

POZEN<sup>®</sup>  
INC.

The Pharmaceutical Development Company

By the Numbers

2002 Annual Report

28 million

8 of 10

Over the course of **6** years,  
POZEN's **27** employees  
have developed **3** product candidates with over  
**\$1 billion** in market potential.

**T**his year, our annual report is all about the numbers. From the staggering number of migraine cases reported each year to the thousands of migraine sufferers who have participated in POZEN's clinical trials, the facts are undeniable. There is a huge untapped market out there, and POZEN is committed to making its product candidates available to migraine patients. To put it simply, we'll let the numbers tell the story.

## TO OUR STOCKHOLDERS

**2002** was an outstanding year for POZEN, marked by the achievement of two major “firsts” in the history of our company.

We submitted our *first marketing application* in October 2002 in the U.K. for MT 100, an oral tablet designed for first-line migraine therapy. And we submitted our *first New Drug Application (NDA)* in December 2002 to the U.S. Food and Drug Administration (FDA) for marketing approval of MT 300, our injectable product candidate for the treatment of severe migraine.

These accomplishments were made possible by our ability to consistently meet objectives and efficiently move product candidates through the development process.

### Meeting the increasing demand for more and better treatment options

This year’s report is focused on letting the numbers tell our story and we believe the numbers are quite compelling. More than 28 million people in the U.S. alone suffer from migraine.

In a recent study for the National Headache Foundation, two of three patients said they delay or avoid taking prescription migraine medication due to concerns about side effects. And almost eight of ten patients said they would consider taking any new therapy with fewer side effects than current prescription medicines. Such numbers shouldn’t be ignored.

Since the inception of POZEN, we have dedicated our efforts to developing medicines for migraine sufferers that are designed to overcome the problems associated with current therapies and have built the most advanced pipeline in the field of migraine.

### Preparing commercially viable products for the market

POZEN has been one of the most, if not the most, active researchers in the field of migraine over the last five years. Again, the numbers tell the story. In total, we have conducted more than 30 clinical trials involving over 11,000 migraine patients in more than 240 sites across the country. And for the first time, we will be presenting data on MT 100 and MT 300 at major scientific symposia throughout 2003.

MT 100, our first-line therapy option for the treatment of migraine, delivers comparable relief with less risk of cardiovascular side effects in single tablet head-to-head studies against Imitrex® 50mg., the leading prescription product for migraine. In addition to the marketing application submitted in the U.K., POZEN is on track to submit an NDA for MT 100 in mid-2003. As agreed with the FDA, we also plan to complete the NDA by submitting the results of a rat carcinogenicity study in early 2004.

MT 300, our injectable therapy for severe migraine attacks, is being developed to provide long-lasting pain relief for patients needing a convenient injectable medicine with reduced side effects. POZEN completed two pivotal Phase III trials in 2002 for MT 300, involving over 1,200 patients, which consistently demonstrated MT 300’s effectiveness in treating migraine pain.

MT 400 represents what we believe will be the most significant step forward in migraine therapy since the introduction of the triptans. Data show that MT 400 provides more than twice the therapeutic gain of a triptan alone. Once we have identified the most suitable triptan for MT 400, we will initiate Phase III clinical trials.



### Maintaining financial stewardship and a flexible infrastructure

We began 2003 with \$50 million in cash and no debt. We remain good stewards of our cash and anticipate cash operating expenses for the year to be in the range of \$19 million to \$21 million.

One of POZEN’s key strengths is the company’s business model and our ability to strategically outsource functions. The model is flexible, lean, and productive.

### Setting the stage for collaborative efforts for commercial success

As I hope the numbers have made clear, 2002 was a productive and successful year for POZEN.

We plan to have our product candidates commercialized by strategic partners and will strive toward maximizing each product candidate’s value. Given our achievements in reaching our milestones in 2002, we remain optimistic that we will collaborate with strategic partners for commercial success.

We are proud of our achievements and I want to thank our stockholders and employees for their continued commitment and confidence in our ability to execute.

2003 will be another exciting year for POZEN as we continue to move our product candidates closer to commercialization.

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

More than

# 28 million

people in the U.S. alone  
suffer from migraine.

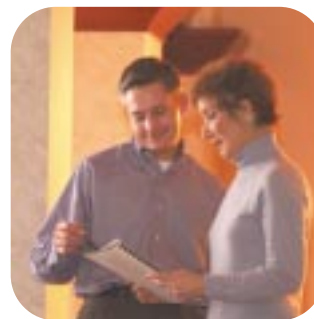
**M**igraine headaches are not only unpredictable, they can be disabling. Over 90% of the 28 million migraine sufferers in the United States report some level of disability from their headaches.

One out of ten adults suffer from migraine, and most sufferers have never been diagnosed or treated with prescription medication.

Migraine attacks are unlike ordinary headaches. Attacks can last from four hours to three days with sharp pulsating pain on one side of the head, nausea, and extreme sensitivity to light and sound. In the most severe attacks, migraine sufferers are unable to pursue basic daily activities and may require bed rest for several days at a time. Life can come to a standstill as a migraineur deals with the consequences of missing work, canceling plans or being unable to take care of family members during an attack.

Millions of Americans regularly seek immediate pain relief or customized therapy for migraine attacks, yet many abandon treatment regimens out of frustration and concerns about side effects or efficacy. Over-the-counter medicines are generally not strong enough to provide real relief. A class of potent drugs called triptans are the most widely

One out of ten adults suffer from migraine, and most sufferers have never been diagnosed or treated with prescription medication.



prescribed migraine medicines today and represent the vast majority of the world's \$3 billion migraine prescription market. Although triptans are effective in treating migraine, their relief of pain is often temporary and their use is cautioned in patients with increased risk of heart disease since they can trigger certain cardiovascular side effects such as pain or tightness in chest and shortness in breath. Finally, almost two-thirds of patients avoid or delay taking current prescription medication because of concern about the risk of these side effects, resulting in more intensive and longer duration of pain.

Simply stated, the migraine market is eager for better products. In a study for the National Headache Foundation involving over 1,000 migraine patients, eight out of ten sufferers said they would consider taking any new therapy with fewer side effects than current prescription medicines.

Since 1996, POZEN has dedicated its efforts to developing medicines for migraine sufferers that are designed to overcome the problems associated with current migraine therapies. ●

Migraine attacks  
can last from  
**4-72**  
hours.

As migraine attacks differ in severity, so should the treatment options. POZEN is developing products that treat the full range of migraine attacks—mild, moderate, and severe, allowing patients and doctors the ability to customize treatment for each patient's need and type of migraine.

Our current portfolio of products in development includes:

### MT 100: FIRST-LINE MIGRAINE THERAPY, ORAL TABLET

Many migraine sufferers seek more effective medicines than those currently offered over-the-counter, yet some are reluctant to take a class of drugs called triptans for fear of their potential cardiovascular side effects.

MT 100 is being developed as an oral first-line therapy designed to provide effective migraine relief with less risk of cardiovascular side effects compared to the triptans.

**Composition:** MT 100 is a patented, sequential release tablet containing naproxen sodium, which relieves pain and reduces inflammation, and metoclopramide hydrochloride, which accelerates the absorption of naproxen and relieves nausea.

**Status:** POZEN filed a marketing application for MT 100 in the U.K. in October 2002. If approved in the U.K., we will seek approval in selected European countries through the European Union Mutual Recognition Procedure. In mid-2003, we plan to submit our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). As already agreed with the FDA, we will complete the MT 100 NDA submission by submitting the results of the rat carcinogenicity study in early 2004. In addition to our regulatory progress, we were awarded a second U.S. patent for MT 100 in November 2002. This patent provides expanded protection through claims relating to additional pharmaceutical compositions and treatment methods.

**Development:** We have completed all Phase III pivotal trials and will continue to conduct Phase IIIb studies to expand marketing claims for MT 100. Our Phase II, Phase III, and Phase IIIb trials involved

Our three proprietary product candidates were developed by POZEN scientists.



more than 7,700 migraine patients. And of those, more than 3,700 patients received some form of MT 100. Data from the trials have consistently shown MT 100's effectiveness in treating migraine pain.

Most notable are the results from two head-to-head studies that show MT 100 provides comparable efficacy to Imitrex® 50mg, the leading prescription product for migraine. If approved, MT 100 will offer patients and physicians the first non-triptan migraine product that delivers triptan-like efficacy. We believe MT 100 will provide patients with an alternative therapy to treat migraine and will eventually become the best entry-level prescription therapy for migraine sufferers.

### MT 300: SEVERE MIGRAINE THERAPY, INJECTABLE

Migraine patients who are unable to take oral medications due to severe nausea may choose to use an injectable form of a triptan, Imitrex® Injection, or another drug such as DHE-45®. However, some patients are bothered by the cardiovascular side effects associated with the injectable triptan.

POZEN's MT 300 is an injectable product candidate designed to provide significant and long-lasting pain relief for patients seeking a convenient, well tolerated injectable therapy.

**Composition:** MT 300 is a proprietary formulation of injectable dihydroergotamine (DHE) in a convenient, pre-filled syringe.



# 8 of 10

patients will  
consider a new  
migraine medication  
with fewer  
side effects.

From a study by **R. Michael Gallagher, DO** and **Robert Kunkel, MD**  
in *Headache* 2003; 43:36-43

POZEN's  
Accomplishments:

89

pre-clinical trials

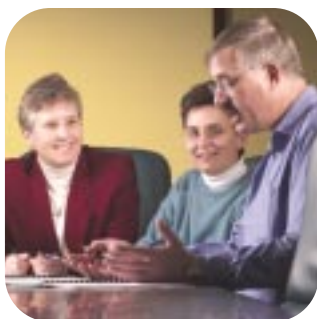
30

clinical trials involving  
over 11,000 patients

2

regulatory filings





**Status:** POZEN submitted an NDA to the FDA for MT 300 in December 2002. The NDA marked our first marketing application in the U.S., a major achievement for the company.

POZEN was also awarded a new patent for MT 300 in January 2003, providing proprietary protection through 2020 with claims relating to therapeutic packages containing a high potency DHE product in a pre-filled syringe.

**Development:** We completed two Phase III pivotal trials in 2002 involving over 1,200 patients. Data from the two trials show a statistically significant improvement in the percentage of patients achieving pain relief at two hours as well as pain relief over the 24-hour period when compared to placebo.

Our clinical trial data also indicate that MT 300 was well tolerated throughout the Phase II and Phase III clinical trial program. As evidence of POZEN's dedication to this product, our clinical program treated more patients—over 600 patients took MT 300—than were treated in any other NDA program for an injectable migraine product.

### MT 400: NEXT GENERATION MIGRAINE THERAPY, ORAL TABLET

We believe MT 400 will represent the most significant step forward in migraine therapy since the introduction of triptans.

**Composition:** MT 400 is being developed as a co-active migraine therapy combining the activity of a triptan drug with that of a non-steroidal anti-inflammatory agent in a single tablet.

**Status:** MT 400 has completed Phase II trials and is ready to move into Phase III in the clinic.

**Development:** In 2002, the FDA approved POZEN's request to submit the MT 400 NDA as a 505(b)(2) application, under which the FDA allows a reduced development program. In the U.K., the Medicines Control Agency agreed to a similar development program. Once we have identified the most suitable triptan for MT 400, we will initiate Phase III clinical trials.

Data from a large Phase II clinical trial involving 972 patients demonstrated a statistically significant improvement in the percentage of patients achieving sustained pain relief with MT 400 when compared to the triptan alone or placebo.

MT 400 also provides faster onset of pain relief than the triptan, while maintaining a similar side-effect profile. Data show 65% of patients taking MT 400 experienced migraine relief at two hours versus 49% of patients taking the triptan.

### POZEN Migraine Product Candidates

PRODUCT	PHASE I	PHASE II	PHASE III	REGULATORY FILING
<b>MT 100</b> First-line Migraine Therapy, oral tablet				(U.K. submitted) (U.S. mid-2003)
<b>MT 300</b> Severe Migraine Therapy, injectable				(U.S. submitted)
<b>MT 400</b> Next Generation Migraine Therapy, oral tablet				

Importantly, 46% of patients taking MT 400 achieved pain relief over a 24-hour period compared to 29% taking the triptan.

We believe MT 400 will be the next generation migraine therapy delivering a major advantage over currently available products. ●

One of the most common remarks we get from visitors at POZEN is how much we have accomplished in so little time and with a staff of only 27.

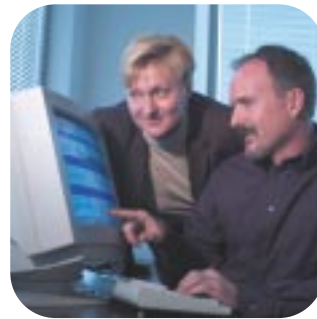
Truth be told, we designed it that way.

Created in 1996, POZEN was founded upon the belief that we could develop products faster and more efficiently than most large pharmaceutical companies. From the start, we have been committed to building a portfolio of product candidates with significant commercial potential. Today, we have the most advanced product-development pipeline in the field of migraine.

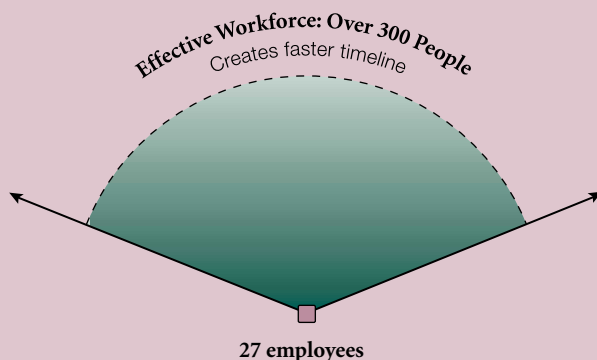
POZEN operates differently than most drug-development companies. Designed with efficiency in mind, our business model allows us to develop innovative products more quickly and more efficiently. How?

Most of our employees are currently dedicated to drug development and we leverage external resources as needed. At any one time, POZEN can indirectly employ over 300 people using strategic

Today, we have the most advanced product-development pipeline in the field of migraine.



#### POZEN Outsource Business Model



outsourcing. We work with strategic partners and contractors to run pre-clinical and clinical studies and manufacture our products. We maintain control over key functions such as design and management of pre-clinical and clinical studies, as well as the development of product candidate formulations.

As proud as we are of our product candidates and our business model, we know from experience that the success in running any company depends on the people you employ.

At POZEN, we have hired some of the best drug-development professionals in the industry, more than half hold advanced degrees. Our drug development experts have participated in the development and approval of over 40 drugs and some of the top-selling prescription drugs in the world.

Our three proprietary product candidates were developed by POZEN scientists.

Best of all, we are a close-knit team dedicated to our cause of developing innovative products quickly and more efficiently and bringing them to the market. ●

**POZEN<sup>®</sup>**  
INC.

The Pharmaceutical Development Company

Form 10-K

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

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**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, 2002.**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_.**

**Commission file number 000-31719**

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**POZEN INC.**

(Exact name of registrant as specified in its charter)

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

**62-1657552**  
(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**  
Common Stock

**Name of each exchange on which registered**  
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 Rule 12b-2 of the Act). 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 28, 2002 was \$119,694,680. As of February 28, 2003 there were outstanding 28,150,412 shares 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 in Part III of this Form 10-K and certain documents are incorporated by reference into Part IV.

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**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 Affecting the Company’s Prospects.” We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

## **PART I**

### **Item 1. Business**

#### **Overview**

We are a pharmaceutical development company committed to building a portfolio of product candidates with significant commercial potential. Our initial focus is the multi-billion dollar global migraine market, where we believe we have the largest portfolio of product candidates currently in development. We have three product candidates, which combined have over \$1 billion in market potential. In addition, we intend to leverage our pharmaceutical product development expertise by acquiring, in-licensing and/or developing commercially attractive products in therapeutic areas outside of migraine.

We plan to enter into collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates. Alternatively, we may elect to develop sales and distribution capabilities internally in order to commercialize one or more of our product candidates. In certain instances, we may also promote our products in collaboration with other pharmaceutical companies. We have had and expect to continue to have discussions with third parties with respect to the commercialization of our product candidates.

MT 100 is being developed as an oral, first-line treatment for migraine pain and associated symptoms. We have completed all planned Phase 3 pivotal clinical trials for MT 100, which consistently demonstrated MT 100’s effectiveness in treating migraine pain. In October 2002, we submitted a Marketing Authorization Application (“MAA”) for MT 100 to the Medicines Control Agency (“MCA”) in the United Kingdom (“UK”). If approved in the UK, we will seek approval in selected European countries through the European Union Mutual Recognition Procedure. We plan to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for MT 100 in mid-2003, and complete the NDA submission by submitting final carcinogenicity data in early 2004.

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

MT 400 is being developed as a co-active acute migraine therapy, combining the activity of a triptan with that of a long-lasting non-steroidal anti-inflammatory drug (“NSAID”). We have completed a 972-patient Phase 2 clinical trial in which MT 400 showed statistically significant superiority over placebo and its components, including an oral triptan, on the identified primary and secondary outcome measures.

## **Business Strategy**

The principal elements of our business strategy are to:

### ***Develop and commercialize our portfolio of product candidates***

A substantial portion of our efforts over the next few years will be devoted to the further development, approval and commercialization of our portfolio of product candidates. We conduct clinical trials and other studies with our product candidates in order to obtain marketing approvals that will allow us to provide new therapeutic alternatives for migraine patients. We will need to establish sales and distribution capabilities, either through arrangements with others or by developing them internally, in order to commercialize our products. In certain instances, we may 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 therapeutic areas with significant commercial potential in which members of our management team have development expertise. These areas of expertise include gastrointestinal disease, respiratory disease, infectious disease and pain. We plan to develop a pipeline of 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 commercialize our product candidates in a cost-effective manner. We have contracted and plan to contract with third parties for product candidate testing, development and manufacturing.

## ***Migraine Market***

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. It is estimated that global sales of prescription pharmaceuticals for the treatment of migraine will approach \$3.7 billion by 2005.

Not all migraine attacks are of the same severity. Consequently, a variety of oral, injectable and intranasal 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 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 2002, according to IMS Health's Retail and Provider Perspective, or IMS, total triptan sales in the U.S. were approximately \$1.7 billion. Imitrex<sup>®</sup>, marketed by GlaxoSmithKline, is the leading triptan product, with, according to IMS, total U.S. sales of approximately \$1.1 billion in 2002. There are currently three triptan formulations commercially available: oral, intranasal and injectable. Oral triptans are often prescribed as a first-line treatment for migraine pain. Intranasal triptans are often prescribed for patients requiring faster relief than oral drugs can provide or for patients who cannot take oral medications. For the most severe attacks, patients sometimes use an injectable form of a triptan.

Because of the problems associated with triptans, and various problems associated with narcotics and analgesics, we believe that an opportunity exists in all migraine therapeutic segments for products designed to deliver an improved onset and duration of relief with reduced side effects, especially those related to cardiovascular events.

## **Products Under Development**

### **MT 100**

#### *Overview*

MT 100 is being developed as an oral first-line therapy for the treatment of migraine pain and associated symptoms. Oral products are currently the most prevalent form of migraine therapy. According to IMS, existing oral prescription products accounted for approximately \$1.4 billion in sales in the U.S. in 2002, of which the Imitrex<sup>®</sup> oral dosage form accounted for approximately \$805 million. In 2002, according to IMS Health, IMS MIDAS, the European prescription migraine market exceeded \$500 million, of which the triptans accounted for 79%. The UK and France, each with sales of approximately \$110 million, led the market.

In October 2002, we submitted an MAA for MT 100 to the MCA in the UK. If approved in the UK, we will seek approval in selected European countries through the European Union Mutual Recognition Procedure (MRP). This procedure allows other European countries to grant national approvals based upon the review and endorsement of the MCA in the UK. We plan to submit an NDA to the FDA for MT 100 in mid-2003, and complete the NDA submission by submitting final carcinogenicity data in early 2004.

MT 100 is a proprietary formulation that combines metoclopramide hydrochloride, a commercially available agent that relieves nausea and enhances stomach emptying, 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 migraines. Results from our pharmacokinetic study in normal volunteers, completed in 1999, indicated that peak naproxen blood levels were approximately 15% higher and were achieved approximately 30 minutes faster following administration of MT 100 than with naproxen sodium alone.

#### *Clinical Development*

Prior to submission of an MAA and an NDA, we are required to demonstrate the efficacy and safety of our product candidates. To demonstrate 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 statistically more patients have achieved sustained pain response, defined as migraine pain relief at two hours that is maintained throughout the next 22 hours ("sustained pain relief"), than patients treated with the component products. We must also show that MT 100 is superior to placebo for relief of nausea, sensitivity to light and sensitivity to sound.

Generally, the FDA requires two successful clinical trials to demonstrate that the product candidate meets each of these standards for approval.



To this end and to demonstrate MT 100's effectiveness as compared to other migraine therapies, we have completed a total of two Phase 2 clinical trials, six Phase 3 clinical trials, and two marketing support Phase 3b studies, involving in total more than 7,700 treated patients, more than 3,700 of whom have received some form of MT 100. The Phase 3 and Phase 3b clinical trials have consistently demonstrated MT 100's effectiveness in treating migraine pain. Significantly, in two Phase 3 trials in which MT 100 was compared to Imitrex<sup>®</sup> and placebo, MT 100 demonstrated comparable efficacy to Imitrex<sup>®</sup>, and a lower percentage of patients taking a single-tablet dose of MT 100 reported adverse events than patients taking Imitrex<sup>®</sup>. Adverse events included drowsiness, diarrhea, abdominal pain, dizziness, infection and nervousness.

Our MT 100 Phase 3 and 3b trials are described below:

- We conducted two Phase 3 clinical trials comparing a single tablet dose of MT 100 with a 50mg dose of Imitrex, the most widely prescribed dose. In both studies, the sustained pain relief rates were nearly identical for MT 100 and Imitrex and both were statistically superior to placebo. A 1,027-patient study completed in 2002 showed that both MT 100 and Imitrex were statistically superior to placebo for the relief of nausea, sensitivity to light and sensitivity to sound within 3 hours of dosing. In the initial comparison, a 546-patient study completed in 2000, MT 100 was also superior to placebo in the relief of nausea, sensitivity to light and sensitivity to sound. The incidence of adverse events was lower for patients taking a single-tablet dose of MT 100 than patients taking Imitrex<sup>®</sup>. These results further confirmed the effectiveness of MT 100 in treating migraine pain, however, it is unlikely the results will affect final product labeling.
- We conducted two Phase 3 pivotal clinical trials, a 2,627 patient trial completed in 2000 and a 1,064-patient trial completed in 1999, comparing MT 100 to its components. In both trials the sustained pain response for patients receiving MT 100 was statistically significantly greater than the rate for patients receiving either naproxen sodium or metoclopramide hydrochloride alone. Using the statistical analysis methodology, logistic regression, specified in the first trial's protocol, MT 100 showed statistically significant superiority over only one of its two components. However, MT 100 showed statistically significant superiority over both components when the results of this trial were analyzed using ordered logistic regression, a refinement of the statistical analysis methodology originally specified in the protocol. The results from the second trial, which was designed based on discussions with the FDA, were analyzed using ordered logistic regression and confirmed the results of the first trial. We therefore believe that we have satisfied the FDA requirement for the successful completion of two Phase 3 clinical trials showing MT 100 to be superior to its components.
- A Phase 3 multiple dosing trial including 427 patients was completed in mid-2000 in which MT 100 showed statistically significant superiority over placebo for sustained pain relief and, within two hours after initial dosing, for relief of nausea, sensitivity to light and sensitivity to sound.
- A Phase 3 long-term safety trial including more than 1,000 patients was completed in February 2001 in which MT 100 was shown to be well tolerated. Only 8% of the patients discontinued the study because of an adverse event including fatigue, drowsiness, restlessness, anxiety and diarrhea. No patients discontinued the study because of chest pain or discomfort.
- A Phase 3b clinical trial including 238 patients was completed in 2002 comparing MT 100 to placebo in patients with an intolerance to a triptan or with cardiovascular risk factors that would warrant cautious use of a triptan, in which MT 100 demonstrated statistically-significant superiority to placebo for sustained pain relief.
- A Phase 3b clinical trial including 343 patients was completed in 2002 comparing a two tablet dose of MT 100 to placebo in patients who had not responded adequately to oral Imitrex. In this trial, MT 100 demonstrated statistically significant superiority to placebo for sustained pain relief.

In addition to the required clinical trials, we completed a six-month oral carcinogenicity study in p53 transgenic mice in 2002. The results from the six-month study indicated that MT 100 was not carcinogenic in the p53 transgenic mice. We commenced a two-year rat carcinogenicity study, in August 2001 and will complete the in-life portion of that study in August 2003. We anticipate that the results of the study will be available in early 2004. The FDA has agreed to accept results from the two-year rat carcinogenicity study during the NDA review period for MT 100. We plan to submit the NDA for MT 100 to the FDA in mid-2003, and complete the NDA submission by submitting final carcinogenicity data in early 2004.

## **MT 300**

### *Overview*

MT 300, a proprietary formulation of injectable DHE in a pre-filled syringe, is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks, with a reduced side effect profile compared to existing injectable products. Currently, patients unable to take oral medications due to severe nausea may choose to use an injectable form of a triptan or another drug such as DHE. However, many patients are unable to tolerate the injections, especially those sensitive to the vascular side effects associated with injectable Imitrex<sup>®</sup>. Nevertheless, according to IMS, injectable migraine therapeutics represented approximately \$214 million in 2002 U.S. sales.

Published clinical trial results indicate that injectable DHE provides comparable efficacy to injectable Imitrex<sup>®</sup> three hours after administration. In addition, in published clinical trials, only 18% of injectable DHE patients experienced headache recurrence within 24 hours as compared to 45% of injectable Imitrex<sup>®</sup> patients. Acute vascular side effects were reported by only 2% of the patients receiving injectable DHE compared to 23% of the patients receiving injectable Imitrex<sup>®</sup>.

### *Clinical Development*

In December 2002, we submitted an NDA to the FDA for MT 300. The NDA was accepted for filing by the FDA in February 2003 and is under review.

We completed the following two MT 300 Phase 3 trials in 2002.

- A Phase 3 clinical trial including 619 patients in which MT 300 provided sustained pain relief and pain relief at two hours in statistically significantly more patients than placebo. Regarding secondary endpoints, MT 300 provided statistically significant relief of sensitivity to light by two hours following dosage, but did not provide relief of sensitivity to sound or nausea over the two-hour post dose period. However, a statistically significantly greater number of patients treated with MT 300 than placebo who were free of nausea, sensitivity to light and sensitivity to sound at 2 two hours, had no recurrence at 24 hours.
- A Phase 3 clinical trial including 550 patients, which showed that a statistically significantly greater percentage of MT 300-treated patients had sustained pain relief and pain relief at two hours post dosing than patients treated with placebo. There were no statistically significant differences between MT 300 and placebo in relief of the secondary symptoms of migraine-nausea and sensitivity to light and sensitivity to sound over the two-hour post dose period, as specified in the study protocol. Further analysis of the data indicated that a statistically significantly greater number of patients treated with MT 300 than placebo had sustained relief of sensitivity to light and sensitivity to sound and the difference between MT 300 and placebo in the sustained relief of nausea was marginally significant. The FDA will consider, as part of its review of the NDA, the evaluation of the secondary endpoints using sustained relief.

## **MT 400**

### *Overview*

MT 400 is being developed as a co-active migraine therapy, combining the activity of a triptan drug with that of an NSAID. We believe that the effective treatment of migraine requires targeted, specific and complementary co-active therapy to achieve maximum therapeutic benefit with the fewest side effects. We expect to complete a development program for U.S. and European regulatory approval for MT 400 using a commercially approved triptan and commercially approved NSAID. We will need to obtain the right to use the triptan that we specify in our NDA for MT 400 if we intend to commercialize MT 400 prior to the expiration of the patent for that triptan. Patents for triptans begin to expire in 2005 in Europe and 2008 in the U.S.

### *Clinical Development*

In 2002, the FDA approved our request to submit the MT 400 NDA as a 505(b)(2) application, under which the FDA allows a reduced development program. In the UK, the MCA agreed to a similar development program. This reduced development plan will allow MT 400 to proceed to Phase 3 clinical trials. Once we have identified the most suitable triptan for MT 400, we will initiate Phase 3 clinical trials.

In 2001, we completed a 972-patient, Phase 2 double-blind, placebo-controlled, single-dose clinical trial in which MT 400 showed statistically significant superiority over placebo and 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 in the relief of migraine associated symptoms.

With respect to the primary endpoint, sustained pain relief, the therapeutic gain with MT 400 was more than twice the therapeutic gain seen with the triptan. Therapeutic gain is equal to the percent of patients with response on active agent minus the percent of patients with response on placebo control agent.

## **Sales and Marketing**

We currently have no sales or distribution capabilities. We plan to enter into collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates. Alternatively, we may elect to develop sales and distribution capabilities internally in order to commercialize one or more of our product candidates. In certain instances, we may also promote our products in collaboration with other pharmaceutical companies.

## **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. Use of third-party manufacturing enables us to focus on our clinical development strengths, 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. under which DSM will supply us with all MT 100 for commercial sale. We, or our commercial partner, are required to purchase all commercial supply of MT 100 from DSM for the initial term of the agreement and any extension thereof, unless DSM is unable to meet our, or our commercial partner's, requirements. We have the right to terminate the agreement under certain circumstances after the third anniversary of the first commercial sale of MT 100 following NDA approval.

In October 2001, we entered into a Commercial Supply Agreement with Lek Pharmaceuticals Inc., 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. Either party may cancel the agreement under certain conditions. 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.

We have agreements with various vendors to supply us with clinical supply materials for our MT 100, MT 300, and MT 400 clinical trials. We believe our current supplier agreements should be sufficient to complete both our ongoing and planned clinical trials.

## **Competition**

Not all migraine attacks are of the same severity. Consequently, 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 2002, total triptan sales in the U.S. were approximately \$1.7 billion. Imitrex®, a triptan product marketed by GlaxoSmithKline, had total U.S. sales of approximately \$1.1 billion in 2002, 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 the existing migraine therapeutics, as well as any therapies developed in the future.

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 in product discovery, development, clinical trial management, FDA regulatory review, manufacturing and marketing than we do.

### **Patents and Proprietary Information**

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

We have five issued U.S. patents and four pending and one allowed U.S. patent applications, and we presently have pending foreign patent applications or issued foreign patents, relating to MT 100, MT 300 and MT 400. Foreign patent applications have been filed under the Patent Cooperation Treaty, or PCT, and are in various stages of prosecution worldwide relating to MT 100, MT 300 and MT 400. We also have U.S. and PCT patent applications pending relating to a novel product concept. 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 have one issued Australian patent. 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 are applications relating to MT 100 that are pending in Canada, Europe and Japan. The expected expiration date of the issued U.S. and Australian patents relating to MT 100 is November 10, 2017. 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 a U.S. patent relating to therapeutic packages containing a high potency formulation of DHE in a pre-filled syringe. We also have a pending U.S. patent application with claims relating to additional high potency formulations and therapeutic packages, and we have patent applications pending in major markets worldwide.

#### ***MT 400***

We have two 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 an issued patent in Australia and pending patent applications relating to MT 400 pending in Canada, Europe and Japan. On January 29, 2003, we received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application with claims directed to the use of triptans and NSAIDs in treating patients with migraine. 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 provisional U.S. patent application with claims directed to formulations of MT 400.



## ***Other Products***

We have filed U.S. and foreign patent applications with claims directed to novel formulations for a new product concept which is currently in the exploratory stage. Should any patents issue from these applications they would be expected to expire on May 31, 2022.

## **Other Intellectual Property**

Much of the know-how of importance to us is dependent upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to proprietary know-how and technology, we require employees, consultants and advisors to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of the company. There can be no assurance that these agreements will effectively prevent disclosure of our confidential information. In the absence of effective patent or other protection of intellectual property, our business may be adversely affected by competitors who develop substantially equivalent or superior technology or know-how.

The patent and other intellectual property positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions. We cannot assure you that:

- our patent rights will provide us with proprietary protection or competitive advantages over our competitors;
- our patent rights will not be challenged, invalidated or circumvented;
- others will not independently develop technologies similar to ours or duplicate our technologies; or
- the patents issued to or licensed by us will not be infringed or challenged.

## **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.

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.

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 FDCA 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.

Even after the 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.

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 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 our safety procedures 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 national route where national authorizations are granted by the competent authorities of individual EU countries 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 an EU member country and where it is intended that the product be marketed in more than one country; authorization must be by way of the MRP. Under the MRP, the competent authorities of designated EU countries are requested to 'mutually recognise' a marketing authorization already granted by another EU country.

An MAA in respect of MT 100 was submitted to the MCA in the UK in October 2002. In the UK, the regulation of medicinal products is governed by the Medicines Act of 1968 and subsequent delegated legislation. Essentially all applications must include full details of the product and the research that has been carried out to establish its efficacy, safety and quality.

The MCA will seek to ensure that the product satisfies the appropriate requirements for efficacy, safety and quality by an assessment carried out by an advisory committee, which may, if it wishes, advise the MCA 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 MCA 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 be such that the combination is safe and effective for a significant population subgroup and the benefit/risk assessment of the fixed combination must equal or exceed the corresponding profile of each of the active ingredients taken alone.

If the MCA 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 MCA based upon an assessment report prepared by the MCA. 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 some countries have used the 90 days 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 FDCA 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.

## Employees

As of February 28, 2003, we had a total of 27 full-time employees. All of our current employees are based at our headquarters in Chapel Hill, North Carolina. Of our 27 employees, 14 hold advanced degrees, including four Pharm.D. or Ph.D. degrees.

## Executive Officers of the Company

Our current executive officers, and their ages as of December 31, 2002, are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
John R. Plachetka, Pharm.D.	49	Chairman, President and Chief Executive Officer
Kristina M. Adomonis	48	Senior Vice President, Business Development
John E. Barnhardt	53	Vice President, Finance and Administration
Matthew E. Czajkowski	53	Chief Financial Officer, Senior 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.

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 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 joined 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.

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 and Principal Accounting Officer of Medco Research, Inc. from 1993 to 1996 and Microwave Laboratories, Inc. from 1988 to 1993. Mr. Barnhardt received a B.S. from North Carolina State University, and while employed at Ernst & Young LLP, received his CPA certification.

Matthew E. Czajkowski joined POZEN in March 2000 as Chief Financial Officer and Senior Vice President of Finance and Administration. Prior to joining POZEN, Mr. Czajkowski was an investment banker. From 1997 through 1998, he was a Managing Director of Mergers and Acquisitions at Société Générale. From 1992 to 1997, he was a Managing Director in charge of Corporate Finance at Wheat First Butcher Singer, Inc. From 1983 to 1991, he was employed with, and served as a Vice President beginning in 1987, at Goldman, Sachs & Co. Mr. Czajkowski received his B.A. from Harvard University and his M.B.A. from Harvard Business School.

The employment of Andrew L. Finn, Pharm.D., formerly the Company's Executive Vice President of Product Development, terminated as of March 27, 2003.

We maintain a website at [www.pozen.com](http://www.pozen.com) and make available free of charge through this website our annual reports on Form 10-K, and make available through this website our quarterly reports on Form 10-Q, 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 furnishes it to, the SEC.



**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. Between July 1997 and March 2002, our corporate facilities were located in the Quadrangle Office Park in Chapel Hill, North Carolina, occupying approximately 7,200 square feet under a lease which expired in February 2003. 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**

The Company is not a party to any material legal proceedings.

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

None.

## PART II

### **Item 5. Market for the Company's Common Stock and Related Stockholder Matters**

#### (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 February 28, 2003, we estimate that we had approximately 209 stockholders of record and approximately 1,778 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.

<b><u>2001 Fiscal Year</u></b>	<b><u>Price Range</u></b>	
	<b><u>High</u></b>	<b><u>Low</u></b>
First Quarter	\$19.25	\$5.75
Second Quarter	\$15.50	\$5.19
Third Quarter	\$11.48	\$3.60
Fourth Quarter	\$ 7.30	\$3.50

<b><u>2002 Fiscal Year</u></b>	<b><u>Price Range</u></b>	
	<b><u>High</u></b>	<b><u>Low</u></b>
First Quarter	\$6.69	\$4.61
Second Quarter	\$6.00	\$3.95
Third Quarter	\$5.62	\$3.39
Fourth Quarter	\$5.49	\$4.30

On February 28, 2003, the closing price for our common stock as reported by The Nasdaq National Market was \$2.91. We paid no cash dividends in 2002. 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.

#### (b) Issuances of Unregistered Securities

On July 11, 2002, we issued 18,617 shares of common stock pursuant to the exercise by an individual of stock purchase warrants issued to such individual in 1997. The consideration received by us was \$18.62 in cash, or a price of \$0.001 per share. These securities were offered and sold by us in reliance upon exemptions from registration under Section 4(2) of the Securities Act of 1933.

## 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 (incorporated by reference) herein.

	For the Year Ended December 31,					Period from September 26, 1996 (inception) through December 31, 2002
	1998	1999	2000	2001	2002	
	(in thousands, except per share data)					
<b>Statement of Operations Data:</b>						
Operating expenses:						
General and administrative .....	\$ 1,478	\$ 2,320	\$ 4,822	\$ 6,455	\$ 6,833	\$ 23,016
Research and development.....	7,569	9,458	19,399	18,627	18,762	76,937
Total operating expenses .....	9,047	11,778	24,221	25,082	25,595	99,953
Interest income (expense), net .....	309	(367)	1,844	3,380	1,040	6,531
Net loss .....	(8,738)	(12,145)	(22,377)	(21,702)	(24,555)	(93,422)
Non-cash preferred stock charge .....	—	—	27,617	—	—	27,617
Preferred stock dividends .....	—	—	934	—	—	934
Common stock dividends .....	—	—	—	—	—	—
Net loss attributable to common stockholders .....	<u>\$(8,738)</u>	<u>\$(12,145)</u>	<u>\$(50,928)</u>	<u>\$(21,702)</u>	<u>\$(24,555)</u>	<u>\$(121,973)</u>
Basic and diluted net loss per common share .....	<u>\$ (1.50)</u>	<u>\$ (2.08)</u>	<u>\$ (4.95)</u>	<u>\$ (0.78)</u>	<u>\$ (0.87)</u>	
Shares used in computing basic and diluted net loss per common share .....	<u>5,835</u>	<u>5,845</u>	<u>10,294</u>	<u>27,955</u>	<u>28,110</u>	
Pro forma net loss per common share—basic and diluted* .....		<u>\$ (1.01)</u>	<u>\$ (2.56)</u>			
Pro forma weighted average common shares outstanding— basic and diluted* .....		<u>12,018</u>	<u>19,915</u>			
	December 31,					
	1998	1999	2000	2001	2002	
<b>Balance Sheet Data:</b>						
Cash and cash equivalents .....	\$ 2,986	\$ 4,171	\$ 92,351	\$ 73,959	\$ 50,056	
Total assets .....	3,113	4,325	92,830	74,144	51,035	
Total liabilities .....	2,066	2,360	3,762	3,523	1,836	
Accumulated deficit .....	(12,642)	(24,787)	(48,099)	(69,801)	(94,356)	
Total stockholders' equity .....	1,047	1,965	89,068	70,621	49,199	

\*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 development company committed to building a portfolio of product candidates with significant commercial potential. The Company's initial focus is the multi-billion dollar global migraine market.

MT 100, our proprietary formulation containing metoclopramide hydrochloride and naproxen sodium, is being developed as an oral, first-line treatment for migraine pain and associated symptoms. The Company completed all planned Phase 3 pivotal clinical trials for MT 100, which consistently demonstrated MT 100's effectiveness in treating migraine pain. In October 2002, POZEN submitted an MAA to the MCA in the UK for MT 100. If approved in the UK, POZEN will seek approval in selected European countries through the European Union Mutual Recognition Procedure. The Company plans to submit an NDA to the FDA for MT 100 in mid-2003, and complete the NDA submission by submitting final carcinogenicity data in early 2004.

MT 300, a proprietary formulation of DHE in a pre-filled syringe, is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks. POZEN has completed all planned Phase 3 pivotal clinical trials for MT 300, which consistently demonstrated MT 300's effectiveness in treating migraine pain. In December 2002, the Company submitted an NDA to the FDA for MT 300.

MT 400 is being developed as a co-active acute migraine therapy, combining the activity of a triptan with that of a long-lasting NSAID. The Company has completed a 972-patient Phase 2 clinical trial in which MT 400 showed statistically significant superiority over placebo and its components, including an oral triptan, on the identified primary and secondary outcome measures.

Specifically, our business activities since inception have included:

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

Historically, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaboration payments payable to us nor have we received any payments that are refundable or subject to performance milestones.

We have incurred significant losses since our inception and have not generated any revenue. As of December 31, 2002, our accumulated deficit was \$94,355,965. Our historical operating losses have resulted principally from our research and development activities, including Phase 3 clinical trial activities for our product candidates MT 100 and MT 300, Phase 2 clinical trial activities for our product candidate MT 400, and general and administrative expenses. We expect to continue to incur operating losses over the next several years as we complete our development of MT 100, MT 300 and MT 400 and apply for regulatory approval, develop any other product candidates, and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- the progress of MT 100, MT 300 and MT 400 in the clinical and regulatory process;
- the establishment of collaborations for the development and commercialization of any of our migraine product candidates; and
- the acquisition and/or in-licensing, and development, of other therapeutic product candidates.

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

In October 2000, we received \$78,265,552 in net proceeds from the sale of 5,750,000 shares of our common stock in our initial public offering, including the exercise of the underwriters' over-allotment option. All of our outstanding preferred shares were converted into shares of our common stock upon the completion of our initial public offering.

In connection with the grant of stock options to employees, we recorded deferred compensation of approximately \$9,236,000 in the three years ended December 31, 2002. The deferred compensation amounts were recorded as a component of stockholders' equity and are being amortized as charges to operations over the vesting period of the options using the straight-line method. The vesting period of these options is generally three years. Approximately \$2,908,000, \$3,146,000 and \$3,054,000 of deferred compensation expense were charged to operations in the years ended December 31, 2002, 2001 and 2000, respectively. As of December 31, 2002, we anticipate charging to operations additional amounts of amortization of deferred compensation of approximately \$510,000 for the year ended December 31, 2003.

## **Critical Accounting Policies**

The methods, estimates and judgments we use in applying our most critical accounting policies can have a significant impact on the results we report in our financial statements. 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.

### *Accrued liabilities, specifically contracted costs*

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. 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 activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. Significant management judgments and estimates must be made and used in connection with the accrued liability in the accounting period. Material differences may result in the amount and timing of the accrued liability for any period if management made different judgments or utilized different estimates.

### *Income Taxes*

We record deferred tax assets and liabilities based on the net tax effects of tax credits, operating loss carryforwards 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 a valuation allowance. Through December 31, 2002, we believe that all of our deferred tax assets will not be realized and, accordingly, we have recorded a valuation allowance against all of our deferred tax assets. 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, 2002 compared to year ended December 31, 2001*

*Revenue:* We generated no revenue during the years ended December 31, 2002 and 2001.

*Research and Development:* Research and development expenses increased 0.7% to \$18,761,630 for the year ended December 31, 2002 as compared to \$18,627,249 for the year ended December 31, 2001. The increase in expense was due to increased costs associated with the development of MT 300 and MT 400, offset by a decrease in development costs for MT 100 and termination of all development activities for MT 500. MT 300 costs increased by \$2,149,000 primarily due to increased Phase 3 clinical trial activities in the second and third quarters of 2002 as compared to the same period of 2001 and costs associated with submission of an NDA to the FDA in December 2002. MT 400 costs increased by \$2,799,000, primarily due to increased costs associated with obtaining drug substance, and increased toxicology activities, as compared to 2001. Costs associated with the development of MT 100 decreased by \$3,490,000 due to a decrease in Phase 3 clinical trial activities during 2002, as compared to 2001. MT 500 costs decreased by \$1,522,000. The costs associated with all other product candidates increased by \$87,000. Other research and development costs increased by \$111,000. Total amortization of deferred stock compensation included in research and development expenses was \$1,282,000 for 2002 as compared to \$1,406,000 for 2001. We expect that research and development expenditures will decrease in 2003 as a result of completion of most planned clinical trials for MT 100 and MT 300 in 2002. We have included in our research and development expenses the personnel costs related to our research activities and costs related to product development, clinical trial and toxicology activities, and regulatory matters.

*General and Administrative:* General and administrative expenses increased 5.8% to \$6,833,336 for the year ended December 31, 2002 from \$6,455,164 for the year ended December 31, 2001. The \$378,000 increase was due to increased services and other costs related to marketing, advertising and intellectual property consulting expenses associated with our business development activities that totaled \$263,000, along with a \$115,000 increase in other general operating expenses. Total amortization of deferred compensation included in general and administrative expenses was \$1,626,000 for 2002 as compared to \$1,740,000 for 2001. We expect that general and administrative expenditures will continue to increase due to increasing fees and expenses associated with the growth in our market research, business development and commercialization efforts. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

*Interest Income, net:* Net interest income decreased to \$1,040,057 for the year ended December 31, 2002 from \$3,379,905 for the year ended December 31, 2001. Interest income declined primarily due to a decline in interest rates along with a decrease in levels of cash and cash equivalents available for investing during the year.

### *Year ended December 31, 2001 compared to year ended December 31, 2000*

*Revenue:* We generated no revenue during the year ended December 31, 2001 or 2000.

*Research and Development:* Research and development expenses decreased 4.0% to \$18,627,249 for the year ended December 31, 2001 from \$19,398,904 for the year ended December 31, 2000. This net decrease of \$772,000 was due primarily to a net decrease in direct product development costs of \$1,268,000.

The costs related to the research and development of MT 100 decreased by \$5,386,000 in 2001, due primarily to decreased clinical trial activities. During the year 2000, while conducting three Phase 3 clinical trials, expenditures related to MT 100 were at their highest historical level. During 2001, the research and development costs related to MT 300 and MT 400 increased by \$2,281,000 and \$1,802,000, respectively, as a result of increased clinical trial activities compared to the prior year. The costs associated with all other product candidates increased by \$35,000. Other research and development costs increased by \$496,000, including an increase of \$487,000 in personnel costs. Total amortization of deferred stock compensation included in research and development expenses was \$1,406,000 for 2001 as compared to \$1,397,000 for 2000. We have included in our research and development expenses the personnel costs related to our research activities and costs related to clinical trial preparations, monitoring expenses, and regulatory matters.

*General and Administrative:* General and administrative expenses increased 33.9% to \$6,455,164 for the year ended December 31, 2001 from \$4,822,102 for the year ended December 31, 2000. This increase of \$1,633,000 includes an increase of \$724,000 in personnel and related benefits, an increase of \$677,000 in fees, services and other costs related to public disclosure and investor communication activities, along with increases in other general operating expenses that totaled \$232,000. Total amortization of deferred compensation included in general and administrative expenses was \$1,740,000 for 2001 as compared to \$1,657,000 for 2000. We have included in our general and administrative expenses the costs of administrative personnel and related facility costs along with legal, accounting and professional fees, services and other costs related to public disclosure and investor communication activities.

*Interest Income, net:* Net interest income increased to \$3,379,905 for the year ended December 31, 2001 from \$1,844,378 for the year ended December 31, 2000. Interest income increased due to increased levels of cash and cash equivalents available for investing resulting from our initial public offering in October 2000.

## **Income Taxes**

As of December 31, 2002, we had federal and state net operating loss carryforwards of approximately \$78.3 million and research and development credit carryforwards of approximately \$4.5 million. These federal and state net operating loss carryforwards and research and development credit carryforwards begin to expire in 2012. The utilization of the loss carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the net loss carryforwards. In addition, the maximum annual use of net loss carryforwards is limited in certain situations where changes occur in our stock ownership.

## **Liquidity and Capital Resources**

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in aggregate net proceeds to us of \$131,804,879. At December 31, 2002, cash and cash equivalents totaled \$50,056,251, a decrease of \$23,902,473 as compared to December 31, 2001. The decrease in cash and cash equivalents resulted primarily from our operating activities.

Cash used by operations of \$23,694,348 during the year ended December 31, 2002 represented a net loss of \$24,554,910 offset by non-cash charges of \$3,024,318, an increase in prepaid and other assets of \$477,185 and a decrease in accounts payable and accrued liabilities of \$1,686,571.

Cash used in investing activities of \$432,594 during the year ended December 31, 2002 reflected the purchase of furniture, equipment and leasehold improvements.

Cash provided by financing activities during the year ended December 31, 2002 totaled \$224,469, reflecting the net proceeds from the exercise of common stock options and warrants.

We believe that our existing liquidity and capital resources, including the proceeds from our initial public offering, will be sufficient to complete our on-going and planned clinical trials reflected in the description of our business, to conduct appropriate development studies, and to satisfy our other currently anticipated cash needs for operating expenses for the next two years.

Below is a summary of our contractual obligations for our operational leases.

<u>Year</u>	<u>Amount</u>
2003	\$ 183,096
2004	369,747
2005	377,486
2006	385,311
2007	393,418
2008-10	880,868
Total	<u>\$ 2,589,926</u>



We do not expect to make any material capital expenditures during the next two years. In addition, we do not currently have any milestone or other required material payment obligations during that period. However, we cannot be certain that additional funding will not be required and, if required, will be available on acceptable terms, or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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

- the number and progress of our clinical trials and other trials and studies;
- our ability to negotiate favorable terms with various contractors assisting in these trials and studies;
- our success in commercializing the products to which we have rights; and
- costs incurred to enforce and defend our patent claims and other intellectual rights.

### **Recent Accounting Pronouncements**

In April 2002, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 146, “Accounting for Costs Associated with Exit or Disposal Activities” (“SFAS 146”). SFAS 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, “Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)” (“Issue 94-3”). SFAS 146 addresses the accounting and reporting for costs associated with exit or disposal activities resulting from entities increasingly engaging in exit and disposal activities where certain costs associated with those activities were recognized as liabilities at a plan (commitment) date under Issue 94-3 but did not meet the definition of a liability in FASB Concepts Statement No. 6, “Elements of Financial Statements.” The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS 146 to have a material impact on our results of operations or financial position.

In December 2002, the FASB issued SFAS No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosure”, (“SFAS 148”). SFAS 148 amends FASB Statement No. 123, Accounting for Stock-Based Compensation, (“SFAS 123”), to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure provisions of SFAS 123 to require disclosure in the summary of significant accounting policies of the effects of an entity’s accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS 148 does not amend SFAS 123 to require companies to account for their employee stock-based awards using the fair value method. However, the disclosure provisions are required for all companies with stock-based employee compensation, regardless of whether they utilize the fair method of accounting described in SFAS 123 or the intrinsic value method described in APB Opinion No. 25, Accounting for Stock Issued to Employees.

SFAS 148’s amendment of the transition and annual disclosure provisions of SFAS 123 are effective for fiscal years ending after December 15, 2002, with earlier application permitted for entities with fiscal years ending prior to December 15, 2002, provided that financial statements for the 2002 fiscal year were not issued prior to the issuance of Statement 148 (December 31, 2002). The disclosure requirements for interim financial statements containing condensed consolidated financial statements are effective for interim periods beginning after December 15, 2002. We do not expect the adoption of SFAS 148 to have an impact on our results of operations or financial position.

### **Factors That May Affect Our Results**

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

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

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

- negative, inconclusive or otherwise unfavorable results from any studies or clinical trials;
- an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of our product candidates;
- an inability to establish collaborative arrangements with third parties for the manufacture and commercialization of our product candidates, or any disruption of any of these arrangements, if established;
- a failure to achieve market acceptance of our product candidates;
- significant delays in any required studies or clinical studies;
- any demand by the FDA that we conduct additional clinical trials or other studies and the expenses relating thereto; and
- significant increases in the costs of any studies or clinical trials.

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

We have incurred losses in each year since our inception and we currently have no source of product revenue. As of December 31, 2002, we had an accumulated deficit of approximately \$94.4 million. We expect to incur significant and increasing operating losses and do not know when or if we will generate product revenue.

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

- develop and obtain regulatory approvals for our product candidates;
- successfully commercialize our product candidates, which may include entering into collaborative agreements; and
- secure contract manufacturing and distribution services.

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

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products. If we market our products abroad, they are also subject to extensive regulation by foreign governments. None of our product candidates have been approved for sale in the United States or any foreign market.

A separate NDA must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA. If we are unable to obtain and maintain FDA and foreign governmental approvals for our product candidates, we will not be permitted to sell them.

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

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

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

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

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

**We depend on collaborations with third parties for the development of our products, which may reduce our product revenues or restrict our ability to commercialize our products.**

Our ability to develop, manufacture, and obtain regulatory approval of our existing and any future product candidates depends upon our ability to enter into and maintain contractual and collaborative arrangements with others.

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

We cannot be sure that we will be able to maintain our existing or future collaborative or contractual arrangements, or that we will be able to enter into future arrangements with third parties on terms acceptable to us, or at all. If we fail to maintain our existing arrangements or to establish new arrangements when and as necessary, we could be required to undertake these activities at our own expense, which would significantly increase our capital requirements and may delay the development of our product candidates.

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

- We may not have day-to-day control over the activities of our contractors or collaborators.
- Third parties may not fulfill their obligations to us.
- We may not realize the contemplated or expected benefits from collaborative or other arrangements.
- Business combinations and changes in the contractors or their business strategy may adversely affect their willingness or ability to complete their obligations to us.
- The contractor or collaborator may have the right to terminate its arrangements with us on limited or no notice and for reasons outside of our control.
- The contractor or collaborator may develop or have rights to competing products or product candidates and withdraw support or cease to perform work on our products.
- Disagreements may arise regarding breach of the arrangement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates, and 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 will be delayed.

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

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

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

The completion of clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Even though we have completed all planned Phase 3 pivotal clinical trials for MT 100 and submitted an NDA for MT 300, and even if we complete our current clinical trials for MT 400, we may be required to conduct additional clinical trials and studies to support our NDAs to the FDA. We may determine to seek to persuade the FDA to evaluate the results of a study or trial in a manner that differs from the way the FDA usually evaluates results. For example, approval of MT 300 will require positive FDA action on our request that secondary endpoints be evaluated based upon sustained response. In addition, we may have unexpected results that require us to reconsider the need for certain studies or trials. For example, results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies. Once submitted, an NDA would require FDA approval before we could distribute or commercialize the product described in the application. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA may require data in certain subpopulations, such as pediatric use, or may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver to delay such studies.

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

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

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

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

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

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

Our product candidates will have to compete with existing and any newly developed migraine therapies. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. Our primary competitors will likely include large pharmaceutical companies, biotechnology companies, universities and public and private research institutions. We face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. These competitors, either alone or with collaborative parties, may succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do. Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

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

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

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

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

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

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

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

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. As a result of such litigation, our patent claims may be found to be invalid, unenforceable or not of sufficient scope to cover the activities of an alleged infringer.

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

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

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

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

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

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

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

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

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved health care product, particularly for indications for which there is no current effective treatment or for which medical care is typically not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance.

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

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

The testing and marketing of pharmaceutical products entails an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have obtained limited product liability insurance coverage only for our human clinical trials. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may fail.

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

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

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing;
- the time and cost involved in obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the effect of changes and developments in our collaborative, licensing and other relationships;
- the terms and timing of any new collaborative, licensing and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

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



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

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

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

**Item 7a. Quantitative and Qualitative Disclosures About Market Risk**

Our proceeds from our initial public offering and private placements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio. However, declines in interest rates reduced our interest income in 2002 as compared to the same period of 2001. Declines in interest rates will reduce our interest income while increases in interest rates will increase our interest income.

**Item 8. Financial Statements and Supplementary Data**

POZEN's 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 III.

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

None.

## PART III

### **Item 10. Directors and Executive Officers of the Registrant**

#### (a) Identification of Directors

Information with respect to the members of the Board of Directors of the Company is set forth under the captions “Nominee for Election as Directors for Terms of Three Years” and “Directors Continuing in Office” in the Company’s definitive proxy statement to be filed pursuant to Regulation 14A, which information is incorporated herein by reference.

#### (b) Identification of Executive Officers

Information with respect to the executive officers of the Company 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.

#### (c) Section 16(a) Beneficial Ownership Reporting Compliance.

Information with respect to the Section 16(a) compliance of the directors and executive officers of the Company is set forth under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in the Company’s definitive proxy statement to be filed pursuant to Regulation 14A, which information is incorporated herein by reference.

### **Item 11. Executive Compensation**

Information required by this Item is set forth under the caption “Executive and Director Compensation” in the Company’s definitive proxy statement to be filed pursuant to Regulation 14A, which information is incorporated herein by reference.

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

Information required by this Item is set forth under the captions “Principal Stockholders” and “Stock Ownership of Directors, Nominees for Director, and Executive Officers” in the Company’s definitive proxy statement to be filed pursuant to Regulation 14A, which information is incorporated herein by reference.

The following table provides information with respect to compensation plans under which equity compensation is authorized at December 31, 2002.

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans</b>
Equity compensation plans approved by security holders	2,428,796	\$ 4.99	1,559,623
Equity compensation plans not approved by security holders	—	—	—
Total	2,428,796	\$ 4.99	1,559,623

### **Item 13. Certain Relationships and Related Transactions**

None.

### **Item 14. Controls and Procedures**

An evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 27, 2003 was carried out by the Company under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures have been designed and are being operated in a manner that provides reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. 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. Subsequent to the date of the most recent evaluation of the Company's internal controls, there were no significant changes in the Company's internal controls or in other factors that could significantly affect the internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

### **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:

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##### **2. Financial Statement Schedules**

Not applicable.

##### **3. List of Exhibits**

See below for a list of the exhibits incorporated by reference herein or filed herewith.

#### **(b) Reports on Form 8-K.**

None.

#### **(c) Exhibits Required by Item 601 of Regulation S-K.**

The exhibits filed as a part of this Form 10-K are listed on the Exhibit Index immediately preceding such Exhibits and include both exhibits submitted with this Report as filed with the Securities and Exchange Commission and those incorporated by reference to other filings.

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant. *
3.2	Amended and Restated Bylaws of the Registrant. *
4.1	See Exhibits 3.1 and 3.2 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 of the Registrant.
10.1	Sublease Agreement between Quintiles, Inc. and the Registrant, dated April 7, 1997. *
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. *
10.5	Investor Rights Agreement dated July 28, 1999 between the Registrant and the holders of the Series D Preferred Stock. *
10.6	Investor Rights Agreement dated March 24, 2000 between the Registrant and the holders of the Series E Preferred Stock. *
10.7	2000 Equity Compensation Plan of the Registrant*
10.8	Investor Rights Agreement dated August 28, 2000 between the Registrant and the holders of the Series F Preferred Stock. *
10.9	Supply Agreement dated January 17, 2001 by and between the Registrant and Catalytica Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Company's Form 10-Q filed May 14, 2001).
10.10	Amended and Restated Executive Employment Agreement with John R. Plachetka dated July 25, 2001 (filed as Exhibit 10.1 to the Company's Form 10-Q filed October 31, 2001). ***
10.11	Executive Employment Agreement with Andrew L. Finn dated July 25, 2001 (filed as Exhibit 10.2 to the Company'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 Company's Form 10-Q filed October 31, 2001). ***
10.13	Executive Employment Agreement with Matthew E. Czajkowski dated July 25, 2001 (filed as Exhibit 10.4 to the Company's Form 10-Q filed October 31, 2001). ***
10.14	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Company's Form 10-Q filed October 31, 2001). ***
10.15	POZEN Inc. 2001 Long Term Incentive Plan (adopted by Board of Directors, subject to stockholder approval) (filed as Exhibit 10.6 to the Company's Form 10-Q filed October 31, 2001).
10.16	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (granted subject to stockholder approval of the Plan) (filed as Exhibit 10.7 to the Company's Form 10-Q filed October 31, 2001). ***
10.17	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.2 to the Company's Form 10-K filed April 1, 2002). †
10.18	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Company's Form 10-K filed April 1, 2002).

10.19	First Amendment of 2000 Equity Compensation Plan.**
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
99.1	Certifications by the Chief Executive Officer and Chief Financial Officer Relating to a Periodic Report Containing Financial Statements.**

\* Incorporated by reference to the same-numbered exhibit of the Company's Registration statement on Form S-1, No. 333-35930.

\*\* Filed herewith.

\*\*\* Compensation Related Contract.

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

## **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 28, 2003

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.

<b><u>Signature</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
<u>/s/ John R. Plachetka</u> John R. Plachetka	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 28, 2003
<u>/s/ Matthew E. Czajkowski</u> Matthew E. Czajkowski	Senior Vice President, Finance and Administration, and Chief Financial Officer (Principal Financial Officer)	March 28, 2003
<u>/s/ John E. Barnhardt</u> John E. Barnhardt	Vice President, Finance and Administration (Principal Accounting Officer)	March 28, 2003
<u>/s/ Kenneth B. Lee, Jr.</u> Kenneth B. Lee Jr.	Director	March 28, 2003
<u>/s/ Jacques F. Rejeange</u> Jacques F. Rejeange	Director	March 28, 2003
<u>/s/ Paul J. Rizzo</u> Paul J. Rizzo	Director	March 28, 2003
<u>/s/ Bruce A. Tomason</u> Bruce A. Tomason	Director	March 28, 2003
<u>/s/ Peter J. Wise</u> Peter J. Wise	Director	March 28, 2003
<u>/s/ Ted G. Wood</u> Ted G. Wood	Director	March 28, 2003

## **CERTIFICATIONS**

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

1. I have reviewed this annual report on Form 10-K of POZEN Inc.;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures 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 annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ John R. Plachetka

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



I, Matthew E. Czajkowski, certify that:

1. I have reviewed this annual report on Form 10-K of POZEN Inc.;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures 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 annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ Matthew E. Czajkowski  
Matthew E. Czajkowski  
Chief Financial Officer

AUDITED FINANCIAL STATEMENTS

POZEN INC.

*(A Development Stage Company)*

*Years ended December 31, 2002, 2001 and 2000 and the period from September 25, 1996  
(inception) through December 31, 2002 with Report of Independent Auditors*

POZEN Inc.  
*(A Development Stage Company)*

Audited Financial Statements

Years ended December 31, 2002, 2001 and 2000 and the  
period from September 25, 1996 (inception) through December 31, 2002

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## Report of Independent Auditors

The Board of Directors  
POZEN Inc.

We have audited the accompanying balance sheets of POZEN Inc. (a development stage company) as of December 31, 2002 and 2001, and the related statements of operations, stockholders' equity and cash flows for each of the three years ended December 31, 2002 and for the period from September 25, 1996 (inception) through December 31, 2002. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audits 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. (a development stage company) at December 31, 2002 and 2001 and the results of its operations and its cash flows for each of the three years ended December 31, 2002 and for the period from September 25, 1996 (inception) through December 31, 2002 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Raleigh, North Carolina  
January 17, 2003

POZEN Inc.  
(A Development Stage Company)

Balance Sheets

	<b>December 31,</b>	
	<b>2002</b>	<b>2001</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 50,056,251	\$ 73,958,724
Prepaid expenses and other current assets	553,371	76,186
Total current assets	50,609,622	74,034,910
 Furniture and fixtures, net of accumulated depreciation	 425,369	 109,014
<b>Total assets</b>	<b>\$ 51,034,991</b>	<b>\$ 74,143,924</b>
 <b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 179,374	\$ 194,138
Accrued expenses	1,657,074	3,328,881
Total current liabilities	1,836,448	3,523,019
 Stockholders' equity:		
Common stock, \$0.001 par value, 90,000,000 shares authorized and issued and 28,147,039 and 27,969,435 shares outstanding, at December 31, 2002 and 2001, respectively	 28,147 144,036,491	 27,969 143,512,559
Additional paid-in capital	—	310,808
Common stock warrants	(510,130)	(3,429,376)
Deferred compensation	(94,355,965)	(69,801,055)
Deficit accumulated during the development stage	49,198,543	70,620,905
Total stockholders' equity	49,198,543	70,620,905
<b>Total liabilities and stockholders' equity</b>	<b>\$ 51,034,991</b>	<b>\$ 74,143,924</b>

*See accompanying notes.*

POZEN Inc.  
(A Development Stage Company)

Statements of Operations

	Year ended December 31,			Period from September 26, 1996 (inception) through December 31,
	2002	2001	2000	2002
Operating expenses:				
General and administrative	\$ 6,833,336	\$ 6,455,164	\$ 4,822,102	\$ 23,015,527
Research and development	18,761,630	18,627,249	19,398,904	76,936,882
Total operating expenses	25,594,966	25,082,413	24,221,006	99,952,409
Interest income net	1,040,056	3,379,905	1,844,378	6,530,922
Net loss	(24,554,910)	(21,702,508)	(22,376,628)	(93,421,487)
Non-cash preferred stock charge	—	—	27,617,105	27,617,105
Preferred stock dividends	—	—	934,478	934,478
Loss attributable to common stockholders	\$ (24,554,910)	\$ (21,702,508)	\$ (50,928,211)	\$ (121,973,070)
Basic and diluted net loss per common share	\$ (0.87)	\$ (0.78)	\$ (4.95)	
Shares used in computing basic and diluted net loss per common share	28,110,352	27,954,697	10,293,605	
Pro forma net loss per common share – basic and diluted			\$ (2.56)	
Pro forma weighted average common shares outstanding – basic and diluted			19,915,147	

See accompanying notes.

POZEN Inc.  
(A Development Stage Company)  
Statements of Stockholders' Equity

	Date of Transaction	Series A Preferred Stock	Series B Preferred Stock	Series C Preferred Stock	Series D Preferred Stock	Common Stock
Issuance of 5,814,190 shares of common stock at \$0.001 per share	September 1996	—	—	—	—	5,814
Issuance of 2,105,931 shares of Series A preferred stock at \$3.15 per share	December 1996	2,106	—	—	—	—
Issuance of 78,776 shares of Series A preferred stock warrants for financing activities	December 1996	—	—	—	—	—
Deferred compensation		—	—	—	—	—
Amortization of deferred compensation		—	—	—	—	—
Net loss		—	—	—	—	—
Balance at December 31, 1996		2,106	—	—	—	5,814
Proceeds from stockholders' receivable		—	—	—	—	—
Issuance of 1,135,000 shares of Series B preferred stock at \$4.00 per share	December 1997	—	1,135	—	—	—
Issuance of 36,450 shares of Series B preferred stock warrants for financing activities		—	—	—	—	—
Deferred compensation		—	—	—	—	—
Amortization of deferred compensation		—	—	—	—	—
Net loss		—	—	—	—	—
Balance at December 31, 1997		2,106	1,135	—	—	5,814
Issuance of 4,377 shares of Series C preferred stock at \$4.00 per share	March 1998	—	4	—	—	—
Issuance of 563,044 shares of Series C preferred stock at \$4.05 per share	March 1998	—	—	563	—	—
Exercise of 29,977 stock options at \$0.19 per share		—	—	—	—	30
Issuance of 8,884 shares of Series C preferred stock warrants for financing activities	March 1998	—	—	—	—	—
Deferred compensation		—	—	—	—	—
Amortization of deferred compensation		—	—	—	—	—
Net loss		—	—	—	—	—
Balance at December 31, 1998		2,106	1,139	563	—	5,844
Issuance of 2,593,750 shares of Series D preferred stock at \$4.80 per share	July and Sept. 1999	—	—	—	2,594	—
Exercise of 3,373 stock options at \$0.19 per share		—	—	—	—	4
Deferred compensation		—	—	—	—	—
Amortization of deferred compensation		—	—	—	—	—
Issuance of 200,000 shares of Series D preferred stock warrants for financing activities	July and Sept. 1999	—	—	—	—	—
Net loss		—	—	—	—	—
Balance at December 31, 1999		2,106	1,139	563	2,594	5,848
Exercise of common stock options		—	—	—	—	208
Deferred compensation		—	—	—	—	—
Amortization of deferred compensation		—	—	—	—	—
Preferred stock dividends		—	—	—	—	—
Conversion of preferred stock into common stock		(2,106)	(1,139)	(563)	(2,594)	15,488
Proceeds from sale of common stock in initial public offering, net of offering costs		—	—	—	—	5,000
Proceeds from sale of common stock		—	—	—	—	750
Exercise of common stock warrants		—	—	—	—	369
Dividends		—	—	—	—	69
Net loss		—	—	—	—	—
Balance at December 31, 2000		—	—	—	—	27,732
Adjustment to deferred compensation for forfeiture of common stock options		—	—	—	—	—
Exercise of common stock options		—	—	—	—	187
Amortization of deferred compensation		—	—	—	—	—
Exercise of common stock warrants		—	—	—	—	50
Net loss		—	—	—	—	—
Balance at December 31, 2001		—	—	—	—	27,969
Adjustment to deferred compensation for forfeiture of common stock options		—	—	—	—	—
Exercise of common stock options		—	—	—	—	159
Amortization of deferred compensation		—	—	—	—	—
Exercise and forfeiture of common stock warrants		—	—	—	—	19
Net loss		—	—	—	—	—
Balance at December 31, 2002		—	—	—	—	28,147

POZEN Inc.  
*(A Development Stage Company)*  
Statements of Stockholders' Equity (continued)

Additional Paid-In Capital	Common Stock Warrants	Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
\$ (1,504)	\$ —	\$ (4,310)	\$ —	\$ —	\$ —
6,231,314	—	(1,000,000)	—	—	5,233,420
—	242,000	—	—	—	242,000
190,385	—	—	(190,385)	—	—
—	—	—	28,267	—	28,267
—	—	—	—	(101,334)	(101,334)
6,420,195	242,000	(1,004,310)	(162,118)	(101,334)	5,402,353
—	—	1,004,310	—	—	1,004,310
4,195,865	—	—	—	—	4,197,000
—	139,000	—	—	—	139,000
1,001,629	—	—	(1,001,629)	—	—
—	—	—	214,272	—	214,272
—	—	—	—	(3,803,030)	(3,803,030)
11,617,689	381,000	—	(949,475)	(3,904,364)	7,153,905
17,508	—	—	—	—	17,512
2,170,250	—	—	—	—	2,170,813
5,525	—	—	—	—	5,555
—	35,000	—	—	—	35,000
362,489	—	—	(362,489)	—	—
—	—	—	401,468	—	401,468
—	—	—	—	(8,737,631)	(8,737,631)
14,173,461	416,000	—	(910,496)	(12,641,995)	1,046,622
11,522,406	—	—	—	—	11,525,000
621	—	—	—	—	625
3,045,666	—	—	(3,045,666)	—	—
—	—	—	612,909	—	612,909
—	925,000	—	—	—	925,000
—	—	—	—	(12,145,446)	(12,145,446)
28,742,154	1,341,000	—	(3,343,253)	(24,787,441)	1,964,710
74,861	—	—	—	—	75,069
6,328,492	—	—	(6,328,492)	—	—
—	—	—	3,054,286	—	3,054,286
—	—	—	—	(934,478)	(934,478)
27,347,019	—	—	—	—	27,356,105
67,798,052	—	—	—	—	67,803,052
10,461,750	—	—	—	—	10,462,500
1,805,682	(914,952)	—	—	—	891,099
772,114	—	—	—	—	772,183
—	—	—	—	(22,376,628)	(22,376,628)
143,330,124	426,048	—	(6,617,459)	(48,098,547)	89,067,898
(42,213)	—	—	42,213	—	—
109,408	—	—	—	—	109,595
—	—	—	3,145,870	—	3,145,870
115,240	(115,240)	—	—	—	50
—	—	—	—	(21,702,508)	(21,702,508)
143,512,559	310,808	—	(3,429,376)	(69,801,055)	70,620,905
(11,167)	—	—	11,167	—	—
224,291	—	—	—	—	224,450
—	—	—	2,908,079	—	2,908,079
310,808	(310,808)	—	—	—	19
—	—	—	—	(24,554,910)	(24,554,910)
\$144,036,491	\$ —	\$ —	\$ (510,130)	\$ (94,355,965)	\$ 49,198,543



POZEN Inc.  
(A Development Stage Company)  
Statements of Cash Flows

	Year ended December 31,			Period from September 26, 1996 (inception) through December 31, 2002
	2002	2001	2000	
<b>Operating activities</b>				
Net loss	\$ (24,554,910)	\$ (21,702,508)	\$ (22,376,628)	\$ (93,421,487)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	113,513	115,640	58,083	395,769
Loss on disposal of equipment	2,726	24,769	—	27,495
Amortization of deferred compensation	2,908,079	3,145,870	3,054,286	10,365,151
Noncash financing charge	—	—	—	450,000
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(477,185)	244,209	(276,825)	(553,371)
Accounts payable and accrued expenses	(1,686,571)	(238,841)	1,401,563	1,836,448
Net cash used in operating activities	(23,694,348)	(18,410,861)	(18,139,521)	(80,899,995)
<b>Investment activities</b>				
Purchase of equipment	(432,594)	(90,643)	(106,512)	(848,633)
Net cash used in investing activities	(432,594)	(90,643)	(106,512)	(848,633)
<b>Financing activities</b>				
Proceeds from issuance of preferred stock	—	—	27,617,105	48,651,850
Proceeds from issuance of common stock	224,469	109,645	78,970,720	79,311,014
Proceeds from stockholders' receivables	—	—	—	1,004,310
Proceeds from notes payable	—	—	—	3,000,000
Payment of dividend	—	—	(162,295)	(162,295)
Net cash provided by financing activities	224,469	109,645	106,425,530	131,804,879
Net (decrease) increase in cash and cash equivalents	(23,902,473)	(18,391,859)	88,179,497	50,056,251
Cash and cash equivalents at beginning of period	73,958,724	92,350,583	4,171,086	—
Cash and cash equivalents at end of period	\$ 50,056,251	\$ 73,958,724	\$ 92,350,583	\$ 50,056,251
<b>Supplemental schedule of cash flow information</b>				
Cash paid for interest	\$ 2,106	\$ 2,162	\$ 5,772	\$ 190,790
<b>Supplemental schedule of noncash investing and financing activities</b>				
Conversion of notes payable to preferred stock	\$ —	\$ —	\$ —	\$ 3,000,000
Preferred stock dividend	\$ —	\$ —	\$ 772,183	\$ 772,183
Forfeiture of common stock options	\$ 11,167	\$ 42,213	\$ —	\$ 53,380
Conversion of common stock warrants to common stock	\$ 49,809	\$ 115,240	\$ 914,952	\$ 1,080,001
Forfeiture of common stock warrants	\$ 260,999	\$ —	\$ —	\$ 260,999

See accompanying notes.

POZEN Inc.  
(A Development Stage Company)

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 development company committed to building a portfolio of product candidates with significant commercial potential. The Company's initial focus is the multi-billion dollar global migraine market. In addition, the Company intends to leverage its pharmaceutical product development expertise by acquiring or in-licensing and developing commercially attractive products in therapeutic areas outside of migraine.

MT 100 is being developed as an oral, first-line treatment for migraine pain and associated symptoms. The Company completed all planned Phase 3 pivotal clinical trials for MT 100, which consistently demonstrated MT 100's effectiveness in treating migraine pain. In October 2002, POZEN submitted a Marketing Authorization Application ("MAA") to the Medicines Control Agency ("MCA") in the United Kingdom for MT 100. If approved in the U.K., POZEN will seek approval in selected European countries through the European Union Mutual Recognition Procedure. The Company plans to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for MT 100 in mid-2003, and complete the NDA submission by submitting final carcinogenicity data in early 2004.

MT 300, a proprietary formulation of dihydroergotamine mesylate ("DHE") packaged in a pre-filled syringe, is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine attacks. POZEN has completed all planned Phase 3 pivotal clinical trials for MT 300, which consistently demonstrated MT 300's effectiveness in treating migraine pain. In December 2002, the Company submitted an NDA to the FDA for MT 300.

MT 400 is being developed as a co-active acute migraine therapy, combining the activity of a triptan with that of a long-lasting non-steroidal anti-inflammatory drug. The Company has completed a 972-patient Phase 2 clinical trial in which MT 400 showed statistically significant superiority over placebo and its components, including an oral triptan, on the identified primary and secondary outcome measures.

### *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.

### *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 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 furniture and fixtures and is recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets ranging from five to seven years.

### *Research and Development Costs*

Research and development costs are charged to operations as incurred.

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**1. Significant Accounting Policies (continued)**

***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", for all periods presented.

In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding during the period.

The following table presents the calculation of basic and diluted net loss per common share for the years ended December 31:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net loss attributable to common stockholders	\$ (24,554,910)	\$ (21,702,508)	\$ (50,928,211)
Basic and diluted:			
Weighted-average shares used in computing basic and diluted net loss per common share	<u>28,110,352</u>	<u>27,954,697</u>	<u>10,293,605</u>
Basic and diluted net loss per common share	<u>\$ (0.87)</u>	<u>\$ (0.78)</u>	<u>\$ (4.95)</u>

The Company's preferred stock and related warrants converted into common stock and common stock warrants upon the closing of the Company's initial public offering in October 2000. For informational purposes, the following pro forma net loss per share data reflect the assumed conversion of the Company's preferred stock into common stock at the later of issuance of the preferred stock during, or at the beginning of, each of the years ended December 31:

	<u>2000</u>
Pro forma:	
Shares used above	10,293,605
Pro forma adjustment to reflect weighted-average effect of assumed conversion of preferred stock	<u>9,621,542</u>
Total weighted-average shares of common stock outstanding pro forma	<u>19,915,147</u>
Basic and diluted proforma net loss per share	<u>\$ (2.56)</u>

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**1. Significant Accounting Policies (continued)**

***Stock-Based Compensation***

The Company accounts for stock options issued to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Under APB 25, no compensation expense is recognized for stock or stock options issued with an exercise price equivalent to the fair value of the Company's common stock. Stock options and other equity instruments granted or issued to consultants and others who are not employees or directors are accounted for in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). For companies that continue to account for stock-based compensation arrangements under APB 25, SFAS 123 requires disclosure of the pro forma effect on net income (loss) as if the fair value-based method prescribed by SFAS 123 had been applied. The Company has adopted the pro forma disclosure requirements of SFAS 123, as amended.

For periods following the Company's initial public offering, the "Black-Scholes" method was used to calculate the fair value of options granted. This method includes the assumptions discussed in Note 6, as well as the estimated volatility of the Company's common stock.

The minimum value option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. In December 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure", an amendment of FASB Statement No. 123 ("SFAS 148"). This statement amends SFAS 123 to provide alternative methods of transition for a voluntary change to the fair value basis method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reporting results (see below). This standard is effective for us beginning with these financial statements and we have adopted its provisions herein.

Had compensation costs for our stock options been determined based upon the fair value at the date of grant consistent with the provisions of SFAS 123, our pro forma net loss and net loss per share would have been as follows:

	Year Ended December 31,		
	2002	2001	2000
Net loss attributable to common stockholders as reported	\$24,554,910	\$21,702,508	\$50,928,211
Net loss attributable to common stockholders, SFAS 123 pro forma	\$24,620,101	\$22,761,596	\$50,947,683
Net loss per common share as reported	\$ (0.87)	\$ (0.78)	\$ (4.95)
Net loss per common share, SFAS 123 pro forma	\$ (0.88)	\$ (0.81)	\$ (4.95)

### ***Recently Issued Accounting Pronouncements***

In April 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)" ("Issue 94-3"). SFAS 146 addresses the accounting and reporting for costs associated with exit or disposal activities resulting from entities increasingly engaging in exit and disposal activities where certain costs associated with those activities were recognized as liabilities at a plan (commitment) date under Issue 94-3 but did not meet the definition of a liability in FASB Concepts Statement No. 6, "Elements of Financial Statements." The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS 146 to have a material impact on our results of operations or financial position.

In December 2002, the FASB issued SFAS 148. SFAS 148 amends SFAS 123 to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure provisions of SFAS 123 to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS 148 does not amend SFAS 123 to require companies to account for their employee stock-based awards using the fair value method. However, the disclosure provisions are required for all companies with stock-based employee compensation, regardless of whether they utilize the fair method of accounting described in SFAS 123 or the intrinsic value method described in APB 25.

SFAS 148's amendments of the transition and annual disclosure provisions of SFAS 123 are effective for fiscal years ending after December 15, 2002, with earlier application permitted for entities with fiscal years ending prior to December 15, 2002, provided that financial statements for the 2002 fiscal year were not issued prior to the issuance of Statement 148 (December 31, 2002). The disclosure requirements for interim financial statements containing condensed consolidated financial statements are effective for interim periods beginning after December 15, 2002. The adoption of SFAS 148 had no material impact on our results of operations or financial position.

### ***Reclassifications***

Certain 2001 financial statement amounts have been reclassified to conform with 2002 presentation. These reclassifications had no effect on stockholders' equity as previously reported.

## **2. Stockholders' Equity**

The Company completed five private placement offerings of its stock as shown in the table set forth below. In connection with four of these offerings, the Company issued warrants to certain key advisors for their services related to the offering. The warrants entitled the warrantee to purchase shares of the related series of convertible preferred stock at a purchase price of \$0.001 per share, except that the warrants to purchase Series D Convertible Preferred Stock were issued at a purchase price of \$3.15 per share. The warrants have been accounted for as offering costs related to the convertible preferred stock issuances at values calculated under the "Black-Scholes" formula.

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

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

## 2. Stockholders Equity (continued)

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 (the "Offering") in October 2000.

In November 2000, common stock warrants valued at \$925,000 were exercised for 269,800 shares of common stock and, in December 2000, common stock warrants valued at \$250,952 were exercised for 99,424 shares of common stock.

On August 28, 2000 and September 14, 2000, the Board of Directors and the stockholders of the Company approved a 1.349-for-1 common stock split to be effective prior to the effectiveness of the Offering. An amendment to the Company's Certificate of Incorporation effecting the stock split was filed with the State of Delaware on October 6, 2000. All common share and per common share amounts for all periods presented in the accompanying financial statements reflect the effect of this common stock split.

In March 2001, common stock warrants valued at \$21,995 were exercised for 9,659 shares of common stock and, in May 2001, common stock warrants valued at \$93,244 were exercised for 39,726 shares of common stock. In July 2002, common stock warrants valued at \$46,505 were exercised for 18,617 shares of common stock and in October 2002, common stock warrants valued at \$260,999 were forfeited.

### *Shares Reserved for Future Issuance*

At December 31, 2002, shares of common stock reserved for future issuance are as follows:

Shares available for grant under stock option plans	1,559,623
Shares issuable pursuant to options granted under stock option plans	2,428,796
Total reserved	<u>3,988,419</u>

## 3. 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 warrants have been accounted for as offering costs related to the issuance of Series E at a value calculated under the "Black Scholes" formula at approximately \$261,000. During 2002, the warrants expired and the reduction of value of the warrants was recorded as additional paid-in capital.

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**3. Redeemable Preferred Stock (continued)**

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 Series F and related Series E warrants 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.

**4. Accrued Expenses**

Accrued expenses consist of the following at December 31:

	2002	2001
Clinical trial contract costs	\$ 634,831	\$ 2,348,663
Compensation costs	931,454	563,891
Other	90,789	416,327
	<u>\$ 1,657,074</u>	<u>\$ 3,328,881</u>

**5. Income Taxes**

At December 31, 2002 and 2001, the Company had federal and state net operating loss carryforwards of approximately \$78.3 million and \$57.6 million, respectively, for income tax purposes. At December 31, 2002 and 2001, the Company had research and development credit carryforwards of approximately \$4.5 million and \$3.7 million, respectively. The federal and state net operating loss carryforwards and 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.

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**5. Income Taxes (continued)**

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:

	2002	2001
Deferred tax assets:		
Net operating loss carryforward	\$ 31,197,000	\$ 23,043,000
Research and development credits	4,483,000	3,715,000
Depreciation	44,000	–
Other	2,000	3,000
Total deferred tax assets	35,726,000	26,761,000
Valuation allowance	(35,726,000)	(26,761,000)
Net deferred tax asset	\$ –	\$ –

The amount of the valuation allowance increased by \$8,965,000 and \$8,659,000 as of December 31, 2002 and 2001, respectively.

**6. 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 Plan include executive and key employees of the Company. The vesting periods range from immediate vesting at issuance to three 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 stockholders 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 became effective upon the completion of the Company's initial public offering in October 2000 and provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units and other stock-based awards to our employees, non-employee directors, advisors, and consultants. The Plan authorizes up to 3,000,000 shares of our 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. 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.



POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**6. Stock Option Plan (continued)**

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

	<b>Number of Shares</b>	<b>Weighted- Average Exercise Price</b>
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

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**6. Stock Option Plan (continued)**

The options outstanding and exercisable at December 31, 2002 are as follows:

<b>Options Outstanding</b>		<b>Weighted-Average Remaining Contractual Life</b>	
<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>(In years)</b>	<b>Vested Options</b>
\$ 0.19	250,617	4.5	250,617
\$ 0.44	50,818	5.7	50,818
\$ 0.89	141,598	3.3	124,736
\$ 1.48	285,089	6.9	240,122
\$ 2.02	103,813	8.1	48,054
\$ 3.40	76,893	7.4	51,262
\$ 3.74	47,215	7.6	18,886
\$ 4.25	32,376	7.8	21,584
\$ 4.30	10,000	9.6	—
\$ 4.53-4.81	204,000	8.9	200,000
\$ 5.15-5.20	447,453	9.0	—
\$ 5.71-5.90	32,000	9.0	5,000
\$ 6.60-6.75	302,639	8.3	75,660
\$ 7.35-7.38	25,000	8.2	6,250
\$ 8.50	80,000	8.2	20,000
\$ 9.84	15,000	8.6	3,750
\$10.89	65,000	8.5	16,250
\$12.50	20,000	8.0	10,000
\$13.19	189,285	8.0	47,321
\$14.16	50,000	8.0	12,500
	2,428,796		1,202,810

The following tables summarize, for the years indicated, the fair value and the weighted average exercise price of options granted. The option grant information has been summarized by (1) grants with an exercise price equal to the stock price on the date of the option grant and (2) grants with an exercise price below the stock price on the date of the option grant.

<b>Type of Option</b>	<b>Fair Value</b>			<b>Weighted-Average Exercise Price</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
Stock price = exercise price	\$ 4.30 to \$ 5.71	\$ 5.90 to \$ 14.16	\$12.50	\$ 5.08	\$ 9.45	\$ 12.50
Stock price > exercise price	—	—	\$20.23 to \$22.48	—	—	\$ 2.36

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**6. Stock Option Plan (continued)**

The Company has elected to follow APB 25 and related interpretations in accounting for its employee stock options because, as discussed above, the alternative fair value accounting provided for under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options.

During the year ended December 31, 2000 in connection with the grant of certain share options to employees, the Company recorded deferred compensation of \$6,328,492 representing the excess of the fair value of the common stock on the date of grant over the exercise price. No such compensation was recorded in 2002 or 2001, as all stock options were issued with an exercise price equal to fair market value. Deferred compensation is included as a reduction of stockholders' equity and is being amortized to expense according to the vesting method. During the years ended December 31, 2002, 2001 and 2000 and from September 26, 1996 (inception) through December 31, 2002, the Company recorded amortization of deferred compensation of \$2,908,080, \$3,145,870, \$3,054,286 and \$10,365,152, respectively.

Pro forma net loss information 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 market 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:

	2002	2001	2000
Expected dividend yield	0%	0%	0%
Risk-free interest rate range	1.73%-4.26%	3.5%-5.0%	5.3% - 6.6%
Expected life	10 years	10 years	10 years
Expected volatility	1.08	1.38	0.00

**7. 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 \$230,000, \$146,000, \$123,000 and \$912,000 for the years ended December 31, 2002, 2001 and 2000 and for the period September 25, 1996 (inception) through December 31, 2002, respectively. The following is a schedule of future minimum lease payments for operating leases at December 31, 2002:

2003	\$ 183,096
2004	369,747
2005	377,486
2006	385,311
2007	393,418
2008-10	880,868
	\$ 2,589,926

POZEN Inc.  
*(A Development Stage Company)*

Notes to Financial Statements (continued)

**8. License Agreement**

In January 2001, the Company entered into a Commercial Supply Agreement with DMS Pharmaceuticals, Inc. under which DMS will supply the Company with all MT 100 for commercial sale. The Company, or its commercial partner, is required to purchase all commercial supply of MT 100 from DMS for the initial term of the agreement and any extension thereof, unless DMS is unable to meet the Company's, or its commercial partner's, requirement. The Company has the right to terminate the agreement under certain circumstances after the third anniversary of first commercial sale of MT 100 following NDA approval.

In October 2001, the Company entered into a Commercial Supply Agreement with Lek Pharmaceuticals Inc., a subsidiary of Novartis Pharma AG, under which Lek has agreed to provide the Company on an exclusive basis with DHE, which the Company will formulate as MT 300. The Company agreed to purchase DHE exclusively from Lek, which exclusivity is dependent upon Lek's ability to meet the Company's supply requirements and certain other conditions. Lek will supply to the Company solely and exclusively, under certain circumstances. The Company will pay Lek a fee in addition to the agreed supply price for DHE, based on a percentage of MT 300 sales revenue. Either party may cancel the agreement under certain conditions. In addition, Lek may terminate the agreement after a certain period of time if Lek decides to permanently cease the manufacture of DHE.

**9. Retirement Savings Plan**

In July 1997, the Company began a defined contribution 401(k) pension 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, 2002 and 2001, and for the period September 25, 1996 (inception) through December 31, 2002, the Company made contributions of \$118,718, \$92,277 and \$210,995, respectively, to the Plan.

**10. Legal Proceedings**

The Company is not a party to any material legal proceedings.

POZEN Inc.  
(A Development Stage Company)

Notes to Financial Statements (continued)

**11. Summary of Operations by Quarters (Unaudited)**

	<b>2002</b>			
	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>
Operating expenses	\$ 7,336,945	\$ 6,906,686	\$ 5,478,910	\$ 5,872,425
Net loss	(7,020,273)	(6,624,749)	(5,233,928)	(5,675,960)
Net loss per share of common stock Basic and diluted	\$ (0.25)	\$ (0.24)	\$ (0.19)	\$ (0.20)
Number of shares used in per share calculation Basic and diluted	28,038,315	28,077,945	28,100,495	28,131,485
<b>2001</b>				
	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>
Operating expenses	\$ 5,759,152	\$ 5,381,743	\$ 5,524,444	\$ 8,417,074
Net loss	(4,533,460)	(4,408,918)	(4,805,986)	(7,954,144)
Net loss per share of common stock Basic and diluted	\$ (0.16)	\$ (0.16)	\$ (0.17)	\$ (0.28)
Number of shares used in per share calculation Basic and diluted	27,838,577	27,915,699	27,964,435	27,969,327

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

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant. *
3.2	Amended and Restated Bylaws of the Registrant. *
4.1	See Exhibits 3.1 and 3.2 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 of the Registrant.
10.20	Sublease Agreement between Quintiles, Inc. and the Registrant, dated April 7, 1997. *
10.21	Stock Option Plan of the Registrant. *
10.22	First Amendment to Stock Option Plan dated February 14, 1997. *
10.23	License Agreement dated September 24, 1999 between the Registrant and F. Hoffman-La Roche Ltd. *
10.24	Investor Rights Agreement dated July 28, 1999 between the Registrant and the holders of the Series D Preferred Stock. *
10.25	Investor Rights Agreement dated March 24, 2000 between the Registrant and the holders of the Series E Preferred Stock. *
10.26	2000 Equity Compensation Plan of the Registrant*
10.27	Investor Rights Agreement dated August 28, 2000 between the Registrant and the holders of the Series F Preferred Stock. *
10.28	Supply Agreement dated January 17, 2001 by and between the Registrant and Catalytica Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Company's Form 10-Q filed May 14, 2001).
10.29	Amended and Restated Executive Employment Agreement with John R. Plachetka dated July 25, 2001 (filed as Exhibit 10.1 to the Company's Form 10-Q filed October 31, 2001). ***
10.30	Executive Employment Agreement with Andrew L. Finn dated July 25, 2001 (filed as Exhibit 10.2 to the Company's Form 10-Q filed October 31, 2001). ***
10.31	Executive Employment Agreement with Kristina M. Adomonis dated July 25, 2001 (filed as Exhibit 10.3 to the Company's Form 10-Q filed October 31, 2001). ***
10.32	Executive Employment Agreement with Matthew E. Czajkowski dated July 25, 2001 (filed as Exhibit 10.4 to the Company's Form 10-Q filed October 31, 2001). ***
10.33	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Company's Form 10-Q filed October 31, 2001). ***
10.34	POZEN Inc. 2001 Long Term Incentive Plan (adopted by Board of Directors, subject to stockholder approval) (filed as Exhibit 10.6 to the Company's Form 10-Q filed October 31, 2001).
10.35	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (granted subject to stockholder approval of the Plan) (filed as Exhibit 10.7 to the Company's Form 10-Q filed October 31, 2001). ***
10.36	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.2 to the Company's Form 10-K filed April 1, 2002). †
10.37	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Company's Form 10-K filed April 1, 2002).

10.38	First Amendment of 2000 Equity Compensation Plan.**
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
99.1	Certifications by the Chief Executive Officer and Chief Financial Officer Relating to a Periodic Report Containing Financial Statements.**

\* Incorporated by reference to the same-numbered exhibit of the Company's Registration statement on Form S-1, No. 333-35930.

\*\* Filed herewith.

\*\*\* Compensation Related Contract.

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

## CORPORATE INFORMATION

### BOARD OF DIRECTORS:

**John R. Plachetka, Pharm.D.**

*Chairman, President and Chief Executive Officer*  
POZEN Inc.

**Peter J. Wise, M.D.**

*Vice Chairman*  
POZEN Inc.

**Kenneth B. Lee, Jr.**

*Independent Consultant*

**Jacques F. Rejeange**

*President*  
Florham Consulting S.A.

**Paul J. Rizzo**

*Chairman of the Board and Partner*  
Franklin Street Partners

**Bruce A. Tomason**

*Principal*  
Apollo Healthcare Partners

**Ted G. Wood**

*Vice Chairman*  
The United Company

### CORPORATE HEADQUARTERS:

POZEN Inc.  
1414 Raleigh Road  
Suite 400  
Chapel Hill, NC 27517  
919.913.1030  
[www.pozen.com](http://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 20, 2003

### STOCKHOLDERS INQUIRIES:

Stockholders and prospective investors seeking information about POZEN should visit the Company's website at [www.pozen.com](http://www.pozen.com) or contact POZEN's Investor Relations Department at 919.913.1030.

### FORWARD-LOOKING STATEMENTS:

Statements included in this annual report and 10-K 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 products; costs and delays in the development and FDA approval of our products; our inability to enter into or maintain, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of our 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 our 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 the Company's Form 10-K for the fiscal year ended December 31, 2002. The Company does not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.



28 million

**POZEN**<sup>®</sup>  
INC.

The Pharmaceutical Development Company

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