567
Bond amortization	(86,511)		(86,511)
Noncash compensation expense	100,098	—	11,375,767
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	258,850	34,058	(805,182)
Accounts payable and accrued expenses	(1,572,524)	(328,441)	3,167,114
Deferred revenue	(2,052,490)	(1,889,500)	14,392,580
Net cash used in operating activities	(8,707,790)	(4,512,606)	(89,684,697)
Investment activities:			
Purchase of equipment	(32,055)	(2,051)	(1,221,768)
Purchase of investments	(18,575,883)	—	(18,575,883)
Net cash used in investing activities	(18,607,938)	(2,051)	(19,797,651)
Financing activities:			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	4	608,340	81,436,888
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	4	608,340	133,930,753
Net increase (decrease) in cash and cash equivalents	(27,315,724)	(3,906,317)	24,448,405
Cash and cash equivalents at beginning of period	51,764,129	60,480,690	—
Cash and cash equivalents at end of period	$ 24,448,405	$56,574,373	$ 24,448,405
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 three product candidates in the migraine area, MT 400, MT 100 and MT 300. We are also exploring the development of product candidates in other acute and chronic pain and pain−related therapeutic areas. We have not obtained regulatory approval for 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 are 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.

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. For those arrangements where royalties are not reasonably estimable, the Company will recognize revenue upon receipt of a statement from the licensee that a royalty is payable.

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.

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 $11,983 of unrealized losses on its investments that are classified as accumulated other comprehensive loss at March 31, 2005.

Comprehensive income consists of the following components for the three months ended March 31, 2005 and 2004:

	Three Months Ended March 31,	
	2005	2004
Net loss	$(5,400,208)	$(2,354,366)
Unrealized (loss) on marketable securities	(11,983)	—
Total comprehensive loss	$(5,412,191)	$(2,354,366)

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," which 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.

In connection with the grant of stock awards to employees, consisting of stock options to employees and a restricted stock unit award made in May 2004 to our Chief Executive Officer, the Company recorded $100,000 of restricted stock compensation expense for the three month period ended March 31, 2005 and no amortized deferred compensation in the three month periods ended March 31, 2004 and 2005. Vesting periods of the options are generally three or four years, and the restricted stock unit award vests in equal amounts on January 1, 2005, January 1, 2006 and January 1, 2007.

On January 3, 2005, pursuant to an incentive program approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 506,772 shares of common stock. 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 U.S. Food and Drug Administration ("FDA") indicating approval of the New Drug Application ("NDA") for the product candidate Trexima™ which is being developed pursuant to the Company's collaboration agreement with GlaxoSmithKline; 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 January 3, 2005 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 exercised price of the options. Regarding the January 3, 2005 stock option grant, for the three months ended March 31, 2005, the Company recorded no variable stock−based compensation expense in its statements of operations because its common stock price on March 31, 2005 was below the options' grant price of $7.06. Because the determination of variable stock−based compensation expense associated with the January 3, 2005 stock option grant 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.

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 March 31,		Year Ended December 31,
	2005	2004	2004
Net loss attributable to common stockholders as reported	$(5,400,208)	$(2,354,366)	$(5,260,472)
Add: Stock−based employee compensation expense reflected in reported net loss, net of related tax effects	100,098	—	400,388
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(1,375,407)	(780,434)	(4,306,553)
Pro forma net loss attributable to common stockholders	$(6,675,517)	$(3,134,800)	$(9,166,637)
Earnings per share			
Net loss per common share as reported−basic and diluted	$ (0.19)	$ (0.08)	$ (0.18)
Net loss per common share pro forma−basic and diluted	$ (0.23)	$ (0.11)	$ (0.32)
Weighted−average shares used in computing basic and diluted net loss per common share	28,912,721	28,555,654	28,748,540

Net Loss Per Share—Basic and diluted net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted−average number of shares of common stock outstanding for the three months ended March 31, 2004 and 2005. During the three months ended March 31, 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 these periods because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share are the same for the three months ended March 31, 2004 and 2005.

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 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. Each Right, when exercisable, will entitle the registered holder to purchase from the Company one one−thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00, subject to adjustment. The Rights Plan is similar to plans adopted by many other publicly−traded companies.

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 FASB123. 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 FASB123 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 FASB123 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 FASB123, 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 income and earnings 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 filed as a single consolidated class action complaint on December 20, 2004. The consolidated 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 a current 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 consolidated class action complaint. All briefing on the motion to dismiss has been completed and we are awaiting the Court's ruling on the motion.

On September 13, 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 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.

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 or financial condition.

Additionally, under commercialization collaborations related to MT 100 and MT 300, the Company has received upfront payments, a portion of which the Company would be required to return if certain conditions are met. Under the MT 100 collaboration, if marketing approvals in certain European countries are not granted, the Company could be required to pay a withdrawal fee in amounts that range from $0.1 million to $0.4 million. Under the MT 300 collaboration, if certain conditions are met, the Company could be required to pay a withdrawal fee $1.0 million. As a result of the related contingencies, $1.4 million in aggregate has not been recognized as revenue and will not be recognized as revenue until the conditions in the agreement have been satisfied.

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

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. Our portfolio currently contains three product candidates in the migraine area, MT 400, MT 100 and MT 300. We are also exploring the development of product candidates in other acute and chronic pain and pain−related therapeutic areas. We have not obtained regulatory approval for 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.

Our portfolio currently contains three product candidates in the migraine area, MT 400, MT 100 and MT 300. We are also exploring the development of product candidates in other acute and chronic pain and pain−related therapeutic areas. We have not obtained regulatory approval for any of our product candidates.

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 GlaxoSmithKline ("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 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 met with the FDA in April 2005 to discuss the results of our two Phase 3 pivotal trials and other information required for the submission of the Trexima NDA. Based upon discussions at the pre−NDA meeting, we believe that no additional pre−clinical or clinical trials are necessary for submission. The Trexima NDA submission is currently planned for the third quarter of 2005.

For MT 100 and MT 300, our current focus is primarily on the regulatory process. MT 100 is a combination of metoclopramide hydrochloride and naproxen sodium. MT 300 is a proprietary formulation of injectable dihydroergotamine mesylate ("DHE") in a pre−filled syringe. In October 2003, we received a not−approvable letter from the FDA related to our NDA for MT 300, which was submitted in December 2002. We are continuing communications with the FDA to assess how best to move forward with MT 300. In May 2004, we received a not−approvable letter from the FDA with respect to our NDA for MT 100. We are continuing communications with the FDA to seek to persuade the FDA that the NDA for MT 100 should be approved. We are also seeking regulatory approval of MT 100 in the United Kingdom ("UK").

We currently have two exploratory programs in pain−related therapeutic areas. We have begun exploratory development work and clinical studies to investigate the development of novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. This exploratory work is being conducted under an exclusive option agreement with Nycomed Danmark ApS ("Nycomed") pursuant to which we may acquire a license to certain rights related to lornoxicam. If we elect to exercise our option to license lornoxicam, which expires in July 2005, we will be required to pay Nycomed a $0.5 million licensing fee, regulatory approval milestones and royalties on sales of any products developed using the licensed rights. In our other exploratory program, we are seeking to identify potential product candidates that combine a proton pump inhibitor ("PPI") with an NSAID. We have begun exploratory formulation development and clinical studies for a combination of a 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 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 entered into three collaboration agreements – with Nycomed for the commercialization of MT 100 in four Nordic countries, GSK for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long−acting NSAID in the U.S. and Valeant Pharmaceuticals North America ("Valeant NA"), a subsidiary of Valeant Pharmaceuticals International (formerly Xcel Pharmaceuticals Inc.) for the further development and commercialization of MT 300 in the U.S. We plan to seek additional partnering opportunities to commercialize our product candidates.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of March 31, 2005, our accumulated deficit was $119.9 million. Our historical operating losses have resulted principally from our research and development activities, including Phase 3 clinical trial activities for our product candidates MT 100 and MT 300, Phase 2 clinical trial activities for our MT 400 technology, 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 three−month period ended March 31, 2005, our research and development expenses represented approximately 69% 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;
- our progress in reversing the FDA's not−approvable decisions with respect to MT 100 and MT 300;
- the establishment of new collaborations and progress 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 under "PART II. Item 1. Legal Proceedings" herein.

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 Trexima, MT 100, MT 300, and our other 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 three month period ended March 31, 2005 were $1.1 million. Other research and development department costs for the three month period ended March 31, 2005 were $0.1 million.

MT 400/Trexima.. As part of our Phase 3 program for Trexima, we have planned 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 addition, we are conducting a long−term, open label safety study. Along with these program trials, GSK is funding and currently conducting two Phase 3b/4 studies.

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. Based upon discussions at the pre−NDA meeting, we believe that no additional pre−clinical or clinical trials are necessary for submission. The Trexima NDA submission is currently planned for the third quarter of 2005.

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 three months ended March 31, 2005 and from inception to date of $3.0 million and $22.0 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 100. In July 2003, we submitted an NDA to the FDA for MT 100. In May 2004, we received a not−approvable letter from the FDA with respect to our NDA. Since the issuance of the not−approvable letter, we have had continuing communications with the staff of the FDA to seek to persuade the FDA that MT 100 should be approved based upon the data that we submitted in the NDA for MT 100. We and the FDA have agreed to present MT 100 data, with particular emphasis on the potential risk of tardive dyskinesia, to an FDA advisory committee. The FDA has advised us that the meeting with the advisory committee has been postponed due to FDA scheduling conflicts. We have been informed by the FDA that the rescheduled meeting date will be available, in advance, when published in the Federal Register.

It is possible that we may be required to conduct another clinical study and/or conduct investigations to provide additional evidence to support the approval of MT 100. We cannot estimate the cost or duration of any such study or investigation or decide whether to conduct such a study or investigation until the results of the meeting with the FDA advisory committee are known and the design of any such study or studies has been determined with the FDA. Our Phase 3 clinical trials for MT 100 took between three months and eighteen months and involved a direct cost per patient of between $2,200 and $3,200. The duration and cost of any new study that we may conduct may be different from our prior clinical trials. No assurance can be given that our efforts to obtain approval of MT 100 will ultimately be successful.

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 the 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 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 any clinical trials for MT 100. However, we are continuing to incur pharmaceutical development costs for product stability testing and costs relating to our continuing efforts to obtain approval of MT 100 from the FDA and in the UK. Additionally, we may incur costs for the commercialization of this product if our applications are approved by the FDA and in the UK. Until the not−approvable letter is definitively resolved with the FDA and we receive final approval of the MAA from the MHRA, we cannot reasonably estimate the amount and timing of additional costs that we may need to incur to satisfy comments or conditions on our applications for approval or when, if and to what extent we will receive cash inflows from MT 100. The additional costs that we may incur include expenses related to clinical trials, formulation, manufacturing and labeling of our product and regulatory consulting expenses required to address the FDA's and MHRA's responses to our applications.

We have incurred direct development costs associated with the development of MT 100, during the three months ended March 31, 2005 and from inception to date, of $0.3 million and $39.1 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. Subsequently, we submitted additional responses to the not−approvable letter and requested a Type A meeting with the FDA's Division of Neuropharmacological Drug Products to present our position in response to the issues identified by the FDA. The Type A meeting was held in December 2004 and a subsequent teleconference with the FDA occurred in January 2005 during 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. Once we receive and review the FDA's meeting minutes, we will evaluate what future steps are available to us regarding MT 300.

Subsequent to receipt of the not−approvable−letter, at our request, a law firm submitted a petition requesting permission to file an Abbreviated New Drug Application ("ANDA") for DHE in a different concentration than that of the marketed DHE product. In April 2005, the FDA denied the petition.

We are not currently conducting any clinical trials for MT 300. However, we are continuing to incur pharmaceutical development costs for product stability testing and costs relating to our continuing efforts to seek approval of MT 300 and may conduct additional Phase 3b marketing studies if our application is approved by the FDA. Until we complete our discussions with the FDA concerning the not−approvable letter and review the minutes from our recent meeting with the FDA, we cannot reasonably estimate the amount and timing of additional costs that we may need to incur with respect to MT 300 or when, if and to what extent we will receive cash inflows from MT 300. The additional costs that we may incur include expenses relating to clinical trials, formulation, manufacturing and labeling of our product and regulatory consulting expenses required to address the FDA's response to our application.

We have incurred direct development costs associated with the development of MT 300, during the three months ended March 31, 2005 and from inception to date of $37,000 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.

PN (PPI / NSAID) Program. Our exploratory development program is intended to identify potential product candidates that combine a 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 suite of potential products. In March 2005, we received a Notice of Allowance on a patent application covering combinations of acid inhibitors and NSAIDs. Our PN suite of product candidates are among the compositions covered by this patent application.

In late 2004, we requested a pre−IND meeting with the FDA to discuss our exploratory proprietary tablet formulations containing an 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 reached agreement on our proposal for studies to demonstrate efficacy of a PPI/NSAID combination. A confirmation of the safety requirements necessary to support an NDA,

particularly in regard to the cardiovascular safety of an NSAID component, was tabled pending the outcome of an FDA advisory committee meeting held in February 2005 addressing the potential cardiovascular risk of COX−2 selective NSAIDs and related drugs. We plan to request the FDA's expectations and recommendations regarding the safety requirements necessary to support an NDA.

We have incurred direct development costs associated with the development of our PN program, for the three month period ended March 31, 2005 and from inception to date, of $0.4 million and $4.6 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. In July 2003, we signed an exclusive option agreement with Nycomed, under which we may acquire a license to certain rights related to lornoxicam, an NSAID that is currently marketed outside the United States (including Europe and Japan).The exclusive option terminates in July 2005. We are exploring whether to develop novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications.

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 committed to provide additional analyses and information requested by the FDA following that meeting which would permit conduct of additional clinical trials with lornoxicam in the United States. We will continue to discuss with the FDA the clinical and non−clinical study requirements anticipated for approval of 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 three month period ended March 31, 2005 and from inception to date, of $0.5 million and $3.0 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Collaborative Arrangements

We have entered into and plan to continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to 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 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 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

In June 2003, we signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries. Under the terms of the agreement, Nycomed will have exclusive rights in Denmark, Sweden, Norway and Finland to commercialize MT 100 upon its approval in these countries. Upon execution of the agreement, Nycomed paid us an upfront fee of $0.5 million. We are eligible to receive milestone payments in an aggregate amount of between $0.5 million and $1.0 million upon the occurrence and timing of certain regulatory approvals, including the approval of the MAA in the UK and in the countries where Nycomed has exclusive rights. In addition, Nycomed is obligated to pay us a specified royalty on all sales of MT 100, based upon the higher of an agreed percentage of sales on a country−by−country basis, subject to reduction in the event of generic competition, or an agreed dollar amount per unit sold subject to reduction under certain conditions, until the latter of the expiration of the last to expire issued applicable patent in the particular country or 15 years from first commercial sale. The scheduled expiration date of the patent that is currently applicable in Sweden, Finland and Denmark is November 12, 2016. There is no applicable patent in Norway. The license agreement will expire on a country−by−country basis upon the later of (a) the date of expiration of all royalty obligations in a particular country, which is scheduled for November 12, 2016 in Sweden, Finland and Denmark, and (b) 15 years after the date of first commercial sale of MT 100 in such country under the agreement. Nycomed has the right to terminate the agreement if we default under the agreement or the MAA is not approved by a specified date or is withdrawn. Nycomed can terminate the applicability of the agreement to a particular country if we withdraw the required regulatory application in that country. If we withdraw a regulatory application in any of the countries identified in the agreement, we will be required to pay a withdrawal fee in amounts that range from $0.1 million to $0.4 million. Assuming the issues raised in the September 2003 MAA comment letter discussed above are satisfactorily resolved and we receive unconditional approval of the MAA from the MHRA, we intend to seek approval of MT 100 in Denmark, Sweden, Norway and Finland through the European Union Mutual Recognition Procedure.

Under the agreement, generally, each party must indemnify the other for damages arising from each party's breach of its representations, warranties and obligations under the agreement. Additionally, Nycomed must indemnify us for any claim brought by a third party arising from Nycomed's development, manufacture or sale of any products, and we must indemnify Nycomed for any claim brought by a third party arising from our development, transportation or manufacture of any products. Furthermore, both parties have a duty to maintain commercially reasonable insurance coverage commensurate with its obligations under the agreement.

At the same time as we entered into the license agreement with Nycomed, we entered into a supply agreement with Nycomed under which Nycomed is obligated to purchase from us, and we are obligated to sell to Nycomed, the MT 100 that Nycomed sells in the countries specified in the agreement, and Nycomed is required to reimburse us for certain costs related to the manufacturing of MT 100. The agreement will expire upon an anniversary date of the first commercial sale of MT 100 following final approval by the FDA of the NDA for MT 100. Either party may terminate the agreement in the event of a material breach or default by the other party of the material terms and conditions of the agreement. Among the material breaches that would entitle Nycomed to terminate the agreement would be our failure to deliver products to Nycomed at a time when Nycomed has established an alternative source of the product.

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 February 2005, Valeant Pharmaceuticals International ("Valeant International") reported that it had entered into a definitive agreement to acquire Valeant NA and on March 1, 2005 reported that the acquisition had been completed. Under the terms of the agreement, Valeant NA will 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. If we determine that additional studies or data that may be 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 this occurs and Valeant NA does not assume control of efforts to seek approval of the NDA, under the conditions outlined in the agreement, then upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a termination fee of $1.0 million. Until such time as we fully understand the FDA's position regarding additional studies or data necessary for approval of the NDA for MT 300, we cannot determine whether we would undertake such expenses. Potential milestone payments of up to $8.0 million will be due 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. Valeant NA is also obligated to pay us royalties on all combined 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

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. Based upon the delayed commercialization of MT 300 due to 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 have mutually agreed, in writing, 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. The parties have previously extended certain time specific provisions of the agreement as a result of the delay in the approval of the NDA for MT 300. Pending the outcome of discussions with the FDA, the parties may need to revisit these time specific provisions in the agreement in the second quarter of 2005. Since the acquisition of Valeant NA, we have had communications with the new owners relating to how best to proceed with the collaboration and our continuing efforts to seek approval of the NDA for MT 300. We can give no assurance that Valeant NA or Valeant International will elect to continue the collaboration with us or that the collaboration will otherwise be successful.

Results of Operations

Three months ended March 31, 2005 compared to the three months ended March 31, 2004

Net income (loss) per share: Net loss attributable to common stockholders for the quarter ended March 31, 2005 was $(5.4) million or $(0.19) per share, as compared to a net loss of $(2.4) million, or $(0.08) per share, for the quarter ended March 31, 2004.

Revenue: We recognized $2.1 million of revenue for the quarter ended March 31, 2005 as compared to $1.9 million for the quarter ended March 31, 2004. Revenue 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. Our licensing 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. Approximately $14.4 million remains in deferred revenue at March 31, 2005. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by $2.9 million to $5.3 million for the first quarter of 2005, as compared to the same period of 2004. The increase was due primarily to an increase in direct development costs for Trexima and increases in personnel costs. Direct development costs for Trexima increased by $2.5 million to $3.0 million, primarily due to Phase 3 clinical trial activities during the first quarter of 2005. Research and development personnel costs increased $0.3 million to $1.1 million as compared to the same period of 2004 primarily due to an in 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 $2.4 million for the first quarter of 2005, as compared to the same period of 2004. The increase was due primarily to an increase in the costs associated with our public company activities. Costs associated with our public company activities increased by $0.3 million to $0.9 million primarily due to legal fees associated with the class action and shareholder derivative litigation pending against us and 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 March 31, 2005 and the quarter ended March 31, 2004 was $0.2 million. Investment income from bond amortization for the period ended March 31, 2005 totaled $0.1 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 $80.1 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 $7.2 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 $5.5 million for the twelve months ending December 31, 2005 and estimate an effective tax rate of 0% for the three months ended March 31, 2005. Our effective tax rate was 0% for the three months ended March 31, 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 of $133.9 million, and since 2003, from upfront and milestone payments from our collaborators, resulting in cash 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.

No operating cash was received during the three−month period ended March 31, 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 filing of the Trexima NDA. The Trexima NDA submission is currently planned for the third quarter of 2005.

During the first quarter of 2005, we moved $20 million into a managed investment account 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 the 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 as comprehensive income or loss.

Based upon the direct method of presenting cash flow, cash paid for operating activities totaled $8.9 million for the three−month period ended March 31, 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. Cash paid for investing activities during the period totaled $20.0 million, reflecting investing activities associated with the purchase of short−term securities. Cash required for our operating activities during 2005 is projected to approximate 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 March 31, 2005, we had $24.4 million in cash and cash equivalents and $18.7 million in short−term cash investments. If our operating expenses in 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, in particular the $20 million milestone payment payable upon the FDA's acceptance for filing of the Trexima NDA, we will not have sufficient cash reserves to maintain our level of business activities throughout 2006. Further, our expenses might increase in 2005 and 2006 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 MT 100, MT 300 and Trexima. 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, our efforts to reverse the FDA's not−approvable letters on MT 100 and MT 300 and other 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, if we elect to withdraw the NDA for MT 300, under certain circumstances, we may be required to pay Valeant NA a termination fee of $1.0 million. 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 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. 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 may 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, particularly MT 100 and Trexima. In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

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

We have incurred losses in each year since our inception. As of March 31, 2005, we had an accumulated deficit of approximately $119.9 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing of payments that we may receive from others. We expect to continue to incur significant operating losses and do not know when, if and to what extent we will generate product revenue.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with Nycomed for MT 100, GSK for Trexima and Valeant NA for MT 300. We may never receive milestone payments from Nycomed or Valeant NA under these agreements. In addition, we will have to pay Nycomed a withdrawal fee in amounts that range from $0.1 million to $0.4 million if we withdraw a required regulatory application for MT 100 in a country specified in the agreement with Nycomed, and we will have to repay Valeant NA $1.0 million if, under certain circumstances, we elect to withdraw the NDA for MT 300. Further, in February 2005, Valeant International reported that it had entered into a definitive agreement to acquire Valeant NA and on March 1, 2005 reported that the acquisition had been completed. We can give no assurance that Valeant NA or Valeant International will elect to continue the collaboration with us on MT 300.

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 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 (the "Advisory") based, in part, upon the recommendation 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 gastro−intestinal events associated with the use of NSAIDs. We do not know if the FDA's actions will adversely affect the approvability of our product candidates which include NSAIDs.

If we, or our 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 and may also be required to pay termination payments under certain of our collaboration 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 factors that follow, we are currently seeking to resolve issues raised by the FDA related to our MT 100 and MT 300 NDAs and by the MHRA related to our MAA for MT 100 in the UK.

Further, our agreements may require us to make certain payments to our collaborators based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. For example, under certain circumstances, we may elect to withdraw the NDA for MT 300. In that case, if we elect to withdraw the NDA for MT 300 for commercial or financial reasons, and the agreement terminates, under the conditions specified in our agreement with Valeant NA, we would be required to pay to Valeant NA a termination fee of $1.0 million. Similarly, under our agreement with Nycomed, we will be required to pay a withdrawal fee, in amounts that range from $0.1 million to $0.4 million, if we withdraw a regulatory application in any of the countries identified in the agreement. In addition, we would forfeit the ability to receive potential aggregate milestone payments of up to $8.0 million under the Valeant NA agreement and of between $0.5 million and $1.0 million under the Nycomed agreement, as well as royalties under either agreement.

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 convince the FDA to reverse its conclusion in its not−approvable letter for MT 100, we will not receive any revenue from sales of MT 100 in the United States.

On May 28, 2004, we received a not−approvable letter from the FDA with respect to our NDA for MT 100. In the letter, the FDA noted that, although we had demonstrated unambiguous statistically significant superiority compared to an appropriate control on a valid measure of pain as well as on the three associated symptoms of nausea, photophobia and phonophobia in one study, MT 100 did not clearly meet these criteria in a second study. The FDA letter cited the apparent lack of superiority of MT 100 over naproxen for sustained pain relief, which was the primary endpoint for the two component studies. The FDA also stated in its letter that, based on

animal studies, there may be a potential risk of carcinogenicity, presumably due to metoclopramide, one of the components of MT 100. Finally, the FDA raised an approvability issue concerning the risk of tardive dyskinesia ("TD") presented by the use of metoclopramide.

Since the issuance of the FDA's not−approvable letter, we have had continuing communications with the FDA to seek to persuade the FDA that MT 100 should be approved based upon the data that we submitted in the NDA for MT 100**.** The FDA and we have agreed to present MT 100 data to an FDA advisory committee. The date for this meeting has not yet been scheduled. We cannot predict the outcome of the meeting with the FDA's advisory committee or whether the FDA will follow the advisory committee's recommendations.

Further, it is possible that we may be required to conduct another clinical study to provide additional evidence that MT 100 meets the requirements of the combination rule and the efficacy standards applicable to MT 100. The FDA may also require that we conduct investigations to evaluate any potential risk of TD with the use of MT 100. We cannot estimate the cost or duration of any such studies or investigations or decide whether to conduct such studies or undertake such investigations until the results of the meeting with the FDA's advisory committee are known and the design of any such studies and the parameters of such investigations have been determined with the FDA. Our Phase 3 clinical trials of MT 100 took between three months and eighteen months and involved a direct cost per patient of between $2,200 and $3,200. However, the duration and cost of any new study that we may conduct may be different from our prior clinical trials. No assurance can be given that our efforts to obtain FDA approval of MT 100 will ultimately be successful.

Without approval of our NDA for MT 100 by the FDA, we would not be able to market MT 100 in the United States. Even if the FDA were to approve the NDA for MT 100, the delay in obtaining such approval may adversely affect our ability to market and sell MT 100 in the United States. Further, as an additional condition of any approval, the FDA could request or require additional studies or analyses of existing data which would require us to incur additional costs and expenses, which could be significant and would further delay the commercialization of MT 100.

Our failure to address satisfactorily the comments we received on our MAA for MT 100 in the UK would adversely impact our ability to market MT 100 in the UK or to use the mutual recognition procedure in the European Union. Even if we obtain required approvals, the need to appropriately price and obtain reimbursement for MT 100 may adversely affect sales or cause delays.

In September 2003, we received a letter of comments relating to the MAA we submitted for MT 100 from an MHRA Advisory. 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. The MHRA is not bound by the MHRA Advisory Committee's comments, and, although we believe we can address 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 supply or that the MHRA will follow the MHRA Advisory Committee's recommendations. Without approval of our MAA in the UK by the MHRA, we would not be able to market MT 100 in the UK. Further, we would not be able to use the mutual recognition process to obtain approval of MT 100 in other European Union countries unless we first obtain approval in another country in the European Union, which would result in increased expenses and time delays.

Even if we are able to obtain approvals in the European Union to market MT 100, potential licensees, including Nycomed and any other party with whom we may enter into an agreement to commercialize MT 100, will not be able to sell MT 100 successfully in some of those European Union countries unless they price MT 100 competitively and obtain necessary regulatory approvals for reimbursement to the patient. In some countries, licensees would need to enter into discussions regarding pricing and reimbursement of MT 100 with the appropriate governmental authorities pursuant to each of such country's individual requirements. Those discussions could further delay successful commercialization of MT 100 because of the time−consuming review processes in some of those countries.

If we are unable to convince the FDA to reverse its conclusion in its not−approvable letter for MT 300, we will not 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 and in a recent communication 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. No assurance can be given that our efforts to obtain FDA approval of MT 300 will ultimately be successful.

Even if the FDA were to approve MT 300, as a condition of approval, the FDA could request or require additional studies or analyses of existing data which would require us to incur additional costs and expenses, which could be significant and would delay the commercialization of MT 300.

Our need to collaborate with third parties to develop and commercialize our products may result in delays in product development and lost revenues, restricting our ability to commercialize our products.

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 arrangements with us 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 collaborations with Nycomed in the Nordic countries and Valeant NA in the United States for the development and commercialization of MT 100 and MT 300, respectively. In all of these collaboration and license agreements, our licensees 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; Nycomed is entitled to terminate its agreement if the MAA for MT 100 is withdrawn and can terminate the applicability of the agreement to a particular country if we withdraw the required regulatory application in that country; and Valeant NA is entitled to terminate its agreement if we choose to withdraw the NDA for MT 300 for commercial or financial reasons under the conditions specified in the agreement. Our receipt of not−approvable letters for MT 100 and MT 300 may suggest to our collaborators that they should terminate their agreements with us. If these licensees exercise their termination rights, 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 these and our other product candidates. Moreover, any future collaborations or license arrangements may not be on terms favorable to us.

A further risk we face with our collaborations is that business combinations and changes in the collaborators or their business strategy may adversely affect their willingness or ability to complete their obligations to us. For example, in February 2005, Valeant International reported that it had entered into a definitive agreement to acquire Valeant NA and on March 1, 2005 reported that the acquisition had been completed. We can give no assurance that Valeant NA or Valeant International will elect to continue the collaboration with us on MT 300. If our agreement with Valeant NA is terminated for this or any other reason and we are unable to enter into a new collaboration agreement to replace the agreement with Valeant NA, we may be unable to commercialize MT 300, assuming its eventual approval by the FDA, and would never receive any further revenue from MT 300.

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, 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 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 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 stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity 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. 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, if we conduct an additional study to address the FDA's concerns in its not−approvable letter on MT 100, there is no assurance that the results of such a study will satisfy all of the FDA's conditions for approval because, among other reasons, migraine affects patients differently, including the presence, or lack or level of severity, of secondary symptoms in a particular patient and the variability of the responsiveness of migraine attacks to given treatments, all of which may affect treatment responses. In addition, 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.

Further, even though we may have completed all planned clinical trials for a product candidate and submitted an NDA for such product candidate, as we have for MT 100 and MT 300, the FDA may require us to conduct additional clinical trials, studies or investigations to support our NDAs. For example, the FDA may require us to conduct additional studies or trials of MT 100 or MT 300 in connection with our efforts to convince the FDA to reverse its not−approvable decisions on these product candidates. We may also determine from time to time, including in connection with our efforts to resolve the FDA's issues raised in the not−approvable letters related to MT 100 and MT 300, 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.

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. Further, although we believed the results of our recently completed MT 100 two−year rat carcinogenicity study provided no evidence that the concomitant administration of maximum tolerated doses of metoclopramide and naproxen, the two active components in MT 100, produced any statistically significant differences in the occurrences and types of tumors seen with metoclopramide alone, the FDA expressed concern about the potential risk of carcinogenicity, presumably due to metoclopramide, in its MT 100 not−approvable letter. The FDA may also require further investigations to assess any potential risk of tardive dyskinesia associated with the use of MT 100.

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., MedPointe Pharmaceuticals, 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.

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 transferred 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.

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. A third party has recently filed a protest regarding the reissuance of that MT 100 patent. We do not know the weight the examiner will give to the protest or whether this may adversely affect our submission for reissuance of the patent.

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 March 31, 2005, we had $43.1 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 in 2005 and if we do not receive any additional milestone payments under any of our collaboration agreements, in particular the $20 million milestone payment payable upon the FDA's acceptance for filing of the Trexima NDA, we will not have sufficient cash reserves to maintain our level of business activities throughout 2006. Further, our expenses might increase in 2005 and 2006 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 MT 100, MT 300 and Trexima. In addition, if we elect to withdraw the NDA for MT 300, under certain circumstances, we may be required to pay Valeant NA a termination fee of $1.0 million.

We may be unable to raise additional equity funds until the uncertainties of the regulatory future of MT 100 and MT 300 resulting from our receipt of not−approvable letters for both product candidates have been resolved. 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 provides for one or two−year terms with automatic one−year renewal terms. If we lose the services of Dr. Plachetka, or are unable to replace the services of our 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 and in the market price of our common stock. Various factors and events may have a significant impact on the market price of our common stock including:

- 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;

- public concern as to the safety and/or efficacy of our products or product candidates; 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. From October 16, 2000, when our common stock began trading on the NASDAQ National Market, through April 22, 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 beneficially hold approximately 33.60% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

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, private placements and 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 class action complaint on December 20, 2004. The consolidated 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 a current 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. On January 27, 2005, we filed a motion to dismiss the consolidated class action complaint. All briefing on the motion to dismiss has been completed and we are awaiting the Court's ruling on the motion.

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 the Company's 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.

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 operations or financial condition.

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

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table presents information with respect to repurchase of common stock made by us during the three months ended March 31, 2005.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
01/01/2005 – 01/31/2005	137,232 (1)	$4.81	—	$—
02/01/2005 – 02/28/2005	—	$ —	—	$—
03/01/2005 – 03/31/2005	—	$ —	—	$—
Total	137,232	$4.81	—	$—

(1) Represents shares of common stock beneficially owned by our chief executive officer that were delivered, by attestation, to us in payment of the exercise price for certain stock options granted to him pursuant to our 2000 Equity Compensation Plan, as amended and restated.

Item 6. Exhibits and Reports on Form 8−K

(a) Exhibits

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)

April 29, 2005 By: /s/ JOHN R. PLACHETKA

John R. Plachetka
President and Chief Executive Officer

April 29, 2005 By: /s/ WILLIAM L. HODGES

William L. Hodges
Chief Financial Officer

April 29, 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: April 29, 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: April 29, 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: April 29, 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.

EXHIBIT 32.2

CFO CERTIFICATION PURSUANT TO

SECTION 906 OF THE SARBANES−OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

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

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

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

Date: April 29, 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.