POZEN® INC.

2004 ANNUAL REPORT

Building On Our Strengths

POZEN is a pharmaceutical company focused primarily on products for the treatment of migraine, acute and chronic pain and other pain-related conditions.

To our stockholders

2004 WAS A CHALLENGING YEAR, but we also saw very positive developments in our business.

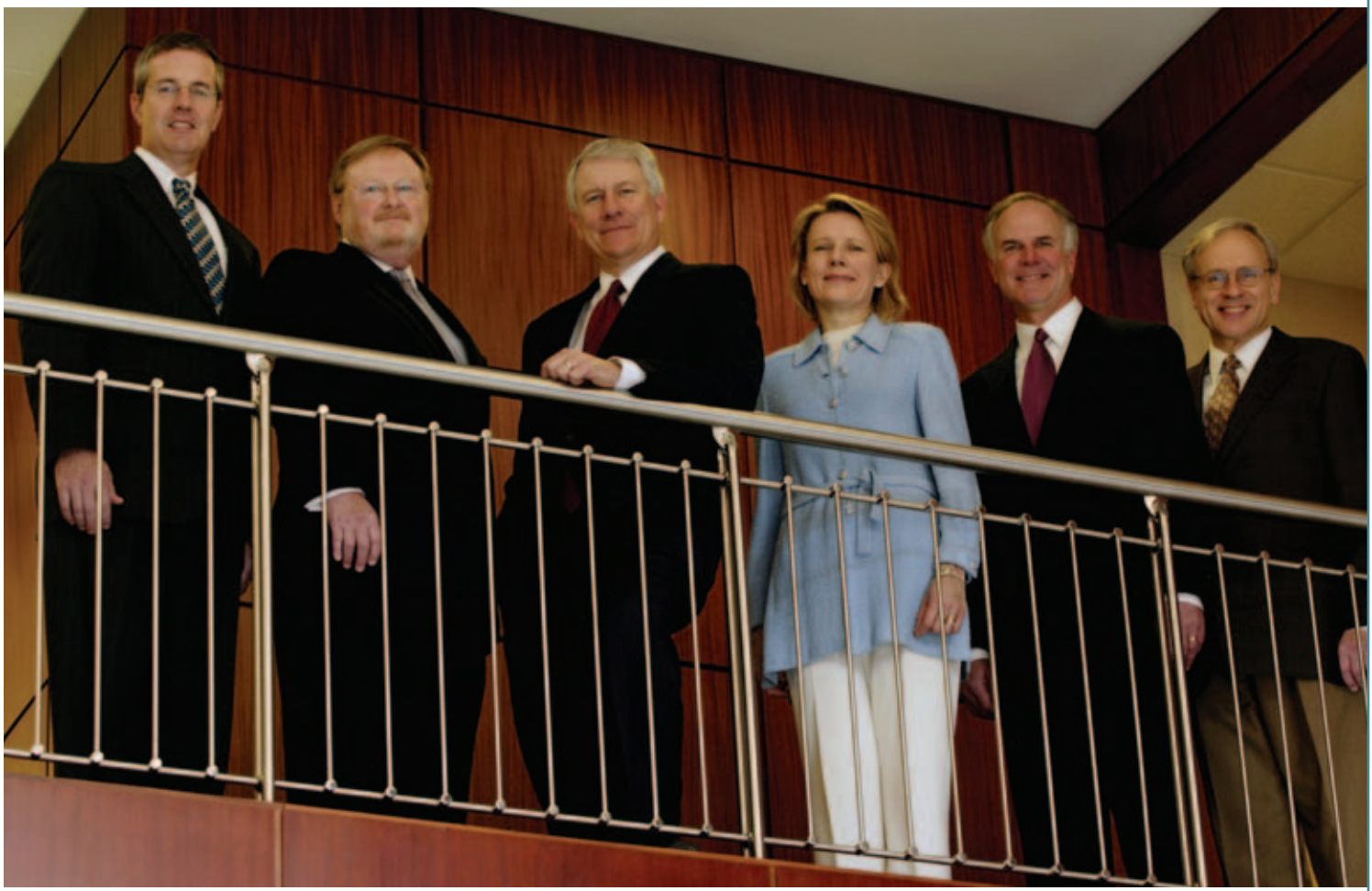
On the positive side, we've received good news about MT 100 in the form of a recommendation from the Committee on Safety of Medicines that MT 100 be approved for sale in the United Kingdom (UK) upon receipt of additional information and meeting certain conditions requested by the Committee. The application now rests with the Medicines and Healthcare Products Regulatory Agency for final action. If all goes well, we expect approval of the MT 100 application later this year. Once that is received, we intend to initiate the Mutual Recognition Procedure in key countries across Europe. First sales of MT 100 in Europe are expected no sooner than 2006.

The Trexima™ program was the source of substantial good news this past year. We received a $15 million payment when we initiated our Phase 3 long-term safety trial during the second quarter of 2004, and that cash infusion narrowed our loss for the year substantially. Two pivotal Phase 3 trials were also initiated and are now completed in the clinic, each involving over 1,400 patients. At the time of this letter, we are awaiting the results of the second Phase 3 trial. Our New Drug Application (NDA) remains on track for submission during the latter half of the year and GlaxoSmithKline (GSK) has begun to talk about Trexima as one of its near-term new product candidates. So, we are grateful for the efforts of our employees, the members of the joint POZEN-GSK Trexima project team, and all the investigators and patients who have participated in this research program.

We plan to expand our clinical pipeline this year by initiating trials for a new type of arthritis product. With the recent concern about the increased risk of cardiovascular events with certain other arthritis medicines, we believe our new PN family of products—patent pending combinations of gastric acid inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs)—holds the promise of delivering effective arthritis pain relief with a better cardiovascular and gastrointestinal safety profile. And, PN products contain naproxen, the only NSAID, other than aspirin, mentioned during the FDA's recent advisory committee review of NSAIDs as being potentially cardioprotective.

On the personnel front, we've added two very experienced senior managers to our team, Dr. Marshall Reese, who heads up all areas of Product Development, and Mr. William Hodges, our CFO. Both have had outstanding careers with extensive experience in the pharma industry, have done their respective jobs before in much larger companies and possess the drive, intelligence and desire to help make POZEN a success. Marty's experience, in particular, will be very valuable in dealing with regulatory agencies around the world.

Now, the disappointments. Regrettably, after receiving the not-approvable letter and several FDA meetings, we are still awaiting the FDA's recommendations about what steps, if any, we might take to get MT 300 approved. As you may recall, in May 2004, we received a not-approvable letter for MT 100, which had been our most advanced oral product for the treatment of migraine. Since then, we've had several meetings with the FDA



(left to right)

William L. Hodges
Senior Vice President, Chief Financial Officer

Marshall E. Reese, Ph.D.
Executive Vice President, Product Development

John R. Plachetka, Pharm.D.
Chairman, President and Chief Executive Officer

Kristina M. Adomonis
Senior Vice President, Business Development

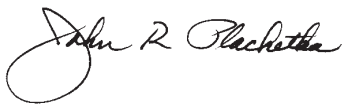
John E. Barnhardt
Vice President, Finance and Administration

W. James Alexander, M.D.
Senior Vice President, Product Development and Chief Medical Officer

and believe we are making some progress. Later this year we expect to participate in an FDA Advisory Committee review of MT 100 as it pertains to the potential risk of tardive dyskinesia. The meeting place and time will be announced in the Federal Register approximately six weeks before it is to take place. For both of these products, we have an uphill battle to get them approved.

Finally, let me say that I'm very excited about our prospects for this year and beyond. Our finances are in order. We have no debt. Although we believe Trexima has tremendous potential, our PN product candidates address a substantially larger market opportunity and could, if approved, be used by many more patients each year.

As always, the employees of POZEN will do all that we can to bring new and innovative products to the market. Not every product candidate we put into development will get approved, but we still believe our business model is one of the most efficient ways to bring new pharmaceutical products to market. Thank you for your continued support.



John R. Plachetka, Pharm.D.
Chairman, President and Chief Executive Officer

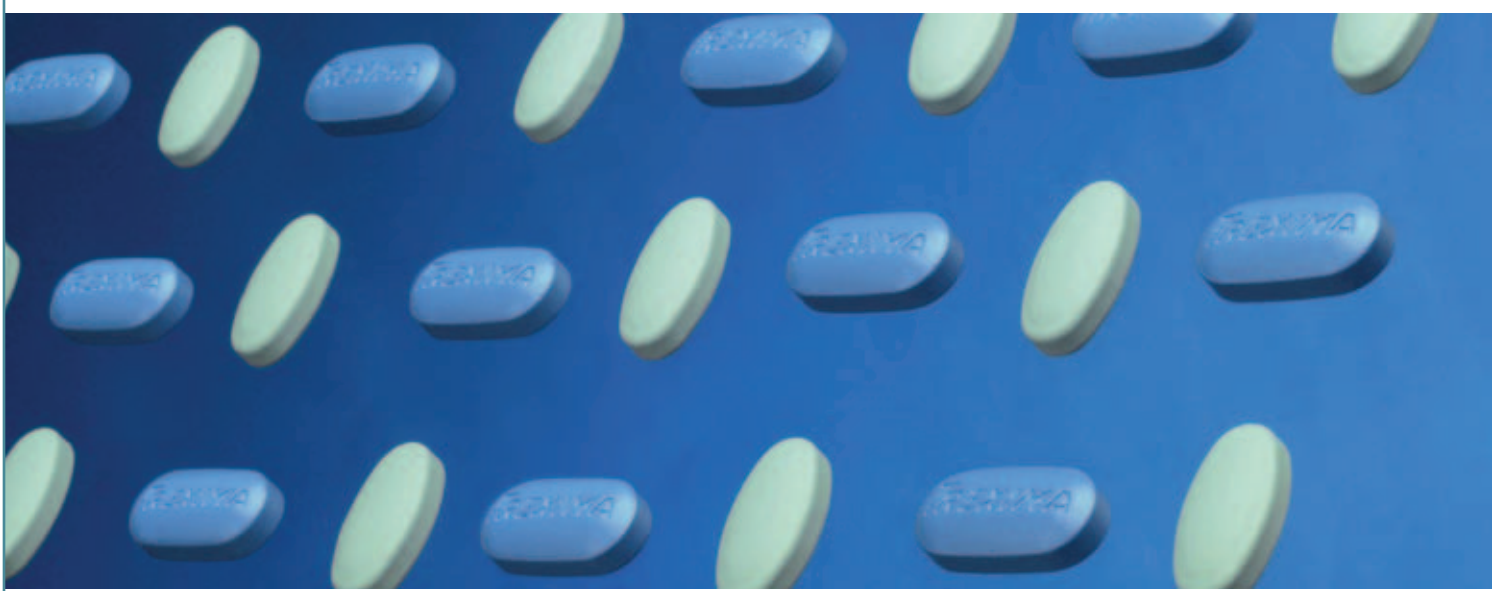
Empowering our people

THE SUCCESS OF POZEN is largely attributable to the dedicated and capable people who make up our organization. All of our employees are managed and motivated by an outstanding and experienced executive team, a team that is committed to empowering the staff to do their very best work.

Founded upon the belief that we could create products faster and more efficiently than the competition, POZEN is committed to forming business relationships with strategic partners and creating innovative products that meet the needs of patients while improving drug efficacy and safety. To do this, we must have exceptionally talented people within our organization.

Our scientists and managers are technically qualified, experienced, motivated and ingenious at turning novel ideas into product candidates and have the capability to take them through development in the most effective and efficient ways possible. These industry veterans are talented managers in their particular discipline of drug development. They have exceptional

POZEN's productivity is directly related to the expertise and dedication of our employees.



POZEN works with partners and contractors to manufacture the clinical supplies.

(left to right)

Marshall E. Reese, Ph.D.
Executive Vice President, Product Development

Donna L. Gilbert, Ph.D.
Vice President, Pharmaceutical Development

Management meets regularly with project leaders to review projects, provide needed support, determine allocation of resources across the teams, and provide strategic direction.

insights into pharmaceutical market dynamics, along with extensive knowledge of the strengths, limitations and interactions associated with current therapeutics. Additionally, our project managers and regulatory personnel are among the best in the business.

As a result of this dedication to innovation, POZEN has been granted six U.S. patents, ten foreign patents and has numerous patents pending. In addition, the team is presently evaluating ten pre-clinical programs to add to our pipeline.

POZEN is dedicated to creating and maintaining a culture that values each employee's distinctive skill set and contribution. We encourage a culture that is market driven; one that rewards performance and encourages entrepreneurial thinking; all in all, a culture that encourages productive, creative and collaborative work.

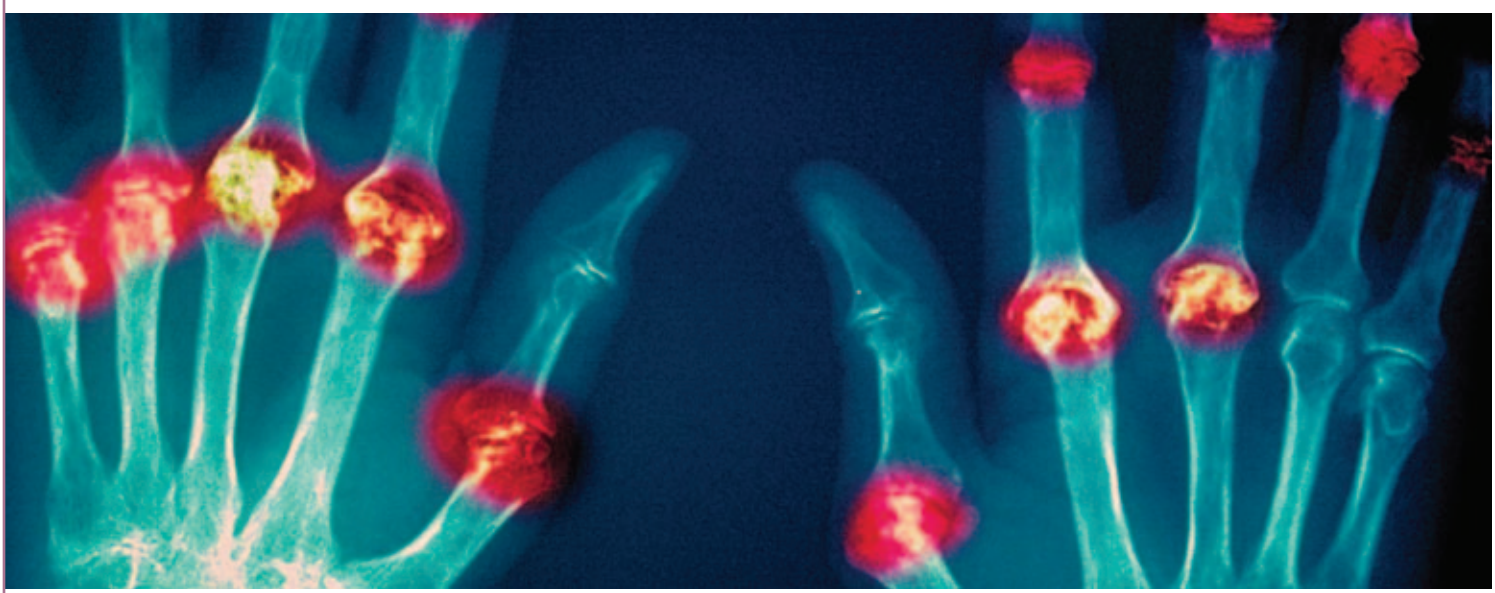
Broadening our pipeline

SINCE POZEN'S FORMATION IN 1996, we have focused on developing product candidates that provide improved treatment options for patients with pain. We plan to continue to build our product pipeline through innovation, in-licensing and/or acquisition of select proprietary product candidates. Today, POZEN has active product candidates designed to provide effective pain relief.

TREXIMA™ is GlaxoSmithKline's (GSK) proposed brand name for the combination of a sumatriptan formulated with GSK's RT Technology™ and naproxen sodium in a single tablet. Developed in collaboration with GSK, Trexima incorporates POZEN's **MT 400™** Technology. We are awaiting results from the second Phase 3 trial for Trexima, which will be available in the second quarter of 2005. The Trexima New Drug Application (NDA) is currently scheduled for filing with the FDA in the second half of 2005.

We are awaiting a response from the Medicines and Healthcare Products Regulatory Agency in the United Kingdom (UK) on approval of our marketing authorization for **MT 100™,** a combination tablet containing naproxen

In the United States alone, products used to treat moderate to severe pain represent a multi-billion dollar market.



Arthritis is a debilitating condition requiring chronic pain medicine. Gastric acid inhibitors may protect against major GI complications including ulcers, hemorrhage, perforation and death.

▲ *(left to right)*

Diane E. Littlefield
Director, Clinical Research

W. James Alexander, M.D.
Senior Vice President, Product Development and Chief Medical Officer

Richard J. Crawley
Vice President, Regulatory and Project Management

Our clinical project team is focused on ensuring our clinical trials are conducted adhering to good clinical practices.

sodium and metoclopramide hydrochloride. If the UK approval is granted unconditionally, POZEN will seek additional approvals through the Mutual Recognition Procedure in other key European countries.

Beyond the field of migraine, POZEN is expanding its focus to products for the treatment of acute and chronic pain and other pain-related conditions. This includes an exploratory development program on an alternative arthritis medicine using a combination tablet containing an agent intended to inhibit acid production along with a non-steroidal anti-inflammatory drug (NSAID). Such a product could be very desirable for physicians and patients in treating arthritis while potentially lowering certain of the adverse effects of current treatments. POZEN is also considering the development of novel product candidates containing lornoxicam, an NSAID currently available in Europe and Japan, alone or in combination with other active ingredients, as potential treatments for pain or other indications.

Expanding our partnerships

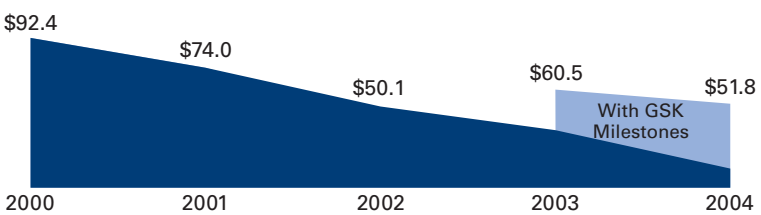
OUR STRATEGY IS TO CONTINUE to collaborate with leading pharmaceutical companies to commercialize our product candidates. To this end, POZEN has entered into selected key partnerships.

Our partnership with GlaxoSmithKline (GSK) represents a significant milestone in our development as a pharmaceutical company. Formed in June 2003, this alliance was created to develop and commercialize Trexima and other combinations of one or more triptans and a long-acting NSAID. Under the agreement, we are receiving milestone payments from GSK throughout the Trexima development process. Upon commercialization by GSK, POZEN will receive sales performance milestone payments based on achievement of certain sales thresholds and royalties based on sales.

As a next-generation migraine product, Trexima could extend GSK's migraine market leadership. The development of Trexima represents the evolution of both a product and a company. Imitrex® was developed and submitted for its first NDA during Dr. Plachetka's nine-year career at Glaxo.

There are definitely benefits to being a David and working with a Goliath.

CASH BALANCES
(dollars in millions)



As a result of POZEN's partnership with GSK on the development of Trexima for the acute treatment of migraine, POZEN has received $40 million of a potential $160 million total upfront and milestone payments.

▲ *(left to right)*

Robert W. Turner
Vice President,
Business Development

Aaron B. Herman
Director,
Business Development

Kristina M. Adomonis
Senior Vice President,
Business Development

Dennis L. McNamara
Vice President,
Business Development

Business Development is responsible for in-licensing, intellectual property and securing commercial partners for product candidates.

Today, under Dr. Plachetka's leadership, POZEN is continuing to create innovative products and develop key partnerships to realize its potential as a prominent pharmaceutical company.

We are also proud of our partnership with Nycomed Danmark ApS, a leading European pharmaceutical company with a strong Nordic base. Nycomed continues to serve as our licensing partner in the Nordic Territories (Denmark, Sweden, Norway and Finland) for MT 100. We also have an option agreement with Nycomed to acquire a license to certain rights related to lornoxicam.

In September 2003, we signed an agreement with Xcel Pharmaceuticals, Inc., which was recently acquired by Valeant Pharmaceuticals International, for the development and commercialization of MT 300. Commercialization of MT 300 has been delayed due to continuing discussions with the FDA; however, POZEN remains committed to our partnership and will await the FDA outcome.

Sustaining our financial position

OUR BUSINESS MODEL allows us to direct approximately three-quarters of our spending to developing products. As a result, POZEN has shunned the high costs associated with discovery research and maintaining a sales and marketing organization, ensuring that we have a strong financial foundation. Specifically, at year end we had over $51 million in cash and no debt. We are proud that we have had zero dilution since our Initial Public Offering (IPO) in 2000.

These successes are directly related to our business model and our ability to strategically outsource functions while maintaining control over key functions of the drug development process, including pre-clinical and clinical studies and development of most product formulations. As a commercially focused pharmaceutical company, POZEN has extensive expertise in the multifaceted aspects of drug development.

Although our headcount has increased to 37 over the past year, we have been able to maintain our historical cash burn rate of between $20 million and $30 million per year.

POZEN continues to have a strong financial position. We are one of the few companies in the IPO class of 2000 that has not returned to the market for additional funding.

(left to right)

William L. Hodges
Senior Vice President, Chief Financial Officer

John E. Barnhardt
Vice President, Finance and Administration

Stacey L. Williams
Senior Financial Administrator

POZEN can indirectly employ over 300 people using strategic outsourcing. This results in efficient use of resources while maintaining financial flexibility.

POZEN® INC.

Form 10-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission file number 000-31719

POZEN INC.
(Exact name of registrant as specified in its charter)

Delaware	**62-1657552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1414 Raleigh Rd, Suite 400, Chapel Hill, NC 27517
(Address of principal executive offices including zip code)

(919) 913-1030
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock	Nasdaq

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐.

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the last reported sale price on June 30, 2004 was $168,498,595. As of March 2, 2005 there were outstanding 28,915,511shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the POZEN Inc. definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year are incorporated by reference into Part III of this Form 10-K and certain documents are incorporated by reference into Part IV.

POZEN INC.
ANNUAL REPORT ON FORM 10-K
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Forward-Looking Information

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed below in the section entitled "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Our Results." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements, other than as is required under the federal securities laws.

PART I

Item 1. Business

Overview

We are a pharmaceutical company focused primarily on products for the treatment of migraine, acute and chronic pain and other pain-related indications. Our product development emphasis is on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception, we have focused our efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. Our portfolio currently contains three product candidates in the migraine area, MT 400, MT 100 and MT 300. We are also exploring the development of product candidates in other acute and chronic pain and pain-related therapeutic areas. We have not obtained regulatory approval for any of our product candidates.

Under our MT 400 technology, which refers to our proprietary combinations of a triptan (5-HT1B/1D agonist) and a non-steroidal anti-inflammatory drug ("NSAID"), we seek to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. In June 2003, we signed an agreement with GlaxoSmithKline ("GSK") for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long-acting NSAID for the U.S. market. The combinations covered by the agreement are among the combinations of our MT 400 technology. Trexima ^{TM} is the proposed brand name for the combination of GSK's sumatriptan and naproxen sodium in a single tablet being developed pursuant to our agreement with GSK. We commenced a Phase 3 clinical program for Trexima in the second half of 2004. We have completed the first of two planned Phase 3 pivotal trials, in which Trexima demonstrated superiority over the individual components measured by sustained pain-free response ($p<.001$) and, with the exception of the incidence of nausea-free at two hours, all other regulatory endpoints were met ($p <.001$). We expect to complete the second Phase 3 pivotal trial in the second quarter of 2005 and to submit the New Drug Application ("NDA") for Trexima to the U.S. Food and Drug Administration ("FDA") in the second half of 2005.

For MT 100 and MT 300, our current focus is primarily on the regulatory process. MT 100 is a combination of metoclopramide hydrochloride and naproxen sodium. MT 300 is a proprietary formulation of injectable dihydroergotamine mesylate ("DHE") in a pre-filled syringe. In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300, which was submitted in December 2002. We are continuing communications with the FDA to assess how best to move forward with MT 300. In May 2004, we received a not-approvable letter from the FDA with respect to our NDA for MT 100. We have continued communications with the FDA to seek to persuade the FDA that the NDA for MT 100 should be approved. We and the FDA have agreed to present MT 100 data to an advisory committee of the FDA for consideration, with particular emphasis on the potential risk of tardive dyskinesia. The FDA has advised us that the meeting with the advisory committee, which we previously reported had been tentatively scheduled for May 2005, has been postponed due to FDA scheduling conflicts. We do not know when the meeting will be rescheduled; however, we have been informed by the FDA that the rescheduled meeting date will be available, in advance, when published in the Federal Register. We are also seeking regulatory approval of MT 100 in the United Kingdom ("UK").

We currently have two exploratory programs in pain-related therapeutic areas. In July 2003, we signed an exclusive option agreement with Nycomed Danmark ApS ("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. We have also begun exploratory formulation development and clinical studies for a combination of a proton pump inhibitor ("PPI") and an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and currently plan to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to manufacture and commercialize our product candidates once approved. To date, we have entered into collaborations with GSK, Xcel Pharmaceuticals Inc. ("Xcel") and Nycomed for the development and commercialization of our current migraine product candidates. In February 2005, Valeant Pharmaceuticals International ("Valeant") reported that it had entered into a definitive agreement to acquire Xcel and on March 1, 2005 reported that the acquisition had been completed.

We have incurred losses attributable to common stockholders of $142.1 million since our inception and have not generated any revenue from product sales. As of December 31, 2004, our accumulated deficit was $114.5 million.

Our Business Strategy

Our goal is to become a leading pharmaceutical development company focused on developing drugs for the treatment of migraine, acute and chronic pain and other pain-related conditions. The principal elements of our business strategy are to:

- ***Develop and commercialize our portfolio of product candidates.*** We expect to focus a substantial portion of our efforts over the next few years on the further development, approval and commercialization of our existing portfolio of product candidates and potential product candidates. Our primary focus in the near-term is the clinical development and regulatory approval of Trexima. A key element of our strategy is to establish collaborations with leading corporations to commercialize our product candidates, and we have entered into and expect to continue to enter into such commercialization collaborations. Where appropriate, we may also elect to develop sales and distribution capabilities internally in order to commercialize (alone or with a partner) one or more of our product candidates. In certain instances, we may also promote our products in collaboration with other pharmaceutical companies.
- ***Build a product pipeline through innovation, in-licensing and acquisition.*** We intend to build our product pipeline through innovation, in-licensing and/or acquisition of select proprietary product candidates. We will focus primarily on developing other products for the treatment of migraine, acute and chronic pain and other pain-related conditions with significant commercial potential in which members of our management team have development or other relevant expertise. These will include novel products that exhibit distinct advantages over currently marketed products, as well as innovative combinations of products in convenient, therapeutically appropriate formulations.
- ***Leverage development efforts through strategic outsourcing.*** While maintaining overall control of the planning, development and regulatory processes, we seek to enter into strategic outsourcing relationships to develop and manufacture our product candidates in as cost-effective a manner as possible. We have contracted and plan to contract with third parties for product candidate testing, development and manufacturing.

Our Product Candidates and Exploratory Programs

Migraine Product Candidates

Migraine Market Overview

Migraine is characterized by recurring attacks of headache, often associated with visual, auditory or gastrointestinal disturbances. While the precise mechanism of migraine is unknown, researchers believe migraine attacks are caused by acute inflammation surrounding selected blood vessels in the head. The average migraine sufferer experiences the first attack during the early teen years, and the attacks generally continue throughout adulthood.

Not all migraine attacks are of the same severity. Consequently, various types of oral, intranasal and injectable therapies are used to treat different types of migraine attacks. Many patients use a personal, individually developed, step-care approach to treat their attacks. Attacks are often treated initially with simple over-the-counter analgesics, particularly if the patient is unable to determine if the attack is a migraine or some other type of headache. If over-the-counter remedies are unsuccessful, patients often turn to more potent prescription drugs, including narcotics, analgesic/narcotic drug combinations and triptans.

Triptans are the family of drugs most commonly prescribed for the treatment of migraine attacks. Triptans have demonstrated the ability to treat migraines by constricting blood vessels in the brain. Although triptans can be effective in treating migraine symptoms, they are often associated with significant side effects and other disadvantages that include:

- the occurrence of cardiovascular related events, including chest pain/discomfort, throat discomfort and warm/cold sensations;
- the potential for other serious cardiovascular events, including death;

- difficulty in producing sustained benefits with a single dose in a majority of patients;
- the occurrence of nausea and dizziness during treatment; and
- the need for cardiovascular evaluations from physicians before initially prescribing triptans to patients with cardiovascular disease risk factors.

Despite these shortcomings, in 2004, according to IMS Health's Retail and Provider Perspective, or IMS, total triptan sales in the U.S. were approximately $1.9 billion. Imitrex®, marketed by GSK, is the leading triptan product. There are currently three types of triptan formulations commercially available: oral, intranasal and injectable. According to IMS, U.S. sales for Imitrex of all three of these formulations totaled approximately $1.1 billion in 2004. An oral triptan is often the physician's first choice as a prescription treatment for migraine pain. Intranasal triptans are often prescribed for patients requiring faster relief than oral drugs can provide or who cannot take oral medications. For the most severe attacks, patients sometimes use an injectable form of a triptan.

MT 400/Trexima

Our MT 400 technology involves the development of compounds 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 400 technology combines the pharmacologic activity of a triptan (5-$HT_{1B/1D}$ agonist) with that of an NSAID. We believe that acute migraine can be treated more effectively with targeted and complementary therapies that achieve maximum therapeutic benefit.

In 2002, the FDA approved our request to submit an NDA for MT 400 as a Section 505(b)(2) application, under which the FDA allows a reduced development program. An application submitted under Section 505(b)(2) permits the FDA to rely, for approval of an NDA, on data not developed by the applicant, including the FDA's previous findings of safety and effectiveness for approved drugs. We believe that the MT 400 NDA, for example, will require very little animal pharmacology and toxicology work and fewer Phase 1 and Phase 2 clinical trials than would be required if the application were not submitted under Section 505(b)(2). This reduced development plan permitted the earlier commencement of Phase 3 clinical trials, as discussed in more detail below. In the UK, the MHRA has agreed to accept a similar development program. The initiation date of the UK clinical program has not yet been determined.

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of one or more of GSK's triptans (5-$HT_{1B/1D}$ agonists) and a long-acting NSAID in the U.S. The combinations covered by our agreement with GSK are among the combinations of our MT 400 technology. Under our collaboration with GSK, we are developing a proprietary combination of GSK's sumatriptan and naproxen sodium in a single tablet, under the proposed brand name Trexima.

Prior to our agreement with GSK, in 2001, we completed a 972-patient, Phase 2 double-blind, placebo-controlled, single-dose clinical trial in which our MT 400 drug candidate showed statistically significant superiority over placebo and each of its components on the identified primary outcome measure of sustained pain relief. In addition, MT 400 showed statistically significant superiority over placebo and its components, including an oral triptan, in the two-hour pain response and effectiveness over placebo at two hours in the relief of the associated symptoms of migraine. Adverse events occurred in 23% of patients who received the MT 400 treatment and in 24% of patients who received the triptan alone, and the types of events (which include the side effects and other disadvantages of triptans identified above under "Migraine Market Overview") were similar for both types of treatments. Within the group receiving placebo, 15% reported adverse events. There were no serious adverse events reported in this trial. We believe that, in all likelihood, the adverse events that will occur from the use of MT 400, including Trexima, in the treatment of migraine will be similar to those reported with the use of the triptans alone. We filed an Investigational New Drug Application ("IND"), with the FDA for Trexima in December 2003.

In May 2004, we met with the FDA to discuss the Phase 3 clinical program for Trexima. At this meeting, the FDA agreed with our proposed Phase 3 development plan for Trexima. The design of the Phase 3 trials, including the endpoints required to evaluate Trexima, is to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours; we believe that this is the current FDA standard for establishing efficacy of migraine products. Additionally, the program is designed to demonstrate that each component makes a contribution to the efficacy of Trexima (the "combination rule" that FDA requires of all combination products). The efficacy endpoint is sustained pain free which is defined as moving from moderate or severe pain to no pain at two hours and remaining at no pain through twenty-four hours without the use of rescue medicine. We commenced the first Phase 3 clinical study (a long-term open label safety study) in May 2004. In the second half of 2004, we began two 1,400 patient Phase 3 pivotal trials, using a formulation of Trexima developed by GSK, designed to determine the effectiveness and safety of Trexima for the acute treatment of migraine as well as to satisfy the requirements of the FDA's combination rule. In addition, in the second half of 2004, we initiated two additional Phase 1 studies requested by the FDA. GSK is also funding and currently conducting two Phase 3b/4 studies.

In February 2005, we completed the first of two Phase 3 pivotal trials, in which Trexima demonstrated superiority over the individual components measured by sustained pain-free response ($p<.001$) and, with the exception of the incidence of nausea-free at two hours, all other regulatory endpoints were met ($p <.001$). Trexima did reach statistical significance for the nausea endpoint compared to placebo after two hours and maintained superiority through twenty-four hours. All of the active treatments (Trexima, sumatriptan and naproxen) had a similar incidence of nausea at two hours compared to placebo. We expect to complete the second Phase 3 pivotal trial in the second quarter of 2005. Submission of the NDA to the FDA is planned for the second half of 2005.

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

MT 100

MT 100 is intended to provide an alternative to oral triptans for the treatment of migraine pain and its associated symptoms with less risk of cardiovascular side effects compared to the triptans. Oral products are currently the most prevalent form of migraine therapy. We believe that MT 100, if approved, could offer migraine sufferers a better alternative to simple oral analgesics, such as aspirin and acetaminophen, in the treatment of migraine. In addition, because MT 100 will be a specific therapy for migraine, we believe that, if approved, MT 100 could replace the use of stronger analgesics, including prescription narcotic analgesics, in migraine therapy. According to IMS, existing oral migraine prescription products, including oral triptan products, accounted for approximately $1.7 billion in sales in the U.S. in 2004, of which the Imitrex oral dosage form accounted for approximately $850 million.

MT 100 is a proprietary formulation that combines metoclopramide hydrochloride, a commercially available agent that relieves nausea, enhances stomach emptying, and possesses some analgesic activity, and naproxen sodium, a commercially available anti-inflammatory and analgesic agent. MT 100 is designed to release metoclopramide hydrochloride initially, followed by naproxen sodium. The metoclopramide is intended to accelerate the absorption of naproxen and to reduce nausea, which can be associated with migraine; its analgesic activity supplements that provided by naproxen.

In order to obtain FDA approval for MT 100, we are required to demonstrate its efficacy and safety. To demonstrate the efficacy of a combination product candidate such as MT 100, which combines two previously approved component products, we must demonstrate in clinical trials that it is both superior to each of its individual components, and more effective in treating all symptoms of migraine when compared to a placebo. For MT 100, this means that we must show that statistically more patients have achieved sustained pain relief, defined as migraine pain relief at two hours that is maintained throughout the next 22 hours without the use of rescue medication, than patients treated with the component products. To demonstrate efficacy as a migraine product, MT 100 must demonstrate superiority to placebo for relief of nausea, photophobia and phonophobia. Generally, the FDA requires two successful clinical trials to demonstrate that the product candidate meets each of these standards for approval.

We have completed a total of two Phase 2 clinical trials, six Phase 3 clinical trials, and three marketing support Phase 3b studies, involving in total more than 8,000 treated patients, more than 3,850 of whom have received some form of MT 100. In addition to the required clinical trials, we also completed a six-month oral-dosing carcinogenicity study in p53 transgenic mice in 2002. We also completed a two-year rat carcinogenicity study in 2003. Adverse events from a long-term safety study included drowsiness, diarrhea, abdominal pain, dizziness infection and nervousness. Adverse events commonly observed in the Phase 3 trials have included drowsiness, diarrhea, dizziness and dyspepsia.

In July 2003, we submitted an NDA to the FDA for MT 100 for the acute treatment of migraine. The NDA was accepted for filing by the FDA in October 2003. In January 2004, we submitted the report of our two-year carcinogenicity study in rats that, as agreed with the FDA, completed our NDA submission. The data in the carcinogenicity study showed that there were no statistically significant differences in findings between the rats that received the maximally tolerated dose ("MTD") of metoclopramide in combination with naproxen and the rats that received metoclopramide alone at its MTD.

In May 2004, we received a not-approvable letter from the FDA with respect to our NDA for MT 100. In its letter, the FDA noted that we had demonstrated unambiguously statistically significant superiority of MT 100 compared to an appropriate control on a valid measure of pain as well as on the three associated migraine symptoms of nausea, photophobia and phonophobia in one study. However, the FDA noted in the not-approvable letter that MT 100 did not clearly meet these criteria in a second study. The FDA also 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 that were designed to satisfy the FDA's combination rule. We noted in our press release issued on June 1, 2004 that this issue appeared to arise primarily from an apparent difference in understanding between the FDA and us as to the appropriate statistical analysis of this endpoint. Additionally, the FDA letter mentioned that, based on animal studies, there may be a potential risk of carcinogenicity, presumably due to metoclopramide,

one of the components of MT 100. The FDA letter also raised, for the first time, an approvability issue concerning the risk of tardive dyskinesia ("TD") presented by the use of metoclopramide.

In July 2004, we received minutes from the FDA of a meeting between the FDA and us held on June 21, 2004. Among other things, these minutes stated the view of the FDA expressed in that meeting 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". 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 safety issues.

Following the receipt of these minutes, we requested a Type A meeting with the FDA's Division of Neuropharmacological Drug Products to present our position in response to the issues identified by the FDA. A Type A meeting is defined by the FDA as a meeting immediately necessary for an otherwise stalled drug development program to proceed. At the Type A meeting held in October 2004, the FDA stated that even if it eventually determined that MT 100 meets the efficacy requirements for a combination drug agent, MT 100 may not be approvable if the benefits of the drug do not, in the FDA's opinion, outweigh the risks of MT 100, including the risk of tardive dyskinesia. As a result of these more recent discussions, the FDA and we have agreed to present the MT 100 data to an FDA advisory committee for consideration, with particular emphasis on the potential risk of tardive dyskinesia. The FD has advised us that the meeting with the advisory committee, which we previously reported had been tentatively scheduled for May 2005, has been postponed due to FDA scheduling conflicts. We do not know when the meeting will be rescheduled, however we have been informed by the FDA that the rescheduled meeting date will be available, in advance, when published in the Federal Register. The role of an FDA advisory committee is to provide independent expert advice and contribute to the quality of the regulatory decision-making process.

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

In October 2002, we submitted a Market Authorization Application ("MAA") to the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK") for MT 100 for the acute treatment of migraine. If marketing authorization for MT 100 is unconditionally approved in the UK, we plan to seek approval in selected European countries through the European Union Mutual Recognition Procedure. This procedure allows other European countries to grant national approvals based upon the review and endorsement of the MHRA in the UK.

In September 2003, we received a letter of comments relating to the MAA from an advisory group to the MHRA, the Committee on Safety of Medicines (the "MHRA Advisory Committee"). The most significant comment in the MHRA Advisory Committee's letter of comments was that we provide additional information supporting the benefits of the combination of metoclopramide hydrochloride and naproxen sodium in MT 100.

In March 2004, we submitted our complete response to the concerns identified by the MHRA Advisory Committee and met with the MHRA Advisory Committee in January 2005 to answer questions concerning our response. Subsequent to the meeting we were notified in a letter that the MHRA Advisory Committee was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided we supply certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. In February 2005 we provided information to the MHRA Advisory Committee which we believe addresses all the conditions set forth in the MHRA Advisory Committee's letter. Although the MHRA is not bound by the MHRA Advisory Committee's recommendations, we understand that it typically agrees with the MHRA Advisory Committee's opinions.

We are not currently conducting any clinical trials for MT 100. However, we are continuing to incur pharmaceutical development costs for product stability testing and costs relating to our continuing efforts to seek approval of MT 100 from the FDA and from the MHRA, and may incur costs for the commercialization of this product if our applications are approved by the FDA and in the UK and other countries in the European Union. Additionally, under our agreement with Nycomed, if we withdraw a regulatory application from any of the countries identified in the agreement, we will be required to pay a withdrawal fee in amounts that range from $0.1 million to $0.4 million.

MT 300

The objective of our MT 300 (dihydroergotamine mesylate, or "DHE") Injection (1 mg/0.5ml) development program is to provide a safe, effective and more convenient way to administer injectable DHE, a migraine treatment that has been marketed in the U.S. for over 50 years as a 1mg/ml ampoule. MT 300 is a proprietary formulation of injectable DHE in a pre-filled syringe that is intended to provide long-lasting pain relief for patients who require a convenient injectable therapy for severe migraine attacks. Currently, patients unable to take oral migraine medications due to severe nausea and/or vomiting may choose to use an injectable form of a triptan or another drug such as DHE. According to IMS, injectable migraine therapeutics represented approximately $212 million in 2004 U.S. sales.

We have performed placebo-controlled trials designed to demonstrate the efficacy and safety of MT 300 in the acute treatment of migraine. We have completed a Phase 2 clinical trial, two Phase 3 clinical trials, and a marketing support Phase 3b study, involving in total more than 1,614 treated patients, more than 648 of whom have received some form of MT 300. DHE is used often in migraine therapy. Its side effect profile, which includes mild nausea that sometimes requires use of an antiemetic, is well-known. Adverse events (excluding injection site reactions) reported in our Phase 3 trials included dizziness, drowsiness, diarrhea, nausea and vomiting.

In December 2002, we submitted an NDA for MT 300 to the FDA. The NDA 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 based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. 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. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre-defined endpoint of sustained pain relief at 24 hours post dose, as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine at two hours (nausea, photophobia and phonophobia). Further, the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours.

In March 2004, we submitted a response to the FDA's not-approvable letter and were notified in April 2004 that the FDA considered our response incomplete because it did not include sufficient information responsive to a question regarding the testing procedures in the manufacturing process for MT 300. Subsequently, we submitted additional responses to the not-approvable letter and requested a Type A meeting with the FDA's Division of Neuropharmacological Drug Products to present our position in response to the issues identified by FDA. The Type A meeting was held in December 2004 at which time the FDA requested additional information. After providing the required information, a subsequent teleconference was held with the FDA in January 2005 during which the FDA restated its concerns that approval of MT 300 was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo. Once we receive written communications from the FDA regarding these recent meetings, we will evaluate what future steps are available to us regarding MT 300.

We are not currently conducting any clinical trials for MT 300. However, we are continuing to incur pharmaceutical development costs for product stability testing and costs relating to our continuing efforts to seek approval of MT 300. Additionally, under our agreement with Xcel, if we withdraw the NDA for MT 300 for commercial or financial reasons, we will have to pay Xcel $1.0 million.

Our Exploratory Programs

Lornoxicam Program

In July 2003, we signed an exclusive option agreement with Nycomed, under which we may acquire a license to certain rights related to lornoxicam, an NSAID that is currently marketed outside the United States (including Europe and Japan).The exclusive option terminates in July 2005. We are exploring whether to develop novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications.

In December 2003, we submitted an IND to the FDA for lornoxicam oral tablets and, in January 2004, received FDA approval to conduct the first human study with this formulation in the United States. This single-site trial evaluated the efficacy and safety of single doses of lornoxicam (at three different dose strengths), ibuprofen and placebo in 125 patients undergoing dental surgery for impacted third molars. The data from this study confirmed the acute safety profile for lornoxicam in these patients and provided preliminary evidence of efficacy in this pain model.

In September 2004, we met with the FDA to review the results of this study, to discuss information provided in the IND, and to discuss non-clinical issues and potential additional clinical studies. We committed to provide additional analyses and information requested by the FDA following that meeting which would permit conduct of additional clinical trials with lornoxicam in the United States. We will continue to discuss with the FDA the clinical and non-clinical study requirements

anticipated for approval of lornoxicam product candidates. In the event that we elect to exercise our option to license lornoxicam, we will be required to pay Nycomed additional fees, including a $0.5 million license fee, regulatory approval milestones and royalties on sales of any products developed using the licensed rights.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any lornoxicam product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any lornoxicam products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

PN (PPI / NSAID) Program

We have initiated an exploratory development program that is intended to identify potential product candidates that combine a PPI with an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone. We have designated these potential product candidates as our PN suite of potential products.

In late 2004, we requested a pre-IND meeting with the FDA to discuss two of our exploratory proprietary tablet formulations containing an NSAID and a PPI. Our studies in human volunteers have suggested that such fixed combinations could provide a degree of protection against the development of gastric and/or duodenal ulcers in patients who require the daily use of an NSAID drug for arthritis or other chronic inflammatory conditions. We met with the FDA in January 2005 and reached agreement on our proposal for studies to demonstrate efficacy of the PPI/NSAID combination. A confirmation of the safety requirements necessary to support the NDA, particularly in regard to the cardiovascular safety of the NSAID component, was tabled pending the outcome of an FDA advisory committee meeting in February 2005 addressing the potential cardiovascular risk of COX-2 selective NSAIDs and related drugs. Subsequent to the FDA's announcement of responses to the advisory committee's recent meeting we will seek confirmation of the safety requirements necessary to support the NDA.

A discussion of the costs and expenses associated with our research and development programs appears below in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Expenses Related to our Product Candidates."

Collaborative Arrangements

We have entered into and plan to continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates. Our existing commercialization collaborations are described below.

GlaxoSmithKline

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the United States to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We are responsible for development of the combination product, while GSK is to provide formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. Additionally, GSK is obligated to make payments to us in an amount up to $40.0 million upon the achievement of specified development and regulatory milestones relating to an NDA and commercialization progress for the first product. In addition, GSK will pay us sales performance milestones of up to $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. GSK will also pay us royalties on all sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017 based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle POZEN to terminate the agreement is GSK's determination not to further develop the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party

generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

Nycomed Danmark ApS

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

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

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

Xcel Pharmaceuticals, Inc.

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 withdraw the NDA for MT 300, we would be required to pay to Xcel a termination fee of $1.0 million. Potential milestone payments of up to $8.0 million will be due upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300. Xcel is also obligated to pay us royalties on all combined sales of MT 300 and Xcel's D.H.E. 45® (dihydroergotamine mesylate) Injection, upon commercialization of MT 300, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that 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 sub licensee of certain technology owned by Xcel. Based upon the delayed commercialization of MT 300 due to the not-approvable letter for MT 300 and our efforts to address with the FDA the issues raised in the that letter, we and Xcel have mutually agreed, in writing, to extend the time for certain activities under our agreement with Xcel that are dependent on the FDA's actions with respect to MT 300. In February 2005, Valeant reported that it had entered into a definitive agreement to acquire Xcel and on March 1, 2005 reported that the acquisition had been completed.

Manufacturing

We currently have no manufacturing capability and we do not intend to establish internal manufacturing capabilities.

To date, we have entered into arrangements with third-party manufacturers for the supply of formulated and packaged MT 100, MT 300 and MT 400 clinical trial materials and clinical supply materials for our exploratory program clinical trials. We believe our current supplier agreements should be sufficient to complete both our ongoing and planned clinical trials. Pursuant to our development and commercialization agreement with GSK for MT 400, GSK will supply us with the required clinical trial materials to conduct our MT 400 clinical trials covered under the agreement. Use of third-party manufacturers enables us to focus on our clinical development activities, minimize fixed costs and capital expenditures and gain access to advanced manufacturing process capabilities and expertise. We also intend to enter into agreements with third-party manufacturers for the commercial scale manufacturing of our products.

In January 2001, we entered into a Commercial Supply Agreement with DSM Pharmaceuticals, Inc. ("DSM", formerly Catalytica Pharmaceuticals, Inc.) under which DSM will supply us with all MT 100 for domestic and non-domestic commercial sale. We, or our commercial partners, are required to purchase all commercial supply of MT 100 from DSM for the initial term of the agreement (the first three years after FDA approval) and any extension thereof, unless DSM is unable to meet our, or our commercial partners', requirements. We have the right to terminate the agreement under certain circumstances after the initial term.

In October 2001, we entered into a Commercial Supply Agreement with Lek Pharmaceuticals Inc. ("Lek"), a subsidiary of Novartis Pharma AG, under which Lek agreed to provide us with DHE, which we will formulate as MT 300. We agreed to purchase DHE exclusively from Lek, which exclusivity is dependent upon Lek's ability to meet our supply requirements and certain other conditions. Lek will supply to us solely and exclusively, under certain circumstances. We will pay Lek, under certain circumstances, a fee in addition to the agreed supply price for DHE, based on a percentage of MT 300 sales revenue. The initial term of the agreement terminates on the fifteenth (15th) anniversary of the date of the first commercial sale of MT 300, but is automatically renewed on an annual basis thereafter unless canceled or terminated. Either party may cancel the agreement upon a material breach. We may terminate the agreement if we elect to stop development or commercialization of MT 300, or after a period of time specified in the agreement. In addition, Lek may terminate the agreement after a certain period of time, under agreed transition, supply and know-how transfer provisions, if Lek decides to permanently cease the manufacture of DHE.

Competition

Competition for our migraine products that receive regulatory approval will come from several different sources. Because not all migraine attacks are of the same severity, a variety of oral, injectable and intranasal therapies are used to treat different types of migraine attacks. Attacks are often treated initially with simple over-the-counter analgesics, particularly if the patient is unable to determine if the attack is a migraine or some other type of headache. These analgesics include Excedrin Migraine®, which is approved for the pain associated with migraine. If over-the-counter remedies are unsuccessful, patients often turn to more potent prescription drugs, including triptans. According to IMS, in 2004, total triptan sales in the U.S. were approximately $1.9 billion. Imitrex, a triptan product marketed by GSK, had total U.S. sales of approximately $1.1 billion in 2004, according to IMS.

Narcotics such as codeine and drugs containing analgesic/narcotic combinations, along with other non-narcotic pain medications, are also used for the treatment of migraine. If approved, our migraine product candidates will most likely compete with one or more of these existing migraine therapeutics, as well as any therapies developed in the future. Based upon their current migraine portfolios, GSK, Merck & Co., MedPointe Pharmaceuticals, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals will be our principal competitors if the Company's migraine product candidates are approved.

The U.S. prescription market for NSAIDs was approximately $6.6 billion in 2004, of which 81% was accounted for by the COX-2 inhibitors, according to IMS. This market is undergoing significant change, due to the voluntary withdrawal of Vioxx by Merck & Co. in September 2004, and the convening of an FDA advisory committee meeting in February 2005 to

review data on the COX-2 inhibitors and other NSAIDs. Uncertainty in this market is likely to continue until the FDA provides guidance after the advisory committee meeting.

The pharmaceutical and biopharmaceutical industries are intensely competitive and are characterized by rapid technological progress. Certain pharmaceutical and biopharmaceutical companies and academic and research organizations currently engage in, or have engaged in, efforts related to the discovery and development of new medicines for the treatment of migraine symptoms. Significant levels of research in chemistry and biotechnology occur in universities and other nonprofit research institutions. These entities have become increasingly active in seeking patent protection and licensing revenues for their research results. They also compete with us in recruiting skilled scientific talent.

Our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products either alone or through outside parties. Some of our competitors have substantially greater financial, research and development, manufacturing, marketing and human resources and greater experience than we do in product discovery, development, clinical trial management, FDA regulatory review, manufacturing and marketing, which may enable them to compete more effectively than we can.

Patents and Proprietary Information

We have obtained and intend to actively seek to obtain, when appropriate, protection for our products and proprietary technology by means of U.S. and foreign patents, trademarks and contractual arrangements. In addition, we rely upon trade secrets and contractual agreements to protect certain of our proprietary technology and products.

We have six issued U.S. patents and five pending U.S. patent applications, and we presently have pending foreign patent applications or issued foreign patents, relating to MT 100, MT 300 and our MT 400 technology. We also have U.S. and foreign patent applications pending relating to novel product concepts. There can be no assurance that our patent applications will issue as patents or, with respect to our issued patents, that they will provide us with significant protection. The following provides a general description of our patent portfolio and is not intended to represent an assessment of claim limitations or claim scope.

MT 100

We have two issued U.S. patents, one with claims relating to dosage forms that can be used in administering metoclopramide and a long-acting NSAID to a patient with migraine headache and one with claims relating to various pharmaceutical compositions and treatment methods that can be used with migraine patients. Within these issued U.S. patents are also claims relating to a method of manufacturing a specific type of dosage form. We submitted one of our issued U.S. patents for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. A third party has filed a protest regarding the reissuance of that MT 100 patent. We do not know the weight the examiner will give to the protest. However, we believe the protest to be without merit. We have issued patents in Australia, Europe and Canada. We have one pending U.S. patent application with claims relating to various pharmaceutical compositions and treatment methods that can be used for migraine patients. In addition, there is an application relating to MT 100 that is pending in Japan. The expected expiration date of all the issued U.S. and foreign patents relating to MT 100 is November 10, 2016. Additional U.S. and foreign patents, if issued, are expected to expire in a similar timeframe.

MT 300

With respect to MT 300, we received U.S., European and Australian patents relating to a high potency formulation of DHE and formulations of DHE in a pre-filled syringe. We also have pending U.S., Canadian, Japanese and Australian patent applications with claims relating to high potency formulations and therapeutic packages, and we have patent applications pending in other major markets worldwide. The expected expiration date of all of the U.S. and foreign patents relating to MT 300 is March 15, 2020. Additional U.S. and foreign patents, if issued, would be expected to expire in a similar timeframe.

MT 400

We have three issued U.S. patents with claims relating to methods, compositions and therapeutic packages involving the use of certain NSAIDs and 5-HT receptor agonists in treating patients with migraine. Outside of the U.S., we have issued patents in Australia and Europe and patent applications relating to our MT 400 technology pending in Canada and Japan. The expected expiration date of the issued U.S. patents relating to MT 400 is August 14, 2017. Foreign patents, if issued, are expected to expire in a similar timeframe. We have also filed a U.S. patent application with claims directed to formulations of MT 400.

Exploratory Programs

We have filed U.S. and foreign patent applications with claims directed to novel compositions and formulations for the combination of PPIs and NSAIDs. Should any patents issue from these applications they would be expected to expire on May 31, 2022. We have filed provisional U.S. patent applications with claims directed to novel compositions and formulations for new product concepts which are currently in the exploratory stage. If we pursue these provisional applications into prosecution as regular patent applications, any patents which issue from these applications would be expected to expire between 2025 and 2026.

Government Regulation

The FDA and comparable regulatory agencies in foreign countries impose substantial requirements on the clinical development, manufacture and marketing of pharmaceutical product candidates. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record-keeping, approval and promotion of our product candidates. All of our product candidates will require regulatory approval before commercialization. In particular, therapeutic product candidates for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time-consuming. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining, regulatory approvals or in complying with other requirements could adversely affect the commercialization of product candidates then being developed by us and our ability to receive product or royalty revenues.

The steps required before a new drug product candidate may be distributed commercially in the U.S. generally include:

- conducting appropriate preclinical laboratory evaluations of the product candidate's chemistry, formulation and stability and preclinical studies in animals to assess the potential safety and efficacy of the product candidate;
- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an investigational new drug application, or IND;
- initiating clinical trials under the IND after the resolution of any safety or regulatory concerns of the FDA;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:

  Phase 1: The product is initially introduced into human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion;

  Phase 2: The product candidate is studied in patients to identify possible adverse effects and safety risks, to determine dosage tolerance and the optimal dosage, and to collect some efficacy data;

  Phase 3: The product candidate is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring primary and secondary endpoints established at the outset of the study;
- submitting the results of preclinical studies, and clinical trials as well as chemistry, manufacturing and control information on the product candidate to the FDA in a New Drug Application form, or NDA; and
- obtaining FDA approval of the NDA prior to any commercial sale or shipment of the product candidate.

This process can take a number of years and require substantial financial resources. The results of preclinical studies and initial clinical trials are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough patients, clinical investigators, product candidate supply or financial support.

Even after FDA approval has been obtained, further studies, including post-marketing studies, may be required. Results of post-marketing studies may limit or expand the further marketing of the products. If we propose any modifications to a product, including changes in indication, manufacturing process, manufacturing facility or labeling, a supplement to our NDA may be required to be submitted to the FDA.

The FDA may also require testing and surveillance programs to monitor the effect of approved product candidates that have been commercialized, and the agency has the power to prevent or limit further marketing of a product candidate based on the results of these post-marketing programs. Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved in the NDA.

The status of the NDAs we have submitted to the FDA for MT 100 and MT 300 is discussed above in "Migraine Product Candidates – MT 100" and "Migraine Product Candidates - MT 300."

In addition to obtaining FDA approval for each indication to be treated with each product candidate, each domestic product candidate manufacturing establishment must register with the FDA, list its product with the FDA, comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation, and permit and pass manufacturing plant inspections by the FDA. Moreover, the submission of applications for approval may require additional time to complete manufacturing stability studies. Foreign establishments manufacturing product for distribution in the U.S. also must list their product candidates with the FDA and comply with cGMP regulations. They are also subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

Any product candidates manufactured or distributed by us pursuant to FDA approvals are subject to extensive continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the product candidate. In addition to continued compliance with standard regulatory requirements, the FDA may also require post-marketing testing and surveillance to monitor the safety and efficacy of the marketed product. Adverse experiences with the product candidate must be reported to the FDA. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product are discovered following approval.

The FFDCA also mandates that products be manufactured consistent with cGMP regulations. In complying with the cGMP regulations, manufacturers must continue to spend time, money and effort in production, record keeping, quality control, and auditing to ensure that the marketed product meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities to ensure compliance with cGMP regulations. Failure to comply subjects the manufacturer to possible FDA action, such as warning letters, suspension of manufacturing, seizure of the product, voluntary recall of a product or injunctive action, as well as possible civil penalties. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and product candidates. These third parties will be required to comply with cGMP regulations.

Products manufactured in the U.S. for distribution abroad will be subject to FDA regulations regarding export, as well as to the requirements of the country to which they are shipped. These latter requirements are likely to cover the conduct of clinical trials, the submission of marketing applications, and all aspects of manufacturing and marketing. Such requirements can vary significantly from country to country.

We and our contractors are also subject to various federal, state and local laws, rules, regulations and policies relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances used in connection with our research work. Although we believe that safety procedures employed for handling and disposing of such materials comply with current federal, state and local laws, rules, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated.

Before a medicinal product can be supplied in the European Union ("EU"), it must first be granted a marketing authorization. There are two routes by which this may be achieved: the centralized procedure whereby an approval granted by the European Commission permits the supply of the product in question throughout the EU or the Mutual Recognition Procedure ("MRP") where a marketing authorization granted by one national authority (the Reference Member State) is "recognized" by the authorities of the other member states (Concerned Member States) when conducting their reviews. This process leads to individual licenses in each member state for the supply of products in that country only. The centralized route is compulsory for biotechnology products and is optional for certain so-called 'high technology' products. All products which are not authorized by the centralized route must be authorized by the MRP unless the product is designed for use in a single country in which case a National Application can be made.

In the UK, the regulation of medicinal products is governed by the Medicines Act of 1968 and subsequent delegated legislation. Essentially all applications, which must include full details of the product and the research that has been carried out to establish its efficacy, safety and quality, must be presented for review by the competent authority, the MHRA.

The MHRA will assess the data presented to ensure that the product satisfies the appropriate requirements for efficacy, safety and quality. They may seek additional evaluation by an advisory committee, the Committee on Safety of Medicines (referred to in this 10-K as the "MHRA Advisory Committee"). The MHRA Advisory Committee may, if it wishes, advise the MHRA to refuse an application.

MT 100 is a fixed combination medicinal product incorporating two previously approved active ingredients. Such products will only be considered acceptable by the MHRA if the proposed combination is based on valid therapeutic principles. The possibility of interactions between the substances will be assessed and it will be necessary to establish that either interactions do not occur, or if they do occur, they are clearly established and defined. Furthermore, special safety and efficacy requirements apply to fixed combination products in that the dosage of each active ingredient within the combination product

must have a documented contribution within the combination and the combination should demonstrate a level of efficacy above that achieved by a single substance with an acceptable safety profile.

The status of the MAA we submitted for MT 100 is discussed above under "Migraine Product Candidates — MT 100."

If the MHRA grants the authorization for the product to be marketed in the UK, further applications will typically be made to the competent authorities of other EU countries by way of the MRP. The competent authorities of the designated EU countries will be requested to recognize the authorization of the MHRA based upon an assessment report prepared by the MHRA. The process should take no longer than 90 days, but if one country makes an objection (which, under the legislation, can only be based on a possible risk to human health, but in practice has been used by some countries to cover issues beyond the scope of the legislation), we have the option to withdraw the application from that country or take the application to arbitration by the Committee for Propriety Medicinal Products (CPMP) of the EMEA. If a referral is made, the procedure is suspended and in the intervening time the only EU country in which the product can be marketed will be the UK, even if all other designated countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reflect the objections or alternatively reach a compromise position acceptable to all EU countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

Once granted, any Marketing Authorization ("MA") remains subject to pharmacovigilance and all competent authorities have the power to vary, suspend or revoke an MA on grounds of safety.

The extent of U.S. and foreign government regulation which might result from future legislation or administrative action cannot be accurately predicted. For example, in the U.S., although the Food and Drug Administration Modernization Act of 1997 modified and created requirements and standards under the FFDCA with the intent of facilitating product development and marketing, the FDA is still in the process of developing regulations implementing the Food and Drug Administration Modernization Act of 1997. Consequently, the actual effect of these and other developments on our own business is uncertain and unpredictable.

Internet Information

We maintain a website at www.pozen.com and make available free of charge through this website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Employees

As of January 31, 2005, we had a total of 38 full-time employees. All of our current employees are based at our headquarters in Chapel Hill, North Carolina**.** Of our 38 employees, 19 hold advanced degrees, including eight with either M.D., Pharm.D. or Ph.D. degrees.

Executive Officers

Our current executive officers, and their ages as of February 1, 2005, are as follows:

Name	Age	Position
John R. Plachetka, Pharm.D.	51	Chairman, President and Chief Executive Officer
William L. Hodges	50	Senior Vice President, Finance and Administration, Chief Financial Officer
Marshall E. Reese, Ph.D.	59	Executive Vice President, Product Development
Kristina M. Adomonis	50	Senior Vice President, Business Development
W. James Alexander, M.D., M.P.H., F.A.C.P.	55	Senior Vice President, Product Development
John E. Barnhardt	55	Vice President, Finance and Administration

John R. Plachetka, Pharm.D. is Chairman of the Board of Directors, a co-founder and President and Chief Executive Officer of POZEN. Prior to founding POZEN, Dr. Plachetka was Vice President of Development at Texas Biotechnology Corporation from 1993 to 1995 and was President and Chief Executive Officer of Clinical Research Foundation-America, a leading clinical research organization, from 1990 to 1992. From 1981 to 1990, he was employed at Glaxo Inc. Dr. Plachetka received his B.S. in Pharmacy from the University of Illinois College of Pharmacy and his Doctor of Pharmacy from the University of Missouri-Kansas City.

William L. Hodges joined POZEN in August 2004 as Senior Vice President of Finance and Administration and Chief Financial Officer. Mr. Hodges began his career in the pharmaceutical industry with Burroughs Wellcome Co. in 1985. In 1991, he moved to London and worked in Group Finance for the Wellcome Foundation, Ltd. Within Group Finance. Mr. Hodges worked on mergers and acquisitions and was Regional Controller for Northern Europe and Japan. In 1993, he returned to Burroughs Wellcome in North Carolina as Director of Procurement. Mr. Hodges was Vice President, Corporate Planning and Business Support at GlaxoWellcome before being appointed acting Senior Vice President and CFO for the fifteen months leading up to the merger between GlaxoWellcome plc and SmithKline Beecham plc which was completed in December of 2000. Most recently Mr. Hodges was Senior Vice President and CFO of Pergo, Inc. located in Raleigh, North Carolina. Mr. Hodges received his B.S. from the University of North Carolina at Chapel Hill and is a Certified Public Accountant.

Marshall E. Reese, Ph.D. joined POZEN in October 2004 as Executive Vice President of Product Development. Dr. Reese was most recently employed at the Swiss-based pharmaceutical company Novartis as senior vice president and global head of research and development, Consumer Health Care. Prior to joining Novartis in 1999, Dr. Reese held several senior executive positions at Glaxo Inc. and GlaxoWellcome, including vice president of global OTC development and manufacturing with GlaxoWellcome, based in the United States, and vice president of development planning and international OTC strategies for Glaxo and GlaxoWellcome, in both the United States and the United Kingdom. Dr. Reese received his B.S., M.S., and Ph.D. degrees from the University of Tennessee at Knoxville.

Kristina M. Adomonis joined POZEN in June 1999 as Senior Vice President of Business Development. Prior to joining POZEN, Ms. Adomonis was Vice President of Global Business Development & Licensing, OTC at Novartis Consumer Health from 1997 to 1999. From 1994 to 1997, she was Director of Business Development in Burroughs Wellcome's and Glaxo Wellcome's U.S. operations. Prior to Glaxo, she served on the Canadian Executive Committees of Burroughs Wellcome and Abbott Laboratories, where she managed the Business Development Units of these two respective operations. She began her career in the industry in 1980 with F. Hoffman-La Roche Ltd. Ms. Adomonis received a B.S. in Chemistry from Tufts University and her M.B.A. from McGill University.

W. James Alexander, M.D., M.P.H., F.A.C.P. joined POZEN in November 2003 as Senior Vice President, Product Development. Prior to joining POZEN, from 1998 to 2003, Dr. Alexander was president and chief medical officer at PharmaResearch Corporation, with global responsibilities for medical and regulatory operations. Most recently in 2003, he was chief medical officer for Inveresk Research Group. From 1996 to 1998, he served as vice president and worldwide director for product safety and pharmacovigilance at GlaxoWellcome. Dr. Alexander received a B.S. from Mississippi State University, his M.D. from the University of Mississippi and his M.P.H. from the University of Alabama at Birmingham. He is board certified in internal medicine and infectious diseases.

John E. Barnhardt joined POZEN in March 1997 as Vice President of Finance and Administration. Prior to joining POZEN, Mr. Barnhardt was Chief Financial Officer of Medco Research, Inc. from 1993 to 1996 and Principal Accounting Officer of Microwave Laboratories, Inc. from 1988 to 1993. Mr. Barnhardt received a B.S. from North Carolina State University, and while employed at Ernst & Ernst (now Ernst & Young LLP), received his CPA certification.

Item 2. Properties

Since March 2002, our corporate facilities have been located in 17,000 square feet in the Exchange Office Building in Chapel Hill, North Carolina under a lease commencing in March 2002 and expiring in 2010. We have the option to renew this lease for two additional terms of up to a total of eight years. We believe that the Exchange Office Building facility is adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

As reported in our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2004, as filed on July 30, 2004 and in our Current Report on Form 8-K filed on September 17, 2004, four purported class action lawsuits claiming violations of securities laws were filed between June 4 and July 28, 2004 in the U.S. District Court for the Middle District of North Carolina by holders of our securities against us and certain of our current and former officers. These actions have been consolidated for pre-trial purposes. A fifth case filed on August 6, 2004 has been consolidated with those actions for pre-trial purposes.

By order dated November 4, 2004, the court appointed a lead plaintiff, who filed a consolidated amended complaint (amended complaint) on December 20, 2004. The defendants named in the amended complaint are POZEN and John R. Plachetka, our chairman and chief executive officer. The amended complaint alleges violations of federal securities laws, including violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5, and violations of Section 20(a) of the Exchange Act against Dr. Plachetka. The amended complaint alleges that we made false and misleading statements concerning our product candidates, MT 100 and MT 300, during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. On January 27, 2005, we moved to dismiss the amended complaint.

Also, as reported in our Current Report on Form 8-K filed on September 17, 2004, two derivative actions were filed on September 13, 2004 against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina. These actions allege violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning our product candidates, MT 100 and MT 300, that are referenced in the various purported class action lawsuits. The cases have been transferred to the North Carolina Business Court.

We believe that the allegations in both the derivative action and the class action complaints are without merit, and we intend to defend these cases vigorously.

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

None.

PART II

Item 5. Market for the Company's Common Stock, Related Stockholder Matters and Issuer Purchases of Equity Securities.

(a) Market Price of and Dividends on the Registrant's Common Equity

The Company's common stock began trading on The Nasdaq National Market under the symbol "POZN" on October 11, 2000. As of March 1, 2005, we estimate that we had approximately 119 stockholders of record and approximately 2,650 beneficial holders of the common stock. The following table details the high and low sales prices for the common stock as reported by The Nasdaq National Market for the periods indicated.

	Price Range	
2004 Fiscal Year	**High**	**Low**
First Quarter	$ 18.46	$ 9.46
Second Quarter	$ 15.14	$ 5.07
Third Quarter	$ 10.00	$ 5.78
Fourth Quarter	$ 9.38	$ 6.48

	Price Range	
2003 Fiscal Year	**High**	**Low**
First Quarter	$ 5.19	$ 2.25
Second Quarter	$ 11.19	$ 3.71
Third Quarter	$ 19.40	$ 10.30
Fourth Quarter	$ 18.40	$ 9.74

On March 1, 2005, the closing price for our common stock as reported by The Nasdaq National Market was $6.18. We paid no cash dividends in 2004. We currently intend to retain all of our future earnings to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future.

Item 6. Selected Financial Data

The following selected financial data are derived from the financial statements of POZEN Inc., which have been audited by Ernst & Young LLP, independent auditors. The data should be read in conjunction with the financial statements, related notes and other financial information included (and incorporated by reference) herein.

	For the Year Ended December 31,					Period from September 26, 1996 (inception) through December 31, 2004
	2000	2001	2002	2003	2004	
	(in thousands, except per share data)					
Statement of Operations Data:						
Revenue	$ —	$ —	$ —	$ 3,717	$ 23,088	$ 26,805
Operating expenses:						
General and administrative	4,822	6,455	6,833	9,211	8,661	40,888
Research and development	19,399	18,627	18,762	9,904	20,399	107,240
Total operating expenses	24,221	25,082	25,595	19,115	29,060	148,128
Interest income (expense), net	1,844	3,380	1,040	535	711	7,777
Net income (loss)	(22,377)	(21,702)	(24,555)	(14,863)	(5,261)	(113,546)
Non-cash preferred stock charge	27,617	—	—	—	—	27,617
Preferred stock dividends	934	—	—	—	—	934
Common stock dividends	—	—	—	—	—	—
Net loss attributable to common stockholders	$ (50,928)	$ (21,702)	$ (24,555)	$ (14,863)	$ (5,261)	$ (142,097)
Basic and diluted net loss per common share	$ (4.95)	$ (0.78)	$ (0.87)	$ (0.52)	$ (0.18)	
Shares used in computing basic and diluted net loss per common share	10,294	27,955	28,110	28,414	28,749	
Pro forma net loss per common share—basic and diluted*	$ (2.56)					
Pro forma weighted average common shares outstanding—basic and diluted*	19,915					

	December 31,				
	2000	2001	2002	2003	2004
Balance Sheet Data:					
Cash and cash equivalents	$ 92,351	$ 73,959	$ 50,056	$ 60,481	$ 51,764
Total assets	92,830	74,144	51,035	61,513	53,296
Total liabilities	3,762	3,523	1,836	25,883	21,585
Accumulated deficit	(48,099)	(69,801)	(94,356)	(109,219)	(114,480)
Total stockholders' equity	89,068	70,621	49,199	35,630	31,711

* Assumes conversion of all outstanding preferred stock into common stock as of the date of the original issuance.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a pharmaceutical company focused primarily on products for the treatment of migraine, acute and chronic pain and other pain-related indications. Our product development emphasis is on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception, we have focused our efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine.

Since inception, our business activities have included:

- product candidate research and development;
- designing and conducting clinical trials for our product candidates;
- regulatory and clinical affairs;
- intellectual property prosecution and expansion; and

- business development, including product acquisition and/or licensing and collaboration activities.

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

Our MT 400 technology refers to our proprietary combinations of a triptan (5-HT1B/1D agonist) and an NSAID. In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long-acting NSAID. The combinations covered by the agreement are among the combinations of our MT 400 technology. Trexima is the proposed brand name for the combination of GSK's sumatriptan and naproxen sodium in a single tablet being developed pursuant to our agreement with GSK. MT 100, a combination of metoclopramide hydrochloride and naproxen sodium, is intended to provide effective migraine relief with less risk of cardiovascular side effects compared to the triptans. MT 300, a proprietary formulation of injectable DHE in a pre-filled syringe, is intended to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks.

We currently have two exploratory programs in pain-related therapeutic areas. We have begun exploratory development work and clinical studies to investigate the development of novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. This exploratory work is being conducted under an exclusive option agreement with Nycomed pursuant to which we may acquire a license to certain rights related to lornoxicam. If we elect to exercise our option to license lornoxicam, which expires in July 2005, we will be required to pay Nycomed a $0.5 million licensing fee, regulatory approval milestones and royalties on sales of any products developed using the licensed rights. In our other exploratory program, we have begun exploratory formulation development and clinical studies for a combination of a PPI and an NSAID in a single tablet intended to provide effective control of pain and inflammation with fewer gastrointestinal complications compared to an NSAID taken alone.

We have financed our operations and internal growth primarily through private placements of preferred stock, our initial public offering and, beginning in 2003, payments received under our collaborations. Beginning in the third quarter of 2003, we began recognizing revenue from initial payments received under our collaboration agreements. We have entered into three collaboration agreements – with Nycomed for the commercialization of MT 100 in four Nordic countries, GSK for the development and commercialization of proprietary combinations of one or more of GSK's triptans and a long-acting NSAID in the U.S. and Xcel for the further development and commercialization of MT 300 in the U.S. We plan to seek additional partnering opportunities to commercialize our product candidates in other countries.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of December 31, 2004, our accumulated deficit was $114.5 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, MT 300 and Trexima, and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented 72% of our total operating expenses. For the year ended December 31, 2004, our research and development expenses represented approximately 70% of our total operating expenses.

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 will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of our product candidates.

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

- our progress in reversing the FDA's not-approvable decisions with respect to MT 100 and MT 300;
- the progress of Trexima and our other product candidates in the clinical and regulatory process;
- the establishment of new collaborations and progress of our existing collaborations for the development and commercialization of any of our product candidates;
- the acquisition and/or in-licensing, and development, of other therapeutic product candidates; and
- our costs related to the lawsuits that have been filed against us and our current or former directors and officers relating to the approvability of MT 100 and MT 300. The status of these proceedings is discussed under "Item 3. Legal Proceedings" herein.

Our ability to generate revenue is dependent upon our ability, alone or with others, to achieve the milestones set forth in our collaboration agreements and successfully develop our migraine and other product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products.

Status and Expenses Related to Our Product Candidates

There follows a brief discussion of the status of the development of each of Trexima, MT 100, MT 300, and our other product candidates**,** as well the costs relating to our development activities. Our direct research and development expenses for the fiscal years ended December 2002, 2003 and 2004 were $16.0 million, $7.2 million, and $16.2 million, respectively. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total compensation and benefit costs for our personnel involved in our research and development activities for the fiscal years ended December 2002, 2003 and 2004 were $2.3 million, $2.1 million, and $3.2 million, respectively. Other research and development department costs for the fiscal years ended December 2002, 2003, and 2004 were $0.5 million, $0.6 million, and $1.0 million, respectively.

MT 400/Trexima. In May 2004, we commenced the Phase 3 clinical program for Trexima. As part of the Phase 3 program, we have planned two Phase 3 pivotal trials designed to determine the effectiveness and safety of Trexima for the acute treatment of migraine as well as to satisfy the requirements of the FDA's combination drug rule, the first of which was completed in February 2005. In addition, we are conducting a long-term, open label safety study. Along with these program trials, GSK is funding and currently conducting two Phase 3b/4 studies. 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 development costs associated with the development of Trexima for the fiscal years ended December 31, 2002, 2003 and 2004 and from inception to date of $4.7 million, $0.9 million, $10.9 million and $19.1 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 100. In July 2003, we submitted an NDA to the FDA for MT 100. In May 2004, we received a not-approvable letter from the FDA with respect to our NDA. Since the issuance of the not-approvable letter, we have had continuing communications with the staff of the FDA to seek to persuade the FDA that MT 100 should be approved based upon the data that we submitted in the NDA for MT 100. We and the FDA have agreed to present MT 100 data, with particular emphasis on the potential risk of tardive dyskinesia, to an FDA advisory committee. The FDA has advised us that the meeting with the advisory committee, which we previously reported had been tentatively scheduled for May 2005, has been postponed due to FDA scheduling conflicts. We do not know when the meeting will be rescheduled, however we have been informed by the FDA that the rescheduled meeting date will be available, in advance, when published in the Federal Register.

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

In October 2002, we submitted an MAA for MT 100 to the MHRA in the UK. In September 2003, we received a letter of comments relating to our MAA from the MHRA Advisory Committee to which we subsequently responded. In January 2005, we were notified that the MHRA Advisory Committee was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided we supply certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. In February 2005, we provided information to the MHRA Advisory Committee which we believe addresses all the conditions set forth by the MHRA Advisory Committee.

We are not currently conducting any clinical trials for MT 100. However, we are continuing to incur pharmaceutical development costs for product stability testing and costs relating to our continuing efforts to obtain approval of MT 100 from the FDA and in the UK. Additionally, we may incur costs for the commercialization of this product if our applications are approved by the FDA and in the UK. Until the not-approvable letter is definitively resolved with the FDA and we receive final approval of the MAA from the MHRA, we cannot reasonably estimate the amount and timing of additional costs that we may

need to incur to satisfy comments or conditions on our applications for approval or when, if and to what extent we will receive cash inflows from MT 100. The additional costs that we may incur include expenses related to clinical trials, formulation, manufacturing and labeling of our product and regulatory consulting expenses required to address the FDA's and MHRA's responses to our applications.

We have incurred direct development costs associated with the development of MT 100 for the fiscal years ended December 31, 2002, 2003 and 2004 and from inception to date of $4.0 million, $3.2 million, $0.8 million and $38.8 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300. In December 2002, we submitted to the FDA an NDA for approval of MT 300. In October 2003, we received a not-approvable letter from the FDA with respect to our NDA for MT 300. Subsequently, we submitted additional responses to the not-approvable letter and requested a Type A meeting with the FDA's Division of Neuropharmacological Drug Products to present our position in response to the issues identified by the FDA. The Type A meeting was held in December 2004 and a subsequent teleconference with the FDA occurred in January 2005 during which the FDA restated its concerns that approval of MT 300 was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo. Once we receive and review the FDA's meeting minutes, we will evaluate what future steps are available to us regarding MT 300.

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

We have incurred direct development costs associated with the development of MT 300 for the fiscal years ended December 31, 2002, 2003 and 2004 and from inception to date of $5.2 million, $0.8 million, $0.3 million and $14.4 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Our Exploratory Programs. In September 2004, we met with the FDA to review the results of our first lornoxicam study, to discuss information provided in the IND, and to discuss non-clinical issues and potential additional clinical studies. We also met with the FDA in January 2005 and reached agreement on our proposal for studies to demonstrate efficacy of a PPI/NSAID combination. We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any lornoxicam or PN product candidates we may seek to develop, or when, if and to what extent we will receive cash inflows from either of these research programs. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities associated with the packaging and labeling of our products and the cost and timing of activities necessary to obtain regulatory approvals.

We have incurred direct development costs associated with the development of our exploratory programs, the lornoxicam and PN product candidates, for the fiscal year ended December 31, 2004 and from inception date to of $2.5 million and $4.3 million, respectively. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Critical Accounting Policies and Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States in the preparation of our financial statements. The development and selection of the critical accounting policies, and the related disclosure about these policies, have been reviewed by the audit committee of our board of directors. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results.

While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe the following accounting policies are the most critical to us in that they are important to the portrayal of our financial statements and require our most difficult, subjective or complex judgments in the preparation of our financial statements.

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 are reached, and royalty payments based on future product sales. We recognize revenue under these agreements in accordance with SEC Staff Accounting Bulletin 101, "Revenue Recognition" as amended by SAB 104 "Revenue Recognition" ("SAB 101"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables."

Under SAB 101 recognition of revenue from non-refundable up-front payments is deferred by us upon receipt and recognized over the period ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates.

We recognize milestone payments 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) if the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria will be recorded as deferred revenue.

Royalty revenue will be recognized related to the manufacture, sale or use of our products or technology. For those arrangements where royalties are reasonably estimable, we 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, we will recognize revenue upon receipt of royalty statements from the licensee. Additionally, our licensing agreements may include payment for services provided by us on an hourly rate and direct expenses. We record such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project.

Management believes that its current assumptions and other considerations used to estimate the periods for revenue recognition described above are appropriate. However, we continually review these estimates, which could result in a change in the deferral period and might impact the timing and amount of revenue recognition. Further, if regulatory approvals relating to MT 100, MT 300 or Trexima are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products would prospectively be accelerated or reduced accordingly.

As of December 31, 2004, we had deferred $16.4 million of revenue, of which from $1.1 million to $1.4 million is refundable under certain termination or cancellation provisions within our licensing agreements. During the twelve-month periods ended December 31, 2004 and 2003, we recognized $23.1 million and $3.7 million of revenue relating to our collaboration agreements, respectively.

Accrued expenses, including contracted costs

Significant management judgments and estimates must be made and used in connection with accrued expenses, including those related to contract costs, such as costs associated with our clinical trials. Specifically, our management must make estimates of costs incurred to date but not yet invoiced in relation to contracted, external costs. Management analyzes the progress of product development, clinical trial and toxicology and related activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. Material differences in the amount and timing of the accrued liability for any period may result if management made different judgments or utilized different estimates.

Management believes that its current assumptions and other considerations used to estimate accrued expenses for the period are appropriate. However, determining the date on which certain contract services commence, the level of services performed on or before a given date and the cost of such services involves subjective judgments and often must be based upon information provided by third parties. In the event that we do not identify certain contract costs which have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported accrued expenses for such period would be too low or too high, as the case may be.

In the years ended December 31, 2004, 2003 and 2002, we recognized $1.4 million, $0.8 million and $0.6 million respectively, for accrued costs related to product development and operating activities, including clinical trials, based upon the progress of these activities covered by the related contracts, invoices received and budgeted costs.

Income Taxes

We record deferred tax assets and liabilities based on the net tax effects of tax credits, operating loss carry-forwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we establish an annual valuation allowance. We have not recorded any tax provision or benefit for the years ended December 31, 2004, 2003, or 2002. Since we are unable to conclude whether we will realize any future benefit from deductible temporary differences and net operating loss carry-forwards of approximately $80.1 million for federal and state income tax purposes, which are available to offset future federal

and state taxable income, if any, and expire between 2011 and 2022, we have provided a valuation allowance for the full amount of our net deferred tax assets. We also have research and development tax credit carry-forwards of approximately $7.2 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, and expire between 2012 and 2022. The Tax Reform Act of 1986 ("the Tax Reform 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 Tax Reform Act) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Tax Reform Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. If results of operations in the future indicate that some or all of the deferred tax assets will be recovered, the reduction of the valuation allowance will be recorded as a tax benefit during one or more periods.

Historical Results of Operations

Year ended December 31, 2004 compared to the year ended December 31, 2003

Net income (loss) per share: Net loss attributable to common stockholders for the year ended December 31, 2004 was $(5.3) million or $(0.18) per share, as compared to a net loss of $(14.9) million, or $(0.52) per share, for the year ended December 31, 2003.

Revenue: We recognized $23.1 million of licensing revenue for the year ended December 31, 2004 as compared to $3.7 million for the year ended December 31, 2003. The $19.4 million increase resulted from the amortization of upfront payments we received in 2003 pursuant to development and commercialization agreements relating to MT 100, MT 300 and MT 400, from a $15.0 million milestone payment we received from GSK as a result of commencement of Trexima Phase 3 clinical trial activities in the second quarter of 2004 and from a $0.8 million payment from GSK for conducting Trexima Phase 1 clinical trial activities in the fourth quarter of 2004. Our license agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. Approximately $16.4 million remained in deferred revenue at December 31, 2004. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by 106% to $20.3 million for the year ended December 31, 2004, as compared to $9.9 million for the year ended December 31, 2003. The $10.5 million increase was due primarily to an increase in direct development costs for Trexima and our current exploratory programs, and other departmental expenses, offset by a decrease in direct development costs associated with MT 100 and MT 300. Direct development costs associated with Trexima increased by $10.0 million to $10.9 million, primarily due to Phase 3 clinical trial activities during 2004, as compared to the same period of 2003. Direct development costs associated with our current exploratory programs increased by $2.0 million to $4.1 million, primarily due to Phase 2 clinical trial activities for our lornoxicam program and pharmaceutical development activities for the lornoxicam and our other exploratory programs during 2004, as compared to 2003. MT 100 direct development costs decreased by $2.4 million to $0.8 million, primarily due to costs incurred in preparing and filing an NDA with the FDA in 2003, as compared to the same period of 2004. Direct development costs associated with MT 300 decreased by $0.5 million to $0.3 million, primarily due to MT 300 product supply expenses incurred during 2003 as compared to the same period of 2004. Research and development departmental expenses increased by $1.4 million to $4.2 million, primarily due to an increase in personnel related costs associated with our product development activities and legal and consulting costs incurred for MT 100 and MT 300 regulatory activities. We have included in our research and development expenses the personnel costs associated with our research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses decreased by 6% to $8.6 million for the year ended December 31, 2004, as compared to $9.2 million for the year ended December 31, 2003. The $0.5 million decrease was due primarily to a decrease in the costs associated with our business development activities and personnel related expenses offset by an increase in costs related to our public company activities. Business development expenses decreased by $0.9 million to $1.9 million, primarily due to a greater level of pre-commercialization activities for MT 100 and MT 300 in 2003, as compared to the same period of 2004. Administrative expenses decreased by $0.7 million to $3.7 million in 2004, as compared to the 2003 period, primarily due to the payment of $1.0 million for incentive compensation to our chief executive officer in 2003. Costs associated with our public company activities increased by $1.1 million to $3.0 million, primarily due to legal fees associated with the class action litigation pending against us and other professional consulting fees incurred in preparing for Sarbanes-Oxley regulatory compliance. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Interest income: Interest income increased to $0.7 million for the year ended December 31, 2004, from $0.5 million for the same period of 2003. This increase was due to an increase in interest rates and our average cash balance available for investing during 2004, as compared to the same period of 2003.

Year ended December 31, 2003 compared to year ended December 31, 2002

Net income (loss) per share: Net loss attributable to common stockholders for the year ended December 31, 2003 was $(14.9) million or $(0.52) per share, as compared to a net loss of $(24.6) million, or $(0.87) per share, for the year ended December 31, 2002.

Revenue: We recognized $3.7 million of licensing revenue for the year ended December 31, 2003 as compared to no revenue for the year ended December 31, 2002. Revenue resulted from initial payments we received pursuant to development and commercialization agreements for MT 100, MT 300 and MT 400. Our license agreements have terms that include upfront

payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. Approximately $23.8 million remained in deferred revenue at December 31, 2003. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses decreased by 47% to $9.9 million for the year ended December 31, 2003 as compared to the year ended December 31, 2002. The $8.9 million decrease was due primarily to a decrease in direct development costs for MT 300 and MT 400. Direct development costs associated with MT 300 decreased by $4.4 million to $0.8 million, primarily due to completion of Phase 3 clinical trial activities and submission of the NDA for MT 300 to the FDA in 2002, as compared to 2003. Direct development costs associated with MT 400 decreased by $3.8 million to $1.0 million, primarily due to a reduction in pharmaceutical development activities, including costs incurred in obtaining drug substance, and reduced costs associated with toxicology activities, as compared to the same period of 2002. Additional research and development expenses, including costs associated with exploratory lornoxicam product development, other exploratory development and departmental expenses, increased by $0.4 million to $4.9 million. The amortization of deferred stock compensation decreased by $1.1 million. Total amortization of deferred stock compensation included in research and development expenses was $0.1 million and $1.2 million for the years ended December 31, 2003 and 2002, respectively. We have included in our research and development expenses the personnel costs associated with our research activities and costs associated with pharmaceutical development, clinical trial and toxicology activities and regulatory matters.

General and administrative: General and administrative expenses increased by 35% to $9.2 million for the year ended December 31, 2003 as compared to the year ended December 31, 2002. The $2.4 million increase was due primarily to increased costs associated with administrative, business development and public company activities. Administrative costs increased by $1.4 million, primarily due to a $1.0 million incentive compensation payment to our chief executive officer pursuant to a performance-based award issued under POZEN's 2001 Long Term Incentive Plan. Costs associated with business development activities increased by $1.4 million due to pre-marketing activities for MT 100 and MT 300, and consulting fees associated with the licensing of our product candidates. Costs associated with our public company activities increased by $0.9 million due to an increase in legal and auditing fees and an increase in director liability insurance and director compensation. Other departmental expenses decreased by $1.3 million, primarily due to a $1.3 million decrease in the amortization of deferred stock compensation. Total amortization of deferred stock compensation included in general and administrative expenses was $0.4 million and $1.6 million for 2003 and 2002, respectively. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development and public company activities.

Interest income: Interest income decreased by 49% to $0.5 million for the year ended December 31, 2003 as compared to the year ended December 31, 2002. Interest income decreased primarily due to a decline in interest rates during the year.

Income Taxes

As of December 31, 2004, we had available net operating loss carry-forwards of approximately $80.1 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2011 and 2022. We also have research and development tax credit carry-forwards of approximately $7.2 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2022. Since our inception, we have incurred substantial losses and expect to incur substantial and recurring losses in future periods. The Tax Reform Act limits the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Tax Reform Act). We have experienced various ownership changes, as defined by the Tax Reform Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal income tax purposes.

Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in cash of $133.9 million, and, since 2003, from upfront and milestone payments from our collaborators, resulting in cash of $43.3 million. As of December 31, 2004, cash and cash equivalents totaled $51.8 million, a decrease of $8.7 million as compared to December 31, 2003. Our cash and cash equivalent are invested primarily in short-term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks.

Operating cash received during the twelve-month period ended December 31, 2004 totaled $15.8 million, resulting from payments received under our collaboration agreement with GSK for our MT 400 technology. A milestone payment of $15.0 million was received in May 2004 for commencement of Phase 3 clinical trial activities relating to Trexima and a $0.8

million payment was received in December 2004 for payment for two Phase 1 clinical trials. We expect to receive additional milestone payments from GSK over the next several years in an aggregate amount of up to $40.0 million upon the satisfaction of specified regulatory and commercialization events for Trexima. Cash received from financing activities during the period totaled $1.3 million, reflecting net proceeds from the exercise of stock options.

Based upon the direct method of presenting cash flow, cash paid for operating activities totaled $26.4 million for the year ended December 31, 2004. The indirect method for presenting cash flow is used in the Statement of Cash Flows. Our operating activities included primarily direct development costs for Trexima, particularly Phase 3 clinical trial activity, and our current exploratory programs, particularly Phase 2 clinical trial activities and pharmaceutical development activities for lornoxicam, along with business development activities and personnel related expenses. Cash paid for operating activities in the fiscal years ended December 31, 2004, 2003, and 2002 was $26.4 million, $18.4 million and $25.1 million, respectively. Cash required for our operating activities during 2005 is projected to approximate our 2004 requirements due to the expected cash required to complete of Phase 3 clinical trial activities for Trexima and to continue development related to our exploratory programs.

As of December 31, 2004, we had $51.8 million in cash and cash equivalents. If our operating expenses in 2005 and 2006 are at the level of our currently expected operating expenses in 2005, and if we do not receive any additional milestone payments under any of our collaboration agreements, during 2005 and 2006, we will not have sufficient cash reserves to maintain our level of business activities throughout 2006. Further, our expenses might increase in 2005 and 2006 if any regulatory agency requires us to conduct additional clinical trials**,** studies or investigations in connection with their consideration, or reconsideration**,** of our regulatory filings for MT 100, MT 300 and Trexima. We 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 or unforeseen developments in the development of our existing and future product candidates may increase our cash requirements beyond our currently assumed needs. If any of the foregoing occurs, we may seek to raise additional funds. Sources of such funds may not be available on terms favorable to us. We regularly assess available funding options and will consider available funding opportunities as they arise. We may issue shares of common stock in the future, including to fund additional unplanned development activities. In February 2004, we filed with the Securities and Exchange Commission a shelf registration statement on Form S-3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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

- the number and progress of our clinical trials and other trials and studies;
- our success in obtaining regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights;
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies; and
- costs incurred in the defense of class action and shareholder derivative lawsuits that have been filed against us or our current or former directors and officers relating to MT 100 and MT 300.

Obligations and Commitments

The following summarizes our contractual obligations as of December 31, 2004, and the expected timing of maturities of those contractual obligations. This table should be read in conjunction with the notes accompanying our financial statements included elsewhere in this Form 10-K.

	Payments Due by Period				
Contractual Obligations	**Total**	**2005**	**2006-2007**	**2008-2009**	**After 2009**
			($ in thousands)		
Operating leases[1]	$ 2,038	$ 378	$ 779	$ 812	$ 69
Product development agreements[2]	2,269	2,113	143	13	—
Total contractual obligations	$ 4,307	$ 2,491	$ 922	$ 825	$ 69

1 These commitments are associated with operating leases. Payments due reflect fixed rent expense.

2 Amounts represent open purchase orders for ongoing pharmaceutical development activities for our product candidates as of December 31, 2004. These agreements may be terminated by us at any time without incurring a termination fee.

Recent Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46(R), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51", and revised the interpretation in December 2003 ("FIN 46(R)"). FIN 46(R) requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46(R) is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46(R) must be applied for the first interim or annual period ending after March 15, 2004. We did not have any ownership in any variable interest entities as of December 31, 2004. We will apply the consolidation requirement of FIN 46(R) in future periods if we own any interest in any variable interest entity.

As permitted by FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("FASB 123"), we currently account for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of the revised FASB 123's ("FASB 123(R)") fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of FASB 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted FASB 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 1 above. FASB 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the decrease in operating cash flows which would have been recognized for such excess tax deductions was $0.9 million and $0.7 million in 2004 and 2003, respectively.

Factors That May Affect Our Results

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

Risks Related to Our Business

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

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of our current product candidates, particularly MT 100 and Trexima. In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

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

We have incurred losses in each year since our inception. As of December 31, 2004, we had an accumulated deficit of approximately $114.5 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing of payments that we may receive from others. We expect to continue to incur significant operating losses and do not know when, if and to what extent we will generate product revenue.

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

Changes in regulatory approval policy or regulations or in the regulatory environment during the development period of any of our product candidates may result in delays in the approval, or rejection, of the application for approval of one or more our product candidates. If we fail to obtain approval, or are delayed in obtaining approval, of our product candidates, our ability to generate revenue will be severely impaired.

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. Further, changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained in conversations and other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX-2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. We do not know if the recommendations of the advisory committee from that meeting or the FDA's actions based upon those recommendations will adversely affect the approvability of our product candidates which include NSAIDs.

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

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the United States. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. None of our product candidates have been approved for sale in the United States or any foreign market and they may never be approved.

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

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

If we or our contract manufacturers do not maintain required regulatory approvals, we may not be able to commercialize our products. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

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

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

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

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

On May 28, 2004, we received a not-approvable letter from the FDA with respect to our NDA for MT 100. In the letter, the FDA noted that, although we had demonstrated unambiguous statistically significant superiority compared to an appropriate control on a valid measure of pain as well as on the three associated symptoms of nausea, photophobia and phonophobia in one study, MT 100 did not clearly meet these criteria in a second study. The FDA letter cited the apparent lack of superiority of MT 100 over naproxen for sustained pain relief, which was the primary endpoint for the two component studies. The FDA also stated in its letter that, based on animal studies, there may be a potential risk of carcinogenicity, presumably due to metoclopramide, one of the components of MT 100. Finally, the FDA raised an approvability issue concerning the risk of tardive dyskinesia ("TD") presented by the use of metoclopramide.

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

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

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

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

In September 2003, we received a letter of comments relating to the MAA we submitted for MT 100 from an MHRA Advisory. The most significant comment in the MHRA Advisory Committee's letter of comments was that we provide additional data to support the benefits of the combination of metoclopramide hydrochloride and naproxen sodium in MT 100. We provided additional data and supplemental information to the MHRA Advisory Committee in 2004 to address the MHRA Advisory Committee's questions and, in January 2005, the MHRA Advisory Committee advised us in a letter that it was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided we supply certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. The MHRA is not bound by the MHRA Advisory Committee's comments, and, although we believe we can address the requests of the MHRA Advisory Committee as set forth in its letter to us, we can give no assurance that the MHRA Advisory Committee will accept

the supplemental information we supply or that the MHRA will follow the MHRA Advisory Committee's recommendations. Without approval of our MAA in the UK by the MHRA, we would not be able to market MT 100 in the UK. Further, we would not be able to use the mutual recognition process to obtain approval of MT 100 in other European Union countries unless we first obtain approval in another country in the European Union, which would result in increased expenses and time delays.

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

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

In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre-defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Further, the FDA noted that the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours. Since our receipt of the not-approvable letter, we have had continuing communications with the FDA regarding the MT 300 NDA and in a recent communication the FDA restated its concerns that approval of MT 300 was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo. No assurance can be given that our efforts to obtain FDA approval of MT 300 will ultimately be successful.

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

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

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

Contractors or collaborators may have the right to terminate their arrangements with us on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology in the United States and collaborations with Nycomed in the Nordic countries and Xcel in the United States for the development and commercialization of MT 100 and MT 300, respectively. In all of these collaboration and license agreements, our licensees have the right to terminate the agreement upon a default by us. In addition, GSK is entitled to terminate its agreement upon 90 days' notice for any reason; Nycomed is entitled to terminate its agreement if the MAA for MT 100 is 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 not-approvable letters for MT 100 and MT 300 may suggest to our collaborators that they should terminate their agreements with us. If these licensees exercise their termination rights, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and commercialize these and our other product candidates. Moreover, any future collaborations or license arrangements may not be on terms favorable to us.

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

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determines, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Trexima clinical trials. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization would delay or eliminate our potential product revenues.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- third parties may not fulfill their regulatory or other obligations;
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and
- disagreements may arise regarding a breach of the arrangement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

A collaborator may withdraw support or cease to perform work on our product candidates if the collaborator determines to develop its own competing product candidate instead.

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

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

We have no sales or distribution personnel or capabilities. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively, we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that,

should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity studies and clinical trials for our product candidates. Any unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could reduce, delay or eliminate our receipt of revenues for one or more of our product candidates and adversely affect our ability to achieve profitability.

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and trials can be very costly and time-consuming. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of our clinical trials are not necessarily predictive of results we will obtain in subsequent clinical trials. This may occur for many reasons, including, among others, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, if we conduct an additional study to address the FDA's concerns in its not-approvable letter on MT 100, there is no assurance that the results of such a study will satisfy all of the FDA's conditions for approval because, among other reasons, migraine affects patients differently, including the presence, or lack or level of severity, of secondary symptoms in a particular patient and the variability of the responsiveness of migraine attacks to given treatments, all of which may affect treatment responses. In addition, our results from our first Phase 3 clinical trial of Trexima differed from the results of the Phase 2 proof-of-concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the Phase 3 study Trexima failed to achieve statistical significance at two hours compared to placebo in the relief of nausea.

The successful completion of clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. For example, even though we are entitled to submit an NDA for Trexima as a 505(b)(2) application, the FDA may require us to conduct more studies or trials than we now believe are necessary.

Further, even though we may have completed all planned clinical trials for a product candidate and submitted an NDA for such product candidate, as we have for MT 100 and MT 300, the FDA may require us to conduct additional clinical trials, studies or investigations to support our NDAs. For example, the FDA may require us to conduct additional studies or trials of MT 100 or MT 300 in connection with our efforts to convince the FDA to reverse its not-approvable decisions on these product candidates. We may also determine from time to time, including in connection with our efforts to resolve the FDA's issues raised in the not-approvable letters related to MT 100 and MT 300, that it would be necessary to seek to persuade the FDA to evaluate the results of a study or trial in a manner that differs from the way the FDA initially evaluated the results, or customarily evaluates results. In addition, we may have unexpected results that require us to reconsider the need for certain studies or trials. For example, results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies.

Once submitted, an NDA requires FDA approval before we can distribute or commercialize the product described in the application. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, although we believe that we provided the necessary data to support approval of the NDAs for MT 100 and MT 300, the FDA issued not-approvable letters for the MT 100 and MT 300 NDAs on May 28, 2004 and October 17, 2003, respectively. Further, although we believed the results of our recently completed MT 100 two-year rat carcinogenicity study provided no evidence that the concomitant administration of maximum tolerated doses of metoclopramide and naproxen, the two active components in MT 100, produced any statistically significant differences in the occurrences and types of tumors seen with metoclopramide alone, the FDA expressed concern about the potential risk of carcinogenicity, presumably due to metoclopramide, in its MT 100 not-approvable letter. The FDA may also require further investigations to assess any potential risk of tardive dyskinesia associated with the use of MT 100.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement.

We face similar regulatory hurdles in other countries to those that we face in the United States. For example, no assurance can be given that the MHRA will follow the MHRA Advisory Committee's recommendation, of which we received notice in January 2005, that marketing authorization be granted in the UK for MT 100, subject to our providing additional information and addressing certain matters set forth in our notice from the MHRA Advisory Committee, or that we will be able to satisfactorily answer and/or address such matters.

Our costs associated with our human clinical trials vary based on a number of factors, including:

- the order and timing of clinical indications pursued;
- the extent of development and financial support from collaborative parties, if any;
- the need to conduct additional clinical trials or studies;
- the number of patients required for enrollment;
- the difficulty of obtaining sufficient patient populations and clinicians;
- the difficulty of obtaining clinical supplies of our product candidates; and
- governmental and regulatory delays.

We currently depend and will in the future depend on third parties to manufacture our product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our product candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture either clinical trial or commercial quantities of products that we may develop or have under development. We rely upon third-party manufacturers to supply us with our product candidates. We also need supply contracts to sell our products commercially. There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if our current manufacturer is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

If our competitors develop and commercialize products faster than we do or if their products are superior to ours, our commercial opportunities will be reduced or eliminated.

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. Our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., MedPointe Pharmaceuticals, Johnson & Johnson and Pfizer, Inc.), biotechnology companies, universities and public and private research institutions. Based upon their migraine portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology.

Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

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

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products before we do. Any delays we encounter in obtaining regulatory approvals for

our product candidates, such as we are currently experiencing as a result of the not-approvable letters we have received from the FDA on MT 100 and MT 300, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

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

Four purported class action lawsuits claiming violations of securities laws were filed between June 4 and July 28, 2004 in the U.S. District Court for the Middle District of North Carolina by holders of our securities against us and certain of our current and former officers. These actions have been consolidated for pre-trial purposes. A fifth case filed on August 6, 2004 has also been consolidated with those actions for pre-trial purposes. By order dated November 4, 2004, the court appointed a lead plaintiff, who filed a consolidated amended complaint (amended complaint) on December 20, 2004. The defendants named in the amended complaint are POZEN and John R. Plachetka, our chairman and chief executive officer. The complaint alleges violations of federal securities laws, including violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5, and violations of Section 20(a) of the Exchange Act against Dr. Plachetka. The amended complaint alleges that we made false and misleading statements concerning our product candidates MT 100 and MT 300 during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. On January 27, 2005, we moved to dismiss the amended complaint.

In September 2004, two derivative actions were filed against certain of our current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina. These actions allege violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning the same product candidates MT 100 and MT 300 that are referenced in the various purported class action lawsuits. The cases have been transferred to the North Carolina Business Court.

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

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

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

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

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such a risk exists with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. A third party has recently filed a protest regarding the reissuance of that MT 100 patent. We do not know the weight the examiner will give to the protest or whether this may adversely affect our submission for reissuance of the patent.

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

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

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

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

As part of our business strategy, we plan to identify, self-invent and/or acquire product candidates or approved products in areas in which we possess particular knowledge. Because we do not directly engage in basic research or drug discovery, we may rely upon third parties to sell or license product opportunities to us. Other companies, including some with substantially greater financial, marketing and sales resources, are competing with us to acquire such products and product candidates. We may not be able to acquire rights to additional products or product candidates on acceptable terms, if at all. In addition, if we acquire new products or product candidates with different marketing strategies, distribution channels and bases of competition than those of our current product candidates**,** we may not be able to compete favorably in those product categories.

None of our future products may be accepted by the market.

Even if our product candidates perform successfully in clinical trials and are approved by the FDA and other regulatory authorities, our future products may not achieve market acceptance and may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the receipt and timing of regulatory approvals;
- the availability of third-party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;
- the price of the product relative to alternative therapies;
- the availability of alternative therapies;
- the extent and effectiveness of marketing efforts by us and third-party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

If we do not receive adequate third-party reimbursements for our future products, our revenues and profitability will be reduced.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved healthcare product. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of healthcare through various means. We expect that a number of federal, state and foreign proposals will seek to control the cost of drugs through governmental regulation. We are unsure of the form that any healthcare reform legislation may take or what actions federal, state, foreign and private payors may take in response to any proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The testing and marketing of pharmaceutical products entails an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our human clinical trials in an amount equal to up to $10.0 million annual aggregate limit with a $0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our products. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

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

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

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing or the need conduct additional trials, studies or other testing;
- the time and cost involved in obtaining any regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

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

For fiscal years 2002 through 2004, our average annual operating expenses (including average non-cash deferred compensation of $2.2 million) were $24.6 million. We are currently expecting operating expenses for the 2005 fiscal year to be between $28 million and $32 million, excluding any non-cash compensation expense that would result from the award of stock options upon the adoption of SFAS 123(R). As of December 31, 2004, we had $51.8 million in cash and cash equivalents. If our operating expenses in 2005 and 2006 are at the level of our currently expected operating expenses in 2005 and if we do not receive any additional milestone payments under any of our collaboration agreements, we will not have sufficient cash reserves to maintain our level of business activities throughout 2006. Further, our expenses might increase in 2005 and 2006 beyond currently expected levels if any regulatory agency requires us to conduct additional clinical trials**,** studies or investigations in connection with their consideration, or reconsideration**,** of our regulatory filings for MT 100, MT 300 and Trexima.

We may be unable to raise additional equity funds until the uncertainties of the regulatory future of MT 100 and MT 300 resulting from our receipt of not-approvable letters for both product candidates have been resolved. We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy.

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

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

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

Factors That May Affect Our Stockholders

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

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

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

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors. From October 16, 2000, when our common stock began trading on the NASDAQ National Market, through March 1, 2005, the high and low closing prices of our common stock ranged from $2.25 to $21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market could depress our stock price.

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and four of our stockholders beneficially hold approximately 33.60% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

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

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

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three-year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;

- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Further, in January 2005 our board of directors adopted a stockholder rights plan, similar to plans adopted by many other publicly-traded companies. The stockholder rights plan is intended to deter an attempt to acquire us in a manner or on terms not approved by our board of directors.

Item 7a. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from our initial public offering, private placements and collaboration agreements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Item 8. Financial Statements and Supplementary Data

Our financial statements and notes thereto are included elsewhere in this annual report on Form 10-K and incorporated herein by reference. See Item 15 of Part IV.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

(a) Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are 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 (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. 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) Our management's report on internal control over financial reporting is included with the financial statements reflected in Item 8 of the annual report on Form 10-K and is incorporated herein by reference.

(c) No change in our internal control over financial reporting occurred during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Information with respect to our executive officers is set forth under the caption "Executive Officers of the Company" contained in Part I, Item 1 of this report, which information is incorporated herein by reference.

Information about our Board of Directors is incorporated by reference from the section entitled "Nomination and Election of Directors" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

Information about the Section 16(a) compliance of our directors and executive officers is incorporated by reference from the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

Information about the audit committee of our board of directors, our audit committee financial expert and our code of business conduct and ethics is incorporated by reference from the section entitled "Board of Directors and Corporate Governance Matters" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

Item 11. Executive Compensation

Information required by this Item is incorporated by reference from the section entitled "Executive and Director Compensation" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this Item is incorporated by reference from the sections entitled "Principal Stockholders" and "Stock Ownership of Directors, Nominees for Director, and Executive Officers" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

The following table provides information with respect to compensation plans under which equity compensation is authorized at December 31, 2004.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders (1)	3,138,419	$ 7.55	2,476,795
Equity compensation plans not approved by security holders	–	–	–
Total	3,138,419	$ 7.55	2,476,795

(1) Includes 98,135 restricted stock units issued under our 2000 Equity Compensation Plan to our president and chief executive officer.

Item 13. Certain Relationships and Related Transactions

None.

Item 14. Principal Accounting Fees and Services.

This information required by this Item is incorporated by reference from the section entitled "Independent Public Accountant Fees and Services" contained in the definitive proxy statement related to our 2005 annual meeting of stockholders scheduled to be held on May 17, 2005, which we intend to file within 120 days of the end of our fiscal year.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a) Financial Statements and Schedules:

1. Financial Statements

The following financial statements and reports of independent auditors are included herein:

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Amended and Restated Bylaws of the Registrant.*
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.2	Stock Option Plan of the Registrant.*
10.3	First Amendment to Stock Option Plan dated February 14, 1997.*
10.4	License Agreement dated September 24, 1999 between the Registrant and F. Hoffman-La Roche Ltd. *
10.7	2000 Equity Compensation Plan of the Registrant, as amended and restated (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed July 30, 2004).***
10.8	Form of incentive stock option agreement under Registrant's 2000 Equity Compensation Plan, as amended and restated (filed as Exhibit 10.2 to the Registrant's Form 10-Q filed July 30, 2004).***
10.9	Form of nonqualified stock option agreement under Registrant's 2000 Equity Compensation Plan, as amended and restated (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed July 30, 2004).***
10.10	Supply Agreement dated January 17, 2001 by and between the Registrant and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed May 14, 2001). †
10.11	Amended and Restated Executive Employment Agreement with John R. Plachetka dated July 25, 2001 (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed October 31, 2001).***
10.12	Executive Employment Agreement with Kristina M. Adomonis dated July 25, 2001 (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed October 31, 2001).***
10.13	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Form 10-Q filed October 31, 2001).***

Exhibit No.	Description
10.14	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed October 27, 2004).***
10.15	Executive Employment Agreement with Marshall E. Reese dated November 8, 2004 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 12, 2004).***
10.16	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Company's Form 10-Q filed October 31, 2001).***
10.17	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Form 10-Q filed October 31, 2001).***
10.18	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.2 to the Registrant's Form 10-K filed April 1, 2002).†
10.19	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Form 10-K filed April 1, 2002).
10.20	First Amendment of 2000 Equity Compensation Plan (filed as Exhibit 10.19 to the Registrant's Form 10-K filed March 28, 2003).***
10.21	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed August 12, 2003).†
10.22	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Form 10-Q filed August 12, 2003).†
10.23	License Agreement dated June 30, 2003 between the Registrant and Nycomed Danmark ApS. (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed August 12, 2003).†
10.24	Collaboration and Licensing Agreement dated September 3, 2003 between POZEN and Xcel Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed November 6, 2003).†
10.25	Form of Non-Qualified Stock Option Agreement Under Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

* Incorporated by reference to the same-numbered exhibit of the Registrant's Registration Statement on Form S-1, No. 333-35930.
** Filed herewith.
*** Compensation Related Contract.
**** The Exhibit attached to this Form 10-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.
† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

(b) Exhibits
See Item 15(a)(3) above.

(c) Financial Statement Schedules.
See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Registrant:

POZEN Inc.

Date: March 9, 2005

By: /s/ John R. Plachetka
John R. Plachetka
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John R. Plachetka John R. Plachetka	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 9, 2005
/s/ William L. Hodges William L. Hodges	Senior Vice President, Finance and Administration (Chief Financial Officer)	March 9, 2005
/s/ John E. Barnhardt John E. Barnhardt	Vice President, Finance and Administration (Principal Financial and Accounting Officer)	March 9, 2005
/s/ James R. Butler James R. Butler	Director	March 9, 2005
/s/ Arthur S. Kirsch Arthur S. Kirsch	Director	March 9, 2005
/s/ Kenneth B. Lee, Jr. Kenneth B. Lee Jr.	Director	March 9, 2005
/s/ Paul J. Rizzo Paul J. Rizzo	Director	March 9, 2005
/s/ Bruce A. Tomason Bruce A. Tomason	Director	March 9, 2005
/s/ Peter J. Wise Peter J. Wise	Director	March 9, 2005
/s/ Ted G. Wood Ted G. Wood	Director	March 9, 2005

POZEN Inc.
(A Development Stage Company)

Audited Financial Statements

Contents

Management's Report on Internal Control Over Financial Reporting

Management of POZEN Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management evaluated the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (COSO). As a result of this assessment and based on the criteria in the COSO framework, management has concluded that, as of December 31, 2004, the Company's internal control over financial reporting was effective.

The Company's independent auditors, Ernst & Young, LLC, have audited management's assessment of the Company's internal control over financial reporting. Their opinion on management's assessment and their opinions on the effectiveness of the Company's internal control over financial reporting and on the Company's financial statements appear on page 34 in this annual report on Form 10-K.

/s/ John R. Plachetka	/s/ William L. Hodges
Chairman, Chief Executive Officer	Chief Financial Officer

March 7, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors
POZEN Inc.

We have audited the accompanying balance sheets of POZEN Inc. as of December 31, 2004 and 2003, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of POZEN Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of POZEN Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2005 expressed an unqualified opinion thereon.

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/s/ Ernst & Young LLP

Raleigh, North Carolina
March 7, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors
POZEN Inc.

We have audited management's assessment that POZEN Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). POZEN Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that POZEN Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, POZEN Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of POZEN Inc. as of December 31, 2004 and 2003, and the related consolidates statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 7, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 7, 2005

POZEN Inc.
(A Development Stage Company)

Balance Sheets

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,764,129	$ 60,480,690
Prepaid expenses and other current assets	1,064,032	698,209
Total current assets	52,828,161	61,178,899
Equipment, net of accumulated depreciation	467,688	334,096
Total assets	$ 53,295,849	$ 61,512,995
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,330,349	$ 579,903
Accrued compensation	1,182,848	416,053
Accrued expenses	1,626,829	1,103,622
Deferred revenue	8,680,092	7,562,000
Total current liabilities	13,820,118	9,661,578
Long-term liabilities:		
Deferred revenue	7,764,978	16,220,978
Total liabilities	21,585,096	25,882,556
Common stock, $0.001 par value, 90,000,000 shares authorized; 28,852,743 and 28,492,201 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	28,853	28,492
Additional paid-in capital	146,161,655	144,821,230
Deficit accumulated during the development stage	(114,479,755)	(109,219,283)
Total stockholders' equity	31,710,753	35,630,439
Total liabilities and stockholders' equity	$ 53,295,849	$ 61,512,995

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)

Statements of Operations

	Year ended December 31,			Period from September 26, 1996 (inception) through December 31, 2004
	2004	2003	2002	
Revenue	$ 23,087,908	$ 3,717,000	$ —	$ 26,804,908
Operating expenses:				
General and administrative	8,660,832	9,211,341	6,833,336	40,887,700
Research and development	20,398,748	9,904,347	18,761,630	107,239,977
Total operating expenses	29,059,580	19,115,688	25,594,966	148,127,677
Interest income	711,200	535,370	1,040,056	7,777,492
Net income (loss)	(5,260,472)	(14,863,318)	(24,554,910)	(113,545,277)
Non-cash preferred stock charge	—	—	—	27,617,105
Preferred stock dividends	—	—	—	934,478
Net income (loss) attributable to common stockholders	$ (5,260,472)	$ (14,863,318)	$ (24,554,910)	$ (142,096,860)
Basic and diluted net income (loss) per common share	$ (0.18)	$ (0.52)	$ (0.87)	
Shares used in computing basic and diluted net income (loss) per common share	28,748,540	28,329,339	28,110,352	

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)

Statements of Stockholders' Equity

	Preferred Stock	Common Stock	Additional Paid-In Capital	Common Stock Warrants	Receivable From Stockholders	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity
Issuance of common stock	$ —	$ 5,814	$ (1,504)	$ —	$ (4,310)	$ —	$ —	$ —
Issuance of preferred stock	2,106	—	6,231,314	—	(1,000,000)	—	—	5,233,420
Issuance of preferred stock warrants	—	—	—	242,000	—	—	—	242,000
Deferred compensation	—	—	190,385	—	—	(190,385)	—	—
Amortization of deferred compensation	—	—	—	—	—	28,267	—	28,267
Net Loss	—	—	—	—	—	—	(101,334)	(101,334)
Balance at December 31, 1996	2,106	5,814	6,420,195	242,000	(1,004,310)	(162,118)	(101,334)	5,402,353
Proceeds from stockholders' receivable	—	—	—	—	1,004,310	—	—	1,004,310
Issuance of preferred stock	1,135	—	4,195,865	—	—	—	—	4,197,000
Issuance of preferred stock warrants	—	—	—	139,000	—	—	—	139,000
Deferred compensation	—	—	1,001,629	—	—	(1,001,629)	—	—
Amortization of deferred compensation	—	—	—	—	—	214,272	—	214,272
Net Loss	—	—	—	—	—	—	(3,803,030)	(3,803,030)
Balance at December 31, 1997	3,241	5,814	11,617,689	381,000	—	(949,475)	(3,904,364)	7,153,905
Issuance of preferred stock	567	—	2,187,758	—	—	—	—	2,188,325
Issuance of preferred stock warrants	—	—	—	35,000	—	—	—	35,000
Exercise of common stock options	—	30	5,525	—	—	—	—	5,555
Deferred compensation	—	—	362,489	—	—	(362,489)	—	—
Amortization of deferred compensation	—	—	—	—	—	401,468	—	401,468
Net Loss	—	—	—	—	—	—	(8,737,631)	(8,737,631)
Balance at December 31, 1998	3,808	5,844	14,173,461	416,000	—	(910,496)	(12,641,995)	1,046,622
Issuance of preferred stock	2,594	—	11,522,406	—	—	—	—	11,525,000
Issuance of preferred stock warrants	—	—	—	925,000	—	—	—	925,000
Exercise of common stock options	—	4	621	—	—	—	—	625
Deferred compensation	—	—	3,045,666	—	—	(3,045,666)	—	—
Amortization of deferred compensation	—	—	—	—	—	612,909	—	612,909
Net Loss	—	—	—	—	—	—	(12,145,446)	(12,145,446)
Balance at December 31, 1999	6,402	5,848	28,742,154	1,341,000	—	(3,343,253)	(24,787,441)	1,964,710
Proceed from sale of common stock	—	750	10,461,750	—	—	—	—	10,462,500
Proceeds from sale of common stock in IPO, net of offering costs	—	5,000	67,798,052	—	—	—	—	67,803,052
Conversion of preferred stock to common stock	(6,402)	15,488	27,347,019	—	—	—	—	27,356,105
Exercise of common stock options	—	208	74,861	—	—	—	—	75,069
Exercise of common stock warrants	—	369	1,805,682	(914,952)	—	—	—	891,099
Preferred stock dividend	—	—	—	—	—	—	(934,478)	(934,478)
Dividends		69	772,114	—	—	—	—	772,183
Deferred compensation	—	—	6,328,492	—	—	(6,328,492)	—	—
Amortization of deferred compensation	—	—	—	—	—	3,054,286	—	3,054,286
Net Loss	—	—	—	—	—	—	(22,376,628)	(22,376,628)
Balance at December 31, 2000	—	27,732	143,330,124	426,048	—	(6,617,459)	(48,098,547)	89,067,898
Exercise of common stock options	—	187	109,408	—	—	—	—	109,595
Exercise of common stock warrants	—	50	115,240	(115,240)	—	—	—	50
Forfeiture of common stock options	—	—	(42,213)	—	—	42,213	—	—
Amortization of deferred compensation	—	—	—	—	—	3,145,870	—	3,145,870
Net Loss	—	—	—	—	—	—	(21,702,508)	(21,702,508)
Balance at December 31, 2001	—	27,969	143,512,559	310,808	—	(3,429,376)	(69,801,055)	70,620,905
Exercise of common stock options	—	159	224,291	—	—	—	—	224,450
Exercise and forfeiture of common stock warrants	—	19	310,808	(310,808)	—	—	—	19
Forfeiture of common stock options	—	—	(11,167)	—	—	11,167	—	—
Amortization of deferred compensation	—	—	—	—	—	2,908,079	—	2,908,079
Net Loss	—	—	—	—	—	—	(24,554,910)	(24,554,910)
Balance at December 31, 2002	—	28,147	144,036,491	—	—	(510,130)	(94,355,965)	49,198,543
Exercise of common stock options	—	345	784,739	—	—	—	—	785,084
Amortization of deferred compensation	—	—	—	—	—	510,130	—	510,130
Net Loss	—	—	—	—	—	—	(14,863,318)	(14,863,318)
Balance at December 31, 2003	$ —	$ 28,492	$144,821,230	$ —	$ —	$ —	$ (109,219,283)	$ 35,630,439
Exercise of common stock options		$ 361	$ 1,340,425					$ 1,340,786
Net Loss	—	—	—	—	—	—	$ (5,260,472)	$ (5,260,472)
Balance at December 31, 2004	$ —	$ 28,853	$146,161,655	$ —	$ —	$ —	$(114,479,755)	$ 31,710,753

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31,			Period from September 26, 1996 (inception) through December 31, 2004
	2004	2003	2002	
Operating activities				
Net income (loss)	$ (5,260,472)	$ (14,863,318)	$ (24,554,910)	$ (113,545,277)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation	163,129	129,560	113,513	688,458
Loss on disposal of equipment	6,072	—	2,726	33,567
Noncash compensation expense	400,388	510,130	2,908,079	11,275,669
Noncash financing charge	—	—	—	450,000
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(365,823)	(144,838)	(477,185)	(1,064,032)
Accounts payable and accrued expenses	2,640,060	263,130	(1,686,571)	4,739,638
Deferred revenue	(7,337,908)	23,782,978	—	16,445,070
Net cash provided by (used in) operating activities	(9,754,554)	9,677,642	(23,694,348)	(80,976,907)
Investment activities				
Purchase of equipment	(302,793)	(38,287)	(432,594)	(1,189,713)
Net cash used in investing activities	(302,793)	(38,287)	(432,594)	(1,189,713)
Financing activities				
Proceeds from issuance of preferred stock	—	—	—	48,651,850
Proceeds from issuance of common stock	1,340,786	785,084	224,469	81,436,884
Proceeds from collections of stockholders' receivables	—	—	—	1,004,310
Proceeds from notes payable	—	—	—	3,000,000
Payment of dividend	—	—	—	(162,295)
Net cash provided by financing activities	1,340,786	785,084	224,469	133,930,749
Net increase (decrease) in cash and cash equivalents	(8,716,561)	10,424,439	(23,902,473)	51,764,129
Cash and cash equivalents at beginning of period	60,480,690	50,056,251	73,958,724	—
Cash and cash equivalents at end of period	$ 51,764,129	$ 60,480,690	$ 50,056,251	$ 51,764,129
Supplemental schedule of cash flow information				
Cash paid for interest	$ —	$ 538	$ 2,106	$ 191,328
Supplemental schedule of noncash investing and financing activities				
Conversion of notes payable to preferred stock	$ —	$ —	$ —	$ 3,000,000
Preferred stock dividend	$ —	$ —	$ —	$ 772,183
Forfeiture of common stock options and warrants	$ —	$ —	$ 272,166	$ 314,179
Conversion of common stock warrants to common stock	$ —	$ —	$ 49,809	$ 1,080,001

See accompanying Notes to Financial Statements.

1. Significant Accounting Policies

Development Stage Company

POZEN Inc. ("POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996. The Company is a pharmaceutical company focused primarily on products for the treatment of migraine, acute and chronic pain and other pain-related indications. POZEN's product development emphasis is on diseases with unmet medical needs where it can improve efficacy, safety and/or patient convenience. Since the Company's inception, it has focused its efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. The Company's portfolio currently contains three product candidates in the migraine area, MT 400, MT 100 and MT 300. The Company is also exploring the development of product candidates in other pain-related therapeutic areas. POZEN has not obtained regulatory approval for any of its product candidates. Statement of Financial Accounting Standards Board No. ("SFAS") 7, "Accounting and Reporting by Development Stage Enterprises," states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. The Company will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of the Company's product candidates.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from the estimates and assumptions used.

Revenue Recognition

The Company's licensing agreements have terms that include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and royalty payments based on future product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition", as amended by SAB 104, "Revenue Recognition" (" SAB 101"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables." Non-refundable upfront payments received under the Company's existing agreements are deferred by the Company upon receipt and recognized on a straightline basis over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates.

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

Royalty revenue will be recognized when earned with respect to the manufacture, sale or use of the Company's products or technology. For those arrangements where royalties are reasonably estimable, the Company will recognize revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. For those arrangements where royalties are not reasonably estimable, the Company will recognize revenue upon receipt of a statement from the licensee that a royalty is payable.

Additionally, the Company's licensing agreements may include payment for services provided by the Company on an hourly rate and direct expenses. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash is invested in interest-bearing investment-grade securities. Cash is restricted by a $124,000 letter of credit, maintained in compliance with the terms of the Company's lease.

Cash and cash equivalents include financial instruments that potentially subject the Company to a concentration of credit risk. Cash and cash equivalents are deposited with high credit quality financial institutions which invest primarily in U.S. Government securities, highly rated commercial paper and certificates of deposit guaranteed by banks which are members of the FDIC. The counterparties to the agreements relating to the Company's investments consist primarily of the U.S. Government and various major corporations with high credit standings.

Equipment

Equipment consists primarily of computer hardware and software and furniture and fixtures and is recorded at cost. Depreciation is computed using the Modified Accelerated Cost Recovery System (MACRS) over the estimated useful lives of the assets ranging from five to seven years. Accumulated depreciation for the period ended December 31, 2003 and 2004 totaled $0.3 million and $0.4 million, respectively.

Research and Development Costs, including clinical trial expenses

Research and development costs are charged to operations as incurred. The Company has included research and development expenses the personnel costs associated with research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

Income Taxes

The Company accounts for income taxes using the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities.

Net Loss Per Share

Basic and diluted net loss per common share amounts are presented in conformity with Statement of Financial Accounting Standards No. ("SFAS") 128, "Earnings per Share." In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the years ended December 31, 2004, 2003 and 2002.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents and accounts payable. The carrying values of cash and cash equivalents and accounts payable approximate the fair value due to the short-term nature of such instruments.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's statements of operations.

Comprehensive Loss

The Company has adopted the provisions of SFAS 130, "Comprehensive Income." SFAS 130 establishes standards for the reporting and display of comprehensive income and its components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

Stock-Based Compensation

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

In connection with the grant of stock awards to employees, consisting of stock options to employees and a restricted stock unit award made in May 2004 to the Company's Chief Executive Officer, the Company recorded $400,000 of restricted stock compensation expense for the twelve-month period ended December 31, 2004 and amortized deferred compensation of $-0-, $510,000 and $2,908,000 in the twelve-month periods ended December 31, 2004, 2003, and 2002, respectively. The deferred compensation recognized in these periods related to the grant of stock options and was recorded as a component of stockholders' equity. This deferred compensation was amortized as charges to operations over the vesting periods of the options using the straight-line method. The vesting periods of the options are generally three or four years. The restricted stock award vests in equal amounts on January 1, 2005, January 1, 2006 and January 1, 2007.

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.

	Years Ended December 31,		
	2004	2003	2002
Net loss attributed to common stockholders as reported	$ (5,260,472)	$ (14,863,318)	$ (24,554,910)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects	400,388	510,130	2,908,079
Deduct: Total stock-based employee compensation expense determined under the fair value-based method for all awards, net of related tax effects	(4,306,553)	(3,338,823)	(5,716,748)
Pro forma net loss attributed to common stockholders	$ (9,166,637)	$ (17,692,011)	$ (27,363,579)
Earnings per share			
Basic net income (loss) per common share as reported	$ (0.18)	$ (0.52)	$ (0.87)
Basic net income (loss) per common share pro forma	$ (0.32)	$ (0.62)	$ (0.97)
Weighted average shares used in computing basic and diluted net loss per common share	28,748,540	28,329,339	28,110,352

Contingencies

Five purported class action lawsuits were filed during 2004 by holders of the Company's securities against the Company and certain of its current and former officers, in the United States District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions were filed as a single consolidated class action complaint on December 20, 2004. The consolidated complaint alleges, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 and Section 20(a) of the Exchange Act against the Company and a current officer, arising out of allegedly false and misleading statements made by the Company concerning its product candidates, MT 100 and MT 300, during the class period. On January 27, 2005, the Company filed a motion to dismiss the consolidated class action complaint.

On September 13, 2004, two derivative actions were also filed against certain of the Company's current and former directors and officers in the Superior Court for the County of Orange in the State of North Carolina, alleging violations of state law, including breaches of fiduciary duties and insider sales, relating to the same allegedly misleading statements concerning the Company's product candidates, MT 100 and MT 300 that are referenced in the various purported class action lawsuits.

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

Recently Issued Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51", and revised the interpretation in December 2003 ("FIN 46(R)"). FIN 46(R) requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46(R) is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46(R) must be applied for the first interim or annual period ended after March 15, 2004. The Company did not have any ownership in any variable interest entities as of December 31, 2004. The Company will apply the provisions of FIN 46R in future periods if it owns an interest in any variable interest entity.

As permitted by FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("FASB 123"), the Company currently accounts for share-based payments to employees using APB 25's intrinsic value method. Accordingly, the adoption of the revised FASB 123's ("FASB 123(R)") fair value method will have a significant impact on the Company's result of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of FASB 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted FASB 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss and loss per share in Note 1 above. FASB 123(R)

also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While the Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the decrease in operating cash flows which would have been recognized for such excess tax deductions was $947,600 and $710,600 in 2004 and 2003, respectively

2. License Agreements

The Company has entered into various license agreements to further develop, sell and manufacture its product candidates.

In June 2003, the Company signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries. Under the terms of the agreement, Nycomed will have exclusive rights in Denmark, Sweden, Norway and Finland to commercialize MT 100 upon its approval in these countries. Upon execution of the agreement, Nycomed paid the Company an upfront fee of $500,000. The Company is eligible to receive milestone payments in an aggregate amount of between $500,000 and $1.0 million upon the occurrence and timing of certain regulatory approvals, including the approval of the MAA in the UK and in the other countries where Nycomed has rights. In addition, Nycomed is obligated to pay the Company a specified royalty on all sales of MT 100, based upon the higher of an agreed percentage of sales on a country-by-country basis, subject to reduction in the event of generic competition, or an agreed dollar amount per unit sold subject to reduction under certain conditions, until the latter of the expiration of the last to expire issued applicable patent in the particular country or 15 years. The scheduled expiration date of the patent that is currently applicable in Sweden, Finland and Denmark is November 12, 2016. There is no applicable patent in Norway. The license agreement will expire on a country-by-country basis upon the later of (a) the date of expiration of all royalty obligations in a particular country, which is scheduled for November 12, 2016 in Sweden, Finland and Denmark, and (b) 15 years after the date of first commercial sale of MT 100 in such country under the agreement. Nycomed has the right to terminate the agreement if the Company defaults 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 the Company withdraws the required regulatory application in that country. If the Company withdraws a regulatory application in any of the countries identified in the agreement, it will be required to pay a withdrawal fee in amounts that range from $112,500 to $400,000.In September 2003, the Company received a letter of comments on the MAA from the MHRA Advisory Committee. In March 2004, the Company submitted its complete response to the concerns identified by the MHRA Advisory Committee and met with the MHRA Advisory Committee in January 2005 to answer questions concerning the Company's response. In January 2005 the Company was notified that the MHRA Advisory Committee was prepared to advise the MHRA that a marketing authorization could be granted for MT 100 in the UK, provided the Company supplied certain additional information and meet certain conditions, as outlined by the MHRA Advisory Committee. The Company has provided the information which it believes addresses all the conditions set forth by the MHRA Advisory Committee. Assuming the issues raised in the September 2003 MAA comment letter are satisfactorily resolved and the Company receives unconditional approval of the MAA from the MHRA, the Company intends 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 the Company for any claim brought by a third party arising from Nycomed's development, manufacture or sale of any products, and the Company 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 the Company entered into the license agreement with Nycomed, it entered into a supply agreement with Nycomed under which Nycomed is obligated to purchase from the Company, and the Company is obligated to sell to Nycomed, the MT 100 that Nycomed sells in the countries specified in the agreement, and Nycomed is required to reimburse the Company for certain costs related to the manufacturing of MT 100. The agreement will expire upon an anniversary date of the first commercial sale of MT 100 following final approval by the FDA of the NDA for MT 100. Either party may terminate the agreement in the event of a material breach or default by the other party of the material terms and conditions of the agreement. Among the material breaches that would entitle Nycomed to terminate the agreement would be the Company's failure to deliver products to Nycomed at a time when Nycomed has established an alternative source of the product.

In June 2003, the Company signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the United States to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. The Company is responsible for development of the combination

product, while GSK is to provide formulation development and manufacturing. Pursuant to the terms of the agreement, the Company 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, the Company received a $15.0 million milestone payment as a result of its commencement of Phase 3 clinical trial activities. Additionally, GSK is obligated to make payments to the Company 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 the Company 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 the Company 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 the Company for any reason or no reason. Among the contract breaches that would entitle POZEN to terminate the agreement is GSK's determination not to further develop the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, the Company has the right, at its own expense, to bring the appropriate action. With regard to certain other patent infringements, the Company has 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. The Company also has 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, the Company 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 the Company an upfront fee of $2.0 million. Under certain circumstances, if the Company withdraws the NDA for MT 300, it 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 the Company royalties on all combined sales of MT 300 and Xcel's D.H.E. 45® (dihydroergotamine mesylate) Injection, once MT 300 is commercialized, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances for the effects 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 the Company for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while the Company must indemnify Xcel for any damages arising from such development, manufacture or use prior to the effective date. The Company must also indemnify Xcel for any use by the Company or any sublicensee of certain technology owned by Xcel. Based upon the delayed commercialization of MT 300 due to the not-approvable letter for MT 300 and the Company's efforts to address with the FDA the issues raised in that letter, POZEN and Xcel have mutually agreed, in writing, to extend the time for certain activities under our agreement with Xcel that are dependent on the FDA's actions with respect to MT 300.

Management believes current assumptions and other considerations used to estimate the period for revenue recognition are appropriate. However, if regulatory approvals relating to MT 100, MT 300 or MT 400 are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products will be accelerated or reduced accordingly.

3. Stockholders' Equity

Prior to 2000, the Company completed five private placement offerings of preferred stock as shown in the table set forth below. In connection with four of these offerings, warrants were issued to certain key advisors for their services related to the offerings. The warrants have been exercised or have expired.

Year of Issuance	Series	Number of Shares Issued	$ Received (net of offering costs)	Number of Shares Underlying Warrants	Offering Costs Resulting From Warrants	Price at Issuance
1996	A Convertible Preferred	2,105,931	$ 6,475,420	78,776	$ 242,000	$ 3.15
1997	B Convertible Preferred	1,135,000	$ 4,336,000	36,450	$ 139,000	$ 4.00
1998	B Convertible Preferred	4,377	$ 17,512	—	$ —	$ 4.00
1998	C Convertible Preferred	563,044	$ 2,205,813	8,884	$ 35,000	$ 4.05
1999	D Convertible Preferred	2,593,750	$ 12,000,000	200,000	$ 925,000	$ 4.80

All outstanding shares of Series A, Series B, Series C and Series D and the related warrants were converted into 8,636,436 shares of the Company's common stock and warrants for 437,228 shares of the Company's common stock upon the closing of the Company's initial public offering in October 2000.

Shares Reserved for Future Issuance

At December 31, 2004, shares of common stock reserved for future issuance are as follows:

Shares available for grant under stock option plans	2,476,795
Shares issuable pursuant to options granted under stock option plans	3,138,419
Total reserved	5,615,214

4. Redeemable Preferred Stock

On March 24, 2000, the Company completed a private placement of 2,589,927 shares of Series E Convertible Preferred Stock ("Series E") and received cash of $16,875,115, net of offering costs. The Series E holders were entitled to receive cumulative dividends at an annual rate of 8% of the original purchase price payable in cash or shares of Series E at the option of the holder. Dividends were payable when declared by the Board of Directors and upon conversion, liquidation or redemption. The Series E was convertible at a price that decreased from $6.95 to $5.73 since the Company was unable to complete by September 15, 2000 a qualified public offering or to effect a merger or acquisition of the Company that would entitle the holders of the Series E to receive $10.43 or more per share. At the date of issuance, the Company believed the per share price of $6.95 represented the fair value of the preferred stock and was in excess of the deemed fair value of its common stock. Subsequent to the commencement of the Company's initial public offering process, the Company re-evaluated the deemed fair market value of its common stock as of March 2000 and determined it to be $22.48 per share (on a pre-split basis). Accordingly, the incremental fair value of the Series E was deemed to be the equivalent of a preferred stock dividend. The Company recorded the non-cash preferred stock charge at the date of issuance by offsetting charges and credits to additional paid-in capital of $16,875,115, without any effect on total stockholders' equity. The non-cash charge was limited to the net proceeds received from the Series E offering.

In conjunction with the issuance of the Series E, the Company issued warrants to purchase 24,485 shares of Series E at an initial exercise price of $6.95 per share to certain key advisors for their services related to the offering. The value of the warrants was recorded as offering costs related to the issuance of Series E at a value calculated using the "Black Scholes" formula at approximately $261,000. During 2002, the warrants expired unexercised and the reduction of value of the warrants was recorded as additional paid-in capital.

On August 28, 2000, the Company completed a private placement of 1,597,285 shares of Series F Convertible Preferred Stock ("Series E") and received cash of $10,742,000, net of offering costs. The terms of the Series F are substantially similar to those of the Series E. The Company recorded a non-cash preferred stock charge at the date of issuance by offsetting charges and credits to additional paid-in capital of $10,742,000, without any effect on total stockholders' equity.

All outstanding shares of Series E and related Series E warrants and Series F were converted into 6,851,207 shares of the Company's common stock and warrants exercisable for 33,030 shares of the Company's common stock upon the closing of the Company's initial public offering in October 2000. The Series E warrants, value at $260,999, were forfeited in October 2002.

5. Accrued Expenses

Accrued expenses consist of the following at December 31:

	2004	2003
Research and development costs	$ 1,384,598	$ 836,355
Other	242,231	267,267
	$ 1,626,829	$ 1,103,622

6. Income Taxes

At December 31, 2004 and 2003, the Company had federal and state net operating loss carryforwards of approximately $80.1 million and $69.1 million, respectively, and research and development credit carryforwards of approximately $7.2 million and $5.5 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2011 and the research and development credit carryforwards begin to expire in 2012. For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards. When, and if recognized, the tax benefit for those items will be reflected in current operations of the period in which the benefit is recorded as a reduction of income tax expense. The utilization of the loss carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the net operating loss carryforwards. In addition, the maximum annual use of net operating loss carryforwards is limited in certain situations where changes occur in stock ownership.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows at December 31:

	2004	2003
Deferred tax assets:	($ in thousands)	
Net operating loss carryforwards	$ 31,312	$ 27,532
Research and development credits	7,178	5,483
Revenue recognition	6,414	9,071
Options activity/depreciation/other - net	195	23
Total deferred tax assets	45,099	42,109
Valuation allowance	(45,099)	(42,109)
Net deferred tax asset	$ —	$ —

The amount of the valuation allowance increased by $3.0 million and $6.4 million as of December 31, 2004 and 2003, respectively. The actual income tax expense for the years ended December 31, 2004, 2003 and 2002, differed from the amounts computed by applying the U.S. federal tax rate of 35% to pretax earnings as a result of the following:

	2004	2003	2002
		($ in thousands)	
Loss before income tax	$ (5,260)	$ (14,863)	$ (24,555)
Federal tax rate	35%	35%	35%
Federal income tax provision at statutory rate	(1,841)	(5,202)	(8,594)
State tax provision	(210)	(590)	(982)
Increase (decrease) in income tax expense resulting from:			
Research and development credits	(1,326)	(646)	(500)
Non-deductible expenses and other	844	55	1,111
Change in reserve	2,533	6,383	8,965
Tax expense	$ —	$ —	$ —

7. Stock Option Plan

On November 20, 1996, the Company established a Stock Option Plan and authorized the issuance of options for up to 1,605,310 shares of common stock to attract and retain quality employees and to allow such employees to participate in the growth of the Company. Awards may be made to participants in the form of incentive and nonqualified stock options. Eligible participants under the Stock Option Plan include executive and key employees of the Company. The vesting periods range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. The exercise price for incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (110% with respect to incentive stock options granted to optionees who are holders of 10% or more of the Company's common stock).

In May 2000, the Board of Directors adopted, and in June 2000 the stockholders approved, the POZEN Inc. 2000 Equity Compensation Plan (the "Plan"). The Plan became effective upon the completion of the Company's initial public offering in October 2000 after which time no further grants were made under the Stock Option Plan. The Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units, and other stock-based awards to employees, non-employee directors, advisors, and consultants. The Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The vesting periods range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. If options granted under the Plan expire or are terminated for any reason without being exercised, or if stock awards, performance units, or other stock-based awards are forfeited or otherwise terminate, the shares of common stock underlying the grants will again be available for purposes of the Plan.

In May 2004 an award of 98,135 restricted stock units was made to the Company's Chief Executive Officer under the Plan. Those restricted stock units are reflected as a stock option grant in the discussion below.

In 2004, the Board of Directors adopted and the stockholders approved an amendment to and restatement of the Plan. The amendment to the Plan provided for an increase in the number of shares of common stock authorized for issuance under the Plan from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. In addition, the amendment to the Plan limited the number of shares that may be issued pursuant to grants other than options under the Plan to 2,000,000 shares and made certain other clarifying changes.

A summary of the Company's stock option activity, and related information is as follows:

	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 1996	88,562	$ 0.19
Options granted	470,127	0.19
Forfeited	(10,118)	0.19
Balance at December 31, 1997	548,571	0.19
Options granted	194,593	0.33
Exercised	(29,977)	0.19
Forfeited	(104,923)	0.19
Balance at December 31, 1998	608,264	0.23
Options granted	612,221	1.12
Exercised	(3,373)	0.19
Forfeited	(105,222)	0.88
Balance at December 31, 1999	1,111,890	0.66
Options granted	486,762	2.87
Exercised	(208,334)	0.36
Forfeited	(6,745)	1.48
Balance at December 31, 2000	1,383,573	1.49
Options granted	808,591	9.45
Exercised	(187,837)	0.58
Forfeited	(8,545)	2.48
Balance at December 31, 2001	1,995,782	4.79
Options granted	697,453	5.08
Exercised	(158,987)	1.41
Forfeited	(105,452)	7.18
Balance at December 31, 2002	2,428,796	4.99
Options granted	954,792	7.01
Exercised	(345,162)	2.27
Forfeited	(395,124)	4.71
Balance at December 31, 2003	2,643,302	6.11
Options granted	1,073,010	9.57
Exercised	(360,542)	3.72
Forfeited	(217,351)	6.49
Balance at December 31, 2004	3,138,419	$ 7.55

The options outstanding and exercisable at December 31, 2004 are as follows:

Options Outstanding		Weighted-Average		
Exercise Price	Number Outstanding	Exercise Price	Remaining Contractual Life (In years)	Vested Options
$ 0.19-$ 3.74	294,882	$ 0.99	3.6	294,882
$ 4.25-$ 7.38	1,333,754	$ 5.41	7.4	631,194
$ 7.62-$11.84	1,206,009	$ 10.02	8.9	125,000
$12.00-$17.45	303,774	$ 13.47	7.1	171,568
	3,138,419	$ 7.55	7.6	1,222,664

As allowed by the provisions of SFAS 123, the Company has elected to follow APB 25 and related interpretations in accounting for its employee stock options. Pro forma net loss information set forth in Note 1 is required to be disclosed by SFAS 123 and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value for these options was estimated at the date of grant using the minimum value method with the following weighted-average assumptions:

	2004	2003	2002	2001
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate range	3.73%-4.32%	2.72%-4.20%	1.73%-4.26%	3.5%-5.0%
Expected life	7.4 years	10 years	10 years	10 years
Expected volatility	0.98-1.02	1.03-1.08	1.08	1.38

8. Leases

The Company leases its office space and certain equipment under cancelable and noncancelable operating lease agreements. Rent expense incurred by the Company was approximately $354,000, 356,000, $230,000, and $1,457,000 for the years ended December 31, 2004, 2003, and 2002 and for the period September 25, 1996 (inception) through December 31, 2004, respectively. The following is a schedule of future minimum lease payments for operating leases at December 31, 2004:

	($ in thousands)
2005	$ 378
2006	385
2007	394
Thereafter	881
	$ 2,038

9. Retirement Savings Plan

In July 1997, the Company adopted a defined contribution 401(k) plan (the "Plan") covering substantially all employees who are at least 21 years of age. Based upon management's discretion, the Company may elect to make contributions to the Plan. For the year ended December 31, 2000, the Company did not make any contribution to the Plan. During the years ended December 31, 2004, 2003, and 2002, and for the period September 25, 1996 (inception) through December 31, 2004, the Company made contributions of $185,132, $123,701, $118,718, and $519,828, respectively, to the Plan.

10. Subsequent Events

On January 3, 2005, pursuant to an incentive program approved by the Compensation Committee of the Company's Board of Directors, stock options were granted to all of the Company's employees, including the Company's executive officers, to purchase an aggregate of 506,772 shares of common stock. Each option will vest in full upon the later to occur of (i) January 3, 2007 or (ii) the receipt by the Company of an action letter from the FDA indicating approval of the NDA for Trexima; provided, however that 25% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur prior to June 30, 2007, and 100% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur on or before December 31, 2007. The options, which were granted under the Company's Equity Compensation Plan, as amended and restated, have a ten-year term and an exercise price equal to the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant.

Effective as of January 12, 2005, the Company's Board of Directors approved a stockholder rights plan (the "Rights Plan"), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Board declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of

the Company's Common Stock, $0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Each Right, when exercisable, will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00, subject to adjustment. The Rights Plan is similar to plans adopted by many other publicly-traded companies.

11. Summary of Operations by Quarters (Unaudited)

	2004			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue	$ 1,889,500	$ 16,889,500	$ 1,891,499	$ 2,417,409
Operating expenses	4,370,016	5,679,553	7,925,188	11,084,823
Net income loss	(2,354,366)	11,344,770	(5,831,320)	(8,419,556)
Net loss per share of common stock				
Basic and diluted	$ (0.08)	$ 0.39	$ (0.20)	$ (0.29)
Number of shares used in per share calculation				
Basic and diluted	28,555,654	28,786,486	28,799,277	28,852,743

	2003			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue	$ —	$ —	$ 1,886,998	$ 1,830,002
Operating expenses	4,976,015	4,803,996	5,747,273	3,588,404
Net loss	(4,832,746)	(4,680,704)	(3,731,966)	(1,617,902)
Net loss per share of common stock				
Basic and diluted	$ (0.17)	$ (0.17)	$ (0.13)	$ (0.06)
Number of shares used in per share calculation				
Basic and diluted	28,150,319	28,270,902	28,407,093	28,489,043

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Amended and Restated Bylaws of the Registrant.*
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.2	Stock Option Plan of the Registrant.*
10.3	First Amendment to Stock Option Plan dated February 14, 1997.*
10.4	License Agreement dated September 24, 1999 between the Registrant and F. Hoffman-La Roche Ltd. *
10.7	2000 Equity Compensation Plan of the Registrant, as amended and restated (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed July 30, 2004).***
10.8	Form of incentive stock option agreement under Registrant's 2000 Equity Compensation Plan, as amended and restated (filed as Exhibit 10.2 to the Registrant's Form 10-Q filed July 30, 2004).***
10.9	Form of nonqualified stock option agreement under Registrant's 2000 Equity Compensation Plan, as amended and restated (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed July 30, 2004).***
10.10	Supply Agreement dated January 17, 2001 by and between the Registrant and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed May 14, 2001). †
10.11	Amended and Restated Executive Employment Agreement with John R. Plachetka dated July 25, 2001 (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed October 31, 2001).***
10.12	Executive Employment Agreement with Kristina M. Adomonis dated July 25, 2001 (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed October 31, 2001).***
10.13	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Form 10-Q filed October 31, 2001).***
10.14	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed October 27, 2004).***
10.15	Executive Employment Agreement with Marshall E. Reese dated November 8, 2004 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 12, 2004).***
10.16	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Company's Form 10-Q filed October 31, 2001).***
10.17	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Form 10-Q filed October 31, 2001).***
10.18	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.2 to the Registrant's Form 10-K filed April 1, 2002).†
10.19	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Form 10-K filed April 1, 2002).
10.20	First Amendment of 2000 Equity Compensation Plan (filed as Exhibit 10.19 to the Registrant's Form 10-K filed March 28, 2003).***

Exhibit No.	Description
10.21	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed August 12, 2003).†
10.22	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Form 10-Q filed August 12, 2003).†
10.23	License Agreement dated June 30, 2003 between the Registrant and Nycomed Danmark ApS. (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed August 12, 2003).†
10.24	Collaboration and Licensing Agreement dated September 3, 2003 between POZEN and Xcel Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Registrant's Form 10-Q filed November 6, 2003).†
10.25	Form of Non-Qualified Stock Option Agreement Under Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

* Incorporated by reference to the same-numbered exhibit of the Registrant's Registration Statement on Form S-1, No. 333-35930.
** Filed herewith.
*** Compensation Related Contract.
**** The Exhibit attached to this Form 10-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.
† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

EXHIBIT 21.1

POZEN UK Limited

Jurisdiction of incorporation:	United Kingdom
Name under which business conducted:	POZEN UK Limited

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 No. 333-52446 and 333-117962) pertaining to the POZEN Inc. 2000 Equity Compensation Plan, and as amended and restated, the Registration Statement (Form S-3 No. 333-112461) of POZEN Inc. of our reports dated March 7, 2005, with respect to the financial statements of POZEN Inc., POZEN Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of POZEN Inc., included in the 2004 Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 8, 2005

EXHIBIT 31.1

Section 302 Certification

I, John R. Plachetka**,** certify that:

1. I have reviewed this Annual Report on Form 10-K of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2005

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
President and Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

Section 302 Certification

I, William L. Hodges, certify that:

1. I have reviewed this Annual Report on Form 10-K of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2005

/s/ William L. Hodges
William L. Hodges
Senior Vice President, Finance and Administration and
Chief Financial Officer

EXHIBIT 32.1

CEO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Annual Report on Form 10-K of POZEN Inc. (the "Company"), as filed with the Securities and Exchange Commission (the "Report"), I, John R. Plachetka, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2005

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CFO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

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

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2005

/s/ William L. Hodges
William L. Hodges
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

BOARD OF DIRECTORS

John R. Plachetka, Pharm.D.
Chairman, President and Chief Executive Officer
POZEN Inc.

Kenneth B. Lee, Jr.
General Partner
Hatteras BioCapital Fund, L.P.
LEAD INDEPENDENT DIRECTOR
AUDIT COMMITTEE
COMPENSATION COMMITTEE

Peter J. Wise, M.D.
Vice Chairman
POZEN Inc.
COMPENSATION COMMITTEE

Paul J. Rizzo
Chairman of the Board and Partner
Franklin Street Partners
NOMINATING/GOVERNANCE COMMITTEE, CHAIRMAN

James R. Butler
Former President
ALZA International
COMPENSATION COMMITTEE
NOMINATING/GOVERNANCE COMMITTEE

Bruce A. Tomason
Chief Executive Officer
Alterna, LLC
AUDIT COMMITTEE, CHAIRMAN
NOMINATING/GOVERNANCE COMMITTEE

Arthur S. Kirsch
Managing Director
Vector Securities, LLC
AUDIT COMMITTEE

Ted G. Wood
Non-Executive Chairman
King Pharmaceuticals, Inc.
COMPENSATION COMMITTEE, CHAIRMAN

CORPORATE HEADQUARTERS

POZEN Inc.
1414 Raleigh Road
Suite 400
Chapel Hill, NC 27517
(919) 913-1030
www.pozen.com

STOCK TRANSFER AGENT AND REGISTRAR

StockTrans, Inc.
44 West Lancaster Avenue
Ardmore, PA 19003

INDEPENDENT ACCOUNTANTS

Ernst & Young LLP
3200 Beechleaf Court
Suite 700
Raleigh, NC 27604

COMMON STOCK LISTING

Ticker Symbol: POZN
Nasdaq Stock Market

ANNUAL MEETING

Tuesday, May 17, 2005

STOCKHOLDER INQUIRIES

Stockholders and prospective investors seeking information about POZEN should visit the Company's website at www.pozen.com or contact POZEN's Investor Relations Department at (919) 913-1030.

FORWARD-LOOKING STATEMENTS

Statements included in this annual report that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval of our product candidates, including as a result of the need to conduct additional studies, or the failure to obtain such approval of our product candidates, including as a result of changes in regulatory standards or the regulatory environment during the development period of any of our product candidates; uncertainties in clinical trial results or the timing of such trials, resulting in, among other things, an extension in the period over which we recognize deferred revenue or our failure to achieve milestones that would have provided us with revenue; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events, including those discussed herein and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 under "Management's Discussion and Analysis of Financial Condition and Results of Operations." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

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