FORM 10−Q

POZEN INC /NC − POZN

Filed: October 27, 2004 (period: September 30, 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 September 30, 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 October 25, 2004 was 28,852,743

POZEN Inc.

(A Development Stage Company)

FORM 10−Q

For the Three and Nine Months Ended September 30, 2004

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.

(A Development Stage Company)

BALANCE SHEETS

(Unaudited)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,164,102	$ 60,480,690
Prepaid expenses and other current assets	161,439	698,209
Total current assets	61,325,541	61,178,899
Equipment, net of accumulated depreciation	350,496	334,096
Total assets	$ 61,676,037	$ 61,512,995
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,105,365	$ 579,903
Accrued compensation	678,587	416,053
Accrued expenses	1,649,297	1,103,622
Total current liabilities	3,433,249	2,099,578
Long−term liabilities:		
Deferred revenue	18,112,479	23,782,978
Total liabilities	21,545,728	25,882,556
Common stock, $0.001 par value, 90,000,000 shares authorized; 28,852,743 and 28,492,201 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	28,853	28,492
Additional paid−in capital	146,161,655	144,821,230
Deficit accumulated during the development stage	(106,060,199)	(109,219,283)
Total stockholders' equity	40,130,309	35,630,439
Total liabilities and stockholders' equity	$ 61,676,037	$ 61,512,995

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period From Inception (September 26, 1996) Through September 30,
	2004	2003	2004	2003	2004
Revenue:					
Licensing revenue	$ 1,891,499	$ 1,886,998	$ 20,670,499	$ 1,886,998	$ 24,387,499
Operating expenses:					
General and administrative	2,065,869	2,527,858	6,071,475	7,312,061	38,298,343
Research and development	5,859,319	3,219,415	11,903,282	8,215,224	98,744,511
Total operating expenses	7,925,188	5,747,273	17,974,757	15,527,285	137,042,854
Other revenue:					
Interest income	202,369	128,309	463,342	394,871	7,529,634
Net income (loss):	(5,831,320)	(3,731,966)	3,159,084	(13,245,416)	(105,125,721)
Non−cash preferred stock charge	—	—	—	—	27,617,105
Preferred stock dividends	—	—	—	—	934,478
Net income (loss) attributable to common stockholders	$ (5,831,320)	$ (3,731,966)	$ 3,159,084	$ (13,245,416)	$(133,677,304)
Basic net income (loss) per common share	$ (0.20)	$ (0.13)	$ 0.11	$ (0.47)	
Shares used in computing basic net income (loss) per common share	28,799,277	28,407,093	28,713,806	28,276,105	
Diluted net income (loss) per common share	$ —	$ —	$ 0.11	$ —	
Shares used in computing diluted net income (loss) per common share	—	—	29,666,989	—	

See accompanying Notes to Financial Statements.

POZEN Inc.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,		Period from Inception (September 26, 1996) Through September 30, 2004
	2004	2003	
Operating activities:			
Net income (loss)	$ 3,159,084	$(13,245,416)	$(105,125,721)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	93,701	102,602	619,030
Loss on disposal of equipment	—	—	27,495
Deferred compensation	247,544	488,443	11,122,825
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	536,770	473,632	(161,439)
Accounts payable and accrued expenses	1,086,127	1,155,438	3,185,705
Deferred revenue	(5,670,499)	25,612,980	18,112,479
Net cash provided by (used in) operating activities	(547,273)	14,587,679	(71,769,626)
Investment activities:			
Purchase of equipment	(110,101)	(32,224)	(997,021)
Net cash used in investing activities	(110,101)	(32,224)	(997,021)
Financing activities:			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	1,340,786	750,569	81,436,884
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	1,340,786	750,569	133,930,749
Net increase (decrease) in cash and cash equivalents	683,412	15,306,024	61,164,102
Cash and cash equivalents at beginning of period	60,480,690	50,056,251	—
Cash and cash equivalents at end of period	$61,164,102	$ 65,362,275	$ 61,164,102
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 are also exploring the development of product candidates in other pain−related therapeutic areas. Statement of Financial Accounting Standards Board No. ("SFAS") 7, "Accounting and Reporting by Development Stage Enterprises," states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. We believe that we will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of our product candidates.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements—The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission ("SEC") regulations for interim financial information. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring accruals) necessary to present fairly the balance sheets, statements of operations and statements of cash flows for the periods presented in accordance with accounting principles generally accepted in the United States. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to SEC rules and regulations. It is presumed that users of this interim financial information have read or have access to the audited financial statements and footnote disclosure for the preceding fiscal year contained in the Company's Annual Report on Form 10−K. 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 license 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 ("SAB 101"), "Revenue Recognition", as amended by SAB 104, "Revenue Recognition," and Emerging Issues Task Force 00−21 ("EITF 00−21"), "Revenue Arrangements with Multiple Deliverables."

Non−refundable up−front payments received under our existing agreements are 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 when earned with respect to the manufacture, sale or use of the Company's products or technology. For those arrangements where royalties are reasonably estimable, the Company will recognize revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. For those arrangements where royalties are not reasonably estimable, the Company will recognize revenue upon receipt of a statement from the licensee that a royalty is payable.

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 awards to employees, consisting of stock options to employees and a restricted stock unit award made in May 2004 to our Chief Executive Officer, the Company recorded $95,000 and $189,000, respectively, of restricted stock compensation expense for the three− and nine−month periods ended September 30, 2004 and amortized deferred compensation of

$143,000 and $422,000, respectively, in the three− and nine−month periods ended September 30, 2003. The deferred compensation recognized in prior periods related to the grant of stock options and was recorded as a component of stockholders' equity. This deferred compensation was amortized as charges to operations over the vesting periods of the options using the straight−line method. The vesting periods of the options and the restricted stock unit award are generally three or four years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss) attributable to common stockholders as reported	$ (5,831,320)	$ (3,731,966)	$ 3,159,084	$ (13,245,416)
Add: Stock−based employee compensation expense reflected in reported net income (loss), net of related tax effects	94,698	142,693	189,396	422,052
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(1,119,966)	(632,644)	(3,090,456)	(1,729,896)
Pro forma net income (loss) attributable to common stockholders	$ (6,856,588)	$ (5,170,385)	$ 258,024	$ (10,821,294)
Earnings per share				
Basic net income (loss) per common share as reported	$ (0.20)	$ (0.13)	$ 0.11	$ (0.47)
Basic net income (loss) per common share pro forma	$ (0.24)	$ (0.18)	$ 0.01	$ (0.38)
Diluted net income (loss) per common share as reported	$ —	$ —	$ 0.11	$ —
Diluted net income (loss) per common share pro forma	$ —	$ —	$ 0.01	$ —

Net Loss Per Share—Basic and diluted net income (loss) per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net income (loss) per common share amounts have been computed using the weighted−average number of shares of common stock outstanding for the nine months ended September 30, 2004. During the three months ended September 30, 2004 and the three months and nine months ended September 30, 2003, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for these periods because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share are the same for the three months ended September 30, 2004 and the three months and nine months ended September 30, 2003. The following table illustrates the calculation of dilutive shares outstanding.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Weighted−average shares used in computing basic net income (loss) per share	28,799,277	28,407,093	28,713,806	28,276,105
Effect of dilutive securities	—	—	953,183	—
Weighted−average shares used in computing diluted net income (loss) per share	28,799,277	28,407,093	29,666,989	28,276,105

Contingencies –Five purported class action lawsuits have been filed by holders of the Company's securities against us and certain of our current and former officers, in the United States District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions, along with any other similar federal actions that may be filed, will be consolidated for pre−trial purposes. The complaints allege, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b−5 and Section 20(a) of the Exchange Act against the individual defendants, arising out of allegedly false and misleading statements made by the Company concerning its product candidates, MT 100 and MT 300, during the class period. On September 13, 2004, two derivative actions were also filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina, alleging violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning our product candidates, MT 100 and MT 300 that are referenced in the various purported class action lawsuits.

The Company and the other defendants believe that the allegations in these actions are without merit and intend to defend these cases vigorously. While the Company cannot predict the outcome or reasonably estimate the range of potential loss, if any, from this litigation, it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on the Company's results of operations or financial condition.

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 and amended on April 30, 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 except as required by law.

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 focused our efforts primarily on the development of pharmaceutical products for the treatment of migraine.

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 are developing three product candidates in the migraine area. MT 100, a combination of metoclopramide hydrochloride and naproxen sodium, is being developed to provide effective migraine relief with less risk of cardiovascular side effects compared to the triptans. Triptans are the family of drugs most commonly prescribed for the treatment of migraine attacks. 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. 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.

We are also exploring the development of product candidates in other non−migraine, pain−related therapeutic areas. In July 2003, we signed an exclusive option agreement with Nycomed, under which we may acquire a license to certain rights related to lornoxicam, an NSAID. We have begun exploratory development work and clinical studies to investigate the development of multiple novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. In addition, we are also investigating other potential product candidates to improve the safety and/or effectiveness profiles of currently available treatments for pain conditions. For example, we have begun exploratory formulation development and clinical studies for a combination of a proton pump inhibitor ("PPI") and an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone.

We have 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 entered into three collaboration agreements – with Nycomed Danmark ApS ("Nycomed") for the commercialization of MT 100 in four Nordic countries, GlaxoSmithKline ("GSK") for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long−acting NSAID

(Trexima™ is the proposed brand name for the combination of GSK's sumatriptan and naproxen sodium in a single tablet being developed pursuant to our agreement with GSK), and Xcel Pharmaceuticals, Inc. ("Xcel") for the further development and commercialization of MT 300.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of September 30, 2004, our accumulated deficit was $106.1 million. Our historical operating losses have resulted principally from our research and development activities, including Phase 3 clinical trial activities for our product candidates MT 100 and MT 300, Phase 2 clinical trial activities for our MT 400 technology, and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct 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. Since inception, our research and development expenses have represented 72% of our total operating expenses. In the nine−month period ended September 30, 2004, our research and development expenses represented approximately 66% of our total operating expenses.

We expect that we may continue to incur operating losses over the next several years as we seek to obtain regulatory approval of MT 100 and MT 300, complete the development and application for regulatory approval of Trexima, develop other product candidates and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- our progress in reversing the FDA's not−approvable decisions with respect to MT 100 and MT 300;
- the progress of Trexima and other product candidates in the clinical and regulatory process;
- the establishment of collaborations for the development and commercialization of any of our product candidates;
- the acquisition and/or in−licensing, and development, of other therapeutic product candidates; and
- our costs related to the lawsuits that have been filed against us or our current or former directors and officers relating to the approvability of MT 100 and MT 300.

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.

Status of Our Product Candidates

There follows a brief discussion of the status of the development of each of MT 100, MT 300 and Trexima, as well the costs relating to our development activities. The research and development expenses that are not direct product costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total salary and benefit costs for our personnel involved in our research and development activities for the last nine months and for the fiscal years ended December 2001, 2002, and 2003 were $2.3 million, $2.2 million, $2.3 million, and $2.1 million, respectively. Other research and development department costs for the last nine months and for the fiscal years ended December 2001, 2002, and 2003 were $0.7 million, $0.4 million, $0.5 million and $0.6 million, respectively.

MT 100. In July 2003, we submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for MT 100. On January 27, 2004, we submitted to the FDA the results of a two−year rat carcinogenicity study, thereby completing our NDA submission. As previously described in our press release dated June 1, 2004, on May 28, 2004 we received a not−approvable letter from the FDA with respect to our NDA for MT 100. In its letter, the FDA noted that we had demonstrated unambiguous statistically significant superiority compared to an appropriate control on a valid measure of pain as well as on the three associated symptoms of nausea, photophobia and phonophobia in one study. However, the FDA letter noted that MT 100 did not clearly meet these criteria in a second study. We also stated in our press release that the FDA letter cited the apparent lack of superiority of MT 100 over naproxen for sustained pain relief, which was the primary endpoint for the two component studies. We noted in our press release that this issue appears to arise primarily from an apparent difference in understanding between us and the FDA as to the appropriate statistical analysis of this endpoint. Additionally, the FDA letter mentioned that, based on animal studies, there may be a potential risk of carcinogenicity, presumably due to metoclopramide, one of the components of MT 100. Finally, we noted in the press release that, for the first time, the FDA letter raised an approvability issue concerning the risk of tardive dyskinesia ("TD") presented by the use of metoclopramide.

Since our issuance of the press release, we have had further communications with the staff of the FDA. In July 2004, the FDA sent to us minutes of a teleconference we had with the FDA in which we discussed the FDA letter. Among other things, these minutes state the view of the FDA expressed in that teleconference with us that, "[a]ssuming [POZEN] is able to meet the requirements of the Combination Rule and demonstrate efficacy we could describe the TD potential and carcinogenicity findings in labeling." (The [FDA] Combination [Drug] Rule requires that we demonstrate a contribution of each component of MT 100 to the claimed effects of the product.) This statement in the FDA minutes is consistent with the views that we had held prior to our receipt of the not−approvable letter with respect to how the FDA would address those safety issues.

We are continuing communications with the FDA to seek to persuade the FDA that MT 100 should be approved based upon the data that we submitted in the NDA for MT 100. However, it is possible that we may be required to conduct another clinical study to provide additional evidence that MT 100 meets the requirements of the Combination Rule and the efficacy standards applicable to MT 100. We cannot estimate the cost or duration of any such study or decide whether to conduct such a study until the design of such a study has been determined with the FDA. Our Phase 3 clinical trials of MT 100 took between three months and eighteen months and involved a direct cost per patient of between $2,200 and $3,200. The duration and cost of any new study that we may conduct may be different from our prior clinical trials. No assurance can be given that our efforts to obtain approval of MT 100 will ultimately be successful.

In October 2002, we submitted a Marketing Authorization Application ("MAA") for MT 100 to the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK"). In September 2003, we received a letter of comments relating to our MAA from an advisory group to the MHRA, the Committee on Safety of Medicines (the "MHRA Advisory Group"). We had been advised by the MHRA that the MHRA Advisory Group would be consulted on the MAA, consistent with the MHRA's usual practice. Although the MHRA is not bound by the MHRA Advisory Group's comments, it typically agrees with the MHRA Advisory Group's opinions. It is our understanding that letters of comments are often issued in response to MAAs involving new combination products. The most significant comment in the MHRA Advisory Group's letter of comments was that we provide additional data that supports the benefits of the combination of metoclopramide hydrochloride and naproxen sodium in MT 100. We provided additional data to the MHRA Advisory Group in March 2004.

We have scheduled a Type A meeting with the FDA to discuss the not−approvable letter for MT 100. A Type A meeting is defined by the FDA as a meeting immediately necessary for an otherwise stalled drug development program to proceed. We have also scheduled a meeting with the MHRA Advisory Group to discuss the MT 100 MAA and the Advisory Group's comments. We expect both meetings to occur in the fourth quarter of 2004.

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

We have incurred direct product costs associated with the development of MT 100 during the nine months ended September 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and from inception to date of $0.7 million, $7.5 million, $4.0 million, $3.2 million and $38.7 million, respectively. Our direct product costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300. In December 2002, we submitted to the FDA an NDA for approval of MT 300. On October 17, 2003, we received a not−approvable letter from the FDA with respect to our NDA for MT 300, 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. 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 in an effort to resolve the issues raised in the letter. In April 2004, the FDA advised us that it 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 are preparing to submit the additional information to the FDA. Additionally, we have scheduled a Type A meeting with the FDA to discuss the not−approvable letter for MT 300. We expect the meeting to occur in the fourth quarter of 2004.

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

We have incurred direct product costs associated with the development of MT 300 during the nine months ended September 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and from inception to date of $0.3 million, $3.0 million, $5.2 million, $0.8 million and $14.5 million, respectively. Our direct product costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Trexima. In May 2004, we commenced the Phase 3 clinical program for Trexima. We are conducting two Phase 3 pivotal trials designed to determine the effectiveness and safety of Trexima for the acute treatment of migraine as well as to satisfy the requirements of the FDA's Combination Drug Rule. In addition, we are conducting a long−term, open label safety study. We expect to file an NDA for Trexima in the second half of 2005. In addition, GSK is funding and currently conducting two Phase 3b/4 studies.

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

We have incurred direct product costs associated with the development of Trexima during the nine months ended September 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and from inception to date of $4.9 million, $1.9 million, $4.7 million, $0.9 million and $13.0 million, respectively. Our direct product costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Collaboration and License Agreements

The principal terms of our collaboration agreements are discussed below.

In June 2003, we signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries. Under the terms of the agreement, Nycomed will have exclusive rights in Denmark, Sweden, Norway and Finland to commercialize MT 100 upon its approval in these countries. Upon execution of the agreement, Nycomed paid us an upfront fee of $500,000. We are eligible to receive milestone payments in an aggregate amount of between $500,000 and $1.0 million upon the occurrence and timing of certain regulatory approvals, including the approval of the MAA in the UK and in the other countries where Nycomed has rights. In addition, Nycomed is obligated to pay us a specified royalty on all sales of MT 100, based upon the higher of an agreed percentage of sales on a country−by−country basis, subject to reduction in the event of generic competition, or an agreed dollar amount per unit sold subject to reduction under certain conditions, until the latter of the expiration of the last to expire issued applicable patent in the particular country or 15 years. The scheduled expiration date of the patent that is currently applicable in Sweden, Finland and Denmark is November 12, 2016. There is no applicable patent in Norway. The license agreement will expire on a country−by−country basis upon the later of (a) the date of expiration of all royalty obligations in a particular country, which is scheduled for November 12, 2016 in Sweden, Finland and Denmark, and (b) 15 years after the date of first commercial sale of MT 100 in such country under the agreement. Nycomed has the right to terminate the agreement if we default under the agreement or the MAA is not approved by a specified date or is withdrawn. Nycomed can terminate the applicability of the agreement to a particular country if we withdraw the required regulatory application in that country. If the MAA for MT 100 is not approved by a specified date or we withdraw a regulatory application in any of the countries identified in the agreement, we will be required to pay a withdrawal fee in an amount that ranges from $112,500 to $400,000. Assuming satisfactory resolution of the issues raised in the September 2003 MAA comment letter discussed above, we intend to seek approval of MT 100 in Denmark, Sweden, Norway and Finland through the European Union Mutual Recognition Procedure.

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

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

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5−HT $_{1B/1D}$ agonist) and a long−acting NSAID. The combinations covered by the agreement are among the combinations of MT 400.

Under the terms of the agreement, GSK has exclusive rights in the United States to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long−acting NSAID. We are responsible for development of the combination product, while GSK is to provide formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart−Scott−Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. Additionally, GSK is obligated to make payments to us in an amount up to $40.0 million upon the achievement of specified development and regulatory milestones relating to an NDA and commercialization progress for the first product. Up to an additional $10 million is payable upon achievement of milestones relating to other products. GSK will also pay us royalties on all sales of marketed products, and in addition, sales performance milestones of up to $80.0 million if certain sales thresholds are achieved, until at least the expiration of the last to expire issued applicable patent, August 14, 2017 based upon the scheduled expiration of currently issued patents. GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre−determined share of the market for the product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle POZEN to terminate the agreement is GSK's determination not to further develop the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

In September 2003, we signed an agreement with Xcel for the further development and commercialization of MT 300. Under the terms of the agreement, Xcel will have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations. Pursuant to the terms of the agreement, Xcel paid us an upfront fee of $2.0 million. Under certain circumstances, if we elect not to seek approval of the NDA for MT 300, we would be required to pay to Xcel a termination fee of $1.0 million. Potential milestone payments of up to $8.0 million will be due upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300. 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, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that 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 (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent) unless earlier terminated by either party for a material breach or in the event that either party determines not to pursue approval of MT 300. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non−terminating party. Generally, each party must indemnify the other for damages arising from such party's breach of its representations, warranties and obligations under the agreement, as well as for the gross negligence or willful misconduct by either party. Additionally, Xcel must indemnify us for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while we must indemnify Xcel for any damages arising from such development, manufacture or use prior to the effective date. We must also indemnify Xcel for any use by us or any sublicensee of certain technology owned by Xcel. Based upon the delayed commercialization of MT 300 due to the not−approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Xcel have mutually agreed, in writing, to extend the time for certain activities under our agreement with Xcel that are dependent on the FDA's actions with respect to MT 300. Pending the outcome of discussions with the FDA, the parties may need to revisit certain time specific provisions in the agreement in the first quarter of 2005.

Results of Operations

Three months ended September 30, 2004 compared to the three months ended September 30, 2003

Net income (loss) per share: Net loss attributable to common stockholders for the quarter ended September 30, 2004 was $(5,831,000) or $(0.20) per share, as compared to a net loss of $(3,732,000), or $(0.13) per share, for the quarter ended September 30, 2003.

Revenue: We recognized $1,891,000 of licensing revenue for the quarter ended September 30, 2004 as compared to $1,887,000 for the quarter ended September 30, 2003. Revenue resulted from amortization of upfront payments we received in 2003 pursuant to development and commercialization agreements relating to MT 100, MT 300 and MT 400 that we executed in the second and third quarters of 2003 and from a $15 million milestone payment we received from GSK for commencement of Phase 3 clinical trial activities for Trexima in May 2004. Our license agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. Approximately $18.1 million remains in deferred revenue at September 30, 2004. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by 82% to $5,859,000 for the third quarter of 2004, as compared to $3,219,000 for the same period of 2003. The $2,640,000 increase was due primarily to an increase in direct product costs for Trexima and our current exploratory programs, including the lornoxicam and PPI/NSAID programs, and other departmental expenses, offset by a decrease in direct product costs associated with MT 100 and MT 300. Direct product costs associated with the development of Trexima increased by $2,779,000 to $3,135,000, primarily due to Phase 3 clinical trial activities during the third quarter of 2004, as compared to the same period of 2003. Direct product costs associated with our current exploratory programs increased by $887,000 to $1,351,000, primarily due to Phase 2 clinical trial and pharmaceutical development activities for such exploratory programs during the third quarter of 2004, as compared to the same period of 2003. MT 100 direct product costs decreased by $912,000 to $110,000, primarily due to FDA filing fees incurred for submission of the MT 100 NDA in July 2003, as compared to the same period of 2004. Additional research and development expenses, including costs associated with MT 300 and departmental expenses, decreased by $114,000, to $1,263,000. The decrease was primarily due to MT 300 product supply expenses incurred during the third quarter of 2003 as compared to the same period of 2004. We have included in our research and development expenses the personnel costs associated with our research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses decreased by 18% to $2,066,000 for the third quarter of 2004, as compared to $2,528,000 for the same period of 2003. The $462,000 decrease was due primarily to a decrease in the costs associated with our business development activities and personnel related expenses offset by an increase in costs related to our public company activities. Business development expenses decreased by $298,000 to $315,000 primarily due to more pre−commercialization activities for MT 100 and MT 300 in 2003, as compared to the same period of 2004. Administrative expenses decreased by $528,000 to $996,000 in 2004, as compared to the 2003 period, primarily due to a reduction in personnel related expenses for incentive compensation paid to our chief executive officer. Costs associated with our public company activities increased by $364,000 to $755,000 primarily due to legal fees associated with the class action litigation pending against us and other professional consulting fees incurred in preparing for Sarbanes Oxley regulatory compliance. 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 increased to $202,000 for the quarter ended September 30, 2004, from $128,000 for the quarter ended September 30, 2003. This increase was due to an increase in interest rates and our average cash balance available for investing during the period, as compared to the same period of 2003.

Nine months ended September 30, 2004 compared to the nine months ended September 30, 2003

Net income (loss) per share: Net income attributable to common stockholders for the nine−month period ended September 30, 2004 was $3,159,000 or $0.11 per share, as compared to a net loss of $(13,245,000), or $(0.47) per share, for the nine−month period ended September 30, 2003.

Revenue: We recognized $20,670,000 of licensing revenue for the nine−month period ended September 30, 2004 as compared to $1,887,000 during the same period of 2003. Revenue resulted from amortization of upfront payments we received in 2003 pursuant to development and commercialization agreements relating to MT 100, MT 300 and MT 400 and from a $15.0 million milestone payment we received from GSK for commencement of Phase 3 clinical trial activities for Trexima in May 2004. Our license 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. All milestone payments are recognized as revenue upon satisfaction of the contractual event.

Research and development: Research and development expenses increased by 45% to $11,903,000 for the nine−month period ended September 30, 2004, as compared to $8,215,000 for the same period of 2003. The $3,688,000 increase was due primarily to an increase in direct product costs for Trexima, our current exploratory programs, primarily lornoxicam, and other departmental expenses, offset by a decrease in direct product costs associated with MT 100. Direct product costs associated with the development of Trexima increased by $4,251,000 to $4,887,000, primarily due to the commencement of Phase 3 clinical trials in May 2004, as compared to the same period of 2003. Direct product costs associated with our current exploratory programs increased by $1,270,000 to $3,089,000, primarily due to Phase 2 clinical trial activities and pharmaceutical development activities for such exploratory programs during the first nine months of 2004, as compared to the same period of 2003. Costs associated with MT 100 decreased by $2,265,000 to $660,000, primarily due to the completion of clinical, toxicology and regulatory activities required for submission of the MT 100 NDA in July of 2003 as compared to the same period of 2004. Additional research and development expenses, including costs associated with MT 300 and departmental expenses, increased by $432,000 to $3,267,000. The increase was primarily due to an increase in personnel and related expenses for our research and development activities. 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 decreased by 17% to $6,071,000 for the nine−month period ended September 30, 2004, as compared to $7,312,000 for the same period of 2003. The $1,241,000 decrease was due primarily to a decrease in the costs associated with our business development activities and personnel−related expenses offset by an increase in costs related to our public company activities as compared to the same period of 2003. Business development expenses decreased by $1,130,000 to $1,217,000 primarily due to pre−commercialization activities for MT 100 and MT 300 during the nine−month period in 2003, as compared to the same period of 2004. Administrative expenses decreased by $853,000 to $2,763,000 in 2004 as compared to the 2003 period, primarily due to a reduction in personnel related expenses for incentive compensation paid to our chief executive officer. Costs associated with our public company activities increased by $742,000 to $2,091,000 primarily due to an increase in legal fees related to SEC compliance and the class action litigation pending against us, accounting, and other consulting fees incurred in preparing for compliance with the Sarbanes−Oxley Act, and an increase in directors and officers insurance cost, as compared to the same period of 2003. General and administrative expenses consisted primarily of the cost of administrative personnel, facility infrastructure, business development expenses and public company activities.

Interest income: Interest income increased to $463,000 for the nine−month period ending September 30, 2004, from $395,000 for the same period of 2003. This increase was primarily due to an increase in our average cash balance available for investing during the period, as compared to the same period of 2003.

Income Taxes

As of December 31, 2003, we had 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, 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 that expire between 2011 and 2022. We currently estimate a cumulative net operating loss carry−forward of approximately $10,400,000 for the twelve months ending December 31, 2004 and estimate an effective tax rate of 0% for the nine months ended September 30, 2004. Our effective tax rate was 0% for the nine months ended September 30, 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, and, since 2003, from upfront and milestone payments from our collaborators, resulting in cash of $133.9 million and $42.5 million, respectively. Through September 30, 2004 and during 2003, we generated positive cash flows from operations of $0.7 and $9.7 million, respectively. As of September 30, 2004, cash and cash equivalents totaled $61.2 million, an increase of $0.7 million as compared to December 31, 2003.

Operating cash received during the nine−month period ended September 30, 2004 totaled $15.0 million, resulting from a payment received under our collaboration agreement with GSK for our MT 400 technology. The milestone payment was received in May 2004 for commencement of Phase 3 clinical trial activities relating to Trexima. We expect additional milestone payments from GSK over the next several years in an aggregate amount of up to $40.0 million upon the satisfaction of specified regulatory and commercialization events for Trexima. Cash received from financing activities during the period totaled $1.3 million, reflecting the net proceeds from the exercise of stock options.

Cash paid for operating activities totaled $16.0 million for the nine−month period ended September 30, 2004. Cash paid for operating activities in the fiscal years ended December 31, 2003, 2002, and 2001 was $17.8 million, $23.7 million, and $18.4 million, respectively. Cash required for our operating activities during 2004 is projected to increase from our historical requirements due to the commencement of Phase 3 clinical trial activities for Trexima and an increase in expenses related to other exploratory development.

Barring unforeseen developments and provided that our operating expenses for 2005 and 2006 approximate the same level as we expect them to be for 2004, we believe that our existing liquidity and capital resources, including the proceeds from our initial public offering and payments received under our collaboration agreements, should 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 have any milestone or other required material payment obligations during that period. However, our efforts to reverse the FDA’s not−approvable letters on MT 100 and MT 300 and other regulatory delays in the development of our existing and future product candidates may increase our cash requirements beyond our currently assumed needs and may require that we seek additional funds from sources that may or may not be available on terms favorable to us.

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 obtaining regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- costs incurred to enforce and defend our patent claims and other intellectual rights; and
- costs incurred in the defense of class action and shareholder derivative lawsuits that have been filed against us or our current or former directors and officers relating to MT 100 and MT 300.

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

Risks Related to Our Business

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

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of our current product candidates, particularly MT 100 and Trexima. 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 September 30, 2004, we had an accumulated deficit of approximately $106.1 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing of payments that we may receive from others. Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with Nycomed for MT 100, GSK for Trexima and Xcel for MT 300. Given our receipt from the FDA of not−approvable letters with respect to MT 100 and MT 300, we may never receive milestone payments from Nycomed or Xcel. In addition, we will have to pay to Nycomed a withdrawal fee of between $112,500 and $400,000 if the MAA for MT 100 is not approved by a specified date or we withdraw a required regulatory application for MT 100 in a country specified in the agreement with Nycomed, and we will have to repay Xcel $1 million if we determine to terminate development of MT 300. We expect to continue to incur significant operating losses and do not know when, if and to what extent 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, we 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 and they may never be approved.

In the United States, a separate NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek outside the United States. For example, as described in the three risk factors that follow, we are currently seeking to resolve issues raised by the FDA related to our MT 100 and MT 300 NDAs and by the MHRA related to our MAA for MT 100 in the UK. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them.

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 not−approvable letter we have received from the FDA regarding MT 300, we may elect to discontinue seeking approval of the NDA for MT 300. In that case, the terms of our agreement with Xcel would be require us to pay to Xcel a termination fee of $1.0 million. Similarly, under our agreement with Nycomed, we will be required to pay a withdrawal fee if the MAA for MT 100 is not approved by the MHRA by a specified date or we withdraw a regulatory application in any of the countries identified in the agreement in an amount that ranges from $112,500 to $400,000. In addition, we would forfeit the ability to receive potential aggregate milestone payments of up to $8.0 million under the Xcel agreement and of between $500,000 and $1.0 million under the Nycomed agreement, as well as royalties under either 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 therefore would not receive any revenues from that product.

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

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

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

If we are unable to convince the FDA to reverse its conclusion in its not−approvable letter for MT 100, we would not receive any revenue from sales of MT 100.

As previously described in our press release dated June 1, 2004, on May 28, 2004 we received a not−approvable letter from the FDA with respect to our NDA for MT 100. In the letter, the FDA noted that we had demonstrated unambiguous statistically significant superiority compared to an appropriate control on a valid measure of pain as well as on the three associated symptoms of nausea, photophobia and phonophobia in one study. However, the FDA noted that MT 100 did not clearly meet these criteria in a second study. We also stated that the FDA letter cited the apparent lack of superiority of MT 100 over naproxen for sustained pain relief, which was the primary endpoint for the two component studies. We noted in our press release that this issue appears to arise primarily from an apparent difference in understanding between us and the FDA as to the appropriate statistical analysis of this endpoint. Additionally, the FDA mentioned that, based on animal studies, there may be a potential risk of carcinogenicity, presumably due to metoclopramide, one of the components of MT 100. Finally, we noted in the press release that, for the first time, the FDA raised an approvability issue concerning the risk of tardive dyskinesia ("TD") presented by the use of metoclopramide.

We have had and intend to continue to have communications with the FDA to seek to persuade the FDA that MT 100 should be approved based upon the data that we submitted in the NDA for MT 100. However, we may not be successful in those efforts. Further, it is possible that we may be required to conduct another clinical study to provide additional evidence that MT 100 meets the requirements of the Combination Rule and the efficacy standards applicable to MT 100. We cannot estimate the cost or duration of any such study or decide whether to conduct such a study until the design of such a study has been determined with the FDA. Our Phase 3 clinical trials of MT 100 took between three months and eighteen months and involved a direct cost per patient of between $2,200 and $3,200. However, the duration and cost of any new study that we may conduct may be different from our prior clinical trials. No assurance can be given that our efforts to obtain approval of MT 100 will ultimately be successful.

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

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

In October 2002, we submitted our MAA for MT 100 to the MHRA in the UK. In September 2003, we received a letter of comments relating to the MAA from an Advisory Committee to the MHRA. Although the MHRA is not bound by the MHRA Advisory Group's comments, it typically agrees with the MHRA Advisory Group's opinions. The most significant comment in the MHRA Advisory Group's letter of comments was that we provide additional data to support the benefits of the combination of metoclopramide hydrochloride and naproxen sodium in MT 100. We provided additional data to the MHRA Advisory Group in March 2004 to address the MHRA Advisory Group's questions. We can give no assurance that the MHRA Advisory Group 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 in the UK by the MHRA, 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, potential licensees, including Nycomed and any other party with whom we may enter into an agreement to commercialize MT 100, will not be able to sell MT 100 successfully in some of those European Union countries unless they price MT 100 competitively and obtain necessary regulatory approvals for reimbursement to the patient. In some countries, licensees would need to enter into discussions regarding pricing and reimbursement of MT 100 with the appropriate governmental authorities pursuant to each of such country's individual requirements. Those discussions could further delay successful commercialization of MT 100 because of the time−consuming review processes in some of those countries.

If we are unable to convince the FDA to reverse its conclusion in its not−approvable letter for MT 300, we would not receive any revenue from sales of MT 300.

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 in an effort to resolve the issues raised in the letter. In April 2004, the FDA advised us that it 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 half of 2004. There is no assurance that the FDA will accept any 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 and supplemented by us. Even if the FDA were to approve MT 300, as a condition of approval, the FDA could request or require additional studies or analyses of existing data which would require us to incur additional costs and expenses, which could be significant and would delay the commercialization of MT 300.

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

Under our current strategy, and for the foreseeable future, we expect to depend upon collaborations with third parties to develop our product candidates and we expect to depend substantially upon third parties to commercialize our products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and any future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators. In addition, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Collaborative agreements for the acquisition of new compounds or product candidates may require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their arrangements with us on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology in the United States and collaborations with Nycomed in the Nordic countries and 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 for any reason; 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. Our receipt of two not−approvable letters may suggest to our collaborators that they should terminate their agreements with us. If these licensees exercise their termination rights, or if these license agreements terminate because of delays in obtaining regulatory approvals, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and commercialize these and our other product candidates. Moreover, any future collaborations or license arrangements may not be on terms favorable to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determines, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the 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; and
- disagreements may arise regarding a breach of the arrangement, ownership of proprietary rights, clinical results or regulatory approvals;

These factors could lead to delays in the development of our product candidates, and/or the commercialization of our products, 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 license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. Our development and commercialization agreement with GSK is subject to this risk. GSK has publicly disclosed that it is exploring the development of several early−stage compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to work with us on Trexima or any other product candidates that may be developed under the agreement, it has the ability to terminate our agreement upon 90 days' written notice. In such a case, we would need to enter into a new development and commercialization agreement and would need to start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our MT 400 technology, which is not certain, we would face delays and redundant expenses in that development.

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

We have no sales or distribution personnel or capabilities. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively,

we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that, should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity studies and clinical trials for our product candidates. Any unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could reduce or delay our receipt of 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 be noted that the results of our clinical trials are not necessarily predictive of results we will obtain in subsequent clinical trials. This may occur for many reasons, including, among others, the variability of patient characteristics or in the presence of patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, if we conduct an additional study to address the FDA's concerns in its not−approvable letter on MT 100, there is no assurance that the results of such a study will satisfy all of the FDA's conditions for approval because of the way migraine affects different patients, including the presence, or lack or level of severity, of secondary symptoms in a particular patient and the variability of the responsiveness of migraine attacks to given treatments, all of which may affect treatment responses. Further, as contemplated under our collaboration agreement with GSK, GSK has developed a formulation of Trexima for use in our Phase 3 clinical trials of Trexima that is different from the formulation and dose of sumatriptan used in the Phase 2 proof−of−concept trial of MT 400 that we conducted prior to entering into the collaboration with GSK. This formulation has never been used in a clinical trial setting. This different dose and formulation, together with the other factors that affect the results obtained in clinical trials, including those listed above, may cause the results in our Phase 3 trials of Trexima to differ from the results we observed in our Phase 2 trial of MT 400.

The successful completion of clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. For example, even though we are entitled to submit an NDA for Trexima as a 505(b)(2) application, the FDA may require us to conduct more studies or trials than we now believe are necessary. Further, even though we may have completed all planned clinical trials for a product candidate and submitted an NDA for such product candidate, as we have for MT 100 and MT 300, the FDA may require us to conduct additional clinical trials and studies to support our NDAs. For example, the FDA may require us to conduct additional studies or trials of MT 100 or MT 300 in connection with our efforts to convince the FDA to reverse its not−approvable decisions on these product candidates. We may also determine from time to time, including in connection with our efforts to resolve the FDA's issues raised in the not−approvable letters related to MT 100 and MT 300, that it would be necessary to seek to persuade the FDA to evaluate the results of a study or trial in a manner that differs from the way the FDA initially evaluated the results, or customarily evaluates results. In addition, we may have unexpected results that require us to reconsider the need for certain studies or trials. For example, results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies.

Once submitted, an NDA requires FDA approval before we can distribute or commercialize the product described in the application. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, although we believe that we provided the necessary data to support approval of the NDAs for MT 100 and MT 300, the FDA issued not−approvable letters for the MT 100 and MT 300 NDAs on May 28, 2004 and October 17, 2003, respectively. Further, although we believed the results of our recently completed MT 100 two−year rat carcinogenicity study provided no evidence that the concomitant administration of maximum tolerated doses of metoclopramide and naproxen, the two active components in MT 100, produced any statistically significant differences in the occurrences and types of tumors seen with metoclopramide alone, the FDA expressed concern about the potential risk of carcinogenicity, presumably due to metoclopramide, in its MT 100 not−approvable letter. The FDA may also require 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 Group, 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. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we are currently experiencing as a result of the not−approvable letters we have received from the FDA on MT 100 and MT 300, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non−competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive revenues from sales of products.

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

We and certain of our current and former directors and officers are named as defendants in five purported securities class action lawsuits filed in the United States District Court for the Middle District of North Carolina. The lawsuits are brought on behalf of a purported class of purchasers of our securities, and seek unspecified damages. As is typical in this type of litigation, these securities class action lawsuits contain substantially similar allegations, and additional lawsuits containing substantially similar allegations may be filed in the future. These actions have been consolidated for pre−trial purposes and any other similar federal actions that may be filed will also be consolidated with these actions for pre−trial purposes. The lawsuits allege claims based on purportedly misleading statements concerning our product candidates MT 100 and MT 300. Two derivative actions have also been filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina. These actions allege violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning our product candidates MT 100 and MT 300 that are referenced in the various purported class action lawsuits.

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

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

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

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured. If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. In addition, due to the extensive time needed to develop and test our products, any patents that we obtain may expire in a short time after commercialization. This would reduce or eliminate any advantages that such patents may give us.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such a risk exists with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. A third party has recently filed a protest regarding the reissuance of that MT 100 patent. We do not know the weight the examiner will give to the protest. However, we believe the protest to be without merit.

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. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

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

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

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing;
- 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, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

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

For fiscal years 2001 through 2003, our average annual operating expenses (including average non−cash deferred compensation of $2.2 million) were $23.3 million; our average annual operating expenses excluding the non−cash deferred compensation were $21.1 million. We are currently expecting operating expenses for the 2004 fiscal year (including restricted stock compensation expense of $400,000) to be between $26.0 million and $28.0 million. Expenses might increase in 2004 and 2005 if the FDA or the MHRA requires us to conduct additional clinical trials or studies in connection with their reconsideration of our regulatory filings for MT 100 and MT 300. As of September 30, 2004, we had $61.2 million in cash and cash equivalents. If we need to conduct additional studies or trials in order to seek to reverse the FDA’s decisions relating to MT 100 and MT 300 and if our operating expenses in 2004 and 2005 are much higher than our currently expected operating expenses in 2004, and if we do not receive any additional milestone payments under any of our collaboration agreements, we may not have sufficient cash reserves to maintain our level of business activities throughout 2006.

We may be unable to raise additional equity funds until the uncertainties of the regulatory future of MT 100 and MT 300 resulting from our receipt of not−approvable letters for both product candidates has been resolved. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business

strategy.

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

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

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an employment agreement with us on April 1, 1999, as amended and restated on July 25, 2001, for a three−year term with automatic one−year renewal terms. We also entered into employment agreements with certain of our other key management personnel, 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 Dr. Marshall E. Reese, Executive Vice President, Product Development, William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer, Kristina M. Adomonis, Senior Vice President, Business Development, or Dr. W. James Alexander, Senior Vice President, Product Development, or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific personnel. Since our business is very science−oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

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

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

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- public concern as to the safety and 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 October 25, 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 change in market rates would have a significant negative impact on the value of our investment portfolio.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

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

(b) Change in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As reported in our Quarterly Report on Form 10−Q for the three and six months ended June 30, 2004, as filed on July 30, 2004 and in our Current Report on Form 8−K filed on September 17, 2004, between June 4 and July 28, 2004, four purported class action lawsuits claiming violations of securities laws were filed by holders of our securities in the U.S. District Court for the Middle District of North Carolina against us and certain of our current and former officers. These actions have been consolidated for pre−trial purposes. A fifth case filed on August 6, 2004 has been consolidated with those actions and any other similar federal actions that may be filed will also be consolidated with these actions for pre−trial purposes. The complaints allege, among other claims, violations of federal securities laws, including violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b−5, and violations of Section 20(a) of the Exchange Act against the individual defendants. The complaints allege that we made false and misleading statements concerning our product candidates, MT 100 and MT 300, during the class period. The complaints request certification of a plaintiff class consisting of purchasers of our stock between July 3, 2003 and May 28, 2004, and in one complaint, between October 10, 2000 and May 28, 2004, and seek, among other relief, unspecified damages, plus costs and expenses, including attorneys' and experts' fees. As reported in our Current Report on Form 8−K filed on September 17, 2004, on September 13, 2004, two derivative actions were filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina. These actions allege violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning our product candidates, MT 100 and MT 300 that are referenced in the various purported class action lawsuits. We and the other defendants believe that the allegations in these and the class action complaints are without merit and intend to defend these cases vigorously.

Item 6. Exhibits and Reports on Form 8−K

(a) Exhibits

10.1	Executive Employment Agreement dated August 3, 2004 between the Registrant and William L. Hodges.
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.

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)

October 27, 2004 By: /s/ JOHN R. PLACHETKA

John R. Plachetka
President and Chief Executive Officer

October 27, 2004 By: /s/ WILLIAM L. HODGES

William L. Hodges
Chief Financial Officer

October 27, 2004 By: /s/ JOHN E. BARNHARDT

John E. Barnhardt
Principal Accounting Officer

EXHIBIT INDEX

Exhibit Number	Description
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EXECUTIVE EMPLOYMENT AGREEMENT

This EXECUTIVE EMPLOYMENT AGREEMENT (the "Agreement"), is entered into as of August 3, 2004, by and between POZEN Inc. (the "Company"), with offices located at Suite 400, 1414 Raleigh Road, Chapel Hill, North Carolina 27517, and William L. Hodges ("Executive"), whose address is 401 May Court, Raleigh, North Carolina 27609.

WITNESSETH:

WHEREAS, the Company is engaged in certain pharmaceutical research, development and marketing activities; and

WHEREAS, the Company wishes to employ Executive in the position of Senior Vice President, Finance and Administration and Chief Financial Officer, and Executive desires to accept such employment with the Company.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the parties hereby agree as follows:

1. EMPLOYMENT. The Company hereby employs Executive, and Executive hereby accepts employment, as Senior Vice President, Finance and Administration and Chief Financial Officer of the Company, with such duties and responsibilities as are normally related to such position in accordance with the standards of the industry and as specified in **Exhibit A**, attached hereto and incorporated herein by reference, and any additional duties as may be assigned to Executive from time to time by the President or the Board of Directors of the Company.

2. TERM. Executive's employment shall be for a term of one (1) year from the date of execution of this Agreement (the "Term"), and thereafter shall be automatically renewed with additional one (1) year terms to follow consecutively, subject to the termination and severance provisions herein later provided, unless amended or modified by mutual agreement of the parties. As used herein, "Term" shall include the Initial Term and any renewals thereof in accordance with this Agreement.

3. EXCLUSIVE SERVICE. Executive agrees to devote Executive's full time and attention to the performance of Executive's duties and responsibilities on behalf of the Company and to comply with all policies and regulations of the Company.

4. COMPENSATION. During the Term of this Agreement, Executive's compensation shall be determined and paid as follows:

(a) Base Salary. Executive shall receive an annual base salary of at least Two Hundred and Thirty Thousand Dollars ($230,000) payable in accordance with the

Company's payroll practices. Annual increases will be made, if any, based upon performance, and in the sole discretion of the Board of Directors or the Compensation Committee of the Board of Directors (each or collectively, the "Committee"), such increases, if any, to be effective as of January 1 of each year during the Term.

(b) Bonus. Executive shall be eligible to receive an annual cash incentive bonus of up to forty percent (40%) of Executive's annual base salary as may be set by the Committee by March 31 of each year. The determination of the actual bonus earned, if any, shall be at the sole discretion of the Committee and shall be based upon the Committee's assessment of Executive's performance and the achievement of certain objectives which shall be set by the Committee from time to time. Executive's performance shall be evaluated by the Committee on an annual basis, and the Committee shall adjust Executive's salary in its sole discretion. Nothing in this section shall be construed as guaranteeing Executive a bonus in any amount.

(c) Stock Options. Subject to the approval of the Committee, upon the commencement of Executive's employment with the Company, Executive shall be granted an option to purchase Eighty Thousand (80,000) shares of the common stock of the Company at a purchase price equal to closing price of the common stock of the Company as quoted on the NASDAQ Stock Market on the date of grant. Such shares shall vest in accordance with and be governed by the terms of the Company's 2000 Equity Compensation Plan, as amended and restated, and an Incentive Stock Option Agreement issued in accordance therewith.

(d) Benefits. Executive shall be eligible to participate in the Company's standard employee benefit programs made available to employees of the Company from time to time, subject to appropriate premium contributions, benefit elections, etc. In addition, Executive shall be entitled to three (3) weeks of paid vacation per year.

(e) Business Expenses. The Company shall reimburse Executive for all reasonable expenses incurred in the furtherance of the Company's business and interests, including travel and entertainment. Executive agrees to comply with the expense reporting policies and procedures of the Company.

(f) Adequate Office Space. The Company shall provide to Executive adequate office space, facilities, and administrative support appropriate to Executive's position.

5. TERMINATION. This Agreement shall or may be terminated, as the case may be, upon the terms and conditions hereinafter provided.

(a) Voluntary Termination. This Agreement shall be considered voluntarily terminated by the parties if either party provides written notice of such party's intent not to renew this Agreement, provided that such party shall provide at least ninety (90) days' written notice to the other party prior to the last day of the Initial Term or any renewal term.

(b) Involuntary Termination. The Company may terminate this Agreement upon written notice to Executive (or Executive's representative) in any of the following events:

(i) The death of Executive;

(ii) Executive becomes permanently disabled; or

(iii) For Cause, immediately upon written notice to Executive. "Cause" shall be determined by the Board of Directors and shall mean: (A) breach by Executive of the terms of this Agreement; (B) breach of the Nondisclosure, Inventions and Non−Competition Agreement (described in Section 6 below); (C) material failure by Executive to comply with the policies or directives of the Board of Directors; (D) any illegal or dishonest action that is materially detrimental to the Company; or (E) Executive's failure to faithfully carry out the duties of Executive's position, provided that Executive shall be given a period of thirty (30) days after receipt of written notice of such failure during which to correct such failure; and (F) Executive's violation of the Company's policies regarding harassment or unlawful discrimination.

(c) Obligations upon Certain Terminations. Upon voluntary termination of this Agreement, or termination of Executive's employment by the Company for Cause (as defined above) or upon Executive's death or disability, or termination by Executive for other than Good Reason (as defined below), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to Executive through the date of such termination.

(d) Severance. In the event of termination of Executive's employment (i) by the Company for reasons other than Cause or Executive's death or disability, or (ii) by Executive for Good Reason, and provided Executive executes and delivers a Release and Settlement Agreement in a form acceptable to the Company, Executive shall receive a severance benefit in an amount equal to one (1) year's base salary plus the average annual bonus awarded Executive over the previous two (2) years (the "Severance Benefit"). The Severance Benefit will be payable in accordance with the Company's normal payroll policies over a period of twelve (12) months from the date of termination. Executive shall also continue to be entitled to receive all Company benefits to which Executive was entitled as of the date of termination, subject to the terms of all applicable benefit plans and to the extent such benefits can be provided to a non−employee (or to the extent such benefits cannot be provided to non−employees, then the cash equivalent thereof), at the same average level and on the same terms and conditions which applied immediately prior to the date of Executive's termination, for the shorter of (i) one year following the date of such termination or (ii) until Executive obtains comparable coverage from another employer (the "Continuing Benefits"). At any time during the

severance period, the Company may elect to pay a lump sum amount to Executive which represents the reasonable value of the Severance Benefit and/or the Continuing Benefits reduced to their present value in lieu of continuing payment of such benefits.

(e) Good Reason. For purposes of this Agreement, "Good Reason" shall mean, the occurrence, without the consent of Executive, of any of the following events, unless, in the case of (i), (ii) and (iii) below, such event is corrected within thirty (30) days after written notification by Executive to the Company of the same: (i) the office from which Executive performs Executive's principal duties is moved more that 50 miles from the current location of the Company's offices in Chapel Hill, North Carolina; (ii) Executive's duties and responsibilities are substantially reduced or diminished; (iii) the Company materially breaches its obligations under this Agreement; or (iv) a Change of Control (as defined below) occurs and Executive notifies the Company in writing within sixty (60) days of the consummation of such Change of Control that Executive intends to terminate Executive's employment as a result of the Change of Control, in which event such termination shall be effective not less than sixty (60) days after the date of such written notice.

(f) Tax Gross−Up for Parachute Payments.

(A) If at any time or from time to time it shall be determined that any payment to Executive pursuant to this Agreement or any other payment or benefit hereunder or under any other plan or agreement or otherwise ("Potential Parachute Payment") would constitute an "excess parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and thus would be subject to the excise tax imposed by Section 4999 of the Code, or any similar tax payable under any United States federal, state, local, foreign or other law ("Excise Tax"), then Executive shall receive and the Company shall pay or cause to be paid a Tax Gross−Up Payment with respect to all Taxes as defined below. The Tax Gross−Up Payment is intended to compensate Executive for all such excise taxes and federal, state, local, foreign or other income, employment or excise taxes or other taxes ("Taxes") payable by Executive with respect to the Tax Gross−Up Payment and shall be in an amount such that after payment of Taxes on such amount there remains a balance sufficient to pay the taxes being reimbursed. For purposes of determining the amount of the Tax Gross−Up Payment, Executive shall be deemed to pay federal income tax and employment taxes at the highest marginal rate of federal income and employment taxation in the calendar year in which the Tax Gross−Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of Executive's residence (or, if greater, the state and locality in which Executive is required to file a nonresident income tax return with respect to the Potential Parachute Payment), net of the maximum reduction in federal income taxes that may be obtained from the deduction of such state and local taxes.

(B) The determinations to be made under this Section 5(f) shall be made by the Company's independent public accountants (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations both to the

Company and to Executive. Any such determination by the Accounting Firm shall be binding upon the Company and Executive. All fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 5(f) shall be borne solely by the Company, and the Company shall indemnify and hold harmless the Accounting Firm of and from any and all claims, damages and expenses resulting therefrom, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.

(g) Disability. For purposes of this Agreement, Executive shall be considered permanently disabled when a qualified medical doctor mutually acceptable to the Company and Executive or Executive's personal representative shall have certified in writing that: (i) Executive is unable because of medically determinable physical or mental disability to perform substantially all of Executive's duties for more than one hundred eighty (180) calendar days measured from the last full day of work; or (ii) by reason of mental or physical disability, it is unlikely that Executive will be able, within one hundred eighty (180) calendar days, to resume substantially all business duties and responsibilities in which Executive was previously engaged and otherwise discharge Executive's duties under this Agreement.

(h) Change of Control. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:

(i) If any person (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a beneficial owner (as defined in Rule 13d−3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

(ii) Upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote), (B) a sale or other disposition of all or substantially all of the assets of the Company, or (C) a liquidation or dissolution of the Company.

6. NON−DISCLOSURE, INVENTIONS AND NON COMPETITION. As a condition to Executive's employment by the Company and simultaneously with the execution of this Agreement, Executive shall execute and agrees to be bound by the terms of the Company's standard non−disclosure, inventions and non−competition agreement in the form attached hereto as **Exhibit B** and incorporated herein by reference.

7. NOTICES. Any notice required to be given shall be in writing personally delivered by certified mail or registered mail or by facsimile (receipt confirmed) to the address last shown in the Company's records.

8. SEVERABILITY. The provisions of this Agreement shall be deemed severable, and the invalidity or unenforceability of any provision (or part thereof) of this Agreement shall in no way affect the validity or enforceability of any other provision (or remaining part thereof).

9. GOVERNING LAW. This Agreement shall be governed by and construed according to the laws of the State of North Carolina, without reference to the choice of law provisions of such laws.

10. ENTIRE AGREEMENT. This Agreement contains the entire agreement of the parties relating to the subject matter hereof, and the parties hereto have made no agreements, representations, or warranties relating to the subject matter of this Agreement which are not set forth herein. In particular, without limiting the foregoing, this Agreement supersedes in its entirety that certain offer letter from the Company to Executive dated July [21], 2004 and that certain Consulting Agreement by and between the Company and Executive dated July 26, 2004. No modification of this Agreement shall be valid unless made in writing and signed by the parties hereto.

11. BENEFIT. This Agreement shall be binding upon and inure to the benefit of both parties and their respective heirs, representatives, successors and assigns, including any corporation or other entity with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of Executive are personal and shall not be assigned by Executive.

12. EXECUTIVE REPRESENTATIONS.

(a) Executive represents that his performance of this Agreement and as an employee of the Company does not and will not breach any non−competition or other agreement to keep in confidence proprietary information acquired by Executive in confidence or in trust prior to Executive's employment by the Company. Executive represents that he has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Agreement or would prevent or interfere with the company's employment of Executive on the terms set forth herein.

(b) Executive represents that he has not brought and shall not bring with Executive to the Company, or use in the performance of Executive's responsibilities for the

Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to Executive prior to his employment with the Company, unless Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

13. INJUNCTIVE RELIEF. Executive understands and agrees that the Company will suffer irreparable harm in the event that Executive breaches any of Executive's obligations under this Agreement and that monetary damages will be inadequate to compensate the Company for such breach. Accordingly, Executive agrees that, in the event of a breach or threatened breach by Executive of any of the provisions of this Agreement, the Company, in addition to and not in limitation of any other rights, remedies, or damages available to the Company at law or in equity, shall be entitled to a permanent injunction in order to prevent or to restrain any such breach by Executive, or by Executive's partners, agents, representatives, servants, employers, employees and/or any and all persons directly or indirectly acting for or with Executive; provided such injunction shall not affect Executive's ownership rights in the Company or compensation earned or due Executive.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Executive Employment Agreement and affixed their seals as of the day and year first above written.

EMPLOYER:

POZEN INC.

By: /s/ John R. Plachetka

Name: John R. Plachetka, Pharm.D.
Title: Chairman, President and CEO

EMPLOYEE:

/s/ William L. Hodges

William L. Hodges

EXHIBIT A

Senior Vice President, Finance and Administration and Chief Financial Officer

Responsibility and Tasks List

Reporting to the President, the Senior Vice President, Finance and Administration and Chief Financial Officer ("CFO") will assist in developing the strategic direction of the Company and have the skills necessary to lead in the growth of the Company. The CFO will be responsible for all financial activities and relationships of the Company. Importantly, the CFO will be expected to lead anticipated financing and corporate development transactions from conceptualization through to implementation and integration. The CFO will assure that the Company maintains the strong financial infrastructure required to support continued rapid growth. This executive will be widely viewed as a key member of the management team with responsibility for influencing the thinking and decisions behind the Company's overall strategies, plans, and operations. Specific responsibilities will include, among others, the management of:

- Finance – the evaluation, analysis and execution of all capital raising and all other finance related projects.

- Corporate Development – manage the analysis, execution and integration of mergers, acquisitions, and contribute significantly to the analysis, execution and integration of business partnerships, licensing agreements, etc.

- Investor Relations − working closely with the CEO and additional senior management as appropriate, leading the effort to interface with the investment community, specifically in working with institutional investors, research analysts, investment bankers and corporate partners.

- Accounting – management of individuals responsible for the implementation and management of the accounting structure, methods, systems, operating procedures and FASB and SEC requirements.

- Planning/Forecasting – management of corporate−wide financial planning, procedures, measures, budgeting and forecasting, project specific financial analysis and general risk analysis.

- Reporting and Analysis – responsible for the timely and accurate reporting and analysis, both written and oral, of financial and associated business information to internal, external, and regulatory constituencies.

The CFO will be a partner with the rest of the senior management team and get involved in a variety of strategic and business challenges that go beyond the financial function. Skills in oral and written communication, strategic thinking, combined with a personal sense of flexibility and humor, will lead to a successful integration of the new CFO into the Company's culture. Additionally, the CFO will be expected to:

- Supervise corporate communications and all aspects of investor relations.

- Possess an entrepreneurial, can do attitude.

- Possess excellent communication skills and has experience delivering company presentations at investment conferences.

- Be a team player with a pleasant, engaging personality.
- Possess excellent managerial skills.
- Demonstrate a track record of unquestioned integrity and honesty.

EXHIBIT B

NON−DISCLOSURE, INVENTION AND NON−COMPETITION AGREEMENT

THIS NON−DISCLOSURE, INVENTION AND NON−COMPETITION AGREEMENT (the "Agreement") is effective for all purposes and in all respects, by and between POZEN Inc., a Delaware corporation (hereinafter referred to as "Employer"), and _____(hereinafter referred to as "Employee").

WHEREAS, Employer is about to employ Employee in a position of trust and confidence to aid Employer in its business; and

WHEREAS, Employer desires to receive from Employee a covenant not to disclose certain information relating to Employer's business and certain other covenants; and

WHEREAS, as a material inducement to Employer to employ Employee and to pay to Employee compensation for such services, Employee has agreed to such covenants; and

WHEREAS, Employer and Employee desire to set forth in writing the terms and conditions of their agreements and understandings.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises herein contained, and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Disclosure of Information. Employee acknowledges that, in and as a result of his employment by Employer, he will be making use of, acquiring and/or adding to confidential information of a special and unique nature and value, including, without limitation, Employer's trade secrets, products, systems, programs, procedures, manuals, guides (as periodically updated or supplemented), confidential reports and communications (including, without limitation, customer site information, technical information on the performance and reliability of Employer's products and the development or acquisition of future products or product enhancements by Employer) and lists of customers, as well as the nature and type of the services rendered by Employer and the fees paid by Employer's customers. Employee further acknowledges that any information and materials received by Employer from third parties in confidence (or subject to non−disclosure covenants) shall be deemed to be and shall be confidential information within the meaning of this Section 1. As a material inducement to Employer to employ Employee and to pay to Employee compensation for such services to be rendered to Employer by Employee (it being understood and agreed by the parties hereto that such compensation shall also be paid and received in consideration hereof), Employee covenants and agrees that he shall not, except with the prior written consent of the Board of Directors of Employer, at any time during or following the term of his employment with Employer, directly or indirectly, divulge, reveal, report, publish, transfer or disclose, for any purpose whatsoever, any of such confidential information which has been obtained by or disclosed to him as a result of his employment with Employer, including, without limitation, any Proprietary Information, as

defined in Section 2 hereof; Employee agrees further that upon termination of his employment with Employer for any reason, he shall sign the Employee Termination Statement, a form of which is attached hereto. The aforementioned obligation of confidentiality and non−disclosure shall not apply when:

(a) Public Domain. The information disclosed to Employee was in the public domain at the time of disclosure, or at any time after disclosure has become a part of the public domain by publication or otherwise through sources other than Employee, directly or indirectly, and without fault on the part of Employee in failing to keep such information confidential; or

(b) Requirement of Law or Order. Disclosure is required by law or court order, provided Employee gives Employer prior written notice of any such disclosure; or

(c) Agreement. Disclosure is made with the prior written agreement of the Board of Directors of Employer; or

(d) Prior Information. The information is encompassed by the ideas and inventions listed on Schedule A hereto or was in Employee's possession at the time of disclosure, as shown by written records in existence prior to such time, and such information has not been transferred to Employer, and was not acquired, directly or indirectly, from the Employer; or

(e) Third Party Disclosure. The information is lawfully disclosed to Employee after the termination of his employment by a third party who is under no obligation of confidentiality to Employer with respect to such information; or

(f) Independently Developed. Such information is independently developed by Employee subsequent to the termination of his active participation in the business of Employer, as demonstrated by written records of Employee which are contemporaneously maintained.

2. Definition of Proprietary Information. For purposes of this Agreement, the term "Proprietary Information" shall mean all of the following materials and information (whether or not reduced to writing and whether or not patentable or protectable by copyright) which Employee receives, receives access to, conceives of or develops, in whole or in part, as a direct or indirect result of his employment with Employer, in the course of his employment with Employer (in any capacity, whether executive, managerial, planning, technical, sales, research, development, manufacturing, engineering or otherwise) or through the use of any of Employer's facilities or resources:

(i) Manufactured products, assembled or unassembled, and any related goods or systems and any and all future products, software or systems developed or derived therefrom;

(ii) With respect to the items described in Section 2(i) above, all hardware and software relating to design or manufacture; all source and object codes to such hardware and software; all specifications, design concepts, documents and manuals; all security systems relating to the product or procedures, including, without limitation, software security systems;

(iii) Trade secrets, production processes, marketing techniques, mailing lists, purchasing information, price lists, pricing policies, quoting procedures, financial information, customer and prospect names and requirements, customer data, customer site information and other materials or information relating to the manner in which Employer does business;

(iv) Discoveries, concepts and ideas, whether or not patentable or protectable by copyright, including, without limitation, the nature and results of research and development activities, technical information on product or program performance and reliability, processes, formulas, techniques, "know−how", source codes, object codes, designs, drawings and specifications;

(v) Any other material or information related to the business or activities of Employer which is not generally known to others engaged in similar businesses or activities;

(vi) Any other material or information that has been created, discovered or developed, or otherwise becomes known to Employer which has commercial value in the business in which Employer is engaged; and

(vii) All ideas which are derived from or relate to Employee's access to or knowledge of any of the above−enumerated materials and information.

Failure to mark any of the Proprietary Information as confidential shall not affect its status as part of the Proprietary Information under the terms of this Agreement.

3. Ownership of Information.

(i) Employee hereby assigns to Employer all of Employee's right, title and interest in any idea (whether or not patentable or protectable by copyright), product, invention, discovery, computer software program or other computer−related equipment or technology, conceived or developed in whole or in part, or in which Employee may have aided in its development, while employed by Employer, including, without limitation, any Proprietary Information. If any one or more of the aforementioned are deemed in any way to fall within the definition of "work made for hire", as such term is defined in 17 U.S.C. § 101, such work shall be considered "work made for hire", the copyright of which shall be owned solely, completely and exclusively by Employer. If any of the aforementioned are considered to be work not included in the categories of work covered by the "work made for hire" definition contained in 17 U.S.C. § 101, such work shall be owned solely by, or assigned or transferred completely and exclusively to, Employer. Employee agrees to execute any instruments and to do all other things reasonably requested by Employer (both during and after Employee's employment with Employer) in order to more fully vest in Employer all ownership rights in those items thereby transferred by Employee to Employer. Employee further agrees to disclose immediately to

Employer all Proprietary Information conceived of or developed in whole or in part by him during the term of his employment with Employer and to assign to Employer any right, title or interest he may have in such Proprietary Information.

(ii) Employee hereby represents and warrants that Employee has fully disclosed to Employer on Schedule A hereto any idea, invention, product, improvement, computer software program or other equipment or technology related to therapeutic pharmaceuticals (an "Invention") not covered in Section 3(i) above which, prior to his employment with Employer, Employee conceived of or developed, wholly or in part, and in which Employee has any right, title or proprietary interest and which directly relate to Employer's business, but which has not been published or filed with the United States Patent or Copyright Offices or assigned or transferred to Employer. If there is no such list of Schedule A, Employee represents that Employee has made no such Inventions at the time of signing this Agreement or Employee hereby assigns such Inventions to Employer.

(iii) Notwithstanding anything in this Agreement to the contrary, the obligation of Employee to assign or offer to assign his rights in an Invention to Employer shall not extend or apply to an Invention that Employee developed entirely on his own time without using Employer's equipment, supplies, facility or trade secret information unless such Invention (a) relates to Employer's business or actual or demonstrably anticipated research or development, or (b) results from any work performed by Employee for Employer. Employee shall bear the burden of proof in establishing that his Invention qualifies for exclusion under this Section 3(iii). With respect to Section 3(iii), it is agreed and acknowledged that during Employee's employment, Employer may enter other lines of business, which are related or unrelated to its current lines of business, in which case this Agreement would be expanded to cover such new lines of business.

4. Injunctive Relief. Employee understands and agrees that Employer will suffer irreparable harm in the event that Employee breaches any of his obligations under this Agreement and that monetary damages will be inadequate to compensate Employer for such breach. Accordingly, Employee agrees that, in the event of a breach or threatened breach by Employee of any of the provisions of this Agreement, Employer, in addition to and not in limitation of any other rights, remedies or damages available to Employer at law or in equity, shall be entitled to a permanent injunction in order to prevent or to restrain any such breach by Employee, or any of employee's partners, agents, representatives, servants, employers, employees and/or any and all persons directly or indirectly acting for or with him.

5. Records. All notes, data, tapes, reference materials, sketches, drawings, memoranda, models and records in any way relating to any of the information referred to in Sections 1, 2 and 3 hereof (including, without limitation, any Proprietary Information) or to Employer's business shall belong exclusively to Employer, and Employee agrees to turn over to Employer all such materials and all copies of such materials in his possession or then under his control at the request of Employer or, in the absence of such a request, upon the termination of Employee's employment with Employer.

6. Accounting for Profits. Employee covenants and agrees that, if he shall violate any of his covenants or agreements under this Agreement, Employer shall be entitled to an accounting and repayment of all profits, compensation, commissions, remunerations or benefits which Employee directly or indirectly has realized and/or may realize as a result of, growing out of or in connection with any such violation; such remedy shall be in addition to and not in limitation of any injunctive relief or other rights or remedies to which Employer is or may be entitled at law, in equity or under this Agreement.

7. Covenant Not to Compete. It is recognized and understood by the parties hereto that Employee, through Employee's association with Employer as an employee, shall acquire a considerable amount of knowledge and goodwill with respect to the business of Employer, which knowledge and goodwill are extremely valuable to Employer and which would be extremely detrimental to Employer if used by Employee to compete with Employer. It is, therefore, understood and agreed by the parties hereto that, because of the nature of the business of Employer, it is necessary to afford fair protection to Employer from such competition by Employee. Consequently, as a material inducement to employ Employee in the aforementioned positions, Employee covenants and agrees to the following:

(a) Except as otherwise approved in writing by Employer, Employee agrees:

(i) that Employee will not, directly or indirectly, with or through any family member or former director, officer or employee of Employer, or acting alone or as a member of a partnership or as an officer, holder of or investor in as much as 5% of any security of any class, director, employee, consultant or representative of any corporation or other business entity:

(1) at any time while engaged as an employee of Employer and for a period of two (2) years following termination as an employee, interfere with, or seek to interfere with, the relationship between Employer or any affiliate of Employer and the following: (a) any of the employees of such entities; (b) any of the customers of such entities then existing or existing at any time within three (3) years prior to termination of Employee's employment by Employer; or (c) any of the suppliers of such entities then existing or existing at any time within three (3) years prior to termination of Employee's employment by Employer.

(b) The parties hereto agree that in the event that either the length of time or the geographic area set forth in paragraph (a) is deemed too restrictive in any court proceeding, that the court may reduce such restrictions to those which it deems reasonable under the circumstances.

(c) Employee agrees and acknowledges that Employer does not have any adequate remedy at law for the breach or threatened breach by him of this covenant and agrees that Employer may in addition to the other remedies which may be available to it under this Agreement, file a suit in equity to enjoin Employee from such breach or threatened breach.

8. Reasonableness of Restrictions.

(a) Employee has carefully read and considered the provisions of Sections 1 through 7 hereof and, having done so, agrees that the restrictions set forth therein are fair and reasonable and are reasonably required for the protection of the interests of Employer, its officers, directors, stockholders and employees.

(b) In the event that, notwithstanding the foregoing, any part of the covenants set forth in Sections 1 through 7 hereof shall be held to be invalid and unenforceable, the court so deciding may reduce or limit the terms of such provision to allow such provision to be enforced.

9. Burden and Benefit. This Agreement shall be binding upon, and shall inure to the benefit of, Employer and Employee, and their respective heirs, personal and legal representatives, and, in the case of Employer, its successors and assigns.

10. Governing Law. In view of the fact that the principal office of Employer is located in the State of North Carolina, it is understood and agreed that the construction and interpretation of this Agreement shall at all times and in all respects be governed by the laws of the State of North Carolina.

11. Severability. The provisions of this Agreement shall be deemed severable, and the invalidity or unenforceability of any one or more of the provisions hereof shall not affect the validity or enforceability of the other provisions hereof.

12. Employer. As used herein, the term “Employer” shall also include any corporation which is at any time the parent or a subsidiary of Employer, or any corporation or entity which is an affiliate of Employer by virtue of common (although not identical) ownership, and for which Employee is providing services in any form during his employment with Employer or any such other corporation or entity.

13. Notices. Any notice required to be given hereunder shall be sufficient if in writing, and sent by certified or registered mail, return receipt requested, first−class postage prepaid, in the case of Employee, to his address as shown on Employer’s records, and in the case of Employer, to its principal office in the State of North Carolina.

14. Entire Agreement. This Agreement contains the entire agreement and understandings by and between Employer and Employee with respect to the covenants herein described, and no representations, promises, agreements or understandings, written or oral, not herein contained shall be of any force or effect. Nothing contained in this Agreement shall be deemed or construed to constitute an agreement by Employer to employ or continue to employ Employee. No change or modification hereof shall be valid or binding unless the same is in writing and signed by the parties hereto. No waiver of any provision of this Agreement shall be valid unless the same is in writing and signed by the party against whom such waiver is sought to be enforced; moreover, no valid waiver of any provision of this Agreement at any time shall be deemed a waiver of any other provision of this Agreement at such time nor will it be deemed a valid waiver of such provision at any other time.

15. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

16. Effective Date. This Agreement shall be effective as of _____, 2004.

IN WITNESS WHEREOF, Employer and Employee have duly executed this Agreement as of the day and year first above written.

EMPLOYER:

POZEN Inc.

By: _____

Name: John R. Plachetka, Pharm.D.
Title: President and Chief Executive Officer

EMPLOYEE:

_____

_____

SCHEDULE A

Inventions, Ideas, Products, Etc. Not Covered in Section 3(i) of the Agreement

[Note: If Employee has no such items to disclose, write "NONE" on this line: _____.]

EMPLOYEE TERMINATION STATEMENT

1. I am cognizant of my legal obligations, as stated in that certain Non−Disclosure, Invention and Non−Competition Agreement, dated _____, _____, which I signed at the commencement of my employment with respect to confidential information of POZEN Inc. (the "Company"), and hereby specifically reaffirm all of the provisions stated therein.

2. I understand that my obligation not to use or disclose Company confidential information remains in effect after the termination of my employment with the Company and that if, at any time in the future, I wish to utilize, disclose or publish any Company confidential information, or if I should be in doubt as to whether any such information may be confidential to the Company, I will, prior to such use or disclosure, obtain the written consent of the Company to do so. I further understand that such consent may be refused where Company confidential information is involved.

3. I understand that, to the extent permitted by law, any idea, invention, discovery, computer software program or other computer−related equipment or technology, conceived or developed by me in whole or in part, or in which I may have aided in its development during my employment with the Company, belongs exclusively to the Company. I hereby certify that I have made full disclosure in writing to the Company or have discussed with my supervisor at the Company all of such ideas, inventions, discoveries, computer programs and computer−related equipment or technology. I further understand that I still have an obligation subsequent to termination of my employment with the Company to execute such papers as the Company may reasonably request to more fully vest in the Company all ownership rights in the items referenced in this paragraph.

4. I hereby certify that all materials related directly or indirectly to my employment with the Company and all copies thereof, have been returned to my supervisor at the Company. I further certify that no computer listings, programs, object codes, source codes, product development guides, flow−charts or other documents owned by the Company or provided to or used by me in connection with my employment at the Company, whether in machine−readable form or otherwise, have been retained by me or given to any other third person or entity in anticipation of my employment termination or for any other reason, and further certify that none of the aforementioned will be removed from the Company's premises by me.

ACCEPTED:

POZEN Inc.

By: _____ _____

_____ _____

Date Date

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: October 27, 2004

/s/ John R. Plachetka

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

Certifications

I, William L. Hodges, 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: October 27, 2004

/s/ William L. Hodges

William L. Hodges
Chief Financial Officer

Section 1350 Certifications

I, John R. Plachetka, Pharm.D., President and Chief Executive Officer, and I, William L. Hodges, Senior Vice President of Finance and Administration and Chief Financial 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 September 30, 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: October 27, 2004

CHIEF FINANCIAL OFFICER

/s/ William L. Hodges

William L. Hodges

Date: October 27, 2004