POZEN® INC.

2001 Annual Report

Our initial focus is on developing products for migraine therapy, a multi-billion dollar global market.

MARKETS

PRODUCTS

DEVELOPMENT

CORPORATE PROFILE

POZEN is 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 drugs currently in development. We have three product candidates with more than $1 billion in market potential. We plan to bring these product candidates to market through a commercial partner.

HIGHLIGHTS

PRODUCT CANDIDATE STATUS:

- All MT 100 Phase III pivotal migraine trials successfully completed
- MT 100 New Drug Application (NDA) submission planned for first-half 2003
- MT 300 final planned Phase III pivotal trial under way
- MT 300 NDA submission planned by year-end 2002
- MT 400 in Phase II

PRODUCT EFFICACY FOR TREATING MIGRAINE:

- In two Phase III clinical trials involving more than 1,500 patients, MT 100 showed comparable efficacy to market leader Imitrex® 50 mg.
- MT 100 demonstrated consistent effectiveness in treating migraine pain in all six Phase III clinical trials involving more than 7,500 patients.
- In published clinical trials, injectable dihydroergotamine (DHE), the active component of MT 300, provided comparable efficacy to injectable Imitrex® with a substantially lower incidence of cardiovascular adverse events.
- In a Phase II clinical trial involving 972 patients, MT 400 showed a therapeutic gain of more than twice a triptan, the current standard of care, with a similar side effect profile.

TO OUR SHAREHOLDERS:

When we started POZEN five years ago, it was with an eye to meeting the increasing need for mid-size, ready-to-market, innovative products. It was a need we saw increasing as small to mid-cap pharmaceutical companies matured, and larger companies merged to create mega-pharmaceutical companies. Being drug development experts, we believed that we could develop products faster and more efficiently than these other companies. So we focused on developing product candidates with estimated sales of $200 million to $600 million. We knew it was precisely this type of product that both small and large companies would need to acquire to fill the inevitable gaps that would occur in their own pipelines.

Now, after introducing five product candidates into development, securing three U.S. patents for self-invented therapeutic opportunities, conducting 63 pre-clinical studies, and 27 clinical trials involving more than 10,000 patients, this business strategy is more valid than ever. Today, we are preparing to complete the cycle for two of our product candidates by submitting New Drug Applications (NDAs) to the Food and Drug Administration (FDA) and other regulatory bodies in select markets.

Our most advanced product candidate is MT 100, an oral tablet designed for first-line acute migraine therapy. MT 100 has consistently demonstrated its effectiveness in six Phase III clinical trials. One tablet provides similar efficacy to the market leader, Imitrex® 50 mg., and two tablets provide superior sustained benefit. Importantly, MT 100 does this with less risk of cardiovascular side effects compared to the leading products.

Despite MT 100's impressive clinical profile and the lack of any carcinogenicity in the mouse study model, we have been unable to convince the FDA to consider approving it prior to the completion of the required two-year rat carcinogenicity study. However, the FDA has agreed to allow us to submit the final rat data during the NDA review process. Therefore, we plan to submit the NDA during the first-half of 2003 and submit the rat data as soon as the data is available. Overall, we remain confident that MT 100 will not only reach the marketplace, but will become first-line therapy for many patients.

Our injectable product for severe migraine attacks, MT 300, is now scheduled for NDA submission in December of this year. It will actually be the first product for which we file an NDA. We just completed the first Phase III pivotal trial and the second one is under way.

"Today, we are preparing to complete the cycle for two of our product candidates by submitting New Drug Applications to the Food and Drug Administration and other regulatory bodies in select markets."

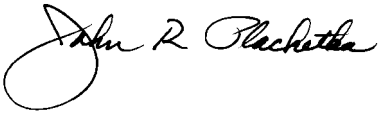
Preliminary data from the first trial indicate a low incidence of nausea and cardiovascular events, mirroring what we observed during our Phase II program. These two categories of side effects are the most commonly observed and the most disturbing with injectable migraine products on the market today.

Our third product candidate, MT 400, potentially represents the most effective oral, acute migraine therapy ever developed. This combination product, for which POZEN holds two U.S. patents, provides more than twice the therapeutic gain of triptan monotherapy. Accordingly, we are moving this product into full development during 2002 by initiating key activities in toxicology and pharmaceutical development and launching several clinical Phase II trials.

We also will be looking for products to acquire this year using our POZEN License-back™ model. The great benefit of this model has been demonstrated with MT 500, which came to us from Roche. MT 500 was intended for daily therapy to prevent migraine and is a true "new chemical entity," a first-in-class 5HT 2_B antagonist. Though we recently discovered high levels of a previously unknown metabolite during our first safety trial in humans and discontinued development, this method of securing new product opportunities substantially limited our downside risk. If this product failure had happened in a traditional discover-and-develop system, the sunk cost would have exceeded $20 million, rather than just a fraction of that amount.

All of our efforts for 2002, as they have been during each year of our existence, are focused on making POZEN products as good as they can be, both scientifically and commercially. Financially, we are well-funded for at least the next three years, and we continue to be good stewards of the cash we've raised. Our primary goal for 2002 and 2003 is to complete the cycle for our initial migraine products – finalize all development activities, file appropriate registration applications in select countries, and secure the best partners to help us commercialize what we created. As those products pass into the commercial phase, we also plan to restock our own pipeline with promising new product candidates, whether self-invented or in-licensed.

While I've enjoyed the first five years of POZEN's life immensely, I believe our most exciting days are still ahead. Thank you for your continued support.



JOHN R. PLACHETKA, PHARM.D.
Chairman, President and Chief Executive Officer

Q.

What is the potential for the migraine market?

A.

The migraine market has enormous potential for expansion:

- There are 600 million migraine attacks per year in the U.S. alone.
- Less than half of these attacks are treated with prescription drugs.
- Sales of prescription migraine drugs are $1.7 billion in the U.S.
- Global prescription sales are expected to approach $3.7 billion by 2005.

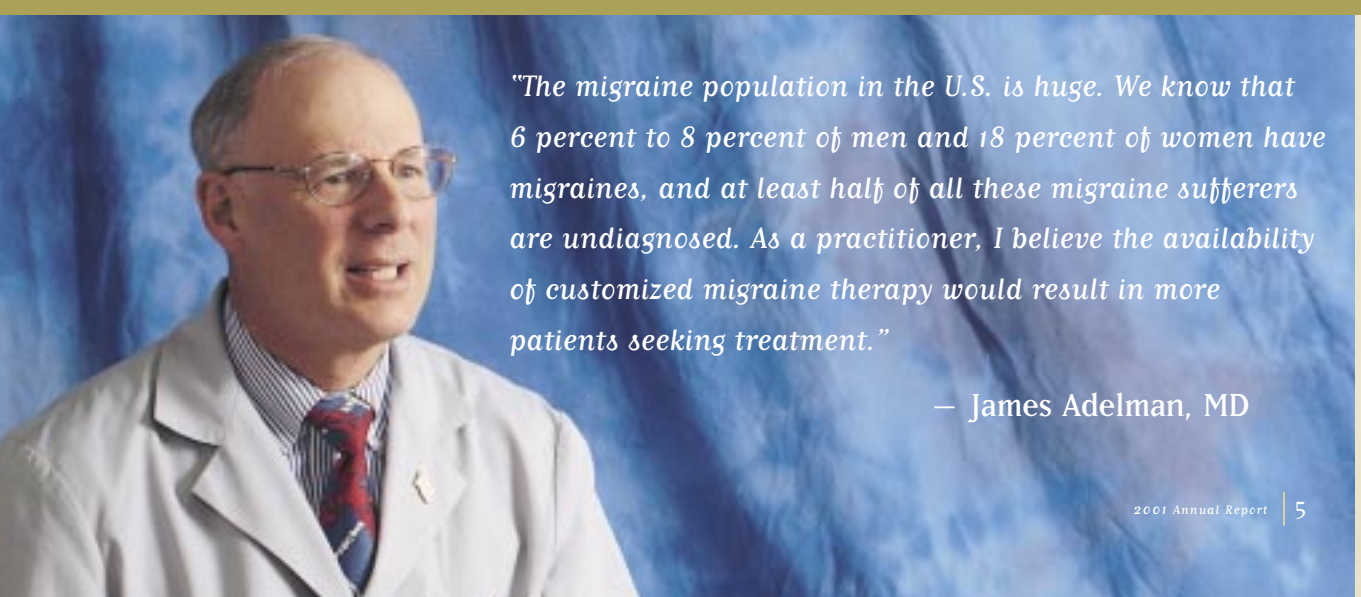
MARKETS

Migraine is characterized by recurring attacks of throbbing headache pain, usually on one side of the head, and often associated with nausea and sensitivity to light and sound. Attacks range from mild to severe and can last from 4 to 72 hours. In the most severe attacks, migraine sufferers are unable to pursue even basic daily activities.

The migraine market is enormous. Roughly 27 million Americans suffer more than 600 million attacks a year. U.S. prescription migraine product sales totaled $1.7 billion in 2001, and worldwide sales were approximately $2.5 billion. The global market is projected to reach $3.7 billion by 2005.

Unlike some other multi-billion dollar prescription markets, the migraine market is vastly underserved. Current therapeutic alternatives often lack efficacy or produce undesirable side effects. Most attacks are untreated with prescription medication. Over-the-counter medicines are generally the first step for many migraine patients, but clearly lack the power of prescription medicines and fail to provide substantive relief. The most recent class of drugs introduced into care are triptans, which are thought to work by selective vasoconstriction. Even though triptans represented a major breakthrough in migraine care, fewer than 40% of triptan patients consistently get 24-hour pain relief. Clearly, there is an enormous opportunity to fill this unmet need.

We designed our product candidates to treat the full range of migraine attacks — mild, moderate, and severe. These product candidates offer patients and physicians an opportunity to customize migraine therapy, which should encourage effective prescription treatment of more attacks and accelerate growth in the prescription migraine market. For these reasons, we believe that our current product candidates can eventually generate sales exceeding $1 billion.



"The migraine population in the U.S. is huge. We know that 6 percent to 8 percent of men and 18 percent of women have migraines, and at least half of all these migraine sufferers are undiagnosed. As a practitioner, I believe the availability of customized migraine therapy would result in more patients seeking treatment."

— James Adelman, MD

Q.

Aren't all migraine headaches the same? Why not develop just one product candidate?

A.

All migraine attacks are not the same. Patients need a variety of therapies to treat different types of attacks. We believe that we are the only company with a portfolio of well-differentiated product candidates that will allow a customized approach to migraine treatment.

PRODUCTS

We have three product candidates, each with a different therapeutic profile. This portfolio approach will allow physicians and patients the opportunity to customize their treatment for individual migraine attacks.

MT 100

MT 100 is being developed as an oral, first-line treatment for migraine pain and associated symptoms, including nausea and sensitivity to light and sound. MT 100 has a unique dual action that provides rapid and long-lasting migraine symptom relief. It is a patented product candidate composed of naproxen sodium — which relieves pain and reduces inflammation — and metoclopramide hydrochloride — which accelerates absorption of naproxen and relieves nausea.

We have completed all planned Phase III pivotal clinical trials for MT 100. The product candidate has consistently demonstrated its effectiveness in treating migraine pain and has outperformed its two components and placebo. The clinical trials involved more than 7,500 patients, and of those, approximately 3,400 received MT 100. In two trials that compared a single dose of MT 100 to the market leading triptan, Imitrex®, MT 100 showed comparable efficacy.

We believe that MT 100's expected therapeutic profile – rapid and long lasting symptom relief with easy tolerability – will make it the drug of choice for first-step prescription therapy.

PRODUCTS

We expect to submit our NDA for MT 100 to the FDA during the first half of 2003 and submit the results of an ongoing rat carcinogenicity study during the NDA review process. The final results from a 26-week study in p53 transgenic mice, a species that was genetically altered to be more susceptible to chemicals that cause cancer, indicated that MT 100 was not carcinogenic.

We plan to commercialize MT 100 through licensing arrangements with established pharmaceutical companies after product approval in the U.S. and elsewhere in the world.

MT 300

Another product candidate approaching commercialization is MT 300. This product candidate is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine, with a reduced side-effect profile compared to existing injectable products. Currently, patients often use an injectable form of a triptan or another drug such as dihydroergotamine (DHE) for severe migraine pain that fails to respond to oral medications. However, some patients are unable to tolerate the vascular side effects of an injectable triptan.

MT 300 is a proprietary formulation of injectable DHE, which is packaged in an easy-to-use pre-filled syringe.

MT 300 is approaching completion of all planned Phase III pivotal clinical trials after demonstrating significant efficacy in our Phase II placebo controlled trial. In a previously published trial, another formulation of injectable DHE provided comparable efficacy to injectable Imitrex® within three hours of administration. Only 18% of injectable DHE patients experienced headache recurrence within 24 hours compared with

"A key element of POZEN's business strategy is to license late-stage products we've developed to strong commercial partners. Because of the large number of near-term patent expiries, industry consolidation, and increased competition, I have never seen a time when the demand for ready-to-market new products has been greater than today."

– **Kristina Adomonis**
Senior Vice President,
Business Development

45% for injectable Imitrex®. In addition, acute vascular side effects were reported by only 2% of the patients receiving injectable DHE compared with 23% of the patients receiving injectable Imitrex®.

We plan to file our NDA for MT 300 by the end of 2002.

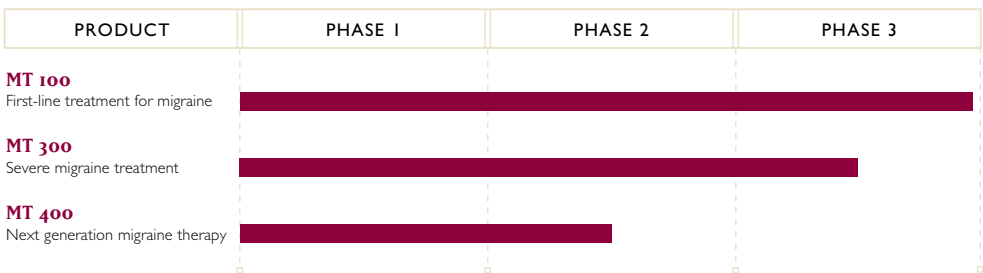
MT 400

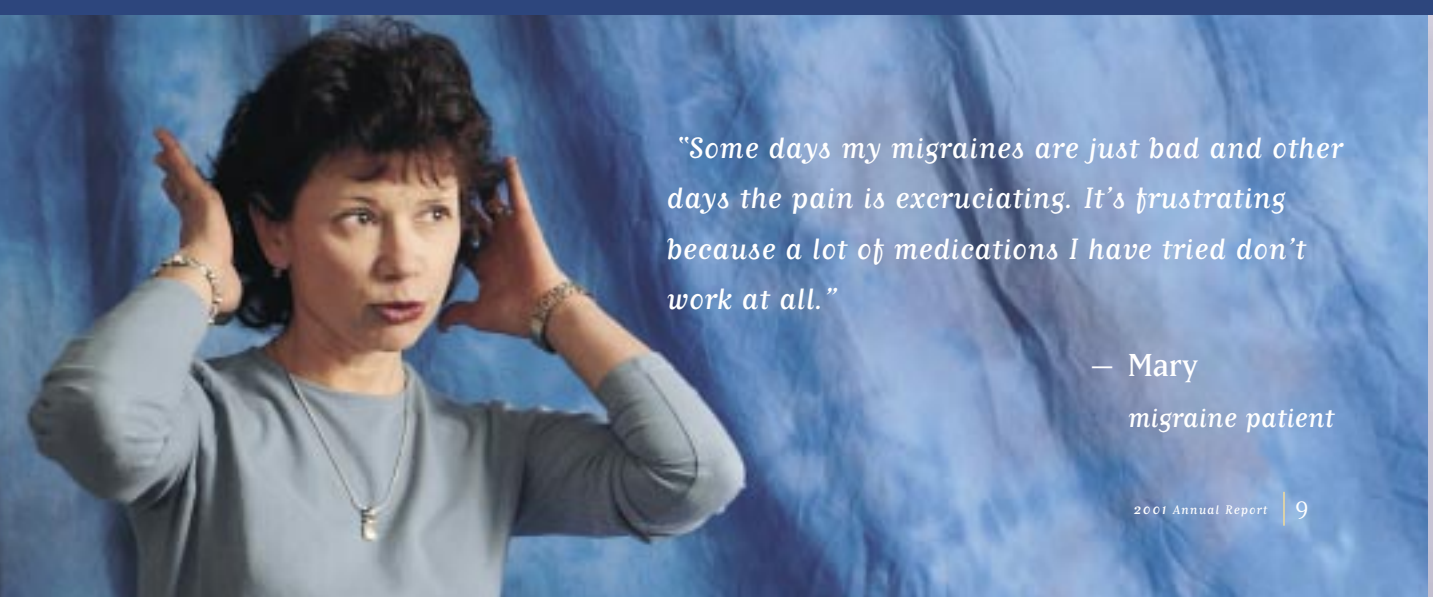
Our third product candidate, MT 400, is being developed as a proprietary co-active migraine treatment combining a commercially approved triptan with a long-acting, non-steroidal, anti-inflammatory drug in a single tablet.

In a Phase II clinical trial involving 972 patients, the therapeutic gain with MT 400 was more than twice that of a triptan. In the same study, MT 400 provided faster onset of pain relief than a triptan, greater two-hour pain relief than a triptan — particularly in patients with severe baseline pain — greater sustained pain relief than a triptan, yet with a side-effect profile similar to a triptan.

We believe MT 400 will be the next generation migraine therapy and a major advance over currently available products.

POZEN Migraine Product Portfolio and Stage of Development





Q.

What can you tell us about the progress of your clinical studies and portfolio growth, and how it was achieved?

A.

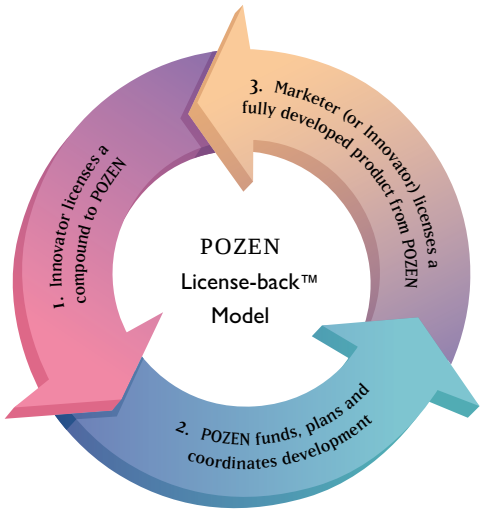
In five years and with less than 30 employees, we've conducted 63 pre-clinical laboratory studies, 27 clinical trials involving more than 10,000 patients, and created several proprietary dosage forms, resulting in the largest portfolio of migraine drugs in development.

This could only have been achieved through POZEN's unique blend of EXPERIENCE, FOCUS and COMMITMENT.

DEVELOPMENT

We are a commercially focused pharmaceutical development company with expertise in all aspects of drug development, non-clinical and clinical. Because we avoid the high costs associated with discovery research and maintaining a commercial infrastructure, approximately 80% of our expenses flow directly into product development.

POZEN has two sources of new products – in-house innovation and in-licensing. POZEN scientists created three of the company's first product candidates. Two of the product candidates are combination products and one is a formulation improvement of a single entity. We expect to introduce additional self-invented products using similar techniques. We also in-license promising product candidates using our proven POZEN License-back™ model. Through this approach, we in-license a product candidate and develop it, while offering the discovering company an option to reacquire the product candidate on pre-set terms and conditions.



Once these products move into development, our strategic outsource model allows us to achieve significant time and cost savings by leveraging appropriate external resources. We design and manage our pre-clinical and clinical studies and also manage the development and scale-up of our product candidate formulations. The execution of these critical activities takes place through our extensive network of contractors.

"Migraine therapy is just one area where currently available prescription and over-the-counter products are lacking for millions of sufferers. We want to identify and advance products that will improve a patient's quality of life over that available with existing therapies."

– Drew Finn, Pharm D.
Executive Vice President,
Product Development

THE POZEN TEAM

People at POZEN are focused on achieving goals. Our entire company devotes all of its time to only a select number of high-potential products. This concentrated effort results in rapid and consistent progress. Our commitment to making our products reach their full potential is uncompromising.

POZEN® INC.

The Pharmaceutical Development Company

Form 10-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001.

OR

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

Commission file number 000-31719

POZEN INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes _X_. 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. [ ]

The aggregate market value of POZEN Inc. Common Stock held by nonaffiliates of POZEN Inc. on February 28, 2002 was approximately $127,320,016. As of February 28, 2002 there were outstanding 28,077,945 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.

POZEN INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

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, which has built a portfolio of product candidates through a combination of innovation and in-licensing. 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 with over $1 billion in market potential. Our plans are to bring these product candidates to market through a commercial partner.

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. MT 300 is being developed to provide long-lasting pain relief for severe migraine. MT 300 is currently in two Phase 3 pivotal trials comparing MT 300's efficacy with placebo. We expect to complete both of these trials by the end of 2002. MT 400 is being developed as a co-active acute migraine therapy. MT 400 is currently in Phase 2 development. We have discontinued further development activities related to MT 500, our early stage migraine product candidate in-licensed from Roche, based upon unexpected Phase 1 trial results.

We plan to enter into collaborations with established pharmaceutical companies to commercialize and manufacture our product candidates. We are in active discussions with respect to the commercialization of MT 100, MT 300 and MT 400. In addition, we intend to leverage our pharmaceutical product development expertise by acquiring or in-licensing and developing commercially attractive products in therapeutic areas outside of migraine.

Business Strategy

The principal elements of our business strategy are to:

Develop and commercialize our portfolio of migraine 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 migraine product candidates. We are conducting clinical trials and other studies with our migraine product candidates in order to obtain marketing approvals that will allow us to provide therapeutic alternatives for all segments of migraine patients. We intend to form collaborations with established pharmaceutical companies for the worldwide commercialization of our migraine product candidates.

Form collaborations for the commercialization of our product candidates

We plan to establish collaborative relationships with pharmaceutical companies for the commercialization of our product candidates. In general, we intend to license our product candidates to pharmaceutical companies for commercialization once we have established substantial evidence of safety and efficacy, at which point we believe that we can obtain favorable economic terms.

Build a product pipeline through innovation, in-licensing and acquisition

We intend to build our product pipeline through innovation, in-licensing and 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 novel products that exhibit distinct advantages over currently marketed products, as well as innovative combinations of products in convenient, therapeutically appropriate formulations.

One of the strategies we will use to gain access to product candidates is to employ our license back option model under which the licensor has an option to license back the product candidate at various stages of development and on set terms and conditions. We believe that this model differs from a traditional in-licensing arrangement in that it affords us improved access to commercially attractive compounds.

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.

Products Under Development

Our product candidates are being developed for the treatment of migraine. If approved for commercial sale, all of the products in our migraine portfolio will be sold by prescription. The following chart sets forth information regarding the status of our development programs:

Product Candidate	Indication	Status
MT 100 Oral tablet	First-line therapy to treat migraine pain and associated symptoms	All planned pivotal Phase 3 trials completed
MT 300 Injection	New formulation of DHE to provide long-lasting pain relief for severe migraine	All planned pivotal Phase 3 trials ongoing
MT 400 Oral tablet	Co-active acute migraine therapy combining the activity of a triptan with that of a long-acting, non-steroidal, anti-inflammatory drug	Phase 2 proof-of-concept trial completed; Phase 2 dose-ranging trials planned

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. We estimate 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.

Currently, we are aware of no narcotics approved specifically for the treatment of migraine. However, narcotics are prescribed outside their approved indications to treat severe migraine attacks due to their ability to mask migraine headache pain. The use of narcotics for the treatment of migraine has been limited because narcotics do not address the non-pain symptoms of migraine such as nausea and vomiting and can cause side effects such as drowsiness, dizziness and constipation, and because of their potential to cause addiction. In addition, analgesics such as acetaminophen and aspirin are generally used to treat only mild migraine attacks, and, similarly to narcotics, do not address the non-pain symptoms of migraines such as nausea and vomiting.

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 pain relief 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 2001, according to IMS Health's Retail and Provider Perspective, or IMS, total triptan sales in the U.S. were approximately $1.6 billion. Imitrex®, marketed by GlaxoSmithKline, is the leading triptan product, with, according to IMS, total U.S. sales of approximately $1.1 billion in 2001. 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, 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.

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 $1.3 billion in sales in the U.S. in 2001, of which the Imitrex® oral dosage form accounted for approximately $786 million.

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 seeking marketing approval from the Food and Drug Administration, or FDA, we must demonstrate the efficacy and safety of our product candidates. To demonstrate efficacy of a combination product candidate like 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 a statistically significant increase in patients achieving sustained response, which is a clinical measure used to evaluate both speed of onset and duration of migraine pain relief at two hours and maintained throughout the next 22 hours. 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 and six Phase 3 clinical trials for MT 100 involving more than 7,500 patients, more than 3,400 of whom have received some form of MT 100. The Phase 3 clinical trials have consistently demonstrated MT 100's effectiveness in treating migraine pain. Significantly, in a Phase 3 trial in which MT 100 was compared to Imitrex® and placebo, MT 100 demonstrated comparable efficacy to Imitrex® and a lower percentage of patients taking a single-tablet dose of MT 100 reported adverse events than patients taking Imitrex®. Adverse events included drowsiness, diarrhea, abdominal pain, dizziness, infection and nervousness.

Our MT 100 trials have included:

- a Phase 3 long-term safety trial completed in December 2000 in which over 600 patients completed at least 6 months of treatment with MT 100, 329 of whom completed one year of treatment;
- a Phase 3 trial including 546 patients completed in August 2000 in which a single-tablet dose of MT 100 was shown to have comparable efficacy to, and a lower percentage of patients reporting adverse events than, a 50 milligram dose of Imitrex®, which is the most widely prescribed dose, and further demonstrated statistically significant superiority over placebo for sustained response and relief of nausea, sensitivity to light and sensitivity to sound;
- a Phase 3 multiple dosing trial including 426 patients completed in May 2000 in which MT 100 showed statistically significant superiority over placebo for sustained response and, within two hours after initial dosing, for relief of nausea, sensitivity to light and sensitivity to sound; and
- two Phase 3 clinical trials, a 1,064-patient trial completed in December 1999 and a 2,623-patient trial completed in November 2000, comparing MT 100 to its components in which the sustained response rate 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 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 a statistical test that was 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 and using this same refined statistical analysis method, 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 comparing MT 100 with its components.

In addition, we recently completed a second Phase 3 clinical trial including 1,010 patients designed both to compare the safety and efficacy of MT 100 with Imitrex®, as well as to support a request for expanded labeling of MT 100. Data from this trial will be available in the first half of 2002.

In addition to the required clinical trial results, the FDA also requires genotoxicity and carcinogenicity testing prior to new drug application, or NDA, approval. The carcinogenicity studies, which are conducted with two species of animals, typically require a two-year dosing period in rats and either a six-month or two-year dosing period in certain mice species. Based primarily on the long history of use of both of MT 100's components, particularly naproxen sodium, as well as results from short-term genotoxicity studies that we conducted, we requested that the FDA waive the carcinogenicity testing requirement.

In January 2001, notwithstanding the short-term genotoxicity results, the FDA notified us that it would still require carcinogenicity testing. As a result, to satisfy the FDA required mouse carcinogenicity study, we commenced a 26-week oral carcinogenicity study in p53 transgenic mice in May 2001 and a two-year rat carcinogenicity study with MT 100 in August 2001. The results from the 26-week study indicated that MT 100 was not carcinogenic in p53 transgenic mice. In recent discussions, the FDA indicated that it would accept the results from the ongoing two-year rat study during the NDA review period for MT 100. We expect to submit the NDA for MT 100 in the first half of 2003.

MT 300

Overview

MT 300 is being developed to provide long-lasting pain relief for patients needing a convenient injectable therapy for severe migraine, with a reduced side effect profile compared to existing injectable products. Currently, patients often use an injectable form of a triptan or another drug such as DHE, which is currently approved for use in the treatment of migraine and cluster headache episodes, to alleviate the symptoms of the most severe migraine attacks quickly and effectively. However, many patients are unable to tolerate the injections, especially those sensitive to the vascular side effects associated with injectable Imitrex®. Nevertheless, according to IMS, injectable migraine therapeutics represented approximately $214 million in 2001 U.S. sales.

MT 300 is a proprietary formulation of injectable DHE that is packaged in an easy-to-use, pre-filled syringe. Published clinical trial results for injectable DHE indicate that injectable DHE provides comparable efficacy to injectable Imitrex® three hours after administration. Specifically, only 18% of injectable DHE patients experienced headache recurrence within 24 hours as compared to 45% of injectable Imitrex® patients. In addition, acute vascular side effects were reported by only 2% of the patients receiving injectable DHE compared to 23% of the patients receiving injectable Imitrex®.

Clinical Development

On February 23, 2001, the FDA approved our request to submit MT 300 as a 505(b)(2) application, under which the FDA requires 12 months of stability data on the final formulation, some short-term pre-clinical studies and two placebo-controlled clinical trials. To date, we have completed the required short-term pre-clinical trials and a Phase 2 placebo-controlled, dose-response trial in which MT 300 demonstrated a statistically significant improvement in the percentage of patients achieving four-hour response rates when compared to placebo and demonstrated a statistically significant lower need for the use of rescue medication. In September 2001, we initiated a 600-patient, placebo-controlled, Phase 3 clinical trial of a single, subcutaneous dose of MT 300 in patients with moderate to severe migraine pain, and, in January 2002, we initiated a second placebo-controlled Phase 3 trial with 400 patients. Given the current timetable for completion of these Phase 3 clinical trials, we anticipate submitting an NDA for MT 300 by the end of 2002.

MT 400

Overview

MT 400 is being developed as a co-active migraine therapy combining the activity of a commercially approved triptan drug with that of a commercially approved long-acting, non-steroidal, anti-inflammatory drug. 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 believe that MT 400 will prove to offer a faster onset of action or a longer duration of migraine symptom relief than use of either drug component by itself. In addition, since lower doses of the triptan components could be used in certain MT 400 formulations than in the triptan itself, we believe that the potential risks of triptan-related side effects may also be reduced with MT 400.

MT 400 represents a commercially attractive opportunity to create multiple products using different combinations of triptans and long acting, non-steroidal, anti-inflammatory drugs. We believe that the resulting MT 400 products will be attractive to a partner due to the partner's potential to increase its penetration in all segments of the migraine market and expand the proprietary life of its existing triptan brands. Consequently, we expect to complete a full development program necessary for U.S. and European regulatory approval for MT 400. We will need to obtain the right to use the triptan that is specified in our NDA for MT 400 if we want 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 March 2001, we completed a 972-patient, Phase 2 double-blind, placebo-controlled, single-dose clinical trial of MT 400 in which MT 400 showed statistically significant superiority over placebo and its components on the identified primary outcome measure of sustained pain response. In addition, MT 400 showed statistically significant superiority over placebo and its components in the two-hour pain response and effectiveness in the relief of migraine associated symptoms. MT 400 was also superior to the oral triptan comparator included in the study as a positive control.

With respect to the primary endpoint, sustained pain response, 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. We expect to commence additional Phase 2 dose-ranging trials for MT 400 in 2002.

MT 500

Overview and Clinical Development

In September 1999, utilizing our license back option model, we obtained an exclusive worldwide license for MT 500, a novel serotonin (5 HT_{2b}) receptor antagonist discovered by Roche. We completed a Phase 1 tolerance study of MT 500 in 2001. The results of this study indicate unexpected levels of metabolite in the patients dosed with MT 500. In light of these results, we have discontinued further development activities related to MT 500. The terms of the licensing agreement provide for the unilateral termination of the agreement with no further obligations to either party.

Product In-Licensing

In order to continue to expand our product pipeline, we intend to complement our internal product innovations by in-licensing additional product candidates. Our in-licensing strategy to obtain new product candidates will include using our license back option model, which we believe should provide us with improved access to promising compounds. Specifically, the major elements of our license back option model are:

- We in-license a product candidate at the late preclinical or Phase 1 development stage.
- We grant the licensor an option to license back the product candidate at various stages of development.
- We assume all development and funding responsibility.
- If the licensor exercises its option to license back the product candidate, we receive certain milestone payments and a royalty on sales of the product candidate.
- If the licensor foregoes its option, we have the right to license the product candidate to another third party or commercialize the product ourselves, with sublicense royalties in both cases being paid to the original licensor.
- All financial terms are set when the original license agreement is signed.

We believe that our license back option model offers advantages to both us and the licensor and will be an effective tool in expanding our product portfolio successfully. The advantages of this model for the licensor include:

- realization of value from product candidates whose development would otherwise be delayed or never undertaken;
- delayed commitment of resources and capital until the product candidate's technical risk and commercial potential are better defined; and
- utilization of our product development and regulatory expertise.

We believe that the advantages of our license back option model for us include:

- improving our access to attractive product candidates;
- limiting our financial exposure to product candidate development expenses due to low upfront costs compared to traditional in-licensing structures; and
- in-licensing product candidates with substantial preclinical development risk removed.

Our success under this license back option model is dependent upon the successful development of the product licensed and the extent to which the milestone and royalty payments we receive from the licensor exceed our development expenses associated with the product candidate.

Sales and Marketing

We currently have no sales or distribution capabilities. We currently intend to commercialize our products through other pharmaceutical companies in exchange for upfront and milestone payments, proceeds from the manufacturing of drug substance and royalties from sales. In the future, we may retain the right to co-promote our products.

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, MT 400 and MT 500 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 Catalytica Pharmaceuticals, Inc. under which Catalytica 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 Catalytica for the initial term of the agreement and any extension thereof, unless Catalytica 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.

In October 2001, we entered into a Commercial Supply Agreement with Lek Pharmaceuticals Inc. under which Lek has 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 2001, total triptan sales in the U.S. were approximately $1.6 billion. Imitrex®, a triptan product marketed by GlaxoSmithKline, had total U.S. sales of approximately $1.1 billion in 2001, 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 own three issued U.S. patents and three pending 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. Applications have been filed under the Patent Cooperation Treaty, or PCT, and are in the international phase relating to MT 300 and MT 400. 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 one issued U.S. patent with claims relating to dosage forms that can be used in administering metoclopramide and a long-acting, non-steroidal, anti-inflammatory drug (NSAID) to a patient with migraine headache. There 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 12, 2016. Additional U.S. and foreign patents, if issued, are expected to expire in a similar timeframe.

MT 300

With respect to MT 300, we presently have one pending U.S. application and multiple pending foreign applications. These have claims relating to liquid pharmaceutical compositions for treating migraine, which contain concentrated dihydroergotamine. There are also claims relating to treating patients for migraine using these compositions and to therapeutic packages that include the compositions.

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 applications relating to MT 400 pending in Canada, Europe and Japan. In addition, we have a pending U.S. application with claims relating to dosage forms and methods of treatment involving a 5-HT receptor agonist and a particular subset of NSAIDs and to the use of MT 400 in the treatment of other types of headache. 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.

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

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.

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

Employees

As of February 28, 2002, we had a total of 28 full-time employees. All of our current employees are based at our headquarters in Chapel Hill, North Carolina**.** Of our 28 employees, 17 hold advanced degrees, including seven Pharm.D. or Ph.D. degrees.

Executive Officers of the Company

Our executive officers and their ages as of December 31, 2001 are as follows:

Name	Age	Position
John R. Plachetka, Pharm.D.	48	Chairman, President and Chief Executive Officer
Kristina M. Adomonis	47	Senior Vice President, Business Development
John E. Barnhardt	52	Vice President, Finance and Administration
Matthew E. Czajkowski	52	Chief Financial Officer, Senior Vice President, Finance and Administration
Andrew L. Finn, Pharm.D.	52	Executive Vice President, Product Development

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.

Andrew L. Finn, Pharm.D., joined POZEN in January 2000 as Executive Vice President of Product Development. Prior to joining POZEN, Dr. Finn co-founded enVision Sciences, a specialized clinical research and regulatory services company, in 1996. From 1991 to 1996, he was Vice President of U.S. Clinical Research and Biometrics for Solvay Pharmaceuticals. He joined Glaxo Inc. in 1981 as Assistant Director of Anti-Infective Development. Dr. Finn received his B.S. in Pharmacy from the University of North Carolina, Chapel Hill and his Doctor of Pharmacy from the University of Michigan.

Item 2. Properties

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 expires in February 2003. Beginning in March 2002, our corporate facilities are located in 17,000 square feet in the Exchange Office Building in Chapel Hill, North Carolina under a lease commencing in March 2002 and expiring in 2010. We have the option to renew this lease for two additional terms of up to a total of eight years. We believe that the Exchange Office Building facility is adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

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

On October 6, 2000, an action was filed against the Company alleging that POZEN owed certain consideration and expenses in connection with the issuance and sale of preferred stock in the twelve-month period following the termination of the engagement of an investment banking firm to assist the Company with the sale of preferred stock in a private placement. In January 2002, the Company settled these issues for amounts that will have no material effect on the financial position or the results of operation of the Company.

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, 2002, we estimate that we had approximately 227 stockholders of record and approximately 1,380 beneficial holders of the common stock. The following table details the high and low sales prices for the common stock as reported by The Nasdaq National Market for the periods indicated.

	Price Range	
2000 Fiscal Year	**High**	**Low**
Fourth Quarter	$21.875	$9.25

	Price Range	
2001 Fiscal Year	**High**	**Low**
First Quarter	$19.25	$5.75
Second Quarter	$15.50	$5.19
Third Quarter	$11.48	$3.60
Fourth Quarter	$ 7.30	$3.50

On February 28, 2002, the closing price for our common stock as reported by The Nasdaq National Market was $5.51. We paid no cash dividends in 2001. 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 March 6, 2001 and May 25, 2001, we issued an aggregate of 49,385 shares of common stock pursuant to the exercise by two individuals of stock purchase warrants issued to such individuals in 1997. The consideration received by us was $49.39 in cash, or a price of $0.001 per share. No underwriting discounts or commissions were paid in connection with the issuances of these shares of common stock.

The above securities were offered and sold by us in reliance upon exemptions from registration under Section 4(2) of the Securities Act of 1933. We did not use any general advertisement or solicitation in connection with the offer or sale of these securities and appropriate legends were affixed to the certificates evidencing these securities.

Item 6. Summary of Selected Financial Data

The following tables set forth selected historical financial data of the Company for the three years ended December 31, 2001 and the period from September 26, 1996 (inception) through December 31, 2001. These tables should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements of the Company included elsewhere herein. The report of Ernst & Young LLP, independent auditors, covering the Company's financial statements for the three years ended December 31, 2001, is also included elsewhere herein.

	For the Year Ended December 31,			Period from September 26, 1996 (inception) through December 31, 2001
	1999	2000	2001	
	(in thousands, except per share data)			
Statement of Operations Data:				
Operating expenses:				
General and administrative	$ 2,320	$ 4,822	$ 6,455	$ 16,182
Research and development	9,458	19,399	18,627	58,175
Total operating expenses	11,778	24,221	25,082	74,357
Interest income (expense), net	(367)	1,844	3,380	5,490
Net loss	(12,145)	(22,377)	(21,702)	(68,867)
Non-cash preferred stock charge	—	27,617	—	27,617
Preferred stock dividends	—	934	—	934
Net loss attributable to common stockholders	$(12,145)	$(50,928)	$(21,702)	$(97,418)
Basic and diluted net loss per common share	$ (2.08)	$ (4.95)	$ (0.78)	
Shares used in computing basic and diluted net loss per common share	5,845	10,294	27,955	
Pro forma net loss per common share—basic and diluted*	$ (1.01)	$ (2.56)		
Pro forma weighted average common shares outstanding—basic and diluted*	12,018	19,915		

	December 31,		
	1999	2000	2001
Balance Sheet Data:			
Cash and cash equivalents	$ 4,171	$ 92,351	$ 73,959
Total assets	4,325	92,830	74,144
Total liabilities	2,360	3,762	3,523
Accumulated deficit	(24,787)	(48,099)	(69,801)
Total stockholders' equity	1,965	89,068	70,621

*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 products with significant commercial potential in select therapeutic areas. Our initial focus is on developing products for migraine therapy, a global market expected to exceed $2.6 billion in 2002.

MT 100, our proprietary formulation combining metoclopramide hydrochloride and naproxen sodium, 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. MT 300, our injectable product candidate consisting of a new and improved formulation of DHE, is being developed to provide long-lasting pain relief for severe migraine.

MT 300 is currently in two Phase 3 pivotal trials comparing MT 300's efficacy with placebo. We expect to complete both of these trials by the end of the first half of 2002.

MT 400 is being developed as a co-active acute migraine therapy combining the activity of a triptan with that of a long acting, non-steroidal, anti-inflammatory drug in a single tablet. MT 400 is currently in Phase 2 development. We have discontinued further development activities related to MT 500, our early stage migraine product candidate in-licensed from Roche, based upon unexpected Phase 1 trial results.

Specifically, our business activities have included:

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

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 we have not generated any revenue. As of December 31, 2001, our accumulated deficit was $69,801,055. Our historical operating losses have resulted principally from our research and development activities, including Phase 3 clinical trial activities for our product candidate MT 100 and Phase 2 clinical trial activities for our product candidates MT 300 and 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 and apply for regulatory approval, continue development of our other migraine therapeutic 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 regulatory process;
- the establishment of collaborations for the development and commercialization of any of our migraine product candidates; and
- the acquisition or in-licensing of other therapeutic product candidates.

Our ability to generate revenue is dependent upon our ability, alone or with others, to successfully develop MT 100 or our other migraine 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 $6,328,000 in the years ended December 31, 2000. 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 $3,146,000 and $3,054,000 of deferred compensation expense was charged to operations in the years ended December 31, 2001 and December 31, 2000, respectively. As of December 31, 2001, we anticipate charging to operations additional amounts of amortization of deferred compensation of approximately, $2,908,000 and $521,000 for the years ended December 31, 2002 and 2003, respectively.

Historical Results of Operations

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 the year ended December 31, 2000. In the future, we plan to generate revenue from upfront and milestone payments related to collaborations for the development and commercialization of product candidates and if any of our product candidates are sold, from royalties from such sales.

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 the year 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 $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 expect that research and development expenditures will increase in 2002 due to the continuation or expansion of clinical trials, the expansion of pharmaceutical development and toxicology study expenditures, and the preparation of NDA's for MT 100 and MT 300. 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 $149,000. 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 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. 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.

Year ended December 31, 2000 compared to year ended December 31, 1999

Revenue: We generated no revenue during the year ended December 31, 2000 or the year ended December 31, 1999.

Research and Development: Research and development expenses increased 105.1% to $19,398,904 for the year ended December 31, 2000 from $9,458,225 for the year ended December 31, 1999. This increase of $9,941,000 was due primarily to a $7,734,000 increase in clinical trial costs of MT 100. Costs associated with MT 400 increased $568,000 due primarily to increased clinical trial activities. The costs associated with MT 500 reflected a net increase of $1,021,000 due to an increase of $2,021,000 in toxicology and pharmaceutical development expenses being offset by a $1,000,000 decrease from the prior year's $1,000,000 product licensing expense. MT 300 costs decreased $1,211,000 reflecting the directing of development efforts toward MT 100. Additional other research and development costs increased $1,829,000 including an increase of $1,429,000 in personnel costs, of which $962,000 represented increased amortization of deferred stock compensation.

General and Administrative: General and administrative expenses increased 107.9% to $4,822,102 for the year ended December 31, 2000 from $2,319,939 for the year ended December 31, 1999. This increase of $2,502,000 resulted from increases of $1,789,000 in personnel and related benefits, of which $1,479,000 represented increased amortization of deferred stock compensation. Additionally, professional and consulting fees increased by $429,000 and an increase of $284,000 was reflected in other costs related to our expanded operational infrastructure.

Interest Income, net: Net interest income increased to $1,844,378 for the year ended December 31, 2000 from a net interest expense of $367,282 for the year ended December 31, 1999. Interest income increased $1,626,000 to $1,845,000 for the year ended December 31, 2000 from $219,000 for the year ended December 31, 1999 due to increased levels of cash and cash equivalents available for investing. During the year ended December 31, 2000 there was nominal interest expense while interest expense was $586,000 for the year ended December 31, 1999 related to a promissory note that was converted to preferred stock during the period.

Income Taxes

As of December 31, 2001, we had federal and state net operating loss carryforwards of approximately $57.6 million and research and development credit carryforwards of approximately $3.7 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 $131,580,410. At December 31, 2001, cash and cash equivalents totaled $73,958,724, a decrease of $18,391,859 as compared to December 31, 2000. The decrease in cash and cash equivalents resulted primarily from our operating activities.

Cash used by operations of $18,410,861 during the year ended December 31, 2001 represented a net loss of $21,702,508 offset by non-cash charges of $3,286,279, an increase in prepaid and other assets of $244,209 and a decrease in accounts payable and accrued liabilities of $238,841.

Cash used in investing activities of $90,643 during the year ended December 31, 2001 reflected the purchase of equipment.

Cash provided by financing activities during the year ended December 31, 2001, totaled $109,645, reflecting the net proceeds from the exercise of common stock options and warrants.

At December 31, 2000, cash and cash equivalents totaled $92,350,583, an increase of $88,179,497 as compared to December 31, 1999. The increase in cash and cash equivalents resulted primarily from our financing activities, offset by the cash used in operating activities.

Cash used by operations of $18,139,520 during the year ended December 31, 2000 represented a net loss of $22,376,628 offset by non-cash charges of $3,112,370, a decrease in prepaid and other assets of $276,825 and an increase in accounts payable and accrued liabilities of $1,401,563. The increase in accounts payable and accrued liabilities was primarily due to the increased spending in our clinical activities.

Cash used in investing activities of $106,512 during the year ended December 31, 2000 reflected the purchase of equipment.

Cash provided by financing activities during the year ended December 31, 2000, which totaled $106,425,529, was generated primarily by net proceeds of $16,875,115 from the sales of the series E preferred stock in March 2000, net proceeds of $10,742,000 from the sales of the series F preferred stock in August 2000, and net proceeds of $78,265,552 from our initial public offering in October 2000.

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 anticipated cash needs for operating expenses for at least the next two years.

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

Year	Amount
2002	$ 199,939
2003	183,096
2004	369,747
2005	377,486
2006	385,311
2007-10	1,274,286
Total	$ 2,789,865

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

On June 29, 2001, the FASB issued SFAS No. 141, *Business Combinations* (SFAS 142) and SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). SFAS 141 eliminates the pooling-of-interests method of accounting for business combinations, except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS 141 also includes new criteria to recognize intangible assets separately from goodwill. The requirements of SFAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under SFAS 142, goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed annually, or more frequently if impairment indicators arise, for impairment. Separate intangible assets that are not deemed to have an indefinite life continue to be amortized over their useful lives. The provisions of SFAS 142 requiring non-amortization of goodwill and indefinite-lived intangible assets apply to goodwill and indefinite-lived intangible assets acquired after June 30, 2001. With respect to goodwill and intangible assets acquired prior to July 1, 2001, the Company is required to adopt SFAS 142 on January 1, 2002; however, the adoption of SFAS 141 and SFAS 142 is not expected to have an impact on the Company's operating results or stockholders' equity for the periods presented.

In August 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations* (SFAS 143). SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for the Company beginning January 1, 2003, and its adoption is not expected to have an impact on the Company's operating results or stockholders' equity.

In October 2001, the FSAB issued SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of* ("SFAS 144"). SFAS 144 addresses how and when to measure impairment on long-lived assets and how to account for long-lived assets that an entity plans to dispose of either through sale, abandonment, exchange, or distribution to owners. The new provisions supersede SFAS 121, which addressed asset impairment, and certain impairment, and certain provisions of APB Opinion 30 related to reporting to the effects of the disposal of a business segment and requires expected future operating losses from discontinued operations to be recorded in the period in which the losses are incurred rather than the measurement date. Under SFAS 144, more dispositions may qualify for discontinued operations treatment in the income statement. The provisions of SFAS 144 became effective for the Company January 1, 2002 and are not expected to have a material impact on the Company's operating results or stockholders' equity.

Factors Affecting the Company's Prospects

We depend heavily on the success of our product candidate, MT 100, which may never be approved for commercial use. If we are unable to develop, gain approval of or commercialize MT 100, we may never be profitable.

Since our founding, we have invested a significant portion of our time and financial resources in the development of MT 100 and anticipate that for the foreseeable future our ability to achieve profitability will be dependent on its successful development, approval and commercialization. Many factors could negatively affect the success of our efforts to develop and commercialize MT 100, including:

- negative, inconclusive or otherwise unfavorable results from our carcinogenicity studies or from any other studies or clinical trials;
- an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of MT 100;
- an inability to establish collaborative arrangements with third parties for the manufacture and commercialization of MT 100, or any disruption of any of these arrangements, if established;
- a failure to achieve market acceptance of MT 100;
- significant delays in our carcinogenicity 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 additional carcinogenicity studies.

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, 2001, we had an accumulated deficit of approximately $69.8 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;
- negotiate collaborative agreements under which we receive upfront and milestone payments 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, including MT 100, have been approved for sale in the United States or any foreign market. We will need to complete preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials, on these product candidates in support of NDA submissions to the FDA for approval to market the product candidates. 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 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.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity studies and clinical trials of all of our product candidates. Any unanticipated costs or delays in these studies or trials, or the need to conduct additional studies or trials, could reduce 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. 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. 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 even if we complete our current clinical trials for MT 100 and our other product candidates, we may be required to conduct additional clinical trials and studies to support our NDA to the FDA. 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 depend on collaborations with third parties, which may reduce our product revenues or restrict our ability to commercialize products.

Our ability to develop, manufacture, commercialize 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 retain 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. We currently intend to market and commercialize our products through others, which will require us to enter into sales, marketing and distribution arrangements with third parties. These arrangements may reduce our product revenues.

Our 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, manufacture and commercialization 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 contractual or collaborative party's business strategy may adversely affect its willingness or ability to complete its obligations to us.
- The contractor or collaborative party may have the right to terminate its arrangements with us on limited or no notice and for reasons outside of our control.
- The contractual or collaborative party 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 or commercialization 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 and commercialization of our product candidates will be delayed.

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 we are unable to build sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize any of our drug candidates.

We currently intend to enter into agreements with third parties to market and sell any of our product candidates approved by the FDA for commercial sale. We may not be able to enter into marketing and sales agreements with others on terms acceptable to us, if at all. To the extent that we enter into marketing and sales agreements with others, our revenues, if any, will be affected by the sales and marketing efforts of others.

We may also retain the right, where possible, to co-promote our products in conjunction with our collaborative parties. If we are unable to enter into third-party sales and marketing agreements, or if we are exercising our rights to co-promote a product, then we will be required to develop internal marketing and sales capabilities. We may not successfully establish marketing and sales capabilities or have sufficient resources to do so.

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 other's 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, including MT 100, 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, including MT 100, 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. In particular, we believe that we will require additional capital to fund the acquisition of new product candidates. 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; and
- the terms and timing of any new collaborative, licensing and other arrangements that we may establish.

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 have entered into employment agreements with four 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 fail to recruit 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. Declines in interest rates will, however, 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 14 of Part IV.

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

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.

Item 13. Certain Relationships and Related Transactions

None.

PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a) Financial Statements and Schedules:

1. Financial Statements

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

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

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.

Exhibit Number	Description
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	Executive Employment Agreement with John R. Plachetka dated April 1, 1999. * ***
10.5	License Agreement dated September 24, 1999 between the Registrant and F. Hoffman-La Roche Ltd. *
10.6	Investor Rights Agreement dated July 28, 1999 between the Registrant and the holders of the Series D Preferred Stock. *
10.7	Investor Rights Agreement dated March 24, 2000 between the Registrant and the holders of the Series E Preferred Stock. *
10.8	2000 Equity Compensation Plan *
10.9	Investor Rights Agreement dated August 28, 2000 between the Registrant and the holders of the Series F Preferred Stock. *
10.10	Sublease Agreement between Intecardia, Inc. and the Registrant dated as of September 1, 2000. *
10.11	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).
10.12	First Amendment to the Executive Employment Agreement with John R. Plachetka, Pharm.D., dated as of April 25, 2001 (filed as Exhibit 10.2 to the Company's Form 10-Q filed May 14, 2001). ***
10.13	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). ***
10.14	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). ***
10.15	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). ***
10.16	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). ***
10.17	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). ***

10.18	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).
10.19	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). ***
10.20	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. † **
10.21	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001. **
23.1	Consent of Ernst & Young LLP, Independent Auditors**

* 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 29, 2002

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

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

Signature	Title	Date
/s/ John R. Plachetka John R. Plachetka	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 29, 2002
/s/ Matthew E. Czajkowski Matthew E. Czajkowski	Senior Vice President, Finance and Administration, and Chief Financial Officer (Principal Financial Officer)	March 29, 2002
/s/ John E. Barnhardt John E. Barnhardt	Vice President, Finance and Administration (Principal Accounting Officer)	March 29, 2002
/s/ Jacques F. Rejeange Jacques F. Rejeange	Director	March 29, 2002
/s/ Bruce A. Tomason Bruce A. Tomason	Director	March 29, 2002
/s/ Peter J. Wise Peter J. Wise	Director	March 29, 2002
/s/ Ted G. Wood Ted G. Wood	Director	March 29, 2002

AUDITED FINANCIAL STATEMENTS

POZEN INC.
(A Development Stage Company)

Years ended December 31, 2001, 2000 and 1999 and the period from September 25, 1996 (inception) through December 31, 2001 with Report of Independent Auditors

POZEN Inc.
(A Development Stage Company)

Audited Financial Statements

Years ended December 31, 2001, 2000 and 1999 and the
period from September 25, 1996 (inception) through December 31, 2001

Contents

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, 2001 and 2000, and the related statements of operations, stockholders' equity and cash flows for each of the three years ended December 31, 2001 and for the period from September 25, 1996 (inception) through December 31, 2001. 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, 2001 and 2000 and the results of its operations and its cash flows for each of the three years ended December 31, 2001 and for the period from September 25, 1996 (inception) through December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Raleigh, North Carolina
January 11, 2002

POZEN Inc.
(A Development Stage Company)

Balance Sheets

	December 31, 2001	December 31, 2000
Assets		
Cash and cash equivalents	$ 73,958,724	$ 92,350,583
Prepaid expenses	67,498	198,144
Accrued interest receivable	688	113,160
Other current assets	8,000	9,091
Total current assets	74,034,910	92,670,978
Furniture and fixtures, net of accumulated depreciation of $82,055 and $166,616	109,014	158,780
Total assets	$ 74,143,924	$ 92,829,758
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 194,138	$ 128,329
Accrued expenses	3,328,881	3,633,531
Total current liabilities	3,523,019	3,761,860
Stockholders' equity:		
Common stock, $0.001 par value, 90,000,000 shares authorized, issued and outstanding, 27,969,435 and 27,732,213 shares at December 31, 2001 and 2000, respectively	27,969	27,732
Additional paid-in capital	143,512,559	143,330,124
Common stock warrants	310,808	426,048
Deferred compensation	(3,429,376)	(6,617,459)
Deficit accumulated during the development stage	(69,801,055)	(48,098,547)
Total stockholders' equity	70,620,905	89,067,898
Total liabilities and stockholders' equity	$ 74,143,924	$ 92,829,758

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,
	2001	**2000**	**1999**	**2001**
Operating expenses:				
General and administrative	$ 6,455,164	$ 4,822,102	$ 2,319,939	$ 16,182,191
Research and development	18,627,249	19,398,904	9,458,225	58,175,252
Total operating expenses	25,082,413	24,221,006	11,778,164	74,357,443
Interest income (expense), net	3,379,905	1,844,378	(367,282)	5,490,866
Net loss	(21,702,508)	(22,376,628)	(12,145,446)	(68,866,577)
Non-cash preferred stock charge	–	27,617,105	–	27,617,105
Preferred stock dividends	–	934,478	–	934,478
Loss attributable to common stockholders	$ (21,702,508)	$ (50,928,211)	$ (12,145,446)	$ (97,418,160)
Basic and diluted net loss per common share	$ (0.78)	$ (4.95)	$ (2.08)	
Shares used in computing basic and diluted net loss per common share	27,954,697	10,293,605	5,845,304	
Pro forma net loss per common share – basic and diluted		$ (2.56)	$ (1.01)	
Pro forma weighted average common shares outstanding – basic and diluted		19,915,147	12,017,944	

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' receivables		–	–	–	–	–
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

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

Additional Paid-In Capital	Preferred 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

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

	Year ended December 31,			Period from September 26, 1996 (inception) through December 31,
	2001	**2000**	**1999**	**2001**
Operating activities				
Net loss	$ (21,702,508)	$ (22,376,628)	$ (12,145,446)	$ (68,866,577)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	115,640	58,083	43,815	282,256
Loss on disposal of equipment	24,769	–	–	24,769
Amortization of deferred compensation	3,145,870	3,054,286	612,909	7,457,072
Noncash financing charge	–	–	450,000	450,000
Changes in operating assets and liabilities:				
Prepaid expenses and accrued interest receivable	243,118	(277,287)	(15,422)	(68,186)
Other assets	1,091	462	(625)	(8,000)
Accounts payable and accrued expenses	(238,841)	1,401,563	293,826	3,523,019
Net cash used in operating activities	(18,410,861)	(18,139,521)	(10,760,943)	(57,205,647)
Investment activities				
Purchase of equipment	(90,643)	(106,512)	(54,676)	(416,039)
Net cash used in investing activities	(90,643)	(106,512)	(54,676)	(416,039)
Financing activities				
Proceeds from issuance of preferred stock	–	27,617,105	9,000,000	48,651,850
Proceeds from issuance of common stock	109,645	78,970,720	625	79,086,545
Proceeds from stockholders' receivables	–	–	–	1,004,310
Proceeds from notes payable	–	–	3,000,000	3,000,000
Payment of dividend	–	(162,295)	–	(162,295)
Net cash provided by financing activities	109,645	106,425,530	12,000,625	131,580,410
Net increase (decrease) in cash and cash equivalents	(18,391,859)	88,179,497	1,185,006	73,958,724
Cash and cash equivalents at beginning of period	92,350,583	4,171,086	2,986,080	–
Cash and cash equivalents at end of period	$ 73,958,724	$ 92,350,583	$ 4,171,086	$ 73,958,724
Supplemental schedule of cash flow information				
Cash paid for interest	$ 2,162	$ 5,772	$ 136,318	$ 186,578
Supplemental schedule of noncash investing and financing activities				
Conversion of notes payable to preferred stock	$ –	$ –	$ 3,000,000	$ 3,000,000
Preferred stock dividend	$ –	$ 772,183	$ –	$ 772,183
Forfeiture of common stock options	$ 42,213	$ –	$ –	$ 42,213
Conversion of preferred stock warrants to common stock	$ 115,240	$ 914,952	$ –	$ 1,030,192

See accompanying notes.

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 products with significant commercial potential in select therapeutic areas. The Company's initial focus is on developing products for migraine therapy.

MT 100, a proprietary formulation combining metoclopramide hydrochloride and naproxen sodium, is being developed as an oral, first-line treatment for migraine pain and associated symptoms. The Company has completed all planned Phase III pivotal clinical trials for MT 100, which consistently demonstrated MT 100's effectiveness in treating migraine pain. MT 300, its injectable product candidate consisting of a new and improved formulation of dihydroergotamine mesylate, or DHE, is being developed to provide long-lasting pain relief for severe migraine. MT 300 is currently in two Phase III pivotal trials comparing MT 300's efficacy with placebo. The Company expects to complete both of these trials by the end of 2002. MT 400 is being developed as a co-active acute migraine therapy combining the activity of a triptan with that of a long-acting, non-steroidal, anti-inflammatory drug in a single tablet. MT 400 is currently in Phase II development. The Company has discontinued further development activities related to MT 500, its early stage migraine product candidate in-licensed from Roche, based upon unexpected Phase I trial results.

The Company plans to enter into collaborations with established pharmaceutical companies to commercialize and manufacture our product candidates. The Company is in active discussions with respect to the commercialization of MT 100 and MT 400. 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.

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.

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. Pro forma basic and diluted net loss per common share amounts, as presented in the statements of operations, have been computed for the years ended December 31, 2001, 2000 and 1999 as described below.

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

	2001	2000	1999
Net loss attributable to common stockholders	$(21,702,508)	$(50,928,211)	$(12,145,446)
Basic and diluted:			
Weighted-average shares used in computing basic and diluted net loss per common share	27,954,697	10,293,605	5,845,304
Basic and diluted net loss per common share	$ (0.78)	$ (4.95)	$ (2.08)

1. Significant Accounting Policies (continued)

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:

	2000	1999
Pro forma:		
Shares used above	10,293,605	5,845,304
Proforma adjustment to reflect weighted-average effect of assumed conversion of preferred stock	9,621,542	6,172,640
Total weighted-average shares of common stock outstanding proforma	19,915,147	12,017,944
Basic and diluted proforma net loss per share	$ (2.56)	$ (1.01)

During all periods presented, the Company had securities outstanding which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. Such outstanding securities consist of the following at December 31:

	2001	2000	1999
Convertible preferred stock	–	–	6,163,192
Outstanding common stock options	1,833,417	814,777	903,261
Outstanding warrants	68,931	418,307	246,516
Total	1,902,348	1,233,084	7,312,969

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. In general, 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.

1. Significant Accounting Policies (continued)

Segment Reporting

As of January 1, 1998, the Company adopted SFAS 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 establishes standards for the way companies report information about operating segments in annual financial statements. It also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company has determined that it does not have any separately reportable operating segments as of December 31, 2001.

Accounting for Derivative Investments and Hedging Activities

In June 1998, the FASB issued SFAS 133, "Accounting for Derivative Investments and Hedging Activities" ("SFAS 133"). SFAS 133 establishes a new model for accounting for derivatives and hedging activities and supersedes several existing standards. SFAS 133, as amended by SFAS 137 and SFAS 138, was effective January 1, 2001. The adoption of SFAS 133 had no impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

On June 29, 2001, the FASB issued SFAS No. 141, "Business Combinations" ("SFAS 141") and SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 141 eliminates the pooling-of-interests method of accounting for business combinations, except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS 141 also includes new criteria to recognize intangible assets separately from goodwill. The requirements of SFAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under SFAS 142, goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed annually for impairment, or more frequently if impairment indicators arise. Separate intangible assets that are not deemed to have an indefinite life continue to be amortized over their useful lives. The provisions of SFAS 142 requiring non-amortization of goodwill and indefinite-lived intangible assets apply to goodwill and indefinite-lived intangible assets acquired after June 30, 2001. With respect to goodwill and intangible assets acquired prior to July 1, 2001, the Company is required to adopt SFAS 142 on January 1, 2002; however, the adoption of SFAS 141 and SFAS 142 is not expected to have an impact on the Company's operating results or stockholders' equity for the periods presented.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"). SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for the Company beginning January 1, 2003, and its adoption is not expected to have an impact on the Company's operating results or stockholders' equity.

In October 2001, the FSAB issued SFAS No. 144, "Accounting for the Impairment of Long-Lived assets and for Long-Lived Assets to be Disposed Of" ("SFAS 144"). SFAS 144 addresses how and when to measure impairment on long-lived assets and how to account for long-lived assets that an entity plans to dispose of either through sale, abandonment, exchange, or distribution to owners. The new provisions supersede SFAS 121, which addressed asset impairment and certain provisions of APB Opinion 30 related to reporting the effects of the disposal of a business segment and requires expected future operating losses from discontinued operations to be recorded in the period in which the losses are incurred rather than on the measurement date. Under SFAS 144, more dispositions may qualify for discontinued operations treatment in the income statement. The provisions of SFAS 144 became effective for the Company January 1, 2002 and are not expected to have an impact on the Company's operating results or stockholders' equity.

2. Stockholders' Equity

In December 1996, the Company completed a private placement of 2,105,931 shares of its Series A Convertible Preferred Stock ("Series A") and received cash of $5,475,420 and notes receivable of $1,000,000, net of offering costs. The notes receivable were collected during 1997. In conjunction with the issuance of the Series A, in January 1997, the Company issued warrants to purchase 78,776 shares of Series A at a purchase price of $0.001 per share to certain key advisors for their services related to financing activities. The warrants have been accounted for as offering costs related to the issuance of the Series A at a value calculated under the "Black-Scholes" formula at approximately $242,000.

In December 1997, the Company completed a private placement of 1,135,000 shares of its Series B Convertible Preferred Stock ("Series B") and received cash of $4,336,000, net of offering costs. At December 31, 1997, the Company issued warrants to purchase 36,450 shares of Series B at a purchase price of $0.001 per share to certain key advisors for their services related to financing activities. The warrants have been accounted for as offering costs related to the issuance of the Series B at a value calculated under the "Black-Scholes" formula at approximately $139,000.

In March 1998, the Company issued an additional 4,377 shares of its Series B for $17,512 of interest accrued on the funds received prior to the December 1997 Series B private placement.

On March 4, 1998, the Company amended its Certificate of Incorporation to increase the number of authorized shares of common stock, par value $.001, from 10,000,000 shares to 20,000,000 shares.

In March 1998, the Company completed a private placement of 563,044 shares of its Series C Convertible Preferred Stock ("Series C") and received cash of $2,205,813, net of offering costs. In conjunction with the issuance of the Series C, the Company issued warrants to purchase 8,884 shares of Series C at a purchase price of $0.001 per share to certain key advisors for their services related to financing activities. The warrants have been accounted for as offering costs related to the issuance of Series C at a value calculated under the "Black-Scholes" formula at approximately $35,000.

In July 1999, the Company amended its Certificate of Incorporation to increase the number of authorized shares of common stock, par value $0.001 per share, from 20,000,000 shares to 30,000,000 shares and the number of authorized shares of preferred stock, par value $0.001 per share, from 10,000,000 shares to 20,000,000 shares.

In July 1999 the Company completed a private placement of 1,875,000 shares of its Series D Convertible Preferred Stock ("Series D") and received cash of $9,000,000. In September 1999, upon completion of the Series D private placement, the previously issued Convertible Promissory Note ("Note") funded by MEDGROWTH S.A. ("MEDGROWTH") in bridge financing, issued on March 1, 1999 for $3,000,000, automatically converted into 625,000 shares of Series D at $4.80 per share. The terms of the Note provided for automatic conversion into shares of Series D on the same terms and conditions extended to other purchasers of Series D, the conversion of the $450,000 loan origination fee into Series D or payable in cash at the time of conversion and the issuance of 200,000 warrants to BB Medtech AG, of which MEDGROWTH is a wholly owned subsidiary, to purchase 200,000 shares of Series D at a purchase price of $3.15 per share with a term of two years for their services related to financing activities. Interest on the Note was paid at a fixed rate of 11% annually. The warrants have been accounted for as offering costs related to the issuance of the Series D at a value calculated under the "Black-Scholes" formula at approximately $925,000. MEDGROWTH elected to receive 93,750 shares of Series D in exchange for the Note's loan origination fee in the amount of $450,000, which was expensed as a financing cost.

2. Stockholders' Equity (continued)

All outstanding shares of Series A, Series B, Series C and Series D and 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, respectively, 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 addition, the Board of Directors and stockholders approved an amendment to the Certificate of Incorporation that took effect upon the completion of the initial public offering, increasing the authorized capital stock to 90,000,000 shares of common stock and reducing the number of authorized preferred stock to 10,000,000, each with a par value of $0.001.

Shares Reserved for Future Issuance

At December 31, 2001, shares of common stock reserved for future issuance are as follows:

Shares available for grant under stock option plans	2,171,409
Shares issuable pursuant to options granted under stock option plans	1,995,782
Shares issuable pursuant to outstanding warrants	51,647
Total reserved	4,218,838

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 terms of the Series E provide for similar rights as those provided to the Series A, Series B, Series C, and Series D. 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 terms of conversion decreased the conversion price 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 is 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.

3. Redeemable Preferred Stock (continued)

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 financing activities. These warrants have since been modified to provide for an additional per share payment upon exercise, equal to the difference between the exercise price otherwise applicable and the initial public offering price per share of common stock. 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.

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.

4. Accrued Expenses

Accrued expenses consist of the following at December 31:

	2001	2000
Clinical trial contract costs	$ 2,348,663	$ 2,793,848
Compensation costs	563,891	407,192
Other	416,327	432,491
	$ 3,328,881	$ 3,633,531

5. Income Taxes

At December 31, 2001 and 2000, the Company had federal and state net operating loss carryforwards of approximately $57.6 million and $39.4 million, respectively, for income tax purposes. At December 31, 2001 and 2000, the Company had research and development credit carryforwards of approximately $3.7 million and $1.9 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.

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:

	2001	2000
Deferred tax assets:		
Net operating loss carryforward	$ 23,043,000	$ 15,760,000
Research and development credits	3,715,000	1,923,000
Other	3,000	419,000
Total deferred tax assets	26,761,000	18,102,000
Valuation allowance	(26,761,000)	(18,102,000)
Net deferred tax asset	$ –	$ –

Valuation allowance increased by $8,659,000 and $8,377,000 as of December 31, 2001 and 2000, 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 10% or more stockholders of the Company).

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 consummation 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.

6. Stock Option Plan (continued)

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

	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 1996	88,562	0.19
Options granted	470,127	0.19
Forfeited	(10,118)	0.19
Balance at December 31, 1997	548,571	0.19
Options granted	194,593	0.33
Exercised	(29,977)	0.19
Forfeited	(104,923)	0.19
Balance at December 31, 1998	608,264	0.23
Options granted	612,221	1.12
Exercised	(3,373)	0.19
Forfeited	(105,222)	0.88
Balance at December 31, 1999	1,111,890	0.66
Options granted	486,762	2.87
Exercised	(208,334)	0.36
Forfeited	(6,745)	1.48
Balance at December 31, 2000	1,383,573	1.49
Options granted	808,591	9.45
Exercised	(187,837)	0.58
Forfeited	(8,545)	2.48
Balance at December 31, 2001	1,995,782	$ 4.79

6. Stock Option Plan (continued)

The options outstanding and exercisable at December 31, 2001 are as follows:

Options Outstanding		Weighted-Average Remaining Contractual	
Exercise Price	**Number Outstanding**	**Life (In years)**	**Vested Options**
$ 0.19	254,664	5.5	254,664
$ 0.44	60,818	6.8	60,818
$ 0.89	191,598	7.3	100,541
$ 1.48	332,304	7.9	165,328
$ 2.02	167,276	8.2	55,759
$ 3.40	76,893	8.4	25,631
$ 3.74	47,215	8.6	9,443
$ 4.25	36,423	8.8	12,140
$ 5.90	20,000	9.8	–
$ 6.60-6.75	302,639	9.3	–
$ 7.35-7.38	25,000	9.2	–
$ 8.50-8.75	130,000	9.2	–
$ 9.84	15,000	9.6	–
$10.89	65,000	9.5	–
$12.50	20,000	9.0	5,000
$13.19	200,952	9.1	–
$14.16	50,000	9.0	–
	1,995,782		689,324

The following table summarizes the fair value of options granted:

	Fair Value			Weighted-Average Exercise Price		
Type of Option	**2001**	**2000**	**1999**	**2001**	**2000**	**1999**
Stock price = exercise price	$ 5.90-$14.16	$12.50	$ –	$ 9.45	$ 12.50	$ –
Stock price > exercise price		$20.23-$22.48	$ 4.05-$ 20.23		$ 2.36	$ 1.12

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 below, 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 years ended December 31, 2000 and 1999 in connection with the grant of certain share options to employees, the Company recorded deferred compensation of $6,328,492 and $3,045,666, respectively, representing the excess of the fair value of the common stock on the date of grant over the exercise price. 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, 2001, 2000 and 1999 and from September 26, 1996 (inception) through December 31, 2001, the Company recorded amortization of deferred compensation of $3,145,870, $3,054,286, $612,909, and $7,457,072, respectively.

Pro forma net loss information is required to be disclosed by SFAS 123 and has been determined as if the Company has 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:

	2001	2000	1999
Expected dividend yield	0%	0%	0%
Risk-free interest rate range	3.5%-5.0%	5.3% - 6.6%	6.5%
Expected life	10 years	10 years	10 years

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 above assumptions, 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. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Had compensation cost for the Company's stock option plans been determined based on the fair value at the grant date consistent with the provisions of SFAS 123, the Company's net loss attributable to common stockholders would not have been materially affected in 2000 and 1999. The Company's pro forma net loss information for 2001 is as follows:

Net loss attributable to common stockholders – as reported	$ (21,702,508)
Net loss attributable to common stockholders – SFAS 123 pro forma	$ (22,761,596)
Net loss per common share – SFAS 123 pro forma	$ (0.81)

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 $146,000, $123,000, $107,000, and $682,000 for the years ended December 31, 2001, 2000 and 1999 and for the period September 25, 1996 (inception) through December 31, 2001, respectively. The following is a schedule of future minimum lease payments for operating leases at December 31, 2001:

2002	$	199,939
2003		183,096
2004		369,747
2005		377,486
2006		385,311
2007-10		1,274,286
	$	2,789,865

8. License Agreement

In September 1999, the Company licensed the migraine prophylactic agent, MT 500, from F. Hoffman-La Roche, Ltd and Syntex ("Roche"). The Company made a one-time non-refundable payment of $1.0 million at the time it entered into the agreement. The Company has charged the $1.0 million payment to research and development expense. In exchange for the upfront payment, Roche granted the Company a royalty-bearing, exclusive, worldwide license to develop and commercialize MT 500. As noted in Note 1 above, the Company has discontinued further development activities related to MT 500.

In January 2001, the Company entered into a Commercial Supply Agreement with Catalytica Pharmaceuticals, Inc. under which Catalytica will supply the Company with all MT 100 for commercial sale. The Company, or its commercial partner, are required to purchase all commercial supply of MT 100 from Catalytica for the initial term of the agreement and any extension thereof, unless Catalytica 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.

In October 2001, the Company entered into a Commercial Supply Agreement with Lek Pharmaceuticals Inc. 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 years ended December 31, 2000, 1999 and 1998 the Company did not make any contribution to the Plan. For the year ended December 31, 2001, and for the period September 25, 1996 (inception) through December 31, 2001, the Company made a contribution of $92,277 to the plan.

10. Legal Proceedings

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

On October 6, 2000, an action was filed against the Company alleging that the Company owed certain consideration and expenses in connection with the issuance and sale of preferred stock in the twelve-month period following the termination of the engagement of an investment banking firm to assist the Company with the sale of preferred stock in a private placement. In January 2002, the Company settled these issues for amounts that will have no material effect on the financial position or the results of operation of the Company.

11. Summary of Operations by Quarters (Unaudited)

	2001			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
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 attributable to common stockholders	(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

	2000			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Operating expenses	$ 3,033,077	$ 6,313,961	$ 8,789,375	$ 6,084,593
Net loss	(2,984,002)	(6,058,224)	(8,554,138)	(4,780,264)
Net loss attributable to common stockholders	(19,859,117)	(6,448,799)	(19,735,435)	(4,884,860)
Net loss per share of common stock				
Basic and diluted	$ (3.43)	$ (1.10)	$ (3.35)	$ (0.21)
Proforma	(1.34)	(0.34)	(1.00)	(0.19)
Number of shares used in per share calculation				
Basic and diluted	5,791,616	5,872,699	5,887,246	23,622,858
Proforma	14,848,011	18,746,829	19,737,305	26,328,444

EXHIBIT INDEX

Exhibit Number	Description
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	Executive Employment Agreement with John R. Plachetka dated April 1, 1999. * ***
10.5	License Agreement dated September 24, 1999 between the Registrant and F. Hoffman-La Roche Ltd. *
10.6	Investor Rights Agreement dated July 28, 1999 between the Registrant and the holders of the Series D Preferred Stock. *
10.7	Investor Rights Agreement dated March 24, 2000 between the Registrant and the holders of the Series E Preferred Stock. *
10.8	2000 Equity Compensation Plan *
10.9	Investor Rights Agreement dated August 28, 2000 between the Registrant and the holders of the Series F Preferred Stock. *
10.10	Sublease Agreement between Intecardia, Inc. and the Registrant dated as of September 1, 2000. *
10.11	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).
10.12	First Amendment to the Executive Employment Agreement with John R. Plachetka, Pharm.D., dated as of April 25, 2001 (filed as Exhibit 10.2 to the Company's Form 10-Q filed May 14, 2001). ***
10.13	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). ***
10.14	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). ***
10.15	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). ***

10.16	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). ***
10.17	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). ***
10.18	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).
10.19	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). ***
10.20	Commercial Supply Agreement dated October, 2001 by and between Registrant and Lek Pharmaceuticals Inc. † **
10.21	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001. **
23.1	Consent of Ernst & Young LLP, Independent Auditors**

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*	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.

Jacques F. Rejeange
President
Florham Consulting S.A.

Bruce A. Tomason
President
Apollo Capital Corporation

Ted G. Wood
President
The United Operating Companies

CORPORATE HEADQUARTERS

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STOCK TRANSFER AGENT AND REGISTRAR

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

INDEPENDENT ACCOUNTANTS

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

COMMON STOCK LISTING

Ticker Symbol: POZN
Nasdaq Stock Market

ANNUAL MEETING

Tuesday, May 21, 2002

POZEN Inc.
1414 Raleigh Road
Suite 400
Chapel Hill, North Carolina 27517
(919) 913-1030

FORM 10-K

A copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, as filed with The Securities and Exchange Commission, is available without charge to stockholders upon written request to:

POZEN Inc.
1414 Raleigh Road
Suite 400
Chapel Hill, North Carolina 27517

FORWARD-LOOKING STATEMENTS

Statements included in this report that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our 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 in the Company's Form 10-K for the fiscal year ended December 31, 2001. 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.

POZEN®
INC.
The Pharmaceutical Development Company

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