FORM 10−Q

POZEN INC /NC − POZN

Filed: May 10, 2004 (period: March 31, 2004)

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, 2004

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, 2004 was 28,783,737.

POZEN Inc.

(A Development Stage Company)

FORM 10−Q

For the Three Months Ended March 31, 2004

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.

(A Development Stage Company)

BALANCE SHEETS

(Unaudited)

	March 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,574,373	$ 60,480,690
Prepaid expenses and other current assets	664,150	698,209
Total current assets	57,238,523	61,178,899
Equipment, net of accumulated depreciation	310,505	334,096
Total assets	$ 57,549,028	$ 61,512,995
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 590,879	$ 579,903
Accrued expenses	1,180,258	1,519,675
Total current liabilities	1,771,137	2,099,578
Long−term liabilities:		
Deferred revenue	21,893,478	23,782,978
Total liabilities	23,664,615	25,882,556
Common stock, $0.001 par value, 90,000,000 shares authorized; 28,707,737 and 28,492,201 shares issued and outstanding at March 31, 2003 and December 31, 2002, respectively	28,708	28,492
Additional paid−in capital	145,429,354	144,821,230
Deficit accumulated during the development stage	(111,573,649)	(109,219,283)
Total stockholders' equity	33,884,413	35,630,439
Total liabilities and stockholders' equity	$ 57,549,028	$ 61,512,995

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,
	2004	2003	2004
Revenue:			
Licensing revenue	$ 1,889,500	—	$ 5,606,500
Operating expenses:			
General and administrative	1,998,049	1,863,151	34,224,917
Research and development	2,371,967	3,112,864	89,213,196
Total operating expenses	4,370,016	4,976,015	123,438,113
Interest income	126,150	143,269	7,192,442
Net loss	(2,354,366)	(4,832,746)	(110,639,171)
Non−cash preferred stock charge	—	—	27,617,105
Preferred stock dividends	—	—	934,478
Net loss attributable to common stockholders	$ (2,354,366)	$ (4,832,746)	$ (139,190,754)
Basic and diluted net loss per common share	$ (0.08)	$ (0.17)	
Shares used in computing basic and diluted net loss per common share	28,555,654	28,150,319	

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,
	2004	2003	2004
Operating activities			
Net loss	$ (2,354,366)	$ (4,832,746)	$ (110,639,171)
Adjustments to reconcile net loss to net cash (used in) operating activities:			
Depreciation	25,643	32,616	550,972
Loss on disposal of equipment	—	—	27,495
Amortization of deferred compensation	—	279,089	10,875,281
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	34,058	53,987	(664,151)
Accounts payable and accrued expenses	(328,441)	384,642	1,771,137
Deferred revenue	(1,889,500)	—	21,893,478
Net cash provided by (used in) operating activities	(4,512,606)	(4,082,412)	(75,734,959)
Investment activities			
Purchase of equipment	(2,051)	(3,901)	(888,971)
Net cash used in investing activities	(2,051)	(3,901)	(888,971)
Financing activities			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	608,340	3,681	80,704,438
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	608,340	3,681	133,198,303
Net (decrease) increase in cash and cash equivalents	(3,906,317)	(4,082,632)	56,574,373
Cash and cash equivalents at beginning of period	60,480,690	50,056,251	—
Cash and cash equivalents at end of period	$ 56,574,373	$ 45,973,619	$ 56,574,373
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 seeking to develop therapeutic advancements in as cost effective a manner as possible. Our product development efforts are focused on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception in 1996, our business activities have been associated primarily with the development of pharmaceutical product candidates for the treatment of migraine. We have developed what we believe to be one of the largest and most advanced product pipelines in the field of migraine. We are also exploring the development of product candidates in other pain−related therapeutic areas.

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 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. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2004.

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

Revenue from non−refundable up−front payments is deferred by the Company upon receipt and recognized 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 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 adjust for differences between the estimated and actual royalties in the following period. For those arrangements where royalties are not reasonably estimable, the Company will recognize revenue up receipt of royalty statements from the licensee.

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.

In connection with the grant of stock options to employees, the Company recorded no deferred compensation in the three months ended March 31, 2004. Deferred compensation recognized in prior periods was recorded as a component of stockholders' equity and was being amortized as charges to operations over the vesting period of the options using the straight−line method. The vesting period of the options is generally three or four years. The Company recorded no deferred compensation for the period ended March 31, 2004 and amortized $279,089 for the three−month period ended March 31, 2003.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, "Accounting for Stock−Based Compensation," to stock−based employee compensation.

	Three Months Ended March 31,		Year Ended December 31,
	2004	2003	2003
Net loss attributed to common stockholders as reported	$ (2,354,366)	$ (4,832,746)	$ (14,863,318)
Add: Stock−based employee compensation expense included in reported net income, net of related tax effects	—	279,089	510,130
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(780,434)	(1,097,252)	(3,338,823)
Pro forma net loss attributed to common stockholders	$ (3,134,800)	$ (5,650,909)	$ (17,692,011)
Earnings per share			
Net loss per common share as reported − basic and diluted	$ (0.08)	$ (0.17)	$ (0.52)
Net loss per common share pro forma – basic and diluted	$ (0.11)	$ (0.20)	$ (0.62)
Weighted−average shares used in computing basic and diluted net loss per common share	28,555,654	28,150,319	28,329,339

Net Loss Per Share—Basic and diluted net loss per common share amounts are presented in conformity with Statement of Financial Accounting Standards No. ("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 2003.

3. Subsequent Event

On May 4, 2004, the Compensation Committee of the Company's Board of Directors granted an award of restricted stock units with respect to 98,135 shares of common stock, par value $0.001 per share, of the Company (the "Restricted Units"), to the Company's President and Chief Executive Officer ("CEO"). The grant was in lieu of a final award under the POZEN Inc. 2001 Long−Term Incentive Plan, as contemplated for grant in early 2004 under the CEO's employment agreement dated July 25, 2001 and was made in recognition of the importance of continuing to provide long−term incentives to the CEO. The Restricted Units were granted pursuant to the POZEN Inc. 2000 Equity Compensation Plan and will vest in three equal installments on January 1, 2005, January 1, 2006 and January 1, 2007. The related compensation expense, equal to the fair value of the underlying shares of common stock on the date of the grant, or $1,201,172, will be amortized over the vesting period of the Restricted Units.

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, 2003, as filed on February 18, 2004.

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 including those discussed herein 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.

Overview

We are a pharmaceutical company seeking to develop therapeutic advancements in as cost effective a manner as possible. Our product development efforts are focused on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception, we have developed what we believe to be one of the largest and most advanced product pipelines in the field of migraine. We are also exploring the development of product candidates in other pain−related therapeutic areas.

Since inception, 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.

We currently have three product candidates in the migraine area. MT 100, a combination of metoclopramide hydrochloride and naproxen sodium, is being developed to be a preferred prescription therapy for migraine attacks. We have completed all planned Phase 3 pivotal clinical trials for MT 100, which consistently demonstrated MT 100's effectiveness in treating migraine pain. In June 2003, we signed a licensing agreement with Nycomed Danmark ApS ("Nycomed") for the commercialization of MT 100 in four Nordic countries. In July 2003, we submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for MT 100. The NDA was accepted for filing by the FDA in October 2003. On January 27, 2004, we submitted to the FDA the report of the results of a two−year rat carcinogenicity study, thereby completing our NDA submission. We believe that the results of the study provided no evidence that the concomitant administration of maximum tolerated doses of metoclopramide and naproxen produced any statistically significant differences in the occurrences and types of tumors from those seen with metoclopramide alone. None of the tumors observed in the study were considered to have been caused directly by the administration of metoclopramide; all were considered to have been caused by the chronic elevation of the hormone prolactin resulting from administration of the metoclopramide. We believe that the results indicate that MT 100 does not increase the carcinogenicity risk that is seen from metoclopramide alone. We cannot provide assurance that the FDA, after completing its analysis, will not reach a different conclusion. We expect the FDA to complete its review of the NDA by May 31, 2004, or 10 months after the date of the FDA's receipt of our NDA in July 2003, which is the FDA's performance goal for review of NDAs established as a result of the Prescription Drug User Fee Act.

In October 2002, we submitted a Marketing Authorization Application ("MAA") for MT 100 to the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK"). If approved in the UK, we will seek approval in selected European countries through the European Union Mutual Recognition Procedure. This procedure allows other European countries to grant national approvals based upon the review and endorsement of the MHRA in the UK. In September 2003, we received a letter of comments relating to the MAA from an advisory group to the MHRA, the Committee on Safety of Medicines (the "MHRA Advisory Committee"). Although the MHRA is not bound by the MHRA Advisory Committee's comments, it typically agrees with the MHRA Advisory Committee's opinions. We provided additional data to the MHRA Advisory Committee in March 2004. We can give no assurance that the MHRA Advisory Committee will accept the supplemental information as supportive of the safety and efficacy of MT 100 and will recommend approval of the MAA to the MHRA.

Our MT 400 technology is the combination of a triptan (5−HT1B/1D agonist) and a long−acting, non−steroidal anti−inflammatory drug (NSAID). MT 400 compounds are being developed to 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. The combinations covered by the agreement are among the combinations of MT 400. We plan to commence Phase 3 clinical trials of MT 400 in 2004.

MT 300, a proprietary formulation of injectable dihydroergotamine mesylate ("DHE") in a pre−filled syringe, is being developed to provide long−lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks. In September 2003, we signed an agreement with Xcel Pharmaceuticals, Inc. ("Xcel") for the further development and commercialization of MT 300. In October 2003, we received a not−approvable letter from the FDA related to our MT 300 NDA, which was submitted in December 2002, 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, the incidence of nausea was statistically significantly higher following MT 300 treatment versus placebo at two hours.

No clinical safety issues were identified in the letter, nor were any non−clinical issues cited as impacting the FDA's decision to issue the not−approvable letter. In March 2004, we submitted a response to the FDA's not−approvable letter and were notified in April 2004 that the FDA considered our response incomplete because it did not include sufficient information responsive to a question regarding the testing procedures in the manufacturing process for MT 300. We plan to submit the additional information during the second quarter of 2004.

We have not obtained regulatory approval for any of our product candidates and do not currently have commercialization or manufacturing capabilities. Accordingly, we have entered into collaborations and currently plan to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. We may also elect in certain circumstances to develop sales and distribution capabilities internally to commercialize one or more of our product candidates.

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

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of March 31, 2004, our accumulated deficit was $111.6 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 and Phase 2 clinical trial activities for our product candidate MT 400, and general and administrative expenses. Our research and development expenses include salaries and benefits for personnel involved in our research activities, and direct product 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. In the quarter ended March 31, 2004, our research and development expenses represented approximately 54% of our total operating expenses for that quarter.

We expect to continue to incur operating losses over the next several years as we complete the development and application for regulatory approval of MT 100, MT 400 and MT 300, 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 MT 100, MT 400 and MT 300 in the clinical and regulatory process;
- the establishment of collaborations for the development and commercialization of any of our product candidates; and
- the acquisition and/or in−licensing, and development, of other therapeutic product candidates.

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 market our future products. We have entered into three collaborations relating to our migraine product candidates to date.

Under the terms of our agreement with Nycomed, we are eligible to receive milestone payments totaling up to $1.0 million upon the occurrence of certain regulatory approvals. Upon certain timeframes and conditions, 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, subject to certain reductions, or an agreed amount per unit sold subject to reduction under certain conditions. The licensing 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 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 and can terminate the applicability of the agreement to a particular country if we withdraw the required regulatory application in such country.

Under the terms of our agreement with GSK, GSK is obligated to make milestone payments over the next several years in an amount up to $55.0 million upon achievement of specified development and regulatory milestones related to the first product developed under the agreement, including the commencement of Phase 3 trials and FDA specified actions relating to an NDA. GSK will also pay us royalties on all sales of the first marketed product, and in addition, potential sales performance milestones of up to $80.0 million if certain sales thresholds are achieved. There are also milestone and royalty payments associated with products developed subsequent to the first product. 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. In addition, we have certain rights to terminate the agreement.

Under the terms of our agreement with Xcel, potential milestone payments of up to $8.0 million will be due upon certain future regulatory approvals and the achievement of a predetermined sales threshold on MT 300. Xcel is also obligated to pay us royalties on all combined sales of MT 300 and Xcel's D.H.E. 45 ® (dihydroergotamine mesylate) Injection, once MT 300 is commercialized, subject to reduction in certain cases, or in the event that Xcel 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 unless earlier terminated by either party for a material breach or in certain other circumstances. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non−terminating party.

Three months ended March 31, 2004 compared to the three months ended March 31, 2003

Net loss per share: Net loss attributable to common stockholders for the quarter ended March 31, 2004 was $2,354,000 or $0.08 per share, as compared to a net loss of $4,833,000, or $0.17 per share, for the quarter ended March 31, 2003.

Revenue: We recognized $1,890,000 of licensing revenue for the quarter ended March 31, 2004 as compared to no revenue during the quarter ended March 31, 2003. Revenue resulted from initial payments we received in 2003 pursuant to development and commercialization agreements for MT 100, MT 300 and MT 400. These agreements have terms that include up−front 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 are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates.

Research and development: Research and development expenses decreased by 24% to $2,372,000 for the first quarter of 2004, as compared to $3,113,000 for the same period of 2003. The $741,000 decrease was due primarily to a decrease in direct product costs for MT 100 and MT 300, offset by an increase in direct product costs associated with MT 400, as well as exploratory development and departmental expenses. Direct product costs associated with the development of MT 100 decreased by $716,000 to $300,000 and direct product costs associated with MT 300 decreased by $352,000 to $162,000 primarily due to Phase 4 clinical trial activities conducted during the first quarter of 2003, as compared to the same period of 2004. MT 400 direct product costs increased by $218,000 to $495,000 primarily due to Phase I clinical trial activities during the first quarter of 2004, as compared to the same period of 2003. Costs associated with lornoxicam product development increased to $212,000. Additional research and development expenses, including costs associated with other exploratory development and departmental expenses, decreased by $103,000, to $1,203,000. We have included in our research and development expenses the personnel costs associated with our research activities and costs associated with pharmaceutical development, clinical trial and toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by 7.0% to $1,998,000 for the first quarter of 2004, as compared to $1,863,000 for the same period of 2003. The $135,000 increase was due primarily to an increase in the costs associated with our business development activities for commercialization of MT 100 and consulting and legal fees related to filing a Form S−3 registration statement with the Securities and Exchange Commission in February 2004, offset by a decrease in the amortization of deferred stock compensation. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Interest income: Interest income decreased to $126,000 for the first quarter of 2004, from $143,000 for the quarter ended March 31, 2003. Interest income decreased primarily due to a decline in interest rates and a decrease in levels of cash and cash equivalents available for investing during the quarter ended March 31, 2004, as compared to the same period of 2003.

Income Taxes

As of December 31, 2003, we had available net operating loss carry−forwards of approximately $68,483,000 for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and which expire between 2011 and 2022. We also have research and development tax credit carry−forwards of approximately $5,483,000 for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2022. We have established an estimated net operating loss carry−forward of approximately $14,800,000 for the twelve months ending December 31, 2004 and estimate an effective rate of 0% for the three months ended March 31, 2004. Our effective tax rate was 0% for the three months ended March 31, 2003. 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 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 aggregate net proceeds to us of $133.2 million. Additionally in 2003, we received $27.5 million in cash in upfront fees related to various collaboration agreements. As of March 31, 2004, cash and cash equivalents totaled $56.6 million, a decrease of $3.9 million as compared to December 31, 2003. The decrease in cash and cash equivalents resulted primarily from expenses associated with our operating activities.

Cash used in operations of $4,513,000 during the three months ended March 31, 2004 represented a net loss of $2,354,000, increased by a decrease in accounts payable and accrued liabilities of $329,000 and $1,890,000 in deferred revenue, offset by non−cash charges of $26,000, and a decrease in prepaid and other assets of $34,000.

Cash used in investing activities of $2,000 during the three months ended March 31, 2004 reflected the purchase of equipment. Cash provided by financing activities during the period totaled $608,000, reflecting the net proceeds from the exercise of common stock options.

Barring unforeseen developments, we believe that our existing liquidity and capital resources, including the proceeds from our initial public offering and payments received under collaboration agreements, will be sufficient to complete planned product development activities reflected in the description of our business and to satisfy our other currently anticipated cash needs for operating expenses for the next two years. We do not currently expect to make any material capital expenditures during the next two years. In addition, we do not currently have any milestone or other required material payment obligations during that period. However, regulatory delays in the development of our existing and future product candidates would increase our cash requirements beyond our current assumed needs and may require that we seek additional funds from sources that may not be available on terms favorable to us.

Further, 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 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 ability to negotiate favorable terms with various contractors assisting in these trials and studies;
- our success in and manner of commercializing our products; and
- costs incurred to enforce and defend our patent claims and other intellectual rights.

We may issue shares of common stock in the future, including to fund additional unplanned development activities. On February 3, 2004, we filed with the Securities and Exchange Commission a shelf registration statement on Form S−3 under which we intend to register 8,540,000 shares of our common stock for sale in one or more public offerings.

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.

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 be profitable.

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 MT 400. Many 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 significant increases in the costs of any of our studies or clinical trials, 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, and failure to achieve market acceptance of our product candidates.

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, 2004, we had an accumulated deficit of approximately $111.6 million. Our ability to achieve profitability 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. Our only current sources of revenue are the payments we receive pursuant to our collaboration agreements with Nycomed for MT 100, GSK for MT 400 and Xcel for MT 300. We expect to continue to incur significant operating losses and do not know when or if we will generate product revenue.

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. If we market our products abroad, they are also subject to extensive regulation by foreign governments. None of our product candidates have been approved for sale in the United States or any foreign market.

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 two risk factors that follow, we are currently seeking to resolve issues raised by the FDA related to our MT 300 NDA and by the MHRA related to our MAA for MT 100 in the UK. If we are unable to obtain and maintain FDA and foreign governmental approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them.

Further, our collaborators may require us to make certain payments to them. For example, if we are unable to satisfactorily resolve the issues in the MT 300 not−approvable letter we have received from the FDA, we may elect to discontinue seeking approval of the NDA for MT 300 and under the terms of our agreement with Xcel, we would be required to pay to Xcel a termination fee of $1.0 million. In addition, we would forfeit the ability to receive potential milestone payments of up to $8.0 million under the agreement.

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 our revenues would suffer.

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 regulatory enforcement action by the FDA. Further, we may not obtain the labeling claims we believe are necessary or desirable for the promotion of our product candidates.

We may not be able to address satisfactorily the comments received on our Marketing Authorization Application for MT 100. This would adversely impact our ability to market MT 100 in the UK or to use the mutual recognition procedure in the European Union, which would cause substantial delays or could prevent marketing approval of MT 100 in certain countries in the European Union.

In October 2002, we submitted our Marketing 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 the MAA from an advisory committee to the MHRA (the "MHRA Advisory Committee"). We had been advised by the MHRA that the MHRA Advisory Committee would be consulted on the MAA, consistent with the MHRA's usual practice. Although the MHRA is not bound by the MHRA Advisory Committee's comments, it typically agrees with the MHRA Advisory Committee's opinions. We provided additional data to the MHRA Advisory Committee in March 2004 to address the MHRA Advisory Committee's questions. We can give no assurance that the MHRA Advisory Committee will accept the supplemental information as supportive of the safety and efficacy of MT 100 and recommend approval of the MAA to the MHRA. Without approval of our MAA by the UK regulatory authorities, we would not be able to market MT 100 in the UK. Further, we would need to obtain approval of MT 100 in another country in the European Union in order to utilize the mutual recognition procedures in other European Union countries, 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, our licensees 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, our licensees will need to enter into discussions 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.

We may not be able to convince the FDA to reverse its conclusions in its not−approvable letter on MT 300, which would eliminate altogether the revenue we expected to receive from MT 300, both under our collaborative agreement with Xcel and otherwise.

In December 2002, we submitted an NDA for MT 300 to the FDA, which was accepted for filing by the FDA in February 2003. In October 2003, we received a not−approvable letter from the FDA related to our MT 300 NDA. 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, the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours.

In March 2004, we submitted a response to the FDA's not−approvable letter and were notified in April 2004 that the FDA considered our response incomplete because it did not include sufficient information responsive to a question regarding the testing procedures in the manufacturing process for MT 300. We plan to submit the additional information during the second quarter of 2004. There is no assurance that the FDA will accept the supplemental information we submit as supportive of the efficacy of MT 300 in the acute treatment of migraine or that it will approve the NDA as submitted. 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 could 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 licensing 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 Xcel 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; Nycomed is entitled to terminate its agreement if the MAA for MT 100 is not approved by a specified date or 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 Xcel is entitled to terminate its agreement if we choose to withdraw the NDA for MT 300. If these licensees exercise their termination rights, or if we are not able to establish additional research and development collaborations or licensing arrangements, it will be difficult for us to develop and commercialize these and our other product candidates. Moreover, any future collaborations or licensing arrangements may not be on terms favorable to us.

Our current or any future collaborations or licensing arrangements ultimately may not be successful. Our agreements with collaborators typically allow them some discretion in electing whether to pursue such activities or with respect to the timing of the development, such as our agreement with GSK that enables GSK to determine the exact composition of MT 400 for use in the next phase of 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 contractual and collaborative 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.
- Business combinations and changes in the contractors or their business strategy may adversely affect their willingness or ability to complete their obligations to us.
- 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, and 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.

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 licensing 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 a collaborator should decide that the collaborator's 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 licensing 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 its 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 MT 400, it has the ability to terminate our agreement upon ninety (90) days' written notice. In such a case, we may need to enter into a new development and commercialization agreement and would need to start the development process for MT 400 all over again. If we were able to negotiate a new development and commercialization agreement to develop MT 400, which is not certain, we would face delays and redundant expenses to develop MT 400.

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 on our product candidates. Any unanticipated costs or delays in 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 or delay our revenues and 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 also be noted that results from preclinical testing and early clinical trials are not necessarily predictive of results obtained in later clinical trials involving large scale testing of patients in comparison to control groups.

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 MT 400 as a 505(b)(2) application, the FDA may require us to conduct more studies or trials than we now believe are necessary. 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 and studies to support our NDAs. We may determine 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 customarily evaluates results. For example, we are seeking to resolve the FDA's issues in its not−approvable letter relating to the NDA for MT 300 issued in October 2003. 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, we believe 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. We cannot assure you, however, that the FDA, after completing its analysis, will not reach a different conclusion from that reached by us. Similarly, the FDA may 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 we will be able to satisfactorily address the issues related to MT 100 raised in September 2003 by the MHRA Advisory Committee, including providing additional support for the benefits of the MT 100 combination.

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 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, 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. These competitors, either alone or with collaborative parties, may 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 approval or commercializing products before we do. 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 be profitable.

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 recently after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued.

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

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know−how, or determine the scope and validity of others' patent or proprietary rights. As a result of such litigation, our patent claims may be found to be invalid, unenforceable or not of sufficient scope to cover the activities of an alleged infringement. If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and

know−how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know−how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

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

As part of our business strategy, we plan to identify, self−invent and 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. We may not be able to acquire rights to additional products on acceptable terms, if at all. In addition, we may acquire new products with different marketing strategies, distribution channels and bases of competition than those of our current products. Therefore, 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 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, particularly for indications for which there is no current effective treatment or for which medical care is typically not sought. 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 the 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 million annual aggregate limit with a $100,000 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. 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 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;
- the time and cost involved in obtaining 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, licensing and other relationships;
- the terms and timing of any additional collaborative, licensing and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

Our average annual operating expenses from 2000 through our 2003 fiscal year were $23.5 million. We are currently expecting operating expenses for the 2004 fiscal year to be between $30.0 million and $34.0 million because of the development activities relating to MT 400 and new exploratory products. Expenses might increase in 2004 if the FDA or the MHRA requires us to conduct additional clinical trials or studies in connection with its consideration of our regulatory filings for MT 100 and MT 300. As of December 31, 2003, we had $60.5 million in cash and cash equivalents. Therefore, if our operating expenses in 2005 are in the same range as our average operating expenses before the current year and we do not obtain additional equity or debt funding or receive any additional milestone payments under any of our collaborative agreements, we may not have sufficient cash reserves to maintain our level of business activities after the end of 2005.

We may be unable to raise sufficient funds to execute our business strategy. In addition, we may not be able to find sufficient debt or equity funding on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs.

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. 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.

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, each of which provides for a two−year term 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 Kristina M. Adomonis, who heads our business development efforts, or W. James Alexander, who heads our product development efforts, 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 efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors. From October 16, 2000, when our common stock began trading on the Nasdaq National Market, through May 5, 2004, 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 three of our stockholders beneficially hold approximately 30% 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.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our proceeds from our initial public offering and private placements 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. 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. However, declines in interest rates reduced our interest income during the three−month period ended March 31, 2004 as compared to the same period of 2003.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and principal financial and accounting officer, evaluated the effectiveness our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and principal financial and accounting 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. 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 6. Exhibits and Reports on Form 8−K

(a) Exhibits

10.1	Release and Settlement Agreement dated as of January 6, 2004 between the Registrant and Matthew E. Czajkowski.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes−Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes−Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer Relating to a Periodic Report Containing Financial Statements.

(b) Reports on Form 8−K

We filed no reports on Form 8−K during the quarter ended March 31, 2004.

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)

May 10, 2004 By: /s/ JOHN R. PLACHETKA

John R. Plachetka
President and Chief Executive Officer

May 10, 2004 /s/ JOHN E. BARNHARDT

John E. Barnhardt
Vice President, Finance and Administration
(Principal financial and accounting officer)

EXHIBIT INDEX

Exhibit Number	Description
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RELEASE AND SETTLEMENT AGREEMENT

This Release and Settlement Agreement ("**Agreement**") is entered into effective January 6, 2004 (the "Effective Date") by and between POZEN Inc., a Delaware corporation (the "**Company**"), and Matthew E. Czajkowski ("**Employee**").

WHEREAS, Employee voluntarily resigned from all positions with the Company and therefore Employee's employment with the Company terminated on the Effective Date, and Employee and the Company now desire to fully and finally settle and resolve all matters arising, directly or indirectly, out of Employee's employment or the conclusion thereof according to the terms of this Agreement; and

WHEREAS, this Agreement provides Employee with valuable consideration to which Employee is not otherwise entitled, and as a partial inducement to the Company to grant such consideration, Employee and the Company have agreed to enter into this Agreement.

NOW, THEREFORE, in consideration of the premises, which are incorporated herein by reference, and the mutual promises contained herein and the payment of the monies hereinafter recited, the receipt and adequacy of which are hereby acknowledged, the parties hereby agree as follows:

1. Employee voluntarily resigned from all positions with the Company and therefore Employee's employment with the Company terminated as of the Effective Date. Employee hereby waives all rights to reemployment or reinstatement from and after that date and Employee agrees that Employee will not reapply for employment with the Company.

2. For and in consideration of the release set forth below in Section 3, the Company shall pay Employee (a) seven month's base salary ($135,562) (the "Salary Severance"); and (b) the average annual bonus awarded Employee over the previous two years ($ 79,720) (the "Bonus Severance"). The Salary Severance and the Bonus Severance will be paid to Employee in twelve equal installments of $ 17,940.17 each (less all applicable withholdings and deductions) commencing on the next regularly scheduled pay date after the eighth day after Employee executes and does not revoke this Agreement. In addition, Employee shall continue to receive at Company's expense all Company benefits to which Employee was entitled as of the Effective Date subject to the terms of the applicable benefit plans and to the extent such benefits can be provided to non−employees at the same average level and upon the same terms and conditions that applied prior to the Effective Date, until the earlier of (i) January 5, 2005; or (ii) until Employee obtains comparable coverage from another employer.

3. (a) In consideration of the payment by the Company of the amounts set forth in Section 2 above, the promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Employee for himself, his executors, heirs, administrators, assigns, and anyone claiming by, through, or under them, hereby irrevocably (except as specifically set forth below) and unconditionally releases and forever discharges the Company and each of its past, present, and future officers, directors, employees and stockholders (the "Company Releasees") from any and all claims, demands,

charges, lawsuits, debts, defenses, actions or causes of action, obligations, damages, sums of money, loss of services, compensation, pain and suffering, attorneys' fees, cost and expenses of suit, and liabilities whatsoever ("Employee Claims"), which Employee had, now has or may have, whether the same be at law, in equity, or mixed, where known or unknown, suspected or unsuspected, now existing or which may arise hereafter, arising out of or related to, any matter, cause, or event which has happened, developed, or occurred before the execution of this Agreement, including without limitation, any and all suits in tort or contract, and any Employee Claims or suits relating to the breach of an oral or written contract, misrepresentation, defamation, and interference with prospective economic advantage, interference with contract, intentional and negligent infliction of emotional distress, negligence, promissory estoppel, invasion of privacy, libel, slander, breach of the covenant of good faith and fair dealing, any claims relating to or arising out of Employee's right to purchase any shares of stock of the Company, including without limitation any claims for misrepresentation, fraud or securities fraud under any state or federal law, and Employee Claims arising out of, based on, or connected with Employee's employment by the Company and the termination of that employment including any causes of action or Employee Claims for unlawful employment discrimination arising under or based on Title VII of the Civil Rights Act of 1964, as amended; the Employee Retirement Income Security Act of 1974, as amended; the Rehabilitation Act of 1973, as amended; the Americans with Disabilities Act; the Occupational Safety and Health Act of 1970, as amended; the National Labor Relations Act of 1935, as amended; the Fair Labor Standards Act of 1938, as amended; the Family and Medical Leave Act of 1993, as amended; the Age Discrimination in Employment Act, as amended; the Older Workers Benefit Protection Act, as amended; Section 1981 of the Civil Rights Act of 1866; the Equal Pay Act of 1963; Section 1985 of the Civil Rights Act of 1871; and any other state or federal equal employment opportunity law, public policy, order, or regulation affecting or relating to the Claims or rights of employees, which Employee ever had, now has, or claims to have against the Company (including all officers, directors and affiliates thereof and all officers, directors, partners and affiliates of any subsidiary thereof), except such rights, benefits, and claims of Employee which expressly accrue under and pursuant to this Agreement. Employee further agrees not to institute any charge, complaint, or lawsuit to challenge the validity of this Agreement or the circumstances surrounding its execution. It is expressly agreed and understood that the release contained herein is a GENERAL RELEASE. Employee agrees that the amount specified above as the consideration for the release granted in this Section 3 is valid consideration to which Employee is not otherwise entitled.

(b) In consideration of the execution of this Agreement by Employee, the promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company hereby irrevocably and unconditionally releases and forever discharges Employee from any and all claims, demands, charges, lawsuits, debts, defenses, actions or causes of action, obligations, damages, sums of money, loss of services, compensation, pain and suffering, attorney's fees, costs, and expenses of suit, and liabilities whatsoever ("Employer Claims") which the Company had, now has or may have, whether the same be at law, in equity or mixed, where known or unknown, suspected or unsuspected, now existing or which may arise hereafter, arising out of or related to, any matter, cause, or event which has happened, developed, or occurred before the execution of this Agreement, including without limitation any and all suits in tort or contract, and any Employer Claims or suits relating to the breach of an oral or written contract, misrepresentation, and interference with contract, negligence, promissory estoppel, libel, slander, breach of the covenant of good faith and fair dealing, and Employer Claims arising out of, based on, or connected with Employee's employment with the Company and the termination of that employment, except for claims relating to fraud, embezzlement, falsification of records or violation of any civil or criminal law.

4. The Company hereby advises Employee to consult with an attorney prior to executing this Agreement. Employee is also advised that he has at least twenty−one (21) days to consider the meaning and effect of this Agreement. If Employee elects to sign this Release and return it to the Company before twenty−one (21) days have elapsed from the date Employee has received this Agreement, Employee acknowledges that any such election is a knowing and voluntary waiver of the right to take twenty−one (21) days to consider this Release and that Employee has made this decision after receiving advice from legal counsel or after rejecting the Company's recommendation that Employee obtain the advice of counsel. Employee further understands that Employee may revoke the releases granted by Employee in Section 3 of this Agreement relating to the Age Discrimination in Employment Act and the Older Workers Benefit Protection Act, (the "Preserved Claims"), for a period of seven (7) days following the date Employee executes this Agreement (the "Revocation Period"). This Agreement shall become effective and enforceable with respect to Employee once the Revocation Period has expired without exercise by Employee of Employee's rights described in this Section 4. If Employee shall exercise the revocation rights contemplated in this Section, Employee shall retain, and not release, his respective rights with respect to the Preserved Claims. Any revocation within the Revocation Period must be submitted in writing to the Company and shall state, "I, Matthew E. Czajkowski, hereby revoke my acceptance of the release by me of the Preserved Claims as described in our Agreement which I signed and dated on January 9, 2004." Any such revocation shall be delivered personally to the Company or sent to the Company by certified mail to the attention of John R. Plachetka and received within seven (7) days of execution of this Agreement. If Employee elects to return this Agreement, Employee must execute and return it to the Company on or before January 29, 2004. Employee acknowledges that the waivers and releases contained herein are made knowingly, consciously, and with full appreciation that Employee will be forever foreclosed from pursuing any of the rights so waived and released.

5. Effective as of the Effective Date, Employee agrees to resign from all positions held by him in the Company, including without limitation Chief Financial Officer, Senior Vice President, Finance and Administration and Assistant Secretary. Notwithstanding any provision of this Agreement to the contrary, nothing in this Agreement is intended to or shall alter, limit, modify, amend, release, or discharge any of Employee's rights (a) to indemnity by or from the Company, whether by contract, operation of law or otherwise; and (b) as a shareholder of the Company or with respect to options to purchase any shares of stock of the Company that have vested on or before the execution of this Agreement.

6. Employee hereby represents and warrants to the Company that Employee is the sole and exclusive owner of the claims or causes of action being released by this Agreement, that Employee has not conveyed or assigned any interest in such claims or causes of action to any person or entity, and that such claims and causes of action have been fully and effectively released for all purposes. Employee further represents and warrants that Employee has no claims, lawsuits or actions pending in his own name or on behalf of any other person or entity against any of the Company Releasees and does not intend to bring any claims on behalf of himself or any other person against any of the Company Releasees. Employee further represents and warrants that Employee will not participate or provide assistance to any person or entity who files a claim or intends to file a claim against the Company, unless ordered to do so by a court of competent jurisdiction.

7. Employee acknowledges that Employee has read this Agreement and fully understands its meaning and intent, and has executed this Agreement knowingly and voluntarily, as a free and voluntary act, without duress, coercion, or undue influence exerted by or on behalf of any person or entity.

8. Neither the Company nor Employee shall be regarded as a prevailing party for any purpose, including, but not limited to, determining responsibility for or entitlement to attorneys' fees under any statute or otherwise. The Company and Employee expressly waive, as to each other, any and all claims for attorneys' fees.

9. This Agreement will not be used or construed by any person or entity as an admission of liability or finding or admission that any party's rights were in any way violated by any other party and this Agreement may not be offered or received in evidence in any action or proceeding as an admission or concession of liability or wrongdoing on the part of any party.

10. Each of the Company and Employee will keep the terms of this Agreement strictly confidential and shall not disclose any information concerning the terms of this Agreement or provide a copy of the same to anyone except the party's spouse (if applicable), legal or tax advisor, unless otherwise required by a court of competent jurisdiction. If required by law to produce a copy or to make such disclosure, Employee will give the Company reasonable advance notice prior to such production or disclosure.

11. Except as required by law, Employee will not do or say anything that a reasonable person would expect at the time would have the effect of diminishing or constraining the goodwill and good reputation of the Company or the Company Releasees or the Company's business, products or services. This obligation will include refraining from making negative statements about the Company Releasees or the Company's methods of doing business, the effectiveness of its business policies, and the quality of any of its services or personnel. Except as required by law, the Company will not do or say anything that a reasonable person would expect at the time would have the effect of diminishing or constraining the goodwill and good reputation of Employee. The Company will not disparage or seek to injure the Employee's reputation.

12. Except as required or permitted by law, Employee will keep strictly confidential and not use for personal benefit or disclose to others any confidential or proprietary business or financial information or trade secrets of the Company, or other technical, business, or financial information, the use or disclosure of which may be contrary to the Company's interests. This obligation shall remain in effect as to any confidential business or financial information or trade secrets of the Company for so long as such confidential business or financial information or such trade secrets shall remain confidential and protected information of the Company under applicable law.

13. Employee will return all property of the Company to the Company wherever located on or before the Effective Date, including, without limitation, all reports, files, memoranda, records, computer hardware and software, laptop computer and accessories, credit cards, card−key passes, door, file, vehicle and other keys, computer access codes, disks and instructional manuals, calculators, cellular telephones, and other physical or personal property which have been provided for Employee's use in connection with his employment with the Company.

14. This Agreement shall be binding upon and inure to the benefit of each of the Company and Employee and their respective predecessors, successors, assigns, heirs, executors, and administrators. Employee shall not assign this Agreement or delegate Employee's obligations hereunder without the prior written consent of the Company.

15. The Company and Employee acknowledge that this Agreement is intended to be a binding contract between them and shall not be modified except by writing signed by each of the Company and Employee. Employee acknowledges that Employee has not relied on any representation or statement by any of the Company Releasees or by any of the Company Releasees' agents, representatives or attorneys regarding the subject matter, basis or effect of this Release

16. Each of the parties acknowledges and recognizes that a violation of this Agreement and its covenants will cause irreparable damage to the other party and that the other party will have no adequate remedy at law for such violation. Accordingly, each of the parties agrees that the other party will be entitled, as a matter of right, to an injunction from any court of competent jurisdiction restraining any further violation of the Agreement or covenant. This right to injunctive relief will be cumulative and in addition to whatever remedies the parties may otherwise have at law.

17. The parties agree that the Company's past, present, and future officers, directors, agents, shareholders, debt holders, employees, and representatives are each beneficiaries of this Agreement, and may rely on it directly for enforcement of the release set forth in Section 3 and the other benefits contained herein.

18. If one or more of the provisions, or portions thereof, of this Agreement are determined to be illegal or unenforceable, the remainder of this Agreement will not be affected by that determination and each remaining provision, or portion thereof, will continue to be valid and effective and will be enforceable to the fullest extent permitted by law.

19. This Agreement is made and entered into in the State of North Carolina and shall be governed by and construed in accordance with the laws of the State of North Carolina.

20. Employee acknowledges receiving this Agreement on the 6th day of January 2004.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound hereby, have executed this RELEASE AND SETTLEMENT AGREEMENT this the 12th day of January, 2004 to be effective as of the Effective Date.

EMPLOYEE:

Signature: /s/ Matthew E. Czajkowski

Matthew E. Czajkowski

POZEN INC.

By: /s/ John R. Plachetka

John R. Plachetka
Chairman, President and CEO

Exhibit 31.1

Certifications

I, John R. Plachetka, Pharm.D., certify that:

1. I have reviewed this Quarterly Report on 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)) 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) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34−47986]

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 quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonable 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: May 10, 2004

/s/ John R. Plachetka

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

Exhibit 31.2

Certifications

I, John E. Barnhardt, certify that:

1. I have reviewed this Quarterly Report on 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)) 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) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34−47986]

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 quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonable 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: May 10, 2004

/s/ John E. Barnhardt

John E. Barnhardt
Vice President, Finance & Administration
(Principal financial and accounting officer)

Exhibit 32.1

Section 1350 Certifications

I, John R. Plachetka, Pharm.D., Chief Executive Officer, and I, John E. Barnhardt, Vice President of Finance and Administration (Principal financial and accounting officer), of POZEN Inc., a Delaware corporation (the "Company"), hereby certify that, to my knowledge:

(1) The Company's periodic report on Form 10−Q for the period ended March 31, 2004 (the "Form 10−Q") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Form 10−Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

* * *

CHIEF EXECUTIVE OFFICER

/s/ John R. Plachetka

John R. Plachetka, Pharm.D.

Date: May 10, 2004

CHIEF FINANCIAL OFFICER

/s/ John E. Barnhardt

John E. Barnhardt

Date: May 10, 2004