



# **FORM 10-Q**

**POZEN INC /NC – POZN**

**Filed: July 30, 2004 (period: June 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**

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**FORM 10-Q**

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

**For the quarterly period ended June 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**

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**POZEN Inc.**

**(Exact name of registrant as specified in its charter)**

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**Delaware**  
**(State or other jurisdiction of**  
  
**incorporation or organization)**

**62-1657552**  
**(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. ☒ 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 July 23, 2004 was 28,789,963.

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**POZEN Inc.**  
**(A Development Stage Company)**

**FORM 10-Q**

For the Three and Six Months Ended June 30, 2004

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

**POZEN Inc.**  
**(A Development Stage Company)**

**BALANCE SHEETS**

(Unaudited)

	June 30, 2004	December 31, 2003
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 67,510,179	\$ 60,480,690
Prepaid expenses and other current assets	414,108	698,209
	<u>          </u>	<u>          </u>
Total current assets	67,924,287	61,178,899
Equipment, net of accumulated depreciation	288,891	334,096
	<u>          </u>	<u>          </u>
Total assets	\$ 68,213,178	\$ 61,512,995
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 253,077	\$ 579,903
Accrued compensation	503,115	416,053
Accrued expenses	1,658,819	1,103,622
	<u>          </u>	<u>          </u>
Total current liabilities	2,415,011	2,099,578
Long-term liabilities:		
Deferred revenue	20,003,978	23,782,978
	<u>          </u>	<u>          </u>
Total liabilities	22,418,989	25,882,556
Common stock, \$0.001 par value, 90,000,000 shares authorized; 28,788,272 and 28,492,201 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	28,788	28,492
Additional paid-in capital	145,994,281	144,821,230
Deficit accumulated during the development stage	(100,228,880)	(109,219,283)
	<u>          </u>	<u>          </u>
Total stockholders' equity	45,794,189	35,630,439
	<u>          </u>	<u>          </u>
Total liabilities and stockholders' equity	\$ 68,213,178	\$ 61,512,995
	<u>          </u>	<u>          </u>

*See accompanying Notes to Financial Statements.*

**POZEN Inc.**  
**(A Development Stage Company)**

**Statements of Operations**

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period From
	2004	2003	2004	2003	Inception
					(September 26,
					1996) Through
					June 30,
					2004
<b>Revenue:</b>					
Licensing revenue	\$ 16,889,500	—	\$ 18,779,000	—	\$ 22,496,000
<b>Operating expenses:</b>					
General and administrative	2,007,557	2,921,052	4,005,606	4,784,203	36,232,474
Research and development	3,671,996	1,882,944	6,043,964	4,995,808	92,885,193
Total operating expenses	5,679,553	4,803,996	10,049,570	9,780,011	129,117,667
<b>Other Revenue:</b>					
Interest income	134,823	123,292	260,973	266,561	7,327,265
<b>Net income (loss)</b>	<b>11,344,770</b>	<b>(4,680,704)</b>	<b>8,990,403</b>	<b>(9,513,450)</b>	<b>(99,294,402)</b>
Non-cash preferred stock charge	—	—	—	—	27,617,105
Preferred stock dividends	—	—	—	—	934,478
Net income (loss) attributable to common stockholders	\$ 11,344,770	\$ (4,680,704)	\$ 8,990,403	\$ (9,513,450)	\$ (127,845,985)
Basic net income (loss) per common share	\$ 0.39	\$ (0.17)	\$ 0.31	\$ (0.34)	
Shares used in computing basic net income (loss) per common share	28,786,486	28,270,902	28,671,070	28,210,610	
Diluted net income (loss) per common share	\$ 0.38	—	\$ 0.30	—	
Shares used in computing diluted net income (loss) per common share	29,704,675	—	29,776,949	—	

See accompanying Notes to Financial Statements.

**POZEN Inc.**  
**(A Development Stage Company)**  
**STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	Six Months Ended June 30,		Period from Inception
	2004	2003	(September 26, 1996)
			Through June 30, 2004
<b>Operating activities</b>			
Net income (loss)	\$ 8,990,403	\$ (9,513,450)	\$ (99,294,402)
Adjustments to reconcile net income (loss) to net			
Cash provided by (used in) operating activities:			
Depreciation	52,152	66,474	577,481
Loss on disposal of equipment	—	—	27,495
Deferred compensation	94,698	422,052	10,969,979
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Prepaid expenses, and other current assets	284,101	(744,629)	(414,108)
Accounts payable and accrued expenses	220,735	1,374,780	2,320,313
Deferred revenue	(3,779,000)	—	20,003,978
Net cash provided by (used in) operating activities	5,863,088	(8,394,773)	(65,359,264)
<b>Investment activities</b>			
Purchase of equipment	(6,947)	(18,052)	(893,867)
Net cash used in investing activities	(6,947)	(18,052)	(893,867)
<b>Financing activities</b>			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	1,173,347	294,921	81,269,445
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	1,173,347	294,921	133,763,310
Net increase (decrease) in cash and cash equivalents	7,029,489	(8,117,904)	67,510,179
Cash and cash equivalents at beginning of period	60,480,690	50,056,251	—
Cash and cash equivalents at end of period	\$67,510,179	\$41,938,347	\$ 67,510,179
<b>Supplemental schedule of cash flow information</b>			
Cash paid for interest	\$ —	\$ —	\$ 191,328
<b>Supplemental schedule of noncash investing and financing activities</b>			
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. 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, which represents our planned principal operations.

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

Revenue from non-refundable up-front payments is deferred by the Company upon receipt and recognized over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates.

Milestone payments are recognized as revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Royalty revenue will be recognized 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 adjust for differences between the estimated and actual royalties in the following period. For those arrangements where royalties are not reasonably estimable, the Company will recognize revenue 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.

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

In connection with the grant of stock awards to employees, the Company recorded \$95,000 of restricted stock compensation expense for both the three- and six-month periods ended June 30, 2004 and amortized deferred compensation of \$143,000 and \$422,000 in the three- and six-month periods ended June 30, 2003. 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 period of the options using the straight-line method. The vesting period of the options is 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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss) attributable to common stockholders as reported	\$ 11,344,770	\$ (4,680,704)	\$ 8,990,404	\$ (9,513,450)
Add: Stock-based employee compensation expense reflected in reported net income (loss), net of related tax effects	94,698	142,693	94,698	422,052
Deduct: Total stock-based employee compensation expense determined under the fair value-based method for all awards, net of related tax effects	(1,190,056)	(632,644)	(1,865,703)	(1,729,896)
Pro forma net income (loss) attributable to common stockholders	\$ 10,249,412	\$ (5,170,385)	\$ 7,114,602	\$ (10,821,294)
Earnings per share				
Basic net income (loss) per common share as reported	\$ 0.39	\$ (0.17)	\$ 0.31	\$ (0.34)
Basic net income (loss) per common share pro forma	\$ 0.36	\$ (0.18)	\$ 0.25	\$ (0.38)
Diluted net income (loss) per common share as reported	\$ 0.38	—	\$ 0.30	—
Diluted net income (loss) per common share pro forma	\$ 0.35	—	\$ 0.24	—

*Net Loss Per Share*—Basic and diluted net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net income (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, 2004 and 2003. The following table illustrates the calculation of dilutive shares outstanding.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Weighted-average shares used in computing basic net income (loss) per share	28,786,486	28,270,902	28,671,070	28,210,610
Effect of dilutive securities	918,189	—	1,105,879	—
Weighted-average shares used in computing diluted net income (loss) per share	29,704,675	28,270,902	29,776,949	28,210,610

## 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 as amended.

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 have 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. Our MT 400 technology is the combination of a triptan (5-HT<sub>1B/1D</sub> 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 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 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 June 30, 2004, our accumulated deficit was \$100.2 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 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 six-month period ended June 30, 2004, our research and development expenses represented approximately 60% 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 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 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 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.

**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 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.

Since our issuance of the press release, we have had further communications with the staff of the FDA. Recently, the FDA sent to us minutes of a teleconference in which we discussed the not–approvable letter with the FDA. Among other things, these minutes state the view of the FDA expressed in our teleconference 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 Combination 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 intend to continue communications, and to request a meeting, 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 by 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 Advisor Committee’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 and have not yet heard from the MHRA as to when the MHRA Advisory Group will meet to discuss the MT 100 MAA.

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 may incur costs for the commercialization of this product if our applications are approved by the FDA and in the UK. Until the FDA responds to our submission, once it is submitted, in response to the not–approvable letter and the UK authorities respond 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 six months ended June 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and to date of \$0.6 million, \$7.5 million, \$4.0 million, \$3.2 million and \$38.6 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 plan to submit the additional information to the FDA during the second half 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 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 six months ended June 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and to date of \$0.2 million, \$3.0 million, \$5.2 million, \$0.8 million and \$14.4 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 a Phase 3 clinical program for Trexima. We plan to conduct two Phase 3 pivotal trials designed to determine the effectiveness and safety of Trexima for the acute treatment of migraine. In addition, we plan to conduct a long-term, open label safety study. We expect to file an NDA for Trexima in the second half of 2005.

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

We have incurred direct product costs associated with the development of Trexima during the six months ended June 30, 2004, the fiscal years ended December 31, 2001, 2002 and 2003 and to date of \$1.8 million, \$1.9 million, \$4.7 million, \$0.9 million and \$9.9 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 licensing 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 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 licensing agreement will expire on a country-by-country basis upon the later of (a) the date of expiration of all royalty obligations in a particular country, 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 licensing 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. While either party may generally terminate the agreement in the event of a material breach or default, Nycomed can terminate the agreement if it establishes an alternative source of the product and we fail to meet certain conditions.

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-HT<sub>1B/1D</sub> 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<sup>®</sup> (sumatriptan succinate) or Amerge<sup>®</sup> (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. In addition, we have certain rights to terminate the agreement. 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<sup>®</sup> (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.

## Results of Operations

### *Three months ended June 30, 2004 compared to the three months ended June 30, 2003*

*Net income (loss) per share:* Net income attributable to common stockholders for the quarter ended June 30, 2004 was \$11,345,000 or \$0.39 per share, as compared to a net loss of \$(4,681,000), or \$(0.17) per share, for the quarter ended June 30, 2003.

*Revenue:* We recognized \$16,890,000 of licensing revenue for the quarter ended June 30, 2004 as compared to no revenue during the quarter ended June 30, 2003. Revenue of \$1,890,000 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. Revenue of \$15.0 million was recorded this quarter for a milestone payment received this quarter from GSK for commencement of Phase 3 clinical trial activities for Trexima under the GSK agreement. 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. Approximately \$20.0 million remains in deferred revenue at June 30, 2004. Substantive milestone payments are recognized as revenue upon completion of the contractual event.

*Research and development:* Research and development expenses increased by 95% to \$3,672,000 for the second quarter of 2004, as compared to \$1,883,000 for the same period of 2003. The \$1,789,000 increase was due primarily to an increase in direct product costs for Trexima and our current exploratory programs, including 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 \$1,254,000 to \$1,257,000, primarily due to the commencement of Phase 3 clinical trials during the second quarter of 2004, as compared to the same period of 2003. Direct product costs associated with our current exploratory programs, including lornoxicam, increased by \$480,000 to \$1,221,000, primarily due to Phase 2 clinical trial and pharmaceutical development activities for such exploratory programs during the second quarter of 2004, as compared to the same period of 2003. MT 100 direct product costs decreased by \$636,000 to \$250,000, primarily due to the completion of regulatory activities required 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, increased by \$691,000, to \$944,000. The increase was primarily due to 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 31% to \$2,008,000 for the second quarter of 2004, as compared to \$2,921,000 for the same period of 2003. The \$913,000 decrease was due primarily to a \$778,000 decrease in the costs associated with our business development activities for the commercialization of MT 100 and MT 300, as compared to the same period of 2003, and a \$135,000 decrease in personnel and related expenses associated with our administrative activities. 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 \$135,000 for the quarter ended June 30, 2004, from \$123,000 for the quarter ended June 30, 2003. Interest income increase primarily due to increased levels of cash and cash equivalents available for investing as compared to the same period of 2003.

### *Six months ended June 30, 2004 compared to the six months ended June 30, 2003*

*Net income (loss) per share:* Net income attributable to common stockholders for the six-month period ended June 30, 2004 was \$8,990,000 or \$0.31 per share, as compared to a net loss of \$(9,513,000), or \$(0.34) per share, for the six-month period ended June 30, 2003.

*Revenue:* We recognized \$18,779,000 of licensing revenue for the six-month period ended June 30, 2004 as compared to no revenue 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 a \$15.0 million milestone 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 21% to \$6,044,000 for the six-month period ended June 30, 2004, as compared to \$4,996,000 for the same period of 2003. The \$1,048,000 increase was due primarily to an increase in direct product costs for Trexima, our current exploratory programs, including 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 \$1,472,000 to \$1,752,000, primarily due to the commencement of Phase 3 clinical trials during the second quarter of 2004, as compared to the same period of 2003. Direct product costs associated with our current exploratory programs, including lornoxicam, increased by \$383,000 to \$1,727,000, primarily due to Phase 2 clinical trial activities and pharmaceutical development activities for such exploratory programs during the first six months of 2004, as compared to the same period of 2003. Costs associated with MT 100 decreased by \$1,352,000 to \$550,000, 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 \$545,000 to \$2,015,000. 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 16% to \$4,006,000 for the six-month period ended June 30, 2004, as compared to \$4,784,000 for the same period of 2003. The \$778,000 decrease was due primarily to a \$890,000 decrease in the costs associated with our business development activities for the commercialization of MT 100 and MT 300 as compared to the same period of 2003, and a \$305,000 decrease in the amortization of deferred stock compensation, offset by a \$378,000 increase in legal and consulting fees related to our public company activities and a \$39,000 increase in other departmental expenses. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

*Interest income:* Interest income decreased to \$261,000 for the six-month period ending June 30, 2004, from \$267,000 for the same period of 2003. Interest income decreased primarily due to a decline in average interest rates during the six-month period ended June 30, 2004 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 which expire between 2011 and 2022. We currently estimate a cumulative net operating loss carry-forward of approximately \$111,200,000 for the twelve months ending December 31, 2004 and estimate an effective rate of 0% for the six months ended June 30, 2004. Our effective tax rate was 0% for the six months ended June 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.

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## Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in aggregate net proceeds to us of \$133.7 million. Additionally, through June 30, 2004 and during 2003, we generated positive cash flows from operations of \$5.9 and \$9.7 million, respectively. As of June 30, 2004, cash and cash equivalents totaled \$67.5 million, an increase of \$7.0 million as compared to December 31, 2003.

Operating cash received during the period ending June 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 amount of up to \$40.0 million upon the satisfaction of specified commercialization and regulatory events for Trexima. Cash received from financing activities during the period totaled \$1.2 million, reflecting the net proceeds from the exercise of stock options.

Cash paid for operating activities totaled \$9.4 million for the six-month period ended June 30, 2004. Cash paid for operating activities in 2003, 2002, and 2001 was \$17.8 million, \$23.7 million, and \$18.4 million, respectively. Cash required for our operating activities during 2004 are 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 are at 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 current assumed needs and may require that we seek additional funds from sources that may not be available on terms favorable to us.

Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements will depend on many factors, including:

- the number and progress of our clinical trials and other trials and studies;
- our ability to negotiate favorable terms with various contractors assisting in these trials and studies;
- our success in 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 stockholder lawsuits that have been filed against us relating to MT 100 and MT 300.

## Factors That May Affect Our Results

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

**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 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 June 30, 2004, we had an accumulated deficit of approximately \$100.2 million. Our ability to achieve profitability is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing of payments that we may receive from others. Our only current sources of revenue are the payments we receive pursuant to our collaboration agreements with Nycomed for MT 100, GSK for 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 or if we will generate product revenue.

**If we, or our collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates and may also be required to pay termination payments under certain of our collaboration agreements.**

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the United States. If we market our products abroad, they are also subject to extensive regulation by foreign governments. None of our product candidates have been approved for sale in the United States or any foreign market and MT 100 and MT 300 may never be approved, given our receipt of not–approvable letters from the FDA for each of these product candidates.

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 governmental approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them.

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

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criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and our revenues would suffer.

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

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

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

**We may not be able to convince the FDA to reverse its conclusions in its not–approvable letter on MT 100, which would eliminate altogether the revenue we expected to receive from 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 communications, and to request a meeting, 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 by 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 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.

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

In October 2002, we submitted our 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 by the UK regulatory authorities, we would not be able to market MT 100 in the UK. Further, we would need to obtain approval of MT 100 in another country in the European Union in order to utilize the mutual recognition procedures in other European Union countries, which would result in increased expenses and time delays.

Even if we are able to obtain approvals in the European Union to market MT 100, 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 with the appropriate governmental authorities pursuant to each of such country's individual requirements. Those discussions could further delay successful commercialization of MT 100 because of the time-consuming review processes in some of those countries.

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

In December 2002, we submitted an NDA for MT 300 to the FDA, which was accepted for filing by the FDA in February 2003. In October 2003, we received a not–approvable letter from the FDA related to our MT 300 NDA. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre–defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours.

In March 2004, we submitted a response to the FDA's not–approvable letter 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 licensing or other collaborative agreements with others, including pharmaceutical companies and research institutions. Collaborative agreements for the acquisition of new compounds or product candidates may require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their arrangements with us on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology in the United States and collaborations with Nycomed in the Nordic countries and Xcel in the United States for the development and commercialization of MT 100 and MT 300, respectively. In all of these collaboration and license agreements, our licensees have the right to terminate the agreement upon a default by us. In

addition, GSK is entitled to terminate its agreement upon 90 days' notice; Nycomed is entitled to terminate its agreement if the MAA for MT 100 is not approved by a specified date or is withdrawn and can terminate the applicability of the agreement to a particular country if we withdraw the required regulatory application in that country; and Xcel is entitled to terminate its agreement if we choose to withdraw the NDA for MT 300. 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 we are not able to establish 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 licensing arrangements may not be on terms favorable to us.

Our current or any future collaborations or licensing arrangements ultimately may not be successful. Our agreements with collaborators typically allow them 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.
- 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 collaborator's product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or licensing agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of 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 ninety (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.

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**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



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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 October 17, 2003 and May 28, 2004, 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



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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 be profitable.

**If there is an adverse outcome in the securities class action litigation that has been filed against us, our business may be materially harmed. Further, defending against the litigation may be expensive and will divert the attention of our management.**

We and certain of our current and former officers are named as defendants in a number of 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 purported securities class action lawsuits contain substantially similar allegations, and we expect that additional lawsuits containing substantially similar allegations may be filed in the near future. The court has entered an order consolidating for pre–trial purposes these and any other similar federal actions that may be filed. The lawsuits allege claims based on purportedly misleading statements concerning our product candidates MT 100 and MT 300.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of this pending litigation. 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 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.

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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.

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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, licensing and other relationships;
- the terms and timing of any additional collaborative, licensing and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

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 \$24.0 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 consideration of our regulatory filings for MT 100 and MT 300. As of June 30, 2004, we had \$67.5 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.

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

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

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an employment agreement with us on April 1, 1999, as amended and restated on July 25, 2001, for a three-year term with automatic one-year renewal terms. We also entered into employment agreements with certain of our other key management personnel, each of which provides for a two-year term with automatic one-year renewal terms. If we lose the services of Dr. Plachetka, or are unable to replace the services of our key personnel who may leave the Company, such as Kristina M. Adomonis, who heads our business development efforts, or W. James Alexander, who heads our product development efforts, or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific personnel. Since our business is very science-oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

***Factors That May Affect Our Stockholders***

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

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

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors. From October 16, 2000, when our common stock began trading on the Nasdaq National Market, through July 29, 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.

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**Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.**

Provisions of our charter and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of POZEN. For example, these provisions:

- authorize the issuance of “blank check” preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three-year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

Our proceeds from our initial public offering and private placements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio. However, declines in average interest rates reduced our interest income during the six-month period ended June 30, 2004 as compared to the same period of 2003.

**Item 4. Controls and Procedures**

(a) Evaluation of Disclosure Controls and Procedures

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

(b) Change in Internal Control over Financial Reporting

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

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

As reported in our Current Reports on Form 8-K filed on June 18, and July 22, 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 and any other similar federal actions that may be filed will also be consolidated with these actions for pre-trial purposes. We expect that a lead plaintiff and lead counsel for the consolidated cases will be appointed. 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. We believe that these allegations are completely without merit and intend to defend these cases vigorously.

### Item 4. Submission of Matters to a Vote of Security Holders

On June 22, 2004, we held our annual meeting of stockholders. The results of the proposals submitted for vote at this meeting were as follows:

1. Election of three directors (there were no abstentions or broker non-votes in connection with the election of directors).

	For:	Withheld:
James R. Butler	19,419,342	2,074,129
Paul J. Rizzo	15,008,100	6,485,371
Ted G. Wood	19,417,842	2,075,629

2. Approval of our 2000 Equity Compensation Plan, as amended and restated, including to increase from 3,000,000 to 5,500,000 the number of shares issuable under the Plan, as amended and restated.

For:	Against:	Abstain:	Broker non-votes:
10,477,889	4,215,727	597,613	6,202,242

3. Ratification of the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2004 (there were no broker non-votes in connection with the ratification of our independent auditor).

For:	Against:	Abstain:
19,923,204	1,328,502	241,765

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

#### (a) Exhibits

- 10.1 Registrant's 2000 Equity Compensation Plan, as amended and restated (as of June 22, 2004).  
10.2 Form of Incentive Stock Option Agreement under Registrant's 2000 Equity Compensation Plan.  
10.3 Form of Nonqualified Stock Option Agreement under Registrant's 2000 Equity Compensation Plan.



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- 10.4 Restricted Stock Unit Agreement dated May 4, 2004, issued to the Registrant's President and CEO, under the 2000 Equity Compensation Plan.
  - 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

Current Report on Form 8-K filed on June 18, 2004, reporting information under Items 5 and 7.

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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.  
(Registrant)

July 30, 2004

By: /s/ JOHN R. PLACHETKA

John R. Plachetka  
President and Chief Executive Officer

July 30, 2004

By: /s/ JOHN E. BARNHARDT

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

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
10.1	Registrant's 2000 Equity Compensation Plan, as amended and restated (as of June 22, 2004).
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10.3	Form of Nonqualified Stock Option Agreement under Registrant's 2000 Equity Compensation Plan.
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POZEN INC.  
2000 EQUITY COMPENSATION PLAN,  
AS AMENDED AND RESTATED

The purpose of the POZEN Inc. 2000 Equity Compensation Plan, as amended and restated (the “Plan”), is to provide (i) designated employees of POZEN Inc. (the “Company”) and its subsidiaries, (ii) certain consultants and advisors who perform services for the Company or its subsidiaries, and (iii) non-employee members of the Board of Directors of the Company (the “Board”) with the opportunity to receive grants of incentive stock options, nonqualified stock options, stock awards, performance units and other stock-based awards. The Company believes that the Plan will encourage the participants to contribute materially to the growth of the Company, thereby benefitting the Company’s stockholders, and will align the economic interests of the participants with those of the stockholders.

1. Administration

(a) Committee. The Plan shall be administered by a committee appointed by the Board (the “Committee”), which may consist of two or more persons who are “outside directors” as defined under section 162(m) of the Internal Revenue Code of 1986, as amended (the “Code”), and related Treasury regulations and “non-employee directors” as defined under Rule 16b-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). However, the Board may ratify or approve any grants as it deems appropriate. The Committee may delegate authority to one or more subcommittees, as it deems appropriate. To the extent that the Board or a subcommittee administers the Plan, references in the Plan to the “Committee” shall be deemed to refer to such Board or such subcommittee.

(b) Committee Authority. The Committee shall have the sole authority to (i) determine the individuals to whom grants shall be made under the Plan, (ii) determine the type, size and terms of the grants to be made to each such individual, (iii) determine the time when the grants will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability, (iv) amend the terms of any previously issued grant, and (v) deal with any other matters arising under the Plan.

(c) Committee Determinations. The Committee shall have full power and authority to administer and interpret the Plan, to make factual determinations and to adopt or amend such rules, regulations, agreements and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Committee’s interpretations of the Plan and all determinations made by the Committee pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any awards granted hereunder. All powers of the Committee shall be executed in its sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.



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(d) Delegation of Authority. In addition to the delegation described in subsection (a) and subject to applicable law, the Board or the Committee may delegate to one or more officers of the Company the authority to designate Employees who shall receive grants under the Plan and to determine the number of grants to be received by such Employees. In that event, the Board or Committee shall specify the maximum number of grants that the officers may award and the prices (or a formula by which such prices shall be determined) at which the grants may be made. The Board or Committee may not authorize an officer to designate himself or herself as a recipient of a grant. To the extent that one or more officers administers the Plan, references in the Plan to the "Committee" shall be deemed to refer to such officers.

## 2. Grants

Awards under the Plan may consist of grants of incentive stock options as described in Section 5 ("Incentive Stock Options"), nonqualified stock options as described in Section 5 ("Nonqualified Stock Options") (Incentive Stock Options and Nonqualified Stock Options are collectively referred to as "Options"), stock awards as described in Section 6 ("Stock Awards"), performance units as described in Section 7 ("Performance Units") and other stock-based awards as described in Section 7 (hereinafter collectively referred to as "Grants"). All Grants shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with this Plan as the Committee deems appropriate and as are specified in writing by the Committee to the individual in a grant instrument or an amendment to the grant instrument (the "Grant Instrument"). The Committee shall approve the form and provisions of each Grant Instrument. Grants under a particular Section of the Plan need not be uniform as among the grantees.

## 3. Shares Subject to the Plan

(a) Shares Authorized. Subject to adjustment as described below, the aggregate number of shares of common stock of the Company ("Company Stock") that may be issued or transferred under the Plan pursuant to all Grants is 5,500,000 shares, and of that number, the maximum aggregate number of shares of Company Stock that may be issued or transferred under the Plan pursuant to Grants other than Options is 2,000,000 shares. The maximum aggregate number of shares of Company Stock that shall be subject to Grants made under the Plan to any individual during any calendar year shall be 1,000,000 shares, subject to adjustment as described below. The shares may be authorized but unissued shares of Company Stock or reacquired shares of Company Stock, including shares purchased by the Company on the open market for purposes of the Plan. If and to the extent Options granted under the Plan terminate, expire, or are canceled, forfeited, exchanged or surrendered without having been exercised or if any Stock Awards, Performance Units or other stock-based awards are forfeited or otherwise terminate, the shares subject to such Grants shall again be available for purposes of the Plan.

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(b) Adjustments. If there is any change in the number or kind of shares of Company Stock outstanding (i) by reason of a stock dividend, spinoff, recapitalization, stock split, or combination or exchange of shares, (ii) by reason of a merger, reorganization or consolidation in which the Company is the surviving corporation, (iii) by reason of a reclassification or change in par value, or (iv) by reason of any other extraordinary or unusual event affecting the outstanding Company Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Company Stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number of shares of Company Stock available for Grants, the maximum number of shares of Company Stock that any individual participating in the Plan may be granted in any year, the number of shares covered by outstanding Grants, the kind of shares issued under the Plan, and the price per share or the applicable market value of such Grants may be appropriately adjusted by the Committee to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of Company Stock to preclude, to the extent practicable, the enlargement or dilution of rights and benefits under such Grants; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. Any adjustments determined by the Committee shall be final, binding and conclusive.

#### 4. Eligibility for Participation

(a) Eligible Persons. All employees of the Company and its subsidiaries ("Employees"), including Employees who are officers or members of the Board, and members of the Board who are not Employees ("Non-Employee Directors") shall be eligible to participate in the Plan. Consultants and advisors who perform services for the Company or any of its subsidiaries ("Key Advisors") shall be eligible to participate in the Plan if the Key Advisors render bona fide services to the Company or its subsidiaries, the services are not in connection with the offer and sale of securities in a capital-raising transaction, and the Key Advisors do not directly or indirectly promote or maintain a market for the Company's securities.

(b) Selection of Grantees. The Committee shall select the Employees, Non-Employee Directors and Key Advisors to receive Grants and shall determine the number of shares of Company Stock subject to a particular Grant in such manner as the Committee determines. Employees, Key Advisors and Non-Employee Directors who receive Grants under this Plan shall hereinafter be referred to as "Grantees".

#### 5. Granting of Options

(a) Number of Shares. The Committee shall determine the number of shares of Company Stock that will be subject to each Grant of Options to Employees, Non-Employee Directors and Key Advisors.

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(b) Type of Option and Price.

(i) The Committee may grant Incentive Stock Options that are intended to qualify as “incentive stock options” within the meaning of section 422 of the Code or Nonqualified Stock Options that are not intended so to qualify or any combination of Incentive Stock Options and Nonqualified Stock Options, all in accordance with the terms and conditions set forth herein. Incentive Stock Options may be granted only to Employees. Nonqualified Stock Options may be granted to Employees, Non-Employee Directors and Key Advisors.

(ii) The purchase price (the “Exercise Price”) of Company Stock subject to an Option shall be determined by the Committee and may be equal to or greater than the Fair Market Value (as defined below) of a share of Company Stock on the date the Option is granted; provided, however, that an Incentive Stock Option may not be granted to an Employee who, at the time of grant, owns stock possessing more than 10 percent of the total combined voting power of all classes of stock of the Company or any parent or subsidiary of the Company, unless the Exercise Price per share is not less than 110% of the Fair Market Value of Company Stock on the date of grant.

(iii) If the Company Stock is publicly traded, then the Fair Market Value per share shall be determined as follows: (x) if the principal trading market for the Company Stock is a national securities exchange or the Nasdaq National Market, the last reported sale price thereof on the relevant date or (if there were no trades on that date) the latest preceding date upon which a sale was reported, or (y) if the Company Stock is not principally traded on such exchange or market, the mean between the last reported “bid” and “asked” prices of Company Stock on the relevant date, as reported on Nasdaq or, if not so reported, as reported by the National Daily Quotation Bureau, Inc. or as reported in a customary financial reporting service, as applicable and as the Committee determines. If the Company Stock is not publicly traded or, if publicly traded, is not subject to reported transactions or “bid” or “asked” quotations as set forth above, the Fair Market Value per share shall be as determined by the Committee.

(c) Option Term. The Committee shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant. However, an Incentive Stock Option that is granted to an Employee who, at the time of grant, owns stock possessing more than 10 percent of the total combined voting power of all classes of stock of the Company, or any parent or subsidiary of the Company, may not have a term that exceeds five years from the date of grant.

(d) Exercisability of Options.

(i) Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Committee and specified in the Grant Instrument. The Committee may accelerate the exercisability of any or all outstanding Options at any time for any reason.

(ii) The Committee may provide in a Grant Instrument that the Grantee may elect to exercise part or all of an Option before it otherwise has become exercisable. Any shares so purchased shall be restricted shares and shall be subject to a repurchase right in favor of the Company during a specified restriction period, with the repurchase price equal to the lesser of the Exercise Price or the Fair Market Value per share of Company Stock at the time of repurchase, or such other restrictions as the Committee deems appropriate.

(e) Termination of Employment, Disability or Death.

(i) Except as provided below, an Option may only be exercised while the Grantee is employed by, or providing service to, the Company as an Employee, Key Advisor or member of the Board. In the event that a Grantee ceases to be employed by, or provide service to, the Company for any reason other than Disability (as defined below), death, or termination for Cause (as defined below), any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within 90 days after the date on which the Grantee ceases to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Company shall terminate as of such date.

(ii) In the event the Grantee ceases to be employed by, or provide service to, the Company on account of a termination for Cause by the Company, any Option held by the Grantee shall terminate as of the date the Grantee ceases to be employed by, or provide service to, the Company. In addition, notwithstanding any other provisions of this Section 5, if the Committee determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Company or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares. Upon any exercise of an Option, the Company may withhold delivery of share certificates pending resolution of an inquiry that could lead to a finding resulting in a forfeiture.

(iii) In the event the Grantee ceases to be employed by, or provide service to, the Company because the Grantee is Disabled, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Grantee's Options which are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Company shall terminate as of such date.

(iv) If the Grantee dies while employed by, or providing service to, the Company or within 90 days after the date on which the Grantee ceases to be employed or provide service on account of a termination specified in Section 5(e)(i) above (or within such other period of time as may be specified by the Committee), any Option that is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Company shall terminate as of such date.

(v) For purposes of this Section 5(e), and Sections 6 and 7:

(A) The term "Company" shall mean the Company and its parent and subsidiary corporations or other entities, as determined by the Committee.

(B) "Employed by, or provide service to, the Company" shall mean employment or service as an Employee, Key Advisor or member of the Board (so that, for purposes of exercising Options and satisfying conditions with respect to Stock Awards, Performance Units and other stock-based grants, a Grantee shall not be considered to have terminated employment or service until the Grantee ceases to be an Employee, Key Advisor and member of the Board), unless the Committee determines otherwise.

(C) "Disability" shall mean a Grantee's becoming disabled within the meaning of section 22(e)(3) of the Code or the Grantee becomes entitled to receive long-term disability benefits under the Company's long-term disability plan.

(D) "Cause" shall mean, except to the extent specified otherwise by the Committee, a finding by the Committee that the Grantee (i) has breached his or her employment or service contract with the Company, (ii) has engaged in disloyalty to the Company, including, without limitation, fraud, embezzlement, theft, commission of a felony or proven dishonesty in the course of his or her employment or service, (iii) has disclosed trade secrets or confidential information of the Company to persons not entitled to receive such information, (iv) has breached any written confidentiality, non-competition or non-solicitation agreement with the Company, or (v) has engaged in such other behavior detrimental to the interests of the Company as the Committee determines.

(f) Exercise of Options. A Grantee may exercise an Option that has become exercisable, in whole or in part, by delivering an irrevocable notice of exercise to the Company. The Grantee shall pay the Exercise Price for an Option as specified by the Committee (w) in cash, (x) with the approval of the Committee, by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) and having a Fair Market Value

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on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price, or (y) by such other method as the Committee may approve. Shares of Company Stock used to exercise an Option shall have been held by the Grantee for the requisite period of time to avoid adverse accounting consequences to the Company with respect to the Option. The Grantee shall pay the Exercise Price and the amount of any withholding tax due prior to the issuance of the shares of Company Stock issuable upon such exercise.

(g) Limits on Incentive Stock Options. Each Incentive Stock Option shall provide that, if the aggregate Fair Market Value of the stock on the date of the grant with respect to which Incentive Stock Options are exercisable for the first time by a Grantee during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds \$100,000, then the Option, as to the excess, shall be treated as a Nonqualified Stock Option. An Incentive Stock Option shall not be granted to any person who is not an Employee of the Company or a parent or subsidiary (within the meaning of section 424(f) of the Code).

## 6. Stock Awards

The Committee may issue or transfer shares of Company Stock to an Employee, Non-Employee Director or Key Advisor under a Stock Award, upon such terms as the Committee deems appropriate. The following provisions are applicable to Stock Awards:

(a) General Requirements. Shares of Company Stock issued or transferred pursuant to Stock Awards may be issued or transferred for consideration or for no consideration, and subject to restrictions or no restrictions, as determined by the Committee. The Committee may, but shall not be required to, establish conditions under which restrictions on Stock Awards shall lapse over a period of time or according to such other criteria as the Committee deems appropriate, including, without limitation, restrictions based upon the achievement of specific performance goals. The period of time during which the Stock Awards will remain subject to restrictions will be designated in the Grant Instrument as the "Restriction Period."

(b) Number of Shares. The Committee shall determine the number of shares of Company Stock to be issued or transferred pursuant to a Stock Award and the restrictions applicable to such shares.

(c) Requirement of Employment or Service. If the Grantee ceases to be employed by, or provide service to, the Company (as defined in Section 5(e)) during a period designated in the Grant Instrument as the Restriction Period, or if other specified conditions are not met, the Stock Award shall terminate as to all shares covered by the Grant as to which the restrictions have not lapsed, and those shares of Company Stock must be immediately returned to the Company. The Committee may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(d) Restrictions on Transfer and Legend on Stock Certificate. During the Restriction Period, a Grantee may not sell, assign, transfer, pledge or otherwise dispose of the shares of a Stock Award except to a Successor Grantee under Section 11(a). Each certificate for a share of a Stock Award shall contain a legend giving appropriate notice of the restrictions in the Grant. The Grantee shall be entitled to have the legend removed from the stock certificate covering the shares subject to restrictions when all restrictions on such shares have lapsed. The Committee may determine that the Company will not issue certificates for Stock Awards until all restrictions on such shares have lapsed, or that the Company will retain possession of certificates for shares of Stock Awards until all restrictions on such shares have lapsed.

(e) Right to Vote and to Receive Dividends. Unless the Committee determines otherwise, during the Restriction Period, the Grantee shall have the right to vote shares of Stock Awards and to receive any dividends or other distributions paid on such shares, subject to any restrictions deemed appropriate by the Committee, including, without limitation, the achievement of specific performance goals.

(f) Lapse of Restrictions. All restrictions imposed on Stock Awards shall lapse upon the expiration of the applicable Restriction Period and the satisfaction of all conditions imposed by the Committee. The Committee may determine, as to any or all Stock Awards, that the restrictions shall lapse without regard to any Restriction Period.

## 7. Performance Units and Other Stock-Based Awards

(a) Performance Units. The Committee may grant performance units ("Performance Units") to an Employee, Non-Employee Director or Key Advisor. Each Performance Unit shall represent the right of the Grantee to receive an amount based on the value of the Performance Unit, if performance goals established by the Committee are met. The value of a Performance Unit shall equal the Fair Market Value of a share of Company Stock. The Committee shall determine the number of Performance Units to be granted and the requirements applicable to such Units.

(b) Performance Period and Performance Goals. When Performance Units are granted, the Committee shall establish the performance period during which performance shall be measured (the "Performance Period"), performance goals applicable to the Units ("Performance Goals") and such other conditions of the Grant as the Committee deems appropriate. Performance Goals may relate to the financial performance of the Company or its operating units, the performance of Company Stock, individual performance, or such other criteria as the Committee deems appropriate.

(c) Payment with respect to Performance Units. At the end of each Performance Period, the Committee shall determine to what extent the Performance Goals and other conditions of the Performance Units are met, the value of the Performance Units (if applicable), and the amount, if any, to be paid with respect to the Performance Units. Payments with respect to

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Performance Units shall be made partly in cash, in Company Stock, or in a combination of the two, as determined by the Committee, provided that the cash portion does not exceed 50% of the amount to be distributed.

(d) Requirement of Employment or Service. If the Grantee ceases to be employed by, or provide service to, the Company (as defined in Section 5(e)) during a Performance Period, or if other conditions established by the Committee are not met, the Grantee's Performance Units shall be forfeited. The Committee may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(e) Other Stock-Based Awards. The Committee may grant other stock-based awards to an Employee, Non-Employee Director or Key Advisor, with such terms and conditions and in such amounts as the Committee determines.

#### 8. Qualified Performance-Based Compensation.

(a) Designation as Qualified Performance-Based Compensation. The Committee may determine that Performance Units, Stock Awards or other stock-based awards granted to an Employee shall be considered "qualified performance-based compensation" under Section 162(m) of the Code. The provisions of this Section 8 shall apply to Grants of Performance Units, Stock Awards and other stock-based awards that are to be considered "qualified performance-based compensation" under section 162(m) of the Code.

(b) Performance Goals. When Performance Units, Stock Awards or other stock-based awards that are to be considered "qualified performance-based compensation" are granted, the Committee shall establish in writing (i) the objective performance goals that must be met, (ii) the Performance Period during which the performance goals must be met, (iii) the threshold, target and maximum amounts that may be paid if the performance goals are met, and (iv) any other conditions that the Committee deems appropriate and consistent with the Plan and section 162(m) of the Code. The performance goals may relate to the Employee's business unit or the performance of the Company and its subsidiaries as a whole, or any combination of the foregoing. The Committee shall use objectively determinable performance goals based on one or more of the following criteria: stock price, earnings per share, net earnings, operating earnings, return on assets, stockholder return, return on equity, growth in assets, unit volume, sales, market share, scientific goals, pre-clinical or clinical goals, regulatory approvals, or strategic business criteria consisting of one or more objectives based on meeting specified revenue goals, market penetration goals, geographic business expansion goals, cost targets, goals relating to acquisitions or divestitures, or strategic partnerships.

(c) Establishment of Goals. The Committee shall establish the performance goals in writing either before the beginning of the Performance Period or during a period ending no later than the earlier of (i) 90 days after the beginning of the Performance Period or (ii) the date on which 25% of the Performance Period has been completed, or such other date as may be required



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or permitted under applicable regulations under section 162(m) of the Code. The performance goals shall satisfy the requirements for “qualified performance-based compensation,” including the requirement that the achievement of the goals be substantially uncertain at the time they are established and that the goals be established in such a way that a third party with knowledge of the relevant facts could determine whether and to what extent the performance goals have been met. The Committee shall not have discretion to increase the amount of compensation that is payable upon achievement of the designated performance goals.

(d) Maximum Payment. Performance Units, Stock Awards and other stock-based awards under this Section 8 may be granted to an Employee with respect to not more than 1,000,000 shares of Company Stock for each year during a Performance Period.

(e) Announcement of Grants. The Committee shall certify and announce the results for each Performance Period to all Grantees immediately following the announcement of the Company’s financial results for the Performance Period. If and to the extent that the Committee does not certify that the performance goals have been met, the grants of Stock Awards, Performance Units or other stock-based awards for the Performance Period shall be forfeited or shall not be made, as applicable.

(f) Death, Disability or Other Circumstances. The Committee may provide that Performance Units or other stock-based awards shall be payable or restrictions on Stock Awards shall lapse, in whole or in part, in the event of the Grantee’s death or Disability (as defined in Section 5(e) above) during the Performance Period, or under other circumstances consistent with the regulations and rulings under section 162(m).

## 9. Deferrals

The Committee may permit or require a Grantee to defer receipt of the payment of cash or the delivery of shares that would otherwise be due to such Grantee in connection with any Option, the lapse or waiver of restrictions applicable to Stock Awards, or the satisfaction of any requirements or objectives with respect to Performance Units or other stock-based awards. If any such deferral election is permitted or required, the Committee shall, in its sole discretion, establish rules and procedures for such deferrals.

## 10. Withholding of Taxes

(a) Required Withholding. All Grants under the Plan shall be subject to applicable federal (including FICA), state and local tax withholding requirements. The Company shall have the right to deduct from all Grants paid in cash, or from other wages paid to the Grantee, any federal, state or local taxes required by law to be withheld with respect to such Grants. In the case of Grants paid in Company Stock, the Company may require that the Grantee or other person receiving or exercising Grants pay to the Company the amount of any federal, state or local taxes that the Company is required to withhold with respect to such Grants, or the Company may deduct from other wages paid by the Company the amount of any withholding taxes due with respect to such Grants.

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(b) Election to Withhold Shares. If the Committee so permits, a Grantee may elect to satisfy the Company's income tax withholding obligation with respect to Grants paid in Company Stock by having shares withheld up to an amount that does not exceed the Grantee's minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities. The election must be in a form and manner prescribed by the Committee and may be subject to the prior approval of the Committee.

#### 11. Transferability of Grants

(a) Nontransferability of Grants. Except as provided below, only the Grantee may exercise rights under a Grant during the Grantee's lifetime. A Grantee may not transfer those rights except by will or by the laws of descent and distribution or, with respect to Grants other than Incentive Stock Options, if permitted in any specific case by the Committee, pursuant to a domestic relations order. When a Grantee dies, the personal representative or other person entitled to succeed to the rights of the Grantee ("Successor Grantee") may exercise such rights. A Successor Grantee must furnish proof satisfactory to the Company of his or her right to receive the Grant under the Grantee's will or under the applicable laws of descent and distribution.

(b) Transfer of Nonqualified Stock Options. Notwithstanding the foregoing, the Committee may provide, in a Grant Instrument, that a Grantee may transfer Nonqualified Stock Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with the applicable securities laws, according to such terms as the Committee may determine; provided that the Grantee receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

#### 12. Change of Control of the Company

As used herein, a "Change of Control" shall be deemed to have occurred if:

(a) Any "person" (as such term is used in sections 13(d) and 14(d) of 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

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(b) Consummation of (i) 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), (ii) a sale or other disposition of all or substantially all of the assets of the Company, or (iii) a liquidation or dissolution of the Company.

### 13. Consequences of a Change of Control

(a) Notice and Acceleration. Upon a Change of Control, unless the Committee determines otherwise, (i) the Company shall provide each Grantee with outstanding Grants written notice of such Change of Control, (ii) all outstanding Options shall automatically accelerate and become fully exercisable, (iii) restrictions and conditions on all outstanding Stock Awards shall immediately lapse, (iv) all Performance Units shall be paid at their target value, or in such other amounts as the Committee may determine, and (v) all other stock-based awards shall become fully exercisable, vested or payable in full, as the case may be.

(b) Assumption of Grants. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Committee determines otherwise, all outstanding Options that are not exercised shall be assumed by, or replaced with comparable options or rights by, the surviving corporation (or a parent of the surviving corporation), and other outstanding Grants shall be converted to similar grants of the surviving corporation (or a parent of the surviving corporation).

(c) Other Alternatives. Notwithstanding the foregoing, in the event of a Change of Control, the Committee may take one or both of the following actions with respect to any or all outstanding Options: the Committee may, (i) under such terms as the Compensation Committee may determine, require that Grantees surrender their outstanding Options in exchange for a payment or payments by the Company, in cash or Company Stock, as determined by the Committee, in an amount equal to the amount by which the then Fair Market Value of the shares of Company Stock subject to the Grantee's unexercised Options exceeds the Exercise Price of the Options, or (ii) after giving Grantees an opportunity to exercise their outstanding Options, terminate any or all unexercised Options at such time as the Committee deems appropriate. With respect to Grantees holding Performance Units and other stock-based awards, the Committee may determine that such Grantees shall receive a payment or payments in settlement of such Grants, in such form and amount and under such terms as shall be determined by the Committee. Such surrender, termination or settlement shall take place as of the date of the Change of Control or such other date as the Committee may specify.

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#### 14. Requirements for Issuance or Transfer of Shares

(a) Limitations on Issuance or Transfer of Shares. No Company Stock shall be issued or transferred in connection with any Grant hereunder unless and until all legal requirements applicable to the issuance or transfer of such Company Stock have been complied with to the satisfaction of the Committee. The Committee shall have the right to condition any Grant made to any Grantee hereunder on such Grantee's undertaking in writing to comply with such restrictions on his or her subsequent disposition of such shares of Company Stock as the Committee shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of Company Stock issued or transferred under the Plan will be subject to such stop-transfer orders and other restrictions as may be required by applicable laws, regulations and interpretations, including any requirement that a legend be placed thereon.

(b) Lock-Up Period. If so requested by the Company or any representative of the underwriters (the "Managing Underwriter") in connection with any underwritten offering of securities of the Company under the Securities Act of 1933, as amended (the "Securities Act"), a Grantee (including any successors or assigns) shall not sell or otherwise transfer any shares or other securities of the Company during the 30-day period preceding and the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act for such underwriting (or such shorter period as may be requested by the Managing Underwriter and agreed to by the Company) (the "Market Standoff Period"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

#### 15. Amendment and Termination of the Plan

(a) Amendment. The Board may amend or terminate the Plan at any time; provided, however, that the Board shall not amend the Plan without stockholder approval if (i) such approval is required in order for Incentive Stock Options granted or to be granted under the Plan to meet the requirements of section 422 of the Code, (ii) such approval is required in order to exempt compensation under the Plan from the deduction limit under section 162(m) of the Code, or (iii) such approval is required by applicable stock exchange requirements.

(b) Stockholder Approval for "Qualified Performance-Based Compensation." If Performance Units, Stock Awards or other stock-based awards are granted as "qualified performance-based compensation" under Section 8 above, the Plan must be reapproved by the stockholders no later than the first stockholders meeting that occurs in the fifth year following the year in which the stockholders previously approved the provisions of Section 8, if required by section 162(m) of the Code or the regulations thereunder.

(c) Termination of Plan. The Plan shall terminate on the day immediately preceding the tenth anniversary of its effective date, unless the Plan is terminated earlier by the Board or is extended by the Board with the approval of the stockholders.

(d) Termination and Amendment of Outstanding Grants. A termination or amendment of the Plan that occurs after a Grant is made shall not materially impair the rights of a Grantee unless the Grantee consents or unless the Committee acts under Section 21(c). The termination of the Plan shall not impair the power and authority of the Committee with respect to an outstanding Grant. Whether or not the Plan has terminated, an outstanding Grant may be terminated or amended under Section 21(c) or may be amended by agreement of the Company and the Grantee consistent with the Plan.

(e) No Repricing Without Stockholder Approval. Notwithstanding anything in the Plan to the contrary, the Committee may not reprice Options, nor may the Board amend the Plan to permit repricing of Options, unless the stockholders of the Company provide prior approval for such repricing. The term “repricing” shall have the meaning given that term for purposes of the Nasdaq (or other applicable stock exchange) rules applicable to stockholder approval of equity compensation plans.

(f) Governing Document. The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

#### 16. Funding of the Plan

This Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Grants under this Plan. In no event shall interest be paid or accrued on any Grant, including unpaid installments of Grants.

#### 17. Rights of Participants

Nothing in this Plan shall entitle any Employee, Key Advisor, Non-Employee Director or other person to any claim or right to be granted a Grant under this Plan. Neither this Plan nor any action taken hereunder shall be construed as giving any individual any rights to be retained by or in the employ of the Company or any other employment rights.

#### 18. No Fractional Shares

No fractional shares of Company Stock shall be issued or delivered pursuant to the Plan or any Grant. The Committee shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

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19. Headings

Section headings are for reference only. In the event of a conflict between a title and the content of a Section, the content of the Section shall control.

20. Effective Date of the Plan.

The Plan (as amended and restated herein) shall be effective as of the date on which it is approved by the stockholders of the Company.

21. Miscellaneous

(a) Grants in Connection with Corporate Transactions and Otherwise. Nothing contained in this Plan shall be construed to (i) limit the right of the Committee to make Grants under this Plan in connection with the acquisition, by purchase, lease, merger, consolidation or otherwise, of the business or assets of any corporation, firm or association, including Grants to employees thereof who become Employees of the Company, or for other proper corporate purposes, or (ii) limit the right of the Company to grant stock options or make other awards outside of this Plan. Without limiting the foregoing, the Committee may make a Grant to an employee of another corporation who becomes an Employee by reason of a corporate merger, consolidation, acquisition of stock or property, reorganization or liquidation involving the Company or any of its subsidiaries in substitution for a stock option or stock awards grant made by such corporation. The terms and conditions of the substitute grants may vary from the terms and conditions required by the Plan and from those of the substituted stock incentives. The Committee shall prescribe the provisions of the substitute grants.

(b) Employees Subject to Taxation Outside the United States. With respect to Grantees who are subject to taxation in countries other than the United States, the Committee may make Grants on such terms and conditions as the Committee deems appropriate to comply with the laws of the applicable countries, and the Committee may create such procedures, addenda and subplans and make such modifications as may be necessary or advisable to comply with such laws.

(c) Compliance with Law. The Plan, the exercise of Options and the obligations of the Company to issue or transfer shares of Company Stock under Grants shall be subject to all applicable laws and to approvals by any governmental or regulatory agency as may be required. With respect to persons subject to section 16 of the Exchange Act, it is the intent of the Company that the Plan and all transactions under the Plan comply with all applicable provisions of Rule 16b-3 or its successors under the Exchange Act. In addition, it is the intent of the Company that the Plan and applicable Grants under the Plan comply with the applicable provisions of section 162(m) of the Code and section 422 of the Code. To the extent that any legal requirement of section 16 of the Exchange Act or section 162(m) or 422 of the Code as set forth in the Plan

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ceases to be required under section 16 of the Exchange Act or section 162(m) or 422 of the Code, that Plan provision shall cease to apply. The Committee may revoke any Grant if it is contrary to law or modify a Grant to bring it into compliance with any valid and mandatory government regulation. The Committee may also adopt rules regarding the withholding of taxes on payments to Grantees. The Committee may, in its sole discretion, agree to limit its authority under this Section.

(d) Governing Law. The validity, construction, interpretation and effect of the Plan and Grant Instruments issued under the Plan shall be governed and construed by and determined in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.

POZEN INC.

## 2000 EQUITY COMPENSATION PLAN, AS AMENDED AND RESTATED

INCENTIVE STOCK OPTION GRANT

This STOCK OPTION GRANT, dated as of \_\_\_\_\_ (the "Date of Grant"), is delivered by POZEN Inc. (the "Company") to \_\_\_\_\_ (the "Grantee").

RECITALS

The POZEN Inc. 2000 Equity Compensation Plan, as amended and restated (the "Plan"), provides for the grant of options to purchase shares of common stock of the Company. The Compensation Committee (the "Committee") of the Board of Directors has decided to make a stock option grant as an inducement for the Grantee to promote the best interests of the Company and its stockholders. A copy of the Plan is attached.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. Grant of Option.

(a) Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee an incentive stock option (the "Option") to purchase \_\_\_\_\_ shares of common stock of the Company ("Shares") at an exercise price of \$ \_\_\_\_\_ per Share. The Option shall become exercisable according to Paragraph 2 below.

(b) The Option is designated as an incentive stock option, as described in Paragraph 5 below. However, if and to the extent the Option exceeds the limits for an incentive stock option, as described in Paragraph 5, the Option shall be a nonqualified stock option.

2. Exercisability of Option. The Option shall become exercisable on the following dates, if the Grantee is employed by, or providing service to, the Company (as defined in the Plan) on the applicable date:

<u>Date</u>	<u>Shares for Which the Option is Exercisable</u>
_____	_____
_____	_____
_____	_____
_____	_____

The exercisability of the Option is cumulative.



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### 3. Term of Option.

(a) The Option shall have a term of ten years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) The Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the 90-day period after the Grantee ceases to be employed by, or provide service to, the Company, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one-year period after the Grantee ceases to be employed by, or provide service to, the Company on account of the Grantee's Disability.

(iii) The expiration of the one-year period after the Grantee ceases to be employed by, or provide service to, the Company, if the Grantee dies while employed by, or providing service to, the Company or within 90 days after the Grantee ceases to be so employed or provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to be employed by, or provide service to, the Company for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if the Grantee engages in conduct that constitutes Cause after the Grantee's employment or service terminates, the Option shall immediately terminate.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is ten years from the Date of Grant. Any portion of the Option that is not exercisable at the time the Grantee ceases to be employed by, or provide service to, the Company shall immediately terminate.

### 4. Exercise Procedures.

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the exercisable Option by giving the Company written notice of intent to exercise in the manner provided in this Agreement, specifying the number of Shares as to which the Option is to be exercised. On the delivery date, the Grantee shall pay the exercise price (i) in cash, (ii) with the approval of the Committee, by delivering Shares of the Company which shall be valued at their fair market value on the date of delivery, (iii) payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board, or (iv) by such other method as the Committee may approve. The Committee may impose from time to time such limitations as it deems appropriate on the use of Shares of the Company to exercise the Option.

(b) The obligation of the Company to deliver Shares upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Committee, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee's death) represent that the Grantee is purchasing Shares for the Grantee's own account and not with a view to or for sale in connection with any distribution of the Shares, or such other representation as the Committee deems appropriate. All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. Subject to Committee approval, the Grantee may elect to satisfy any income tax withholding obligation of the Company with respect to the Option by having Shares withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities.

5. Designation as Incentive Stock Option.

(a) This Option is designated an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). If the aggregate fair market value of the stock on the date of the grant with respect to which incentive stock options are exercisable for the first time by the Grantee during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds \$100,000, then the Option, as to the excess, shall be treated as a nonqualified stock option that does not meet the requirements of Section 422. If and to the extent that the Option fails to qualify as an incentive stock option under the Code, the Option shall remain outstanding according to its terms as a nonqualified stock option.

(b) The Grantee understands that favorable incentive stock option tax treatment is available only if the Option is exercised while the Grantee is an employee of the Company or a parent or subsidiary or within a time specified in the Code after the Grantee ceases to be an employee. The Grantee should consult with his or her tax adviser regarding the tax consequences of the Option.

6. Change of Control. The provisions of the Plan applicable to a Change of Control shall apply to the Option, and, in the event of a Change of Control, the Committee may take such actions as it deems appropriate pursuant to the Plan.

7. Restrictions on Exercise. Only the Grantee may exercise the Option during the Grantee's lifetime. After the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the legal representatives of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is exercisable pursuant to this Agreement.

8. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance

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with the Plan. The grant and exercise of the Option are subject to the provisions of the Plan and to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the Shares, (iii) changes in capitalization of the Company, and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

9. No Employment or Other Rights. The grant of the Option shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

10. No Stockholder Rights. Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a stockholder with respect to the Shares subject to the Option, until certificates for Shares have been issued upon the exercise of the Option.

11. Assignment and Transfers. The rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

12. Applicable Law. The validity, construction, interpretation and effect of this instrument shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the President at 1414 Raleigh Road, Suite 400, Chapel Hill, N.C., 27517, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing. Any notice shall be delivered by hand, sent by telecopy or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

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IN WITNESS WHEREOF, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

POZEN INC.

By: \_\_\_\_\_

Its: \_\_\_\_\_

Accepted: \_\_\_\_\_

[Grantee]

POZEN INC.

## 2000 EQUITY COMPENSATION PLAN, AS AMENDED AND RESTATED

NONQUALIFIED STOCK OPTION GRANT

This STOCK OPTION GRANT, dated as of \_\_\_\_\_ (the "Date of Grant"), is delivered by POZEN Inc. (the "Company") to \_\_\_\_\_ (the "Grantee").

RECITALS

The POZEN Inc. 2000 Equity Compensation Plan, as amended and restated (the "Plan"), provides for the grant of options to purchase shares of common stock of the Company. The Compensation Committee (the "Committee") of the Board of Directors has decided to make a stock option grant as an inducement for the Grantee to promote the best interests of the Company and its stockholders. A copy of the Plan is attached.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. Grant of Option. Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee a nonqualified stock option (the "Option") to purchase \_\_\_\_\_ shares of common stock of the Company ("Shares") at an exercise price of \$ \_\_\_\_\_ per Share. The Option shall become exercisable according to Paragraph 2 below.

2. Exercisability of Option. The Option shall become exercisable on the following dates, if the Grantee is employed by, or providing service to, the Company (as defined in the Plan) on the applicable date:

<u>Date</u>	<u>Shares for Which the Option is Exercisable</u>
_____	_____
_____	_____
_____	_____
_____	_____

The exercisability of the Option is cumulative.

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### 3. Term of Option.

(a) The Option shall have a term of ten years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) The Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the 90-day period after the Grantee ceases to be employed by, or provide service to, the Company, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one-year period after the Grantee ceases to be employed by, or provide service to, the Company on account of the Grantee's Disability.

(iii) The expiration of the one-year period after the Grantee ceases to be employed by, or provide service to, the Company, if the Grantee dies while employed by, or providing service to, the Company or within 90 days after the Grantee ceases to be so employed or provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to be employed by, or provide service to, the Company for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if the Grantee engages in conduct that constitutes Cause after the Grantee's employment or service terminates, the Option shall immediately terminate.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is ten years from the Date of Grant. Any portion of the Option that is not exercisable at the time the Grantee ceases to be employed by, or provide service to, the Company shall immediately terminate.

### 4. Exercise Procedures.

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the exercisable Option by giving the Company written notice of intent to exercise in the manner provided in this Agreement, specifying the number of Shares as to which the Option is to be exercised. On the delivery date, the Grantee shall pay the exercise price (i) in cash, (ii) with the approval of the Committee, by delivering Shares of the Company which shall be valued at their fair market value on the date of delivery, (iii) payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board, or (iv) by such other method as the Committee may approve. The Committee may impose from time to time such limitations as it deems appropriate on the use of Shares of the Company to exercise the Option.

(b) The obligation of the Company to deliver Shares upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Committee, including such actions as Company

counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee's death) represent that the Grantee is purchasing Shares for the Grantee's own account and not with a view to or for sale in connection with any distribution of the Shares, or such other representation as the Committee deems appropriate. All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. Subject to Committee approval, the Grantee may elect to satisfy any income tax withholding obligation of the Company with respect to the Option by having Shares withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities.

5. Change of Control. The provisions of the Plan applicable to a Change of Control shall apply to the Option, and, in the event of a Change of Control, the Committee may take such actions as it deems appropriate pursuant to the Plan.

6. Restrictions on Exercise. Only the Grantee may exercise the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the legal representatives of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is exercisable pursuant to this Agreement.

7. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to the provisions of the Plan and to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the Shares, (iii) changes in capitalization of the Company, and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

8. No Employment or Other Rights. The grant of the Option shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

9. No Stockholder Rights. Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a stockholder with respect to the Shares subject to the Option, until certificates for Shares have been issued upon the exercise of the Option.

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10. Assignment and Transfers. The rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

11. Applicable Law. The validity, construction, interpretation and effect of this instrument shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

12. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the President at 1414 Raleigh Road, Suite 400, Chapel Hill, N.C. 27517, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing. Any notice shall be delivered by hand, sent by telecopy or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

*[Remainder of page intentionally left blank]*



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IN WITNESS WHEREOF, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

POZEN INC.

By: \_\_\_\_\_

Its: \_\_\_\_\_

Accepted: \_\_\_\_\_

[Grantee]

POZEN INC.

## 2000 EQUITY COMPENSATION PLAN

RESTRICTED STOCK UNIT AGREEMENT

This RESTRICTED STOCK UNIT AGREEMENT (the “Agreement”), dated as of May 4, 2004 (the “Date of Grant”), is delivered by POZEN Inc. (“POZEN”), to John R. Plachetka (the “Grantee”).

RECITALS

The POZEN Inc. 2000 Equity Compensation Plan, as amended (the “Plan”) provides for the grant of stock-based awards with respect to shares of common stock, par value \$0.001 per share, of POZEN (the “Common Stock”), in accordance with the terms and conditions of the Plan. The Compensation Committee of the Board of Directors of POZEN (the “Committee”) has decided to make a stock-based award in the form of a grant of stock units, subject to the terms and conditions set forth in this Agreement and the Plan, as an inducement for the Grantee to promote the best interests of POZEN and its stockholders. The Grantee may receive a copy of the Plan by contacting the Department of Finance and Administration at POZEN.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. Grant of Restricted Units. Subject to the terms and conditions set forth in this Agreement and the Plan, POZEN hereby grants to the Grantee 98,135 stock units (the “Restricted Units”) under the Plan. The Grantee accepts the Restricted Units and agrees to be bound by the terms and conditions of this Agreement and the Plan with respect to the Restricted Units.

2. Restricted Unit Account. Restricted Units represent hypothetical shares of Common Stock, and not actual shares of stock. POZEN shall establish and maintain a Restricted Unit account, as a bookkeeping account on its records, for the Grantee and shall record in such account the number of Restricted Units granted to the Grantee. No shares of stock shall be issued to the Grantee at the time the grant is made, and the Grantee shall not be, nor have any of the rights or privileges of, a stockholder of POZEN with respect to any Restricted Units recorded in the account. The Grantee shall not have the right to receive any dividends or other distributions with respect to hypothetical shares of stock recorded in the Restricted Unit account; provided, however, that the Committee may appropriately adjust the number and kind of Restricted Units in the event of a stock split, stock dividend or other change in capitalization of POZEN, as described in the Plan. The Grantee shall not have any interest in any fund or specific assets of POZEN by reason of this award or the Restricted Unit account established for the Grantee.

### 3. Lapse of Restrictions.

(a) The Restricted Units shall be subject to forfeiture until the restrictions on the Restricted Units lapse. The restrictions on the Restricted Units shall lapse, and the Restricted Units shall become vested, according to the following schedule, if the Grantee continues to be employed by, or provide service to, the Company (as defined in Section 5(e)(v)(A) of the Plan) from the Date of Grant until the applicable vesting date:

<u>Vesting Date</u>	<u>Restricted Units</u>
January 1, 2005	1/3
January 1, 2006	1/3
January 1, 2007	1/3

The lapse of restrictions on the Restricted Units shall be cumulative, but shall not exceed 100% of the Restricted Units. If the foregoing schedule would produce fractional Units, the number of Restricted Units on which the restrictions lapse shall be rounded down to the nearest whole Unit, with all restrictions lapsing on the third anniversary of the Date of Grant if the Grantee is then employed by, or providing service to, the Company.

(b) When the restrictions on Restricted Units lapse as described above, the Restricted Units shall be vested and shall no longer be subject to forfeiture. The Restricted Units shall continue to be credited to an account on the Company's records (the "Restricted Unit Account"). When the Grantee ceases to be employed by, or provide service to, the Company, the Company shall pay to the Grantee whole shares of Common Stock equal to the number of vested whole Restricted Units then credited to the Restricted Unit Account, as described in Paragraph 5 below. Any vested amounts representing partial shares shall be paid in cash.

4. Termination of Restricted Units. If the Grantee ceases to be employed by, or provide service to, the Company for any reason before the restrictions on all the Restricted Units lapse, any Restricted Units for which the restrictions have not lapsed according to the vesting schedule above shall automatically terminate and shall be forfeited as of the date of the Grantee's termination of employment or service. No payment shall be made with respect to any Restricted Units that terminate as described in this Paragraph 4.

### 5. Payment of Restricted Units.

(a) As soon as practicable after the Grantee ceases to be employed by, or provide service to, the Company, POZEN will issue to the Grantee one share of Common Stock for each whole vested Restricted Unit credited to the Restricted Unit Account, subject to satisfaction of the Grantee's tax withholding obligations as described below. Any vested amounts representing partial shares shall be paid in cash.

(b) All obligations of POZEN under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for applicable taxes. Subject to Committee approval, the Grantee may elect to satisfy any tax withholding

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obligation of the Company with respect to the Restricted Units by having shares of Common Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state, and local tax liabilities.

(c) The obligation of POZEN to deliver shares hereunder shall also be subject to the condition that if at any time the Committee shall determine in its discretion that the listing, registration or qualification of the shares of Common Stock upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body, is necessary or desirable as a condition of, or in connection with, the issue of shares, the shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Committee. The issuance of shares of Common Stock to the Grantee pursuant to this Agreement is subject to any applicable taxes and other laws or regulations of the United States or of any state having jurisdiction thereof.

(d) The Grantee agrees to be bound by the Company's policies regarding transfer of shares of Common Stock and understands that there may be certain times during the year in which the Grantee will be prohibited from selling, transferring, pledging, donating, assigning, mortgaging, hypothetically or encumbering shares.

6. Change of Control. The provisions of the Plan applicable to a Change of Control (as defined in the Plan) shall apply to the Restricted Units, and, in the event of a Change of Control, the Committee may take such actions as it deems appropriate pursuant to the Plan.

7. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and payment of the Restricted Units are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the shares issued under the Plan, (iii) changes in capitalization of POZEN and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Restricted Units pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

8. No Employment or Other Rights. The grant of the Restricted Units shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

9. No Stockholder Rights. Neither the Grantee, nor any person entitled to receive payment in the event of the Grantee's death, shall have any of the rights and privileges of a stockholder with respect to shares of Common Stock, until certificates for shares have been issued upon payment of Restricted Units.

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10. Assignment and Transfers. Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Restricted Units or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, POZEN may terminate the Restricted Units by notice to the Grantee, and the Restricted Units and all rights hereunder shall thereupon become null and void. The rights and protections of POZEN hereunder shall extend to any successors or assigns of POZEN and to POZEN's parents, subsidiaries, and affiliates. This Agreement may be assigned by POZEN without the Grantee's consent.

11. Unfunded Arrangement. The Grantee's rights to receive payments under this Agreement shall be no greater than the right of an unsecured general creditor of the Company. All payments shall be made from the general assets of the Company, and no special or separate fund shall be established and no segregation of assets shall be made to assure payment.

12. Applicable Law. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. Notice. Any notice to POZEN provided for in this Agreement shall be addressed to POZEN in care of the Vice President, Finance and Administration, at the corporate headquarters of POZEN, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of POZEN, or to such other address as the Grantee may designate to POZEN in writing. Any notice shall be delivered by hand, sent by telecopy or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

IN WITNESS WHEREOF, POZEN has caused its duly authorized officer to execute this Restricted Stock Unit Agreement, and the Grantee has placed his signature hereon, effective as of the Date of Grant.

POZEN INC.

By: /s/ John E. Barnhardt

Name: John. E. Barnhardt  
Title: Vice President, Finance and Administration

I hereby accept the award of Restricted Units described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby agree that all of the decisions and determinations of the Committee with respect to the Restricted Units shall be final and binding.

/s/ John R. Plachetka

Grantee

May 4, 2004  
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: July 30, 2004

/s/ John R. Plachetka

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

**Certifications**

I, John E. Barnhardt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of POZEN Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986]
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonable likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 30, 2004

/s/ John E. Barnhardt

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



**Section 1350 Certifications**

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

(1) The Company's periodic report on Form 10-Q for the period ended June 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.

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CHIEF EXECUTIVE OFFICER

/s/ John R. Plachetka

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John R. Plachetka, Pharm.D.

Date: July 30, 2004

CHIEF FINANCIAL OFFICER

/s/ John E. Barnhardt

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John E. Barnhardt

Date: July 30, 2004