POZEN INC /NC
Form 10-Q
August 12, 2003
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended June 30, 2003**

**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)**

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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. x 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). x Yes ¨ No

The number of shares outstanding of the registrant s common stock as of July 15, 2003 was 28,360,655.

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**POZEN Inc.**

**(A Development Stage Company)**

**FORM 10-Q**

For the Three and Six Months Ended June 30, 2003

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**POZEN Inc.**

**(A Development Stage Company)**

**BALANCE SHEETS**

**(Unaudited)**

| | June 30, 2003 | December 31, 2002 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 41,938,347 | $ 50,056,251 |
| Prepaid expenses and other current assets | 1,298,000 | 553,371 |
| Total current assets | 43,236,347 | 50,609,622 |
| Equipment, net of accumulated depreciation | 376,947 | 425,369 |
| Total assets | $ 43,613,294 | $ 51,034,991 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 403,033 | $ 179,374 |
| Accrued expenses | 2,308,195 | 1,657,074 |
| Total current liabilities | 2,711,228 | 1,836,448 |
| Long-term liabilities: | | |
| Deferred revenue | 500,000 | |
| Total liabilities | 3,211,228 | 1,836,448 |
| Common stock, $0.001 par value, 90,000,000 shares authorized; 28,352,420 and 28,147,039 shares issued and outstanding at June 30, 2003 and December 31, 2002, respectively | 28,352 | 28,147 |
| Additional paid-in capital | 144,331,207 | 144,036,491 |
| Deferred compensation | (88,078) | (510,130) |
| Deficit accumulated during the development stage | (103,869,415) | (94,355,965) |
| Total stockholders equity | 40,402,066 | 49,198,543 |
| Total liabilities and stockholders equity | $ 43,613,294 | $ 51,034,991 |

*See accompanying Notes to Financial Statements.*

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**POZEN Inc.**

**(A Development Stage Company)**

**Statements of Operations**

**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | | Period From Inception (September 26, 1996) Through June 30, |
|---|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 | 2003 |
| Operating expenses: | | | | | |
| General and administrative | $ 2,921,052 | $ 1,683,405 | $ 4,784,203 | $ 3,440,906 | $ 27,799,730 |
| Research and development | 1,882,944 | 5,223,281 | 4,995,808 | 10,802,725 | 81,932,690 |
| Total operating expenses | 4,803,996 | 6,906,686 | 9,780,011 | 14,243,631 | 109,732,420 |
| Interest income, net | 123,292 | 281,937 | 266,561 | 598,609 | 6,797,483 |
| Net loss | (4,680,704) | (6,624,749) | (9,513,450) | (13,645,022) | (102,934,937) |
| Non-cash preferred stock charge | | | | | 27,617,105 |
| Preferred stock dividends | | | | | 934,478 |
| Net loss attributable to common stockholders | $ (4,680,704) | $ (6,624,749) | $ (9,513,450) | $ (13,645,022) | $ (131,486,520) |
| Basic and diluted net loss per common share | $ (0.17) | $ (0.24) | $ (0.34) | $ (0.49) | |
| Shares used in computing basic and diluted net loss per common share | 28,270,902 | 28,077,945 | 28,210,610 | 28,058,130 | |

*See accompanying Notes to Financial Statements.*

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**POZEN Inc.**

**(A Development Stage Company)**

**STATEMENTS OF CASH FLOWS**

**(Unaudited)**

| | Six Months Ended June 30, | | Period from Inception (September 26, 1996) Through June 30, |
|---|---|---|---|
| | 2003 | 2002 | 2003 |
| **Operating activities** | | | |
| Net loss | $ (9,513,450) | $ (13,645,022) | $ (102,934,937) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 66,474 | 51,638 | 462,243 |
| Loss on disposal of equipment | | | 27,495 |
| Amortization of deferred compensation | 422,052 | 1,480,672 | 10,787,203 |
| Noncash financing charge | | | 450,000 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses, accrued interest receivable, and other assets | (744,629) | (57,895) | (1,298,000) |
| Accounts payable and accrued expenses | 1,374,780 | (556,750) | 3,211,228 |
| Net cash used in operating activities | (8,394,773) | (12,727,357) | (89,294,768) |
| **Investment activities** | | | |
| Purchase of equipment | (18,052) | (374,223) | (866,685) |
| Net cash used in investing activities | (18,052) | (374,223) | (866,685) |
| **Financing activities** | | | |
| Proceeds from issuance of preferred stock | | | 48,651,850 |
| Proceeds from issuance of common stock | 294,921 | 147,384 | 79,605,935 |
| 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 | 294,921 | 147,384 | 132,099,800 |
| Net (decrease) increase in cash and cash equivalents | (8,117,904) | (12,954,196) | 41,938,347 |
| Cash and cash equivalents at beginning of period | 50,056,251 | 73,958,724 | |
| Cash and cash equivalents at end of period | $ 41,938,347 | $ 61,004,528 | $ 41,938,347 |
| **Supplemental schedule of cash flow information** | | | |
| Cash paid for interest | $ | $ | $ 190,790 |
| **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.*

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**POZEN Inc.**

**(A Development Stage Company)**

**NOTES TO FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Organization**

POZEN Inc. ( POZEN or the Company ) was incorporated in the state of Delaware on September 25, 1996. We are a pharmaceutical company developing therapeutic advancements in a cost effective manner. Product development efforts are focused on diseases with unmet medical needs where POZEN can improve efficacy, safety, and/or patient convenience. Since its inception, POZEN has developed the largest and most advanced product pipeline in the field of migraine.

**2. Summary of Significant Accounting Policies**

*Unaudited Interim Financial Statements* The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission ( SEC ) regulations for interim financial information. These financial statements are unaudited and, in the opinion of management, include all adjustments necessary to present fairly the balance sheets, statements of operations and statements of cash flows for the periods presented in accordance with accounting principles generally accepted in the United States. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to SEC rules and regulations. It is presumed that users of this interim financial information have read or have access to the audited financial statements and footnote disclosure for the preceding fiscal year contained in the Company s Annual Report on Form 10-K. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

*Stock-based Compensation* The Company accounts for non-cash stock-based compensation in accordance with the provisions of Accounting Principles Board Opinion No. ( APB ) 25, Accounting for Stock Issued to Employees, which states that no compensation expense is recognized for stock options or other stock-based awards that are granted to employees with an exercise price equal to or above the estimated fair value of the Company s common stock on the grant date. In the event that stock options are granted with an exercise price below the estimated fair market value of the Company s common stock at the grant date, the difference between the fair market value of the Company s common stock and the exercise price of the stock option is recorded as deferred compensation.

In connection with the grant of stock options to employees, the Company recorded no deferred compensation in the six months ended June 30, 2003. Deferred compensation recognized in prior periods was recorded as a component of stockholders equity and is being amortized as charges to operations over the vesting period of the options using the straight-line method. The vesting period of the options is generally three or four years. The Company recorded amortization of deferred compensation of $143,000 and $736,000 for the three-month periods, and $422,000 and $1,481,000 for the six-month periods, ended June 30, 2003 and 2002, respectively.

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

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| | Six Months Ended June 30, | |
|---|---|---|
| | 2003 | 2002 |
| Net loss attributed to common stockholders as reported | $ (9,513,450) | $ (13,645,022) |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects | 442,052 | 1,480,672 |
| Deduct: Total stock-based employee compensation expense determined under the fair value-based method for all awards, net of related tax effects | (1,729,896) | (3,583,284) |
| Pro forma net loss attributed to common stockholders | $ (10,801,294) | $ (15,747,634) |
| Earnings per share | | |
| Net loss per common share as reported - basic and diluted | $ (0.34) | $ (0.49) |
| Net loss per common share pro forma basic and diluted | $ (0.38) | $ (0.56) |
| Weighted-average shares used in computing basic and diluted net loss per common share | 28,210,610 | 28,058,130 |

*Net Loss Per Share* Basic and diluted net loss per common share amounts are presented in conformity with Statement of Financial Accounting Standards No. ( SFAS ) 128, Earnings per Share, for all periods presented. In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the six months ended June 30, 2003 and 2002.

**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, 2002, as filed on March 28, 2003.

This report includes forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as may, will, should, could, expect, plan, anticipate, believe, estimate, predict, potential, continue and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties including those discussed herein under Factors That May Affect Our Results. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

***Overview***

We are a pharmaceutical company developing therapeutic advancements in a cost effective manner. Product development efforts are focused on diseases with unmet medical needs where POZEN can improve efficacy, safety, and/or patient convenience. Since our inception, POZEN has developed the largest and most advanced product pipeline in the field of migraine.

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Our business activities since inception have included:

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

MT 100 is being developed as an oral, first-line treatment for migraine pain and associated symptoms. We have completed all planned Phase 3 pivotal clinical trials for MT 100, which consistently demonstrated MT 100 s effectiveness in treating migraine pain. In October 2002, we submitted a Marketing Authorization Application ( MAA ) for MT 100 to the Medicines Control Agency ( MCA ) in the United Kingdom ( UK ). If approved in the UK, we will seek approval in selected European countries through the European Union Mutual Recognition Procedure.

In June 2003, we signed a licensing agreement with Nycomed Danmark ApS 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 POZEN an upfront fee of $500,000. Potential milestone payments totaling $1 million will be paid upon the occurrence of certain regulatory approvals. In addition, Nycomed will pay POZEN royalty rates on sales of MT 100 in these countries. In July 2003, we submitted a New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) for MT 100, and plan to complete the NDA submission by submitting final carcinogenicity data in early 2004.

MT 300, a proprietary formulation of injectable dihydroergotamine mesylate ( DHE ) in a pre-filled syringe, is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks. We have completed all planned Phase 3 pivotal clinical trials for MT 300, which consistently demonstrated MT 300 s effectiveness in treating migraine pain. In December 2002, we submitted an NDA to the FDA for MT 300. The NDA was accepted for filing by the FDA in February 2003 and is under review.

Our MT 400 technology, which we refer to as MT 400, is being developed as a co-active acute migraine therapy, combining the activity of a triptan with that of a long-lasting non-steroidal anti-inflammatory drug ( NSAID ). In 2002, we completed a 972-patient Phase 2 clinical trial in which MT 400, using a marketed triptan and an NSAID, provided a greater than 50% improvement for sustained pain relief over triptan monotherapy with a similar side effect profile. Sustained pain relief is defined as patients achieving pain relief within two hours of dosing and neither relapsing nor using rescue medicine over the next 22 hours.

In June 2003, we signed an agreement with GlaxoSmithKline ( 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 will have exclusive rights in the United States to commercialize all combinations which combine either of GSK s currently marketed triptans, Imitrex® (sumatriptan, sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. POZEN will be responsible for development, while GSK will provide formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25 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. Additionally, GSK will pay POZEN potential milestone payments over the next several years of $55 million relating to

development progress, regulatory submissions and approvals. GSK will also pay POZEN royalties on sales of marketed products, and in addition, potential sales performance milestones of up to $80 million, if certain sales thresholds are achieved. We plan to commence Phase 3 clinical trials in 2004.

In July 2003, the United States Patent Trademark Offices issued a patent for MT 400 which strengthened our claims relating to pharmaceutical treatment methods that can be used for migraine patients. Rights under this newly issued patent are included in the licensing agreement with GSK.

Historically, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering rather than through collaborative or partnership agreements. As described above, we have received $25 million in upfront payments from GSK under the licensing agreement. These payments are not refundable or subject to future performance milestones. A copy of the GSK agreement is included at Exhibit 10.1 to this Form 10-Q. In July 2003, we received a $500,000 upfront payment from Nycomed as partial payment for the rights and license to commercialize MT 100 in the European Nordic countries. The receipt is subject to certain payments by us to Nycomed if, among other circumstances, the European MAA is

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permanently removed from consideration by the regulatory authorities in the UK. A copy of the Nycomed license agreement is included at Exhibit 10.3 of this Form 10-Q.

We have incurred significant losses since our inception and have not generated any revenue. As of June 30, 2003, our accumulated deficit was $103,869,415. 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 using MT 400, and general and administrative expenses. We may continue to incur operating losses over the next several years as we complete our development of MT 100, MT 300 and MT 400 and apply for regulatory approval, develop other potential product candidates, and acquire and develop product portfolios in other therapeutic areas.

Our results may vary depending on many factors, including:

Ø the progress of MT 100, MT 300 and MT 400 in the clinical and regulatory process;

Ø the establishment and maintenance of collaborations for the development and commercialization of any of our migraine product candidates; and

Ø the acquisition and/or in-licensing, and development, of other therapeutic product candidates.

Our ability to generate revenue is dependent upon our ability, alone or with others, to successfully develop our migraine and other product candidates, obtain regulatory approvals and, alone or with others, successfully manufacture and market our future products.

***Three months ended June 30, 2003 compared to the three months ended June 30, 2002***

*Net loss per share:* Net loss attributable to common stockholders for the quarter ended June 30, 2003 was $4,680,704, or $0.17 per share, as compared to a net loss of $6,624,749, or $0.24 per share, for the quarter ended June 30, 2002.

*Revenue*: We generated no revenue during the quarters ended June 30, 2003 and 2002.

*Research and development*: Research and development expenses decreased by 64% to $1,883,000 for the second quarter of 2003, as compared to $5,223,000 for the same period of 2002. The $3,340,000 decrease was due primarily to a decrease in development costs for MT 300 and MT 400, offset by an increase in the formulation development and clinical trial costs associated with exploratory research and development relating to potential new product candidates. Costs associated with the development of MT 300 decreased by $1,822,000 primarily due to a reduction in Phase 3 clinical trial activities and a $533,000 refund authorization from the Food and Drug Administration ( FDA ) for the New Drug Application ( NDA ) filing fees paid in 2002. A refund of the MT 300 filing fee was granted by the FDA in May 2003, under the small business waiver provision. Under the provision, a waiver of the application fee is granted to a small business for the first human drug application submitted to the FDA for review. We received payment of the refund from the FDA in July 2003. MT 400 costs decreased by $1,578,000, primarily due to decreased costs associated with obtaining drug substance and toxicology activities, as compared to the same period of 2002. Additional research and development costs, including departmental expenses and other exploratory development, increased $322,000, offset by a decrease of $262,000 in the

amortization of deferred stock compensation. Total amortization of deferred stock compensation included in research and development expenses was $59,000 and $321,000 for the quarters ended June 30, 2003 and 2002, respectively. We have included in our research and development expenses the personnel costs related to our research activities and costs related to product development, clinical trial and toxicology activities, and regulatory matters.

*General and administrative*: General and administrative expenses increased by 74% to $2,921,000 for the second quarter of 2003, as compared to $1,683,000 for the same period of 2002. The $1,238,000 increase was due primarily to increased costs related to our marketing, business development, corporate infrastructure and public company activities. Marketing and business development activities increased by $838,000 due to pre-marketing activities and consulting costs for MT 100 and MT 300, and fees associated with the licensing of MT 400. Public company activities increased by $321,000 due to an increase in insurance, director compensation and compliance with securities regulations. All other costs, including the cost of administrative personnel, increased by $410,000, which included a $333,000 compensation payment to our chief executive officer pursuant to an award issued under POZEN s 2001 Long Term Incentive Plan, offset by a decrease of $331,000 in the amortization of deferred compensation. Total amortization of deferred stock compensation included in general and administrative expenses was $84,000 and $415,000 for the quarters ended June 30, 2003 and 2002, respectively. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

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*Interest income*: Interest income decreased to $123,000 for the second quarter of 2003, from $282,000 for the quarter ended June 30, 2002. Interest income decreased due to a decrease in levels of cash and cash equivalents available for investing along with a decline in interest rates during the quarter ended June 30, 2003, as compared to the same period of 2002.

***Six months ended June 30, 2003 compared to the six months ended June 30, 2002***

*Net loss per share:* Net loss attributable to common stockholders for the six month period ended June 30, 2003 was $9,513,450, or $0.34 per share, as compared to $13,645,022, or $0.49 per share for the same period of 2002.

*Revenue*: We generated no revenue during the six-month periods ended June 30, 2003 and June 30, 2002.

*Research and development*: Research and development expenses decreased by 54% to $4,996,000 for the six-month period ended June 30, 2002, as compared to $10,803,000 for the same period of 2002. The $5,807,000 decrease was due primarily to decreased costs associated with the development of MT 100, MT 300 and MT 400, offset by an increase in the formulation development and clinical trial costs associated with exploratory research and development relating to potential new product candidates. MT 100 costs decreased by $956,000, primarily due to decreased clinical trial activities, during the first and second quarters of 2003, as compared to the same period of 2002. MT 300 costs decreased by $2,492,000, primarily due to decreased cost associated with Phase 3 clinical trial activities, in the second quarter of 2003, as compared to the same period of 2002. Costs associated with the development of MT 400 decreased by $2,645,000 primarily due to a decrease in the cost of obtaining drug substance, manufacturing and toxicology activities in the first and second quarters of 2003, as compared to the same period of 2002. Additional research and development expenses, including departmental expenses and other exploratory development, increased by $816,000, offset by a decrease of $530,000 in the amortization of deferred stock compensation. Total amortization of deferred stock compensation included in research and development expenses was $117,000 and $647,000, for the six months ended June 30, 2003 and 2002, respectively. We have included in our research and development expenses the personnel costs related to our research activities and costs related to product development, clinical trial and toxicology activities, and regulatory matters.

*General and administrative*: General and administrative expenses increased by 39% to $4,784,000 for the six-month period ended June 30, 2003 as compared to $3,441,000 for the same period of 2002. The $1,343,000 increase was due primarily to increased costs related to our marketing, business development, corporate infrastructure and public company activities. Marketing and business development activities increased by $976,000 due to pre-marketing activities and consulting costs for MT 100 and MT 300, and fees associated with the licensing of MT 400. Public company activities increased by $410,000 due to an increase in costs for insurance, director compensation and compliance with securities regulations. All other costs, including the cost of administrative personnel, increased by $486,000, which included a $333,000 compensation payment to our chief executive officer pursuant to an award issued under POZEN s 2001 Long Term Incentive Plan, offset by a decrease of $529,000 in the amortization of deferred compensation. Total amortization of deferred compensation included in general and administrative expenses was $305,000 and $834,000 for the six-month period ended June 30, 2003 and 2002, respectively. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, marketing expenses and public reporting.

*Interest income*: Interest income decreased to $267,000 for the six-month period ended June 30, 2003 from $599,000 for the same period of 2002. Interest income decreased due to decreased levels of cash and cash equivalents available for investing along with a decline in interest rates during the six-month period ended June 30, 2003 as compared to the same period of 2002.

**Income Taxes**

As of June 30, 2003, we had federal and state net operating loss carryforwards of approximately $86,863,000 and research and development credit carryforwards of approximately $4,976,000. These federal and state net operating loss carryforwards and research and development credit carryforwards begin to expire in 2012. The utilization of the loss carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the net loss carryforwards. In addition, the maximum annual use of net loss carryforwards is limited in certain situations where changes occur in our stock ownership.

**Liquidity and Capital Resources**

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in aggregate net proceeds to us of $132,099,800. As of June 30, 2003, cash and cash equivalents totaled $41,938,347, a decrease of $8,117,904 as compared to December 31, 2002. The decrease in cash and

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cash equivalents resulted primarily from expenses associated with our operating activities.

Cash used in operations of $8,394,773 during the six months ended June 30, 2003 represented a net loss of $9,513,450 offset by non-cash charges of $488,526, an increase in prepaid and other assets of $744,629 and an increase in accounts payable and other liabilities of $1,374,780. The increase in prepaids and other assets included a $533,000 refund of filing fees paid to the FDA in connection with the MT 300 NDA filing, and a $500,000 receivable due from Nycomed, pursuant to a license agreement with Nycomed to commercialize MT 100 in the European Nordic countries, offset by a decrease in prepaid assets of $288,000. The increase in accounts payable and other liabilities included the $500,000 of deferred revenue for the MT 100 licensing fee, and an increase in accrued expenses related to the pre-marketing activities of MT 100 and MT 300 and other business development activities.

Cash used in investing activities of $18,052 during the six months ended June 30,2003 reflected the purchase of equipment. Since inception through June 30, 2003, approximately $867,000 has been spent on furniture, equipment and leasehold improvements.

Cash provided by financing activities during the six months ended June 30, 2003, which totaled $295,000, was generated by the exercise of stock options.

We believe that our existing liquidity and capital resources, including the initial GSK payments, along with future milestone payments, and the proceeds from our initial public offering, will be sufficient to complete our on-going and planned clinical trials, to conduct appropriate development studies, and to satisfy our other currently anticipated cash needs for operating expenses for at least the next two years.

**Factors That May Affect Our Results**

Our business is subject to certain risks and uncertainties, each of which could materially adversely affect our business, financial condition, cash flows and results of operations. Additional risks that are not presently known to us or that we currently believe to be immaterial may also adversely affect 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 be profitable.**

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of our current product candidates, particularly MT 100 and MT 400. Many factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including:

- negative, inconclusive or otherwise unfavorable results from any studies or clinical trials;
- an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of our product candidates;
- an inability to establish collaborative arrangements with third parties for the manufacture and commercialization of our product candidates, or any disruption of any of these arrangements, if established;

- a failure to achieve market acceptance of our product candidates;
- significant delays in any required studies or clinical studies;
- any demand by the FDA that we conduct additional clinical trials or other studies and the expenses relating thereto; and
- significant increases in the costs of any studies or clinical trials.

**We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We do not have a current source of product revenue and may never be profitable.**

We have incurred losses in each year since our inception and we currently have no source of product revenue. As of June 30, 2003, we had an accumulated deficit of approximately $103.9 million. We expect to incur significant and increasing operating losses and do not know when or if we will generate product revenue.

We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter as a result of increases and decreases in development efforts, the timing of payments that we may receive from others, and other factors. Our ability to achieve profitability is dependent on a number of factors, including our ability to:

- develop and obtain regulatory approvals for our product candidates;
- successfully commercialize our product candidates, which may include entering into collaborative agreements; and

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- secure contract manufacturing and distribution services.

**If we, or our collaborators, do not obtain and maintain required regulatory approvals, we will be unable to commercialize our product candidates.**

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

A separate NDA 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. If we are unable to obtain and maintain FDA and foreign governmental approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them.

Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug s use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and our revenues would suffer.

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

Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third-party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, resulting 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 approved products for unapproved, or off-label, uses. These regulations and the FDA s interpretation of them may impair our ability to effectively market products for which we gain approval. Failure to comply with these requirements can result in regulatory enforcement action by the FDA. Further, we may not obtain the labeling claims we believe are necessary or desirable for the promotion of our product candidates.

Similarly, the above considerations and risks apply to regulatory approvals in foreign markets, including the application with respect to MT 100 submitted to the MCA in the UK.

**We depend on collaborations with third parties, including our recent agreements with GSK and Nycomed, for the development and commercialization of our products, which may reduce our product revenues or restrict our ability to**

**commercialize our products.**

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 have, and intend in the future to continue to have, contract manufacturers and clinical trial investigators. In addition, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into licensing or other collaborative agreements with others, including pharmaceutical companies and research institutions. These third-party contractual or collaborative arrangements may require us to grant rights, including marketing rights, to one or more parties. These arrangements may also contain covenants restricting our product development or business efforts in the future, or other terms that are burdensome to us, and may involve the acquisition of our equity securities. 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.

We cannot be sure that we will be able to maintain our existing or future collaborative or contractual arrangements, or that we will be able to enter into future arrangements with third parties on terms acceptable to us, or at all. If we fail to maintain our existing arrangements or to establish new arrangements when and as necessary, we could be required to undertake these

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activities at our own expense, which would significantly increase our capital requirements and may delay the development of our product candidates.

We are subject to a number of risks associated with contractual and collaborative arrangements with others:

- We may not have day-to-day control over the activities of our contractors or collaborators.
- Third parties may not fulfill their obligations to us.
- 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.
- The contractor or collaborator may have the right to terminate its arrangements with us on limited or no notice and for reasons outside of our control.
- The contractor or collaborator may develop or have rights to competing products or product candidates and withdraw support or cease to perform work on our products.
- Disagreements may arise regarding 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.

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

**We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity studies and clinical trials on our product candidates. Any unanticipated costs or delays in these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could reduce or delay our revenues and profitability.**

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA. Our product candidates are in various stages of clinical development. Depending upon the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and trials can be very costly and time-consuming. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs. It should also be noted that results from preclinical testing and early clinical trials are not necessarily predictive of results obtained in later clinical trials involving large scale testing of patients in comparison to control groups.

The 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. Even though we have completed all planned Phase 3 pivotal clinical trials for MT 100 and submitted an NDA for MT 300, and even if we may have completed all planned clinical trials for a product candidate and submitted an NDA for that product candidate, we may be required to conduct additional clinical trials and studies to support our NDAs to the FDA. We may determine 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 usually evaluates

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results. For example, approval of MT 300 will require positive FDA action on our request that secondary endpoints be evaluated based upon sustained response. 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 would require FDA approval before we could distribute or commercialize the product described in the application. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA may require data in certain subpopulations, such as pediatric use, or may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver to delay such studies.

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.

Even if we obtain positive preclinical or clinical study results initially, future clinical trial results may not be similarly positive.

**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 are 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. 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. 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, biotechnology companies, universities and public and private research institutions. We face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. These competitors, either alone or with collaborative parties, may succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do. Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

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

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. Our competitors may also develop products or technologies that are superior to those

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that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

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

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions.

Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

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

We may need to 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 infringer.

If we are found to infringe the patent rights of others, then we may be forced to pay damages sufficient to irreparably harm the Company and/or be prevented from continuing our product development and marketing activities. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that will 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 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 must 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.

**Any of our future products may not be accepted by the market, which would limit the commercial opportunities for our products.**

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;

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- the availability of third-party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by health care 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 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 any of 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 health care 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 health care 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 health care 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, health care 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 obtained limited product liability insurance coverage only for our human clinical trials. 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 may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may fail.

**We may need substantial 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 expect 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 effect of changes and developments in, or termination of, our collaborative, licensing and other relationships;
- the terms and timing of any collaborative, licensing and other arrangements that we establish; and
- our ability to arrange for the commercialization of our product candidates.

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

The sale by us of additional equity securities or the expectation that we will sell additional equity securities may have an adverse effect on the price of our common stock. In addition, collaborative arrangements may require us to grant product development programs or licenses to third parties for products that we might otherwise seek to develop or commercialize ourselves.

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

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an employment agreement with us on April 1, 1999, as amended and restated on July 25, 2001, for a three-year term with automatic one-year renewal terms. As of July 25, 2001, 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 the services of any of our other key personnel, or are unable to replace the services of our key personnel who may leave the Company, 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 will also depend in part on the continued service of our other key management personnel.

**Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our proceeds from our initial public offering and private placements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio. However, declines in interest rates reduced our interest income during the six-month period ended June 30, 2003 as compared to the same period of 2002. Declines in interest rates will reduce our interest income while increases in interest rates will increase our interest income.

**Item 4. Controls and Procedures**

(a) Evaluation of Disclosure Controls and Procedures

The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness the Company s 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 the Company s 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 the Company 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. The Company believes 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 the Company s internal control over financial reporting occurred during the Company s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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**PART II. OTHER INFORMATION**

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits

| | |
|---|---|
| 10.1 | Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd* |
| 10.2 | Letter Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd* |
| 10.3 | License Agreement dated June 30, 2003 between the Registrant and Nycomed Danmark ApS* |
| 31.1 | Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of the Chief Executive Officer and Chief Financial Officer Relating to a Periodic Report Containing Financial Statements. |

(b) Reports on Form 8-K

None.

* Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission

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**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.<br>(Registrant) |
| August 12, 2003 | By: /s/ JOHN R. PLACHETKA<br>John R. Plachetka<br>President and Chief Executive Officer |
| August 12, 2003 | /s/ MATTHEW E. CZAJKOWSKI<br>Matthew E. Czajkowski<br>Chief Financial Officer<br>(Principal Financial Officer) |
| August 12, 2003 | /s/ JOHN E. BARNHARDT<br>John E. Barnhardt<br>Vice President, Finance and Administration<br>(Principal Accounting Officer) |

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**EXHIBIT INDEX**

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| 32.1 | Certification of the Chief Executive Officer and Chief Financial Officer Relating to a Periodic Report Containing Financial Statements. |

* Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.