2008 ANNUAL REPORT

Breakthroughs for better living

POZEN® INC.

The Pharmaceutical Development Company

STOCKHOLDER LETTER

Treximet® is now available to the millions of migraine sufferers in the United States.

DEAR POZEN STOCKHOLDER:

2008 was an interesting and productive year for POZEN, highlighted by the FDA's approval of our first product in the United States, *Treximet®* (sumatriptan and naproxen sodium). We are proud that this unique medicine is now available to the millions of migraine sufferers in the United States. Although sales started a bit slowly, recent prescription trends are encouraging and we believe that momentum is building.

Our other development programs also made considerable progress this past year. PN 400, which has been licensed to AstraZeneca worldwide (excluding Japan), is a novel arthritis medicine combining two well-known active ingredients. At the heart of this product lies a sequential delivery of these two active ingredients, one intended to protect the gastrointestinal tract from the ulcerogenic effect of the other ingredient, which provides relief from the signs and symptoms of arthritis. We have finished all the clinical trials we believe are necessary to submit for product approval. In accordance with our agreement with AstraZeneca, we are waiting for a final decision from our partner to submit the NDA, which is targeted for this summer. If approved, we believe PN 400 could represent the first new oral arthritis medicine in quite some time.

Our remaining pipeline projects have also advanced. Our concept for a safer form of aspirin, that is, aspirin with less ulcerogenic potential than currently available dosage forms, is embodied in several different product concepts. PA32540 is intended for use in the secondary prevention of cardiovascular events and stroke. As PA32540 has an agreed Phase 3 program with the FDA, we intend to initiate our pivotal trials this summer. Two other programs, one for treatment of chronic pain and another for prevention of cancer, may be advanced later this year as we obtain proof-of-concept data and agreement of a regulatory pathway with the FDA.

Finally, let me mention again the advantages of our business model. Unlike many other small pharma companies, POZEN is well capitalized, we have no debt, we have a product on the market, and we believe we have a very promising pipeline of late stage product candidates.

So, I thank you for your support and interest, and I want you to know that now, more than ever, I believe we are well positioned for growth.

Sincerely,

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

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, 2008

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(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	NASDAQ Stock Market LLC

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

Preferred Share Purchase Right

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in 12b-2 of the Act). Yes ☐ No ☒.

The aggregate market value of the common stock held by non-affiliates computed by reference to the last reported sale price on June 30, 2008 was approximately $283,273,000. As of February 20, 2009, there were outstanding 29,778,310 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 into Part III of this Form 10-K and certain documents are incorporated by reference into Part IV.

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

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed below in the section entitled "Item 1A --Risk Factors." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements, other than as is required under the federal securities laws.

PART I

Item 1. Business

Overview

We are a pharmaceutical company focused on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. We operate a business model that focuses on the following:

- obtaining patents for innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas through proof of concept by working with strategic outsource partners;
- agreeing a regulatory pathway with the appropriate agency; and
- licensing the resulting product or technology to a strong pharmaceutical partner to commercialize.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize "best in class" resources as required.

After we establish the proof of concept for an innovative idea, we work with the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies to design a clear path forward to the filing of a new drug application, or NDA, or its foreign equivalent. We may then decide to seek a strong pharmaceutical partner to license the product or technology to collaborate with us in the remaining development and to commercialize the product or technology after approval. The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial partners to successfully commercialize the products.

Treximet

We have developed Treximet® (formerly known as Trexima™) in collaboration with GlaxoSmithKline, or GSK. Treximet is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and Treximet was available in pharmacies in May 2008.

Treximet incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a non-steroidal anti-inflammatory drug, or NSAID. Under our MT 400 technology, we seek to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed the NDA for Treximet with the FDA in August 2005. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults.

Our Principal Product Candidates

We are developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor, or PPI, with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca AB, or AstraZeneca, to co-develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet using our PN formulation technology, which agreement was amended in September 2007 and October 2008. We began the Phase 3 program in September 2007. As part of the program, we conducted two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which is the reduction in the incidence of endoscopic gastric ulcers. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition to the Phase 3 pivotal trials, we are conducting a long-term, open label safety study. We have terminated a non-pivotal smaller study in patients at high risk of gastrointestinal related events from NSAIDs which we believe is not required for approval. We are also conducting additional studies, which AstraZeneca is paying us to conduct. The NDA submission is planned for mid-2009.

Another product candidate, PA, a combination of a PPI and aspirin, is currently in formulation and clinical development testing. Our PA product candidates are excluded from our agreement with AstraZeneca. We have met with the FDA to discuss the overall development program requirements. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. We have completed a study which demonstrated the bioequivalence of the salicylic acid component of PA32540 as compared to 325 mg of enteric coated aspirin which we believe will satisfy the FDA's bioequivalence requirement. We filed a Special Protocol Assessment, or SPA, with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in the incidence of endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In February 2009, we received written confirmation from the FDA that endoscopic gastric ulcer incidence was an acceptable primary endpoint for the Phase 3 clinical studies we proposed in our SPA for PA 32540.

We are also conducting both formulation development and early stage clinical studies with new product concepts that are currently in the exploratory stage. If warranted, we may file U.S. and international patent applications with claims directed toward these novel combinations and formulations.

Overview of Our Results of Operations

We have incurred significant losses since our inception and have generated limited revenue from product sales. As of December 31, 2008, our accumulated deficit was approximately $133.1 million. We record revenue under two categories: licensing revenues and development revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the royalty payments based on product sales. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 74% of our total operating expenses. For the year ended December 31, 2008, our research and development expenses represented approximately 83% of our total operating expenses.

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

- The progress of our PN and PA product candidates and our other product candidates in the clinical and regulatory process;
- The ability of GSK to successfully commercialize Treximet in the U.S. For example, Treximet was available in pharmacies within one month from the date of its approval, but initial promotional and professional materials for the product, including direct to consumer advertising, were not approved on a timely basis by the FDA. The lack of approved materials and delay of the advertising launch may have had an adverse impact on uptake of the product, thus negatively impacting our royalty revenue;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates; and
- The acquisition and/or in-licensing, and development, of other therapeutic product candidates.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and may enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and successfully develop product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Annual Report on Form 10-K. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Our Business Strategy

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

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

Migraine Market Overview

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

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

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

- the occurrence of cardiovascular related events, including chest pain/discomfort, throat discomfort and warm/cold sensations;
- the potential for other serious cardiovascular events, including death;
- difficulty in producing sustained benefits with a single dose in a majority of patients;
- the occurrence of nausea and dizziness during treatment; and
- the need for cardiovascular evaluations from physicians before initially prescribing triptans to patients with cardiovascular disease risk factors.

Despite these shortcomings, according to IMS Health's IMS National Sales Perspective™, or IMS, in 2008 total triptan sales in the U.S. were approximately $2.5 billion. Imitrex®, marketed by GSK, is the leading triptan product. There are currently three types of Imitrex formulations commercially available: oral, intranasal and injectable. According to IMS, U.S. sales for Imitrex of all three formulations totaled approximately $1.3 billion in 2008. In November 2008, the first generic versions of sumatriptan were introduced by Dr. Reddy's Laboratories (oral), Par Pharmaceutical Companies Inc. (injection) and Sandoz Inc. (injection and intranasal). Generic sumatriptan sales in all dosage forms in 2008 totaled $99 million, of which $72 million were sales of the oral formulations. An oral triptan is often the physician's first choice as a prescription treatment for migraine pain. Intranasal triptans are often prescribed for patients requiring faster relief than oral drugs can provide or who cannot take oral medications. For the most severe attacks, patients sometimes use an injectable form of a triptan.

MT 400/Treximet

On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and was available in pharmacies in May 2008. As part of our NDA program for Treximet, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial using a formulation of Treximet developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Treximet, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Treximet (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK continues to conduct market support studies for Treximet. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for Treximet to GSK on May 14, 2008, and GSK now has responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

We incurred $0.3 million in direct development costs associated with the development of MT400/Treximet for the fiscal year ended December 31, 2008. We received in the fiscal year ended December 31, 2008, $20.0 million in milestone payments from GSK for the approval of, and GSK's intent to commercialize Treximet and we recorded $2.4 million of Treximet royalty revenue, of which $1.2 million is in accounts receivable at December 31, 2008. We billed GSK $0.2 million for Treximet activities for the fiscal year ended December 31, 2008. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

We received notices of paragraph IV certifications from Par Pharmaceutical, Inc., or Par, and Alphapharm Pty Ltd., or Alphapharm, and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg

tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm. We filed suit against Par on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

Status of Our Product Candidates and Exploratory Programs

Pain Market Overview

Pain affects more Americans than diabetes, heart disease and cancer combined. An estimated 76.5 million Americans report that they have had non-acute pain that persisted for more than 24 hours in duration. Of these, over two-thirds said the pain lasted for more than one month, while 42% said the pain lasted longer than one year. Low back pain is among the most common complaints, along with migraine or severe headache, and joint pain, aching or stiffness. Osteoarthritis, affecting 21 million Americans, is one of the leading causes of chronic joint aches, pains and stiffness. Rheumatoid arthritis affects another 2.1 million Americans and causes chronic, debilitating joint damage and pain.

Non-steroidal anti-inflammatory drugs, or NSAIDs, both over-the-counter and prescription, are commonly taken to manage the pain of backache, osteoarthritis, rheumatoid arthritis, headache and other painful conditions. In 2008, approximately 89 million anti-arthritis NSAID prescriptions were dispensed for the management of pain. Of these prescriptions, an estimated 60% of uses were for chronic therapy. Prescription sales of anti-arthritis NSAIDs in the U.S. in 2008 were $2.6 billion. In spite of their widespread use and apparent safety, according to the Agency for Healthcare Research and Quality Statistical Brief released in December 2008, in 2006, there were approximately 16,300 deaths and 246,000 hospitalizations with a primary diagnosis of upper gastrointestinal, or GI, bleeding. The most common underlying conditions of GI bleeding were gastric, duodenal, peptic, or gastrojeujunal ulcers or perforations, conditions frequently associated with NSAID use. We are responding to this unmet medical need to provide a “safer NSAID” through development of our PN product candidates for the treatment of conditions such as osteoarthritis in patients who are at risk for developing NSAID-associated gastric ulcers.

PN Program

Under our PN program, we have completed formulation development and clinical studies for several combinations of a PPI and an NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to a NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We initially conducted studies with two PN product formulations in this program - PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen, prior to entering into our collaboration with AstraZeneca. Our present development and commercialization efforts under the PN program are covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006 and which was amended in September 2007 and October 1, 2008. Under our agreement with AstraZeneca, we and AstraZeneca are co-developing, and AstraZeneca will commercialize, proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. The initial product to be developed under the agreement, PN 400, is being studied for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID-associated gastric ulcers. On March 2, 2007, we filed an IND with the FDA for PN 400 and in April 2007, the first Phase 1 study was initiated.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and PN 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for chronic use of naproxen in adults would accrue to the PN product, if clinical trials successfully demonstrated improved safety (lower incidence of gastric ulcers) of the PN product compared with naproxen alone and the PN formulation was shown to be bioequivalent to marketed formulations of enteric coated, or EC, naproxen. Prior to entering into our collaboration agreement with AstraZeneca, we completed a study designed to demonstrate the bioequivalence of the naproxen component of our PN 200 product candidate development formulation to EC naproxen. This study demonstrated that the PN 200 product was bioequivalent to the reference drug, EC Naprosyn® with respect to the naproxen component.

In early 2006, we submitted a Special Protocol Assessment, or SPA, to the FDA for our pivotal Phase 3 clinical trials for PN 200. The SPA is a process in which the FDA provides evaluations and guidance on clinical trial protocols for pivotal Phase 3 clinical trials. In April 2006, we announced that we had reached an agreement with the FDA on the Phase 3 pivotal clinical trials for PN 200 for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. We also reached agreement with the FDA that the development program and study design proposed for PN 200 would be applicable to a product that contained an isomer of omeprazole combined with naproxen. In light of our collaboration agreement with AstraZeneca, we, along with AstraZeneca have met with the FDA and confirmed the core development program and the principles in the SPA already agreed upon do apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen. In late January 2009, the FDA informed us that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our PN 400 clinical program.

In the third quarter of 2006, we began recruiting subjects for a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy. The primary endpoint for the trial was the cumulative incidence of gastric ulcers over six months of treatment. Because we did not have final results until the fourth quarter of 2007, we, together with AstraZeneca reviewed the interim results of this trial prior to commencing Phase 3 studies of PN 400 in September 2007. This study has now been completed and the results which have been presented publicly, indicated significantly fewer endoscopically confirmed gastric ulcers during the six month treatment period in subjects on PN 200 compared to subjects receiving enteric coated naproxen alone. We have completed two PN 400 Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which is the reduction in endoscopic gastric ulcers. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition, we are conducting a long-term, open label safety study for PN 400. We have terminated a non-pivotal smaller study in patients at high risk (i.e., previous bleeding from a gastric ulcer) of gastrointestinal related events from NSAIDs which is not required for approval. We are also conducting additional studies at AstraZeneca's expense.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID-containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen safety concerns becomes available, long-term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN product candidates.

Additionally, we have met with four national European regulatory agencies to discuss the proposed development program for PN. Under our agreement with AstraZeneca, AstraZeneca has responsibility for the development program for PN outside the U.S., including interactions with regulatory agencies. It is our understanding that AstraZeneca intends to file marketing applications for PN 400 in certain ex-US countries based upon clinical data being generated for the NDA after the NDA is filed.

We cannot reasonably estimate or know the amount or timing of the costs necessary to obtain regulatory approval of PN 400. Nor can we reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PN product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PN products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN program of $45.4 million for the fiscal year ended December 31, 2008, $28.7 million of which was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PA Program

As part of our PA program, we are exploring the development of a combination of a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program.

Our initial PA product candidate, PA32540, is currently in early-stage clinical development. We completed a Phase 1 proof of concept study in Canada of an earlier formulation of PA containing 325 mg of aspirin and 20 mg of omeprazole (PA32520) in the first quarter of 2007. The primary endpoint was gastrointestinal damage as measured by the Lanza scoring system used in our previous PN studies. The results were highly significant ($p<0.001$) with 10 percent of the PA group having Lanza 3 or 4 gastrointestinal damage, whereas 57.5% of the EC aspirin group had this level of gastrointestinal damage during the 28 day study. We also completed a second proof of concept study with PA32520 as compared to 81 mg of EC aspirin. These results confirmed the earlier levels of gastric damage as measured by Lanza scoring at about 10% for PA32520. While these results in the second study were numerically different between treatment groups, they did not achieve statistical significance from the results obtained with 81mg EC aspirin (21%). After reviewing these data, we decided to increase the dose of omeprazole to 40 mg per tablet and conduct an additional 28 day Phase 1 study using the formulation containing 40 mg of immediate release of omeprazole and 325 mg of aspirin (PA32540) compared to 325 mg EC aspirin. Topline results from this study indicate a highly significant ($P=0.003$) reduction in gastrointestinal damage with the higher strength PA32540 tablet as compared with 325 mg EC aspirin (2.5% vs. 27.5% grade 3 or 4 Lanza scores, respectively). In this last study, 75% of subjects treated with the PA32540 tablet showed no gastrointestinal damage at all as compared to < 50% with the PA32520 tablet. An IND for the product was filed in the fourth quarter of 2007 and we met with the FDA in July 2007 to discuss the overall development program requirements. We completed a study which demonstrated that the salicylic acid component of PA32540 was bioequivalent to the reference drug, EC aspirin, with respect to the aspirin component, and which we believe will allow our PA product to receive all the cardio- and cerebrovascular secondary prevention claims of aspirin.

In June 2008, we filed an SPA with the FDA for our pivotal Phase 3 trials for PA32540, the primary endpoint for which is the reduction in endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In February 2009, we received written confirmation from FDA that endoscopic gastric ulcer incidence was an acceptable endpoint for the Phase 3 clinical studies we proposed in our SPA for PA32540. We are also conducting both formulation development and early stage clinical studies with other PA product candidates for indications in addition to cardiovascular protection.

Additionally, we have met with three national European regulatory agencies to discuss the proposed development program for PA. Each of these regulatory agencies has indicated that reduction in gastric ulcers is an appropriate endpoint for the pivotal trials, along with demonstrating bioequivalence to the reference drug, EC aspirin, with respect to the aspirin component. Dose ranging studies may also be required.

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

We incurred direct development costs associated with the development of our PA program of $5.0 million during the fiscal year ended December 31, 2008. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Collaborative Arrangements

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

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the NDA for Treximet, the trade name for the product. On April 26, 2008 we received, from GSK, $20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, Treximet. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. In 2008, we recorded $2.4 million of Treximet royalty revenue, of which $1.2 million was in accounts receivable at December 31, 2008. GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017) based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. GSK elected not to exercise its first right to bring an infringement suit against Par and Alphapharm, both of which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets before the expiration of our patents and we filed suit against both Par and Alphapharm in the federal court of the Eastern District of Texas. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

We received notices of paragraph IV certifications from Par and Alphapharm and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm. We filed suit against Par on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca had the right, which has now expired, to elect to include Japan in the licensed territory within two years after the effective date of the agreement. Pursuant to the terms of the agreement, we received an upfront license fee of $40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

In September 2007, we agreed with AstraZeneca to amend our collaboration and license agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to $345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007, we received a $10.0 million payment upon execution of the amendment and a $20.0 million payment in recognition of the achievement of the primary endpoints for the PN 400-104 study, a study which compared acid suppression of different doses of PN 400, and achievement of the interim results of the PN 200-301 study, a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy, meeting mutually agreed success criteria. An additional $55.0 million will be paid upon achievement of certain development and regulatory milestones, and $260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved. Under the original agreement, we were to have received development and regulatory milestones totaling $160.0 million, of which $20.0 million was to be paid upon the successful completion of the proof of concept studies, and sales performance milestones totaling $175.0 million.

In addition, the amendment revised the royalty rates we were to have received under the original agreement. Under the original agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the amendment, we will now receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revises the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure.

Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We further amended the collaboration and license agreement effective October 1, 2008 to shorten the timing of AstraZeneca's reimbursement obligation for certain development expenses incurred by us under the collaboration and license agreement and to update the description of the target product profile studies (as defined in the Agreement) for PN 400.

We retain responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We have agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

Valeant Pharmaceuticals North America (Valeant NA) (formerly Xcel Pharmaceuticals Inc.)

In September 2003, we signed an agreement with Valeant NA for the further development and commercialization of MT 300. In March 2005, Valeant Pharmaceuticals International (Valeant International) acquired Valeant NA. Under the terms of the agreement, Valeant NA would have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations.

Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant NA of this situation and Valeant NA does not assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the

agreement will terminate and we would be required to pay Valeant NA a withdrawal fee of $1.0 million. If Valeant NA decides to assume development, it would be credited $1.0 million in development expense. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300. In July 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. We do not believe that the withdrawal fee is payable based on our receipt of a not-approvable letter from the FDA with respect to our NDA for MT 300. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. We intend to vigorously defend our position under the agreement, although the last written communication from Valeant NA was received in March, 2006. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA upon the ultimate resolution of this dispute.

Based upon the delays related to commercialization of MT 300 due to our receipt of the not-approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Valeant NA had previously agreed to extend the time for certain activities under our agreement with Valeant NA that are dependent on the FDA's actions with respect to MT 300. In the event of termination of the agreement, these obligations will not be relevant. We can give no assurance that Valeant NA or Valeant International will agree to termination terms acceptable to us or that we will not be required to pay Valeant NA the withdrawal fee of $1.0 million described above. The $1.0 million upfront fee was taken into revenue as of December 31, 2008, so any required payment to Valeant NA in the future would have an impact on our statements of operations.

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 clinical trial materials. We believe our current supplier agreements should be sufficient to complete our planned clinical trials. Under our agreements with GSK and AstraZeneca, it is the obligation of our partners to supply clinical trial material required to conduct clinical trials, as well as commercial supplies of products developed under those agreements. Use of third-party manufacturers enables us to focus on our clinical development activities, minimize fixed costs and capital expenditures and gain access to advanced manufacturing process capabilities and expertise. We also intend to enter into agreements with third-party manufacturers for the commercial scale manufacturing of our products.

In October 2001, we entered into a commercial supply agreement with Lek Pharmaceuticals Inc., or Lek, a subsidiary of Novartis Pharma AG, under which Lek agreed to provide us with dihydroergotamine mesylate, or DHE, the active pharmaceutical ingredient of 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 may, upon 90 days' notice to us, convert its exclusive supply obligation under the agreement to a non-exclusive obligation. The agreement provides that we will pay Lek, under certain circumstances, a fee in addition to the agreed supply price for DHE, based on a percentage of MT 300 sales revenue. The initial term of the agreement terminates on the fifteenth (15th) anniversary of the date of the first commercial sale of MT 300, but is automatically renewed on an annual basis thereafter unless canceled or terminated. Either party may cancel the agreement upon a material breach. We may terminate the agreement if we elect to stop development or commercialization of MT 300, or after a period of time specified in the agreement. In addition, Lek may terminate the agreement after a certain period of time, under agreed transition, supply and know-how transfer provisions, if Lek decides to permanently cease the manufacture of DHE.

Competition

Competition for our migraine products that receive regulatory approval will come from several different sources. Because not all migraine attacks are of the same severity, a variety of oral, injectable and intranasal therapies are used to treat different types of migraine attacks. Attacks are often treated initially with simple over-the-counter analgesics, particularly if the patient is unable to determine if the attack is a migraine or some other type of headache. These analgesics include Excedrin Migraine®, which is approved for the pain associated with migraine. If over-the-counter remedies are unsuccessful, patients often turn to more potent prescription drugs, including triptans. According to IMS, in 2008, total triptan sales in the U.S. were approximately $2.5 billion. Imitrex, a triptan product marketed by GSK, had total U.S. sales of approximately $1.3 billion in 2008, according to IMS.

Narcotics such as codeine and drugs containing analgesic/narcotic combinations, along with other non-narcotic pain medications, are also used for the treatment of migraine. If approved, our migraine product candidates will most likely compete

with one or more of these existing migraine therapeutics, as well as any therapies developed in the future. Based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals will be our principal competitors if our migraine product candidates are approved.

The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™) and the only remaining COX-2 inhibitor, Celebrex®. The U.S. prescription market for oral solid NSAIDs was approximately $2.6 billion in 2008, of which 73% was accounted for by Celebrex, according to IMS. This market is continuing to undergo significant change, due to the voluntary withdrawal of Vioxx® by Merck & Co. in September 2004, the FDA-ordered withdrawal of Bextra® by Pfizer in April 2005 and the issuance of a Public Health Advisory by the FDA in April 2005 stating that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005 that addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. However, based on a meeting with the FDA in September 2005, we believe, although we cannot guarantee, that long-term cardiovascular safety studies may not be required at this time for FDA approval of our PN product candidates containing naproxen.

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

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

Patents and Proprietary Information

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

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

MT 400/Treximet

We have three issued U.S. patents and one pending U.S. application with claims relating to methods, compositions and therapeutic packages involving the use of certain NSAIDs and 5-HT receptor agonists in treating patients with migraine. Outside of the U.S., we have issued patents in Australia, Canada, Europe, Hong Kong and Japan. The expected expiration date of the issued patents relating to MT 400 is August 14, 2017.

Oppositions were filed against the issued European patent in October 2005 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. We filed a response to these oppositions in May 2006, and in March 2007, the Opposition Division of the European Patent Office called for oral proceedings. During the oral proceedings and in the written opinion subsequently provided, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-$HT_{1B/1D}$ agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence.

We also have an issued U.S. patent with claims relating to formulations of MT 400 which, we expect to expire in October 2025. We have additional pending U.S. and foreign patent applications with claims directed to formulations of MT 400 which, if issued, we expect to expire between December 2023 and March 2027.

PN/PA

We have issued patents in the U.S., Australia, Mexico and Eurasia, with claims directed to certain compositions containing a combination of acid inhibitors, including PPIs, and NSAIDs. The issued patents also have claims to treatment methods involving the use of such compositions. We have pending U.S. and foreign patent applications that also have claims to compositions containing acid inhibitors and NSAIDs and to various treatment methods involving such compositions. The issued U.S. patent and related U.S. patent applications will expire on February 28, 2023. We expect the foreign patents, as well as additional patents which issue from the pending foreign patent applications, to expire on May 31, 2022.

MT 300

With respect to MT 300, we received U.S., as well as European, Australian and other foreign patents relating to a high potency formulation of DHE and formulations of DHE in a pre-filled syringe. The expected expiration date of all of the U.S. and foreign patents relating to MT 300 is March 15, 2020. We began abandoning our foreign issued patents and our pending foreign patent applications relating to MT 300 during 2006 and 2007.

Exploratory Programs

We have filed U.S. and international patent applications with claims directed to novel compositions and formulations for new product concepts that are currently in the exploratory stage. If we pursue these provisional applications into prosecution as regular patent applications, any patents which issue from these applications would be expected to expire between 2026 and 2028.

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, or 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 IND;
- initiating clinical trials under the IND and addressing any safety or regulatory concerns of the FDA;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:

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

Phase 2: The product candidate is studied in patients to identify possible adverse effects and safety risks, to determine dosage tolerance and the optimal dosage, and to collect some efficacy data;
Phase 3: The product candidate is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring primary and secondary endpoints established at the outset of the study;

- submitting the results of preclinical studies, and clinical trials as well as chemistry, manufacturing and control information on the product candidate to the FDA in a 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. Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective on October 1, 2007 for the fiscal year 2008, the user fee for an application requiring clinical data, such as an NDA, is $1,178,000. PDUFA also imposes an annual product fee for marketed prescription drugs ($65,030), and an annual establishment fee ($392,700) on facilities used to manufacture prescription drugs and biologics. For fiscal year 2009, the user fee for an application requiring clinical data is $1,247,200, the annual product fee for marketed prescription drugs is $71,520, and the annual establishment fee on facilities is $425,600. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. However, there are no waivers for product or establishment fees.

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 and financial support.

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

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

The status of the NDAs we have submitted to the FDA for Treximet and MT 300 is discussed above in "Status of Our Product Candidates and Exploratory Programs - MT 400/Treximet", and "Status of Our Product Candidates and Exploratory Programs – MT 300."

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

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

The FFDCA also mandates that products be manufactured consistent with cGMP regulations. In complying with the cGMP regulations, manufacturers must continue to spend time, money and effort in production, record keeping, quality control, and auditing to ensure that the marketed product meets applicable specifications and other requirements. The FDA

periodically inspects manufacturing facilities to ensure compliance with cGMP regulations. Failure to comply subjects the manufacturer to possible FDA action, such as warning letters, suspension of manufacturing, seizure of the product, voluntary recall of a product or injunctive action, as well as possible civil penalties. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and product candidates. These third parties will be required to comply with cGMP regulations.

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

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

Before a medicinal product can be supplied in the European Union, or EU, it must first be granted a marketing authorization. There are three routes by which this may be achieved: the centralized procedure whereby a single European license is granted by the European Commission permits the supply of the product in question throughout the EU or the decentralized, or DC, or mutual recognition procedures, or MRP, through which the views of one national authority (Reference Member State, or RMS) are "recognized" by other authorities (Concerned Member States, or CMS) when conducting their reviews; the DC applies if the medicinal product in question has not yet received a marketing authorization in any member state at the time of the application whereas the MRP applies to a currently approved medicinal product. These latter two processes lead to individual licenses in each member state for the supply of products in that country only. The centralized route is compulsory for biotechnology products and is optional for certain so-called "high technology" products and products containing entirely new active substances. All products which are not authorized by the centralized route must be authorized by the DC or MRP unless the product is designed for use in a single country in which case a National Application can be made.

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

The MHRA will assess the data presented to ensure that the product satisfies the appropriate requirements for efficacy, safety and quality. They may seek additional evaluation by an advisory committee, the Commission on Human Medicines. The Commission on Human Medicines may, if it wishes, advise the MHRA to refuse an application.

Fixed combination medicinal products that incorporate two previously approved active ingredients, such as certain of our combination product candidates, are only considered acceptable by the MHRA if the proposed combination is based on valid therapeutic principles. The possibility of interactions between the substances is assessed and to establish that either interactions do not occur, or if they do occur, they are clearly established and defined. Furthermore, special safety and efficacy requirements apply to fixed combination products in that the dosage of each active ingredient within the combination product must have a documented contribution within the combination and the combination should demonstrate a level of efficacy above that achieved by a single substance with an acceptable safety profile.

In making an application for a new medicinal product not governed compulsorily by the centralized procedure, typically use will be made of the DC although the MRP would be used if a marketing authorization were first secured in an RMS. The procedural steps for the DC and the MRP are governed by Directive 2001/83/EC, as amended, and are described in the Notice to Applicants, Volume 2A Chapter 2 - Mutual Recognition (updated version - November 2005). The procedures provide for set time periods for each process (DC - 120 days; MRP – 90 days) but if consensus is not reached between all the CMS and the RMS in that time, the application is referred to arbitration through the Co-ordination Group for Mutual Recognition and Decentralized Procedures, or CMD, with referral to the Committee for Human Medicinal Products, or CHMP. If a referral is made, the procedure is suspended; marketing of the product would only be possible in the RMS in the case of an MRP. The opinion of the CMD/CHMP, which is binding, could support or reject the objections or alternatively reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may require the delivery of additional data.

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

The extent of U.S. and foreign government regulation which might result from future legislation or administrative action cannot be accurately predicted. For example, in the U.S., although the Food and Drug Administration Modernization Act of 1997, or FDAMA, 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 FDAMA and the more recent Food and Drug Administration Amendments Act of 2007, or FDAAA. FDA has been actively implementing drug safety plans called Risk Evaluation and Mitigation Strategies, or REMS, as authorized by FDAAA, as a condition of drug approval, or after initial marketing, if FDA becomes aware of new safety data about the drug. These and other legislative initiatives may impose additional regulatory requirements on us, and may impact approval of our drugs or our marketing plans. The actual effect of these and other developments on our own business is uncertain and unpredictable.

Corporate Information

We were incorporated in Delaware on September 25, 1996. Our principal offices are located in the Exchange Office Building at 1414 Raleigh Road, Suite 400, Chapel Hill, NC 27517. Our telephone number is (919) 913-1030. We maintain a website at www.pozen.com and make available free of charge through this website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. We are not including the information contained at www.pozen.com, or at any other Internet address as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

In addition, we make available on our website (i) the charters for the committees of our Board of Directors, including the Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and The NASDAQ Stock Market.

Employees

As of January 31, 2009, we had a total of 34 full-time employees. All of our current employees are based at our headquarters in Chapel Hill, North Carolina**.** Of our 34 employees, 19 hold advanced degrees, including nine with M.D., Pharm.D. or Ph.D. degrees.

Officers and Key Employees

Our current officers and key employees, and their ages as of February 1, 2009, are as follows:

Name	Age	Position
John R. Plachetka, Pharm.D.	55	Chairman, President and Chief Executive Officer
William L. Hodges	54	Senior Vice President, Finance and Administration, Chief Financial Officer
Marshall E. Reese, Ph.D.	63	Executive Vice President, Product Development
Gilda M. Thomas	54	Senior Vice President, General Counsel
John E. Barnhardt	59	Vice President, Finance & Administration
Everardus Orlemans , Ph.D.	52	Senior Vice President, Product Development
John G. Fort, M.D.	54	Chief Medical Officer

John R. Plachetka, Pharm.D. is Chairman of the Board of Directors, a co-founder, President and Chief Executive Officer of POZEN and has held such positions since our inception in 1996. Prior to founding POZEN, Dr. Plachetka was Vice President of Development at Texas Biotechnology Corporation from 1993 to 1995 and was President and Chief Executive

Officer of Clinical Research Foundation-America, a leading clinical research organization, from 1990 to 1992. From 1981 to 1990, he was employed at Glaxo Inc. Dr. Plachetka received his B.S. in Pharmacy from the University of Illinois College of Pharmacy and his Doctor of Pharmacy from the University of Missouri-Kansas City.

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

Marshall E. Reese, Ph.D. joined POZEN in October 2004 as Executive Vice President of Product Development. From July 1999 to July 2003, Dr. Reese was employed at the Swiss-based pharmaceutical company Novartis as Senior Vice President and Global Head of Research and Development, Consumer Health Care. Prior to joining Novartis in 1999, Dr. Reese held several senior executive positions at Glaxo Inc. and GlaxoWellcome, including Vice President of Global OTC Development and Manufacturing with GlaxoWellcome, based in the United States, and Vice President of Development Planning and International OTC Strategies for Glaxo and GlaxoWellcome, in both the United States and the United Kingdom. Dr. Reese received his B.S., M.S., and Ph.D. degrees from the University of Tennessee at Knoxville. Dr. Reese has informed us of his intention to retire effective as of March 31, 2009.

Gilda M. Thomas joined POZEN in January 2007 as Senior Vice President and General Counsel. Prior to joining POZEN, Ms. Thomas was Vice President, General Counsel and company secretary at EMD Pharmaceuticals, Inc., an affiliate of Merck KGaA, Darmstadt, Germany from July 2001 to December 2006. Prior to joining EMD, she spent 14 years at Burroughs Wellcome Co., which merged into Glaxo Welcome, Inc. At Glaxo Wellcome Ms. Thomas was Associate General Counsel responsible for the 13 member corporate section of the legal department. Ms. Thomas received her J.D. from Harvard Law School, a M.S. from Simmons College and a B.S. degree from Wellesley College.

John E. Barnhardt, joined POZEN in 1997 as Vice President, Finance and Administration and Principal Accounting Officer. Prior to joining POZEN, Mr. Barnhardt held finance and accounting positions with publicly traded companies beginning in 1988. These positions included Chief Financial Officer of Medco Research, Inc., engaged in the research and development of pharmaceutical products primarily for the diagnosis and treatment of cardiovascular disease, and Principal Accounting Officer of Microwave Laboratories, Inc., a defense contractor developing and manufacturing traveling wave tubes for electronic countermeasure systems. Mr. Barnhardt received his B.S. in Zoology from North Carolina State University, and while employed at Ernst & Ernst (now Ernst & Young LLP), became a Certified Public Accountant.

Everardus Orlemans, Ph.D. joined POZEN in November 2005 as Vice President, Clinical Research and was promoted to Senior Vice President, Product Development in January 2009. Dr. Orlemans began his professional career with Organon NV, a pharmaceutical company based in the Netherlands, before transferring to its U.S. subsidiary, Organon Pharmaceuticals USA, Inc., where his most recent position was Executive Director of the Clinical Development Unit. Dr. Orlemans was an employee of Organon NV and/or its U.S. Subsidiary from October 1988 to March 2005. He received a M.S. in Chemistry from Catholic University of Nijmegen in the Netherlands and his Ph.D. degree from the University of Twente, also located in the Netherlands.

John G. Fort, M.D. joined POZEN in July 2007 as Chief Medical Officer. Prior to joining POZEN, Dr. Fort was Vice President, Medical Affairs at Adolor Corporation and held positions with Pfizer Inc., including Vice President, Medical Affairs, and was Vice President, Arthritis and Pain at G.D. Searle & Co., Monsanto Corporation from September 1994 to December 2003. Prior to joining the pharmaceutical industry, he was an Associate Professor of Medicine at Thomas Jefferson University, Division of Rheumatology. Dr. Fort received his M.D. from the University of Valencia Faculty of Medicine and is board certified in internal medicine with a subspecialty certification in rheumatology.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other

companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Product revenue is dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of GSK relating to Treximet.

We have incurred significant losses since our inception. As of December 31, 2008, we had an accumulated deficit of approximately $133.1 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing and amount of payments that we may receive from others. We expect to continue to incur significant operating losses associated with our research and development efforts and do not know the amount or timing of product revenue we will receive as a result of sales of Treximet by GlaxoSmithKline, or GSK, or future sales of our other product candidates by our commercial partners. For example, GSK's inability to launch Treximet with approved promotional and professional materials, including direct to consumer advertising, may have had an adverse impact on uptake of the product, thus affecting our royalty revenue.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with GSK and AstraZeneca. We received the remaining regulatory milestone payments under our collaboration agreement with GSK related to Treximet payable upon FDA approval and notification of GSK's intent to commercialize Treximet, receipt of which were delayed as a result of our receipt of a second approvable letter for the product on August 1, 2007.

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

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of Treximet and our current product candidates. Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, approval of Treximet for commercial use was significantly delayed by our receipt of two approvable letters, the first of which we received in June 2006 in which the FDA requested additional safety information on Treximet, some of which required new studies. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity.

In October 2008, the FDA has also informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for PN 400 and the proposed primary endpoint in the current study design of the Phase 3 trials for our PA32540 product. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. If the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint in clinical trials, we might have been required to conduct additional trials and provide additional data which would have required additional expenses and delayed NDA approval of PN 400.

In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

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

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then

current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. For example, in October 2008, the FDA has informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for PN 400. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In the event the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint, we might have been required to conduct additional trials and provide additional data which would have required additional expenses and delayed NDA approval of PN 400. Further, changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained in conversations and other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX-2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. On April 7, 2005, the FDA issued a Public Health Advisory, or the Advisory, based, in part, upon the recommendations of the advisory committee. The Advisory stated that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our PN or other product candidates that contain NSAIDs.

If we, or our current or future collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates. Further, if we are delayed in obtaining or unable to obtain, any required approvals, our collaborators may terminate, or be entitled to terminate, their agreements with us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the United States. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. Except for Treximet, which was approved for commercial sale in the U.S. on April 15, 2008, none of our other product candidates have been approved for sale in the U.S. or any foreign market and they may never be approved. For example, we received two approvable letters relating to our NDA for Treximet which communicated FDA's concerns that delayed marketing approval. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In June 2006, we received the first approvable letter in which the FDA requested additional safety information on Treximet, and in August 2007, we received a second approvable letter in which the FDA requested that we address their concern about the potential implications from one preclinical in vitro chromosomal aberration study in which a signal for genotoxicity was seen for the combination of naproxen sodium and sumatriptan. We have also previously received not-approvable letters from the FDA relating to our NDAs for MT 100 and MT 300.

In the U.S., a separate NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek in the future outside the U.S.

Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. For example, under our PN collaboration agreement with AstraZeneca, AstraZeneca has the right to

terminate the agreement if certain delays occur or specified development and regulatory objectives are not met. For example, this termination right could have been triggered by AstraZeneca if the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for PN 400. Both AstraZeneca and GSK have the right to terminate their respective agreement with us upon 90 days notice for any reason. If we or our contract manufacturers do not maintain required regulatory approvals, we may not be able to commercialize our products. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

We and our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third-party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, which could result in a delay or an inability to manufacture the products. If we or our partners wish or need to identify an alternative manufacturer, delays in obtaining FDA approval of the alternative manufacturing facility could cause an interruption in the supply of our products.

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

If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly and time consuming and could negatively impact the commercialization of Treximet and/or any of our products that we develop or acquire. We have received notice of paragraph IV certifications notifying us of the filing of ANDAs with the FDA for approval to market a generic version of Treximet. We filed patent infringement lawsuits in response to these ANDAs that could lead to costly and time consuming patent litigation.

The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing pharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights. There has been substantial litigation regarding patents and other intellectual property rights in the pharmaceutical industry. For example, third parties seeking to market generic versions of branded pharmaceutical products often file ANDAs with the FDA, containing a certifications stating that the ANDA applicant believes that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed. Such certifications are commonly referred to as a paragraph IV certification.

We received notices of paragraph IV certifications from Par Pharmaceutical, Inc., or Par, and Alphapharm Pty Ltd., or Alphapharm, and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring an infringement suits against Par and Alphapharm. We filed suit against Par in on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier.

Litigation can be time consuming and costly and we cannot predict with certainty the outcome. If we are unsuccessful in such a proceeding and the FDA approved a generic version of our product, such an outcome would have a material adverse effect on sales of Treximet and our business.

Our reliance on collaborations with third parties to develop and commercialize our products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

Under our current strategy, we expect to depend upon collaborations with third parties to develop our product candidates and we expect to depend substantially upon third parties to commercialize our products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and any future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology, including Treximet, in the U.S., a global collaboration with AstraZeneca for the development and commercialization of proprietary combinations of gastroprotective agents and naproxen, and a collaboration with Valeant NA in the U.S. for the development and commercialization of MT 300. In these collaboration agreements, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK and AstraZeneca are entitled to terminate their respective agreements with us upon 90 days' notice for any reason. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors attain a pre-determined share of the market for products marketed under the agreements, or if either GSK or AstraZeneca must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca is also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives are not met. This termination could have been triggered by AstraZeneca if the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for PN 400. Valeant NA is entitled to terminate its agreement with us and a $1.0 million withdrawal fee payable by us in the event we choose to withdraw the NDA if we determine that additional studies or data that are required by the FDA for approval of the NDA would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300. Due to our belief that the FDA will not approve the NDA for MT 300 and there are no additional required studies, we began discussions with Valeant NA regarding termination of our agreement. Valeant NA has demanded payment of the $1.0 million withdrawal fee, which we are disputing.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with our collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determined, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Treximet clinical trials. Similarly, under our agreement with AstraZeneca, AstraZeneca has the right to manufacture clinical trial material itself or through a third party. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in FDA approval we experienced as a result of approvable letters we received from the FDA in June 2006 and August 2007 related to our Treximet NDA, or a delay in FDA approval of PN 400 which could have occurred if the FDA determined that endoscopic gastric ulcers were no longer an acceptable primary endpoint in clinical trials and we were required to conduct additional clinical trials for the product, would delay or possibly eliminate our potential product revenues. Further, our collaborators may be able to exercise control, under

certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements and would have exclusive control over such enforcement litigation. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets and we have filed suit against both companies in the federal court of the Eastern District of Texas.

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

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;
- third parties may not fulfill their regulatory or other obligations;
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and
- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

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

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

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

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

We have no sales or distribution personnel or capabilities at the present time. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively, we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, such as our agreement with GSK which gives GSK responsibility for marketing and selling Treximet in the United States, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that, should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

Because we do not believe it is possible to convince the FDA to reverse its conclusion as stated in its not-approvable letter for MT 300, we do not expect to receive any revenue from sales of MT 300 in the U.S.

In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre-defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Further, the FDA noted that the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours. After our receipt of the not-approvable letter, we had continuing communications with the FDA regarding the MT 300 NDA. Based upon our understandings from our most recent communications with the FDA in 2005 and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the MT 300 NDA. Therefore, we do not believe that we will receive any revenue from sales of MT 300 in the U.S.

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

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the type of product candidate and the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity and other safety 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. For example, long-term cardiovascular safety studies, such as those the FDA has indicated will be required for approval of certain product candidates containing NSAIDs, typically take approximately three years. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, differences in study design, including inclusion/exclusion criteria, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of Treximet differed from the results of our second Phase 3 clinical trial and from the Phase 2 proof-of-concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the first Phase 3 study Treximet failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, Treximet demonstrated superiority over the individual components measured by sustained pain-free response ($p<0.001$ vs. naproxen; $p=0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

The successful completion of any of our clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that are unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of a marketing application, we may be required to conduct additional clinical trials, studies or investigations or to submit additional data to support our marketing applications. In addition, we and/or our marketing or development partners may determine that pre-approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could a have material impact on the approval of filed or planned market applications or could result in limits placed on the marketing of the product. We may also determine from time to time that it would be necessary to seek to provide justification to the FDA or other regulatory agency

that would result in evaluation of the results of a study or clinical trial in a manner that differs from the way the regulatory agency initially or customarily evaluated the results. In addition, we may have unexpected results in our preclinical or clinical trials or other studies that require us to reconsider the need for certain studies or trials or cause us to discontinue development of a product candidate. For example, in reviewing our NDA for Treximet, the FDA expressed concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Once submitted, an NDA requires FDA approval before the product described in the application can be distributed or commercialized. 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 requested additional safety information on Treximet in the approvable letter we received in June 2006 relating to our NDA for Treximet, which required conduct of additional studies, and in August 2007, we received a second approvable letter in which the FDA raised an additional concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Further, although we believed that we provided the necessary data to support approval of the NDAs for MT 100, our proprietary combination of metoclopramide hydrochloride and naproxen sodium, and MT 300, the FDA issued not-approvable letters for the MT 100 and MT 300 NDAs in May 2004 and October 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 and have withdrawn the MAA for the product in the U.K.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement. We face similar regulatory hurdles in other countries to those that we face in the U.S.

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

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

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

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

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

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous

competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals), biotechnology companies, universities and public and private research institutions. The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX-2 inhibitor, Celebrex®, and new agents such as Prasugrel, which has been approved in several countries and is currently under review by FDA.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

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

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

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products where we cannot or before we do. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we experienced as a result of the approvable letters we received from the FDA in June 2006 and August 2007 relating to the Treximet NDA, and as a result of the not-approvable letters we received from the FDA on MT 100 and MT 300 increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If there is an adverse outcome in the securities class action lawsuit that has been filed against us or our current directors and officers, or we are unable to defend our patents in patent infringement lawsuits against generic companies filing ANDAs for our products, our business may be materially harmed. Further, defending against these lawsuits may be expensive and will divert the attention of our management.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by us concerning our migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, we received the plaintiffs' amended and consolidated complaint which added two of our current officers as additional defendants. We and the individual defendants filed a motion to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of our directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs have stated that they intend to file objections to the Recommendation and, if plaintiffs do object, there can be no assurance that the Court will accept the Recommendation. If plaintiffs do file objections to the Recommendation, the Company and the individual defendants intend to continue to defend these claims vigorously.

We received notices of paragraph IV certifications from Par and Alphapharm and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a

generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm. We filed suit against Par in on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

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

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

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

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured**.** If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. For example, if we are unsuccessful in litigation against Par, Alphapharm and other companies who may file ANDAs for Treximet, such companies could market a generic version of the product after marketing exclusivity expires. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us.

In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. Such opposition proceedings and related appeals may not be resolved for several years, and may result in the partial or total revocation of the issued patent. For example, in October 2005 oppositions were filed against our issued European patent for MT 400 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. As a result of these oppositions and subsequent proceedings, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-HT 1B/1D agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such was the case with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. In April 2006, we received an office action on the reissue application and, consistent with our decision not to devote further resources to the development of this product in the U.S., the reissue application was abandoned in January 2007.

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

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. For example, we filed patent infringement lawsuits against Par and Alphapharm in the federal court

in the Eastern District of Texas in connection with their respective ANDA submissions to the FDA containing paragraph IV certifications for approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets, a generic version of Treximet tablets, before the expiration of our patents. With respect to some of our product candidates, under certain circumstances, our development or commercialization collaborators have the first right to enforce our patents and would have exclusive control over such enforcement litigation. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements. GSK advised us that it elected not to exercise its first right to bring an infringement suit against Par and Alphapharm, both of which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets.

If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Additionally, if we or our development or commercialization collaborator seek to enforce our patents and are unsuccessful, we may be subject to claims for bringing a failed enforcement action, including claims alleging various forms of antitrust violations (both state and federal) and unfair competition. If we are found to be liable for such claims, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and commercialization activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

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

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

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

None of our products may be accepted by the market.

The commercial success of our product candidates depends upon the acceptance of these products in the marketplace. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of a product will not be known until after it is launched and a product may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

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

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

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

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

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

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our commercialized product and human clinical trials in an amount equal to up to $10 million annual aggregate limit with a $0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We will explore, on an on-going basis, expanding our insurance coverage related to the sale of Treximet and for the inclusion of future marketed products when we obtain marketing approval for such products and commercial sales of such products begin. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

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

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

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

Our operating expenses for the year ended December 31, 2008 totaled $74.2 million, ($45.5 million net of development revenue received from AstraZeneca for development activities performed under the agreement) including non-cash compensation expense of $6.0 million related to stock options and other stock-based awards, primarily associated with our adoption of SFAS No. 123(R) on January 1, 2006. For fiscal years 2006 through 2008, our average annual operating expenses (including average non-cash deferred compensation of $5.3 million) were $53.6 million ($36.5 million net of development revenue received from AstraZeneca for development activities performed under the agreement). As of December 31, 2008, we had an aggregate of $61.7 million in cash, cash equivalents and short-term investments. If our operating expenses for 2009 and

2010 approximate the net level of our operating expenses in 2008, we believe that we will have sufficient cash reserves to maintain that level of business activities through 2010 provided certain increased development expenses are paid by AstraZeneca, as outlined in the agreement. However, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of $1.0 million if we do not prevail in our current dispute with them as to whether a withdrawal fee is payable under our MT 300 collaboration agreement.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy. Further, to the extent that we obtain additional funding through collaboration and licensing arrangements, it may be necessary for us to give up valuable rights to our development programs or technologies or grant licenses on terms that may not be favorable to us.

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

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

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, which was amended on September 28, 2007, for a three-year term with automatic one-year renewal terms. We have also entered into employment agreements with certain of our other key management personnel, which provide for one or two-year terms with automatic one-year renewal terms which were amended on September 28, 2007. If we should lose the services of Dr. Plachetka, or are unable to replace the services of our other key personnel who may leave the Company, such as Dr. Marshall E. Reese, Executive Vice President, Product Development, or William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. Dr. Reese has informed us of his intention to retire effective as of March 31, 2009. We anticipate an orderly transition of Dr. Reese's responsibilities to other key POZEN employees upon his retirement. There is intense competition for qualified scientific personnel. Since our business is very science-oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

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

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

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

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. From October 16, 2000, when our common stock began trading on The NASDAQ National Market (now known as The NASDAQ Global Market), through February 20, 2009, the high and low sales prices of our common stock ranged from $2.25 to $21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

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

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and two of our stockholders and their affiliates beneficially hold approximately 21% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, our chief executive officer and one of our directors may sell up to an aggregate of 1,180,000 shares pursuant to Rule 10b5-1 trading plans. Sales under those plans began in October 2006. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We filed with the Securities and Exchange Commission a shelf registration statement on Form S-3, which became effective January 15, 2009, for an offering under which we may register up to 8,540,000 shares of our common stock for sale to the public in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to 540,000 of such shares, and we would not receive any of the proceeds from sales of those shares.

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Since March 2002, our corporate facilities have been located in 17,000 square feet in the Exchange Office Building in Chapel Hill, North Carolina under a lease commencing in March 2002 and expiring in 2010. We have exercised our option to renew this lease for an additional five year and seven month term, terminating on September 30, 2015, and we have an additional option to renew the extended term for one additional three year period. 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

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and

chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed a motion to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of the Company's directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs have stated that they intend to file objections to the Recommendation and, if plaintiffs do object, there can be no assurance that the Court will accept the Recommendation. If plaintiffs do file objections to the Recommendation, the Company and the individual defendants intend to continue to defend these claims vigorously.

We received notices of paragraph IV certifications from Par Pharmaceutical, Inc., or Par, and Alphapharm Pty Ltd., or Alphapharm, and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring an infringement suits against Par and Alphapharm. We filed suit against Par in on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit, approval of Par's ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

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

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

None

PART II

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

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

Our common stock began trading on The NASDAQ National Market (now known as The NASDAQ Global Market) under the symbol "POZN" on October 11, 2000. As of February 20, 2009, we estimate that we had approximately 103 stockholders of record and approximately 6,440 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 Global Market for the periods indicated.

	Price Range	
2008 Fiscal Year	High	Low
First Quarter	$ 13.63	$ 9.61
Second Quarter	$ 14.85	$ 9.81
Third Quarter	$ 13.48	$ 9.50
Fourth Quarter	$ 10.91	$ 4.61

	Price Range	
2007 Fiscal Year	High	Low
First Quarter	$ 17.52	$ 13.83
Second Quarter	$ 19.11	$ 13.38
Third Quarter	$ 19.75	$ 8.29
Fourth Quarter	$ 12.94	$ 8.94

On February 20, 2009, the closing price for our common stock as reported by The NASDAQ Global Market was $5.78. We paid no cash dividends in 2008 or 2007. 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.

Equity Compensation Plans

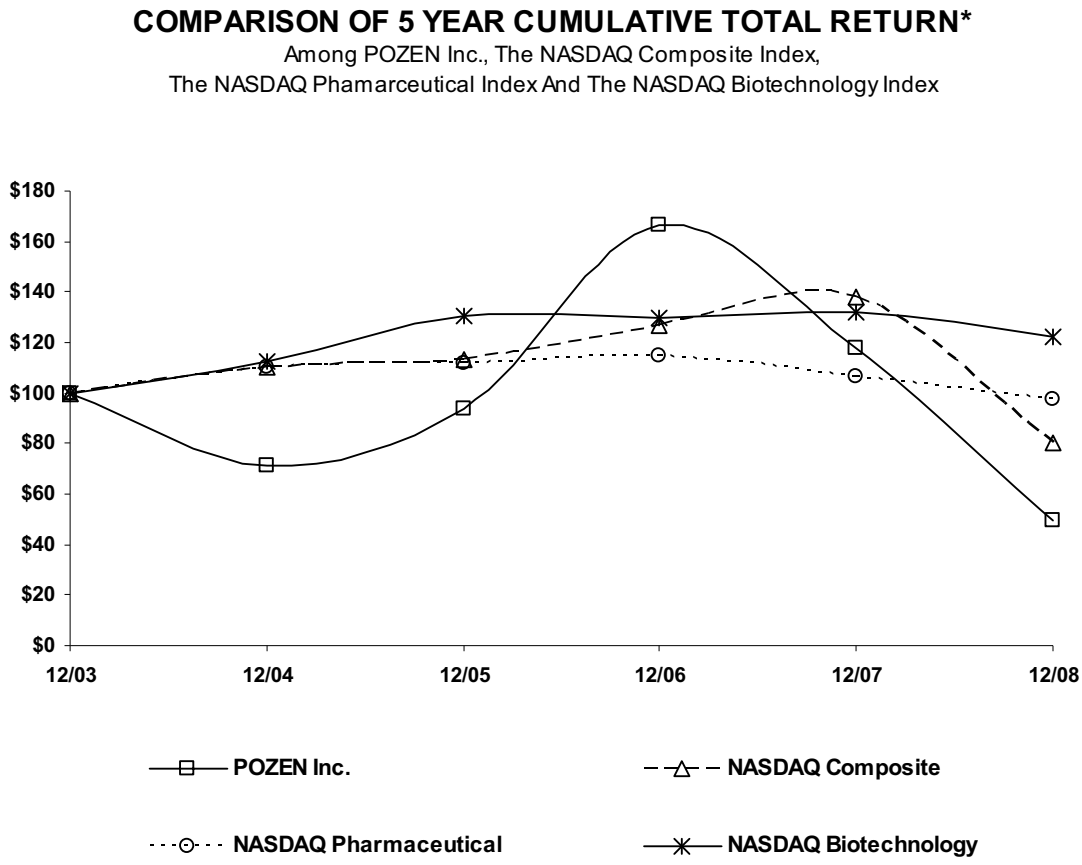
The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2008.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders[(1)]	4,045,312	$ 9.86	1,392,316
Equity compensation plans not approved by security holders	—	—	—
Total	4,045,312	$ 9.86	1,392,316

(1) Excludes 114,785 restricted stock units issued under our 2000 Equity Compensation Plan, as amended and restated, to our president and chief executive officer along with our board of directors members.

Stock Performance Graph

The following graph compares the yearly change in the total stockholder return on our common stock during the period from December 31, 2003 through December 31, 2008 with the total return on the NASDAQ Composite Index, the NASDAQ Biotechnology Index and the NASDAQ Pharmaceutical Index. The comparison assumes that $100 was invested on December 31, 2003 in our common stock and in each of the foregoing indices and assumes reinvestment of dividends, if any.



*$100 invested on 12/31/03 in stock & index-including reinvestment of dividends.
Fiscal year ending December 31.

Item 6. Selected Financial Data

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

	For the Year Ended December 31,				
	2004	2005	2006	2007	2008
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
Licensing revenue	$ 22,562	$ 28,419	$ 8,682	$ 34,459	$37,221
Development revenue	526	228	4,835	18,985	28,912
Total revenue	23,088	28,647	13,517	53,444	66,133
Operating expenses:					
General and administrative	8,661	9,185	12,822	11,474	12,315
Research and development	20,399	18,769	22,359	39,963	61,934
Total operating expenses	29,060	27,954	35,181	51,437	74,249
Interest income (expense), net	711	1,266	2,354	3,326	2,140
Income (loss) before income tax expense	(5,261)	1,959	(19,310)	5,333	(5,976)
Income tax expense	—	—	—	(667)	—
Net income (loss) attributable to common stockholders	$ (5,261)	$ 1,959	$ (19,310)	$ 4,666	$ (5,976)
Basic net income (loss) per common share	$ (0.18)	$ 0.07	$ (0.66)	$ 0.16	$ (0.20)
Shares used in computing basic net income (loss) per common share	28,749	28,939	29,225	29,593	29,762
Diluted net income per common share	$ (0.18)	$ 0.07	$ (0.66)	$ 0.15	$ (0.20)
Shares used in computing diluted net income per common share	28,749	29,623	29,225	30,581	29,762

	December 31,				
	2004	2005	2006	2007	2008
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 51,764	$ 45,838	$ 62,582	$ 73,942	$ 61,682
Total assets	53,296	46,687	67,141	77,387	70,436
Total liabilities	21,585	12,788	43,027	42,136	34,784
Accumulated deficit	(114,480)	(112,521)	(131,831)	(127,165)	(133,140)
Total stockholders' equity	31,711	33,899	24,114	35,251	35,652

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

Overview

We are a pharmaceutical company focused on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. We operate a business model that focuses on the following:

- obtaining patents for innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas through proof of concept by working with strategic outsource partners;
- agreeing a regulatory pathway with the appropriate agency; and
- licensing the resulting product or technology to a strong pharmaceutical partner to commercialize.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize "best in class" resources as required.

After we establish the proof of concept for an innovative idea, we work with the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies to design a clear path forward to the filing of a new drug application, or NDA, or its foreign equivalent. We may then decide to seek a strong pharmaceutical partner to license the product or technology to collaborate with us in the remaining development and to commercialize the product or technology after approval. The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial partners to successfully commercialize the products.

We have developed Treximet® (formerly known as Trexima™) in collaboration with GlaxoSmithKline, or GSK. Treximet is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and Treximet was available in pharmacies in May 2008.

Treximet incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a non-steroidal anti-inflammatory drug, or NSAID. Under our MT 400 technology, we sought to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed the NDA for Treximet with the FDA in August 2005, and in June 2006 we received an approvable letter requiring us to provide certain additional safety information relating to Treximet, some of which required new studies. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In early January 2007, we delivered a full response to this approvable letter that provided additional data and analyses and supporting information addressing the FDA's safety concerns, including cardiovascular safety. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity. In response to this approvable letter, we submitted the results of three non-clinical (in vitro) studies that provided clarifying information about the Chinese Hamster Ovary, or CHO, assay and data from a clinical evaluation of the genotoxic potential of Treximet in human volunteers which indicated that no chromosomal aberrations were induced in peripheral blood lymphocytes when Treximet was administered to volunteers for seven days. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults.

We are also developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor, or PPI, with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca AB, or AstraZeneca, to co-develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet using our PN formulation technology, which agreement was amended in September 2007. We began the Phase 3 program in September 2007. As part of the program, conducted two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which was the reduction in endoscopic gastric ulcers. In October 2008, he FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for POZEN's clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition to the Phase 3 pivotal trials, we are conducting a long-term, open label safety study. We have terminated a non-pivotal smaller study in patients at high risk of gastrointestinal related events from NSAIDs which we believe is not required for approval. We are also conducting additional studies, for which AstraZeneca is paying us to conduct.

Another product candidate, PA, a combination of a PPI and aspirin, is currently in formulation and clinical development testing. Our PA product candidates are excluded from our agreement with AstraZeneca. We have met with the FDA to discuss the overall development program requirements. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. We have completed a study which demonstrated the bioequivalence of the salicylic acid component of PA32540 as compared to 325 mg of enteric coated aspirin which we believe will satisfy the FDA's bioequivalence

requirement. We filed a Special Protocol Assessment, or SPA, with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In February 2009, we received written confirmation from the FDA that endoscopic gastric ulcer incidence was an acceptable primary endpoint for the Phase 3 clinical studies we proposed in our SPA for PA 32540.

We are also conducting both formulation development and early stage clinical studies with new product concepts that are currently in the exploratory stage. If warranted, we may file U.S. and international patent applications with claims directed toward these novel combinations and formulations.

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of December 31, 2008, our accumulated deficit was approximately $133.1 million. We record revenue under two categories: licensing revenues and development revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the royalty payments based on product sales. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 74% of our total operating expenses. For the fiscal year ended December 31, 2008, our research and development expenses represented approximately 83% of our total operating expenses.

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

- The progress of our PN and PA product candidates and our other product candidates in the clinical and regulatory process;
- The ability of GSK to successfully commercialize Treximet in the U.S. For example, Treximet was available in pharmacies within one month from the date of its approval, but promotional and professional materials for the product, including direct to consumer advertising, were not approved on a timely basis by the FDA. The lack of approved materials and delayed advertising launch may have had an adverse impact on uptake of the product, thus negatively impacting our royalty revenue;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates; and
- The acquisition and/or in-licensing, and development of our therapeutic product candidates.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and may enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and successfully develop product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Annual Report on Form 10-K. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Status and Expenses Related to Our Product Candidates

There follows a brief discussion of the status of the development of our product candidates, as well as the costs relating to our development activities. Our direct research and development expenses were $15.4 million for the fiscal year ended December 31, 2006, $33.7 million for the fiscal year ended December 31, 2007, and $53.9 million for the fiscal year ended December 31, 2008. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We generally do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total compensation and benefit costs for our personnel involved in research and development were $6.4 million for the fiscal year ended December 31, 2006, $5.9 million for the fiscal year ended December 31, 2007, and $7.6 million for the fiscal year ended December 31, 2008. Total compensation for 2006, 2007 and 2008, respectively included a $1.8 million, $1.2 million and a $2.2 million charge for non-cash compensation for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. Other research and development department costs were $0.6 million for the fiscal year ended December 31, 2006, $0.4 million for the fiscal year ended December 31, 2007, and $0.5 million for the fiscal year ended December 31, 2008.

Treximet. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and was available in pharmacies in May 2008. As part of our NDA program for Treximet, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial using a formulation of Treximet developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Treximet, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Treximet (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK continues to conduct market support studies for Treximet. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for Treximet to GSK on May 14, 2008, and GSK now has responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

We incurred $0.3 million in direct development costs associated with the development of MT400/Treximet for the fiscal year ended December 31, 2008. We received in the fiscal year ended December 31, 2008, $20.0 million in milestone payments from GSK for the approval of, and GSK's intent to commercialize Treximet and we recorded $2.4 million of Treximet royalty revenue, of which $1.2 million is in accounts receivable at December 31, 2008. We billed GSK $0.2 million for Treximet activities for the fiscal year ended December 31, 2008. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

We received notices of paragraph IV certifications from Par Pharmaceutical, Inc., or Par, and Alphapharm Pty Ltd., Alphapharm, and its designated agent, Mylan Pharmaceuticals Inc., or Mylan, informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring an infringement suits against Par and Alphapharm. We filed suit against Par in on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies. Pediatric studies are underway and expected to complete in 2009.

PN Program. Under our PN program, we have completed formulation development and clinical studies for several combinations of a PPI and a NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to a NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We initially conducted studies with two PN product formulations in this program - PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen, prior to entering into our collaboration with AstraZeneca. Our present development and commercialization efforts under the PN program are covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006 and which was amended in September 2007 and October 2008. Under our agreement with AstraZeneca, we are co-developing with AstraZeneca, and AstraZeneca will commercialize, proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single

tablet. The initial product to be developed under the agreement, PN 400, is being studied for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID-associated gastric ulcers. On March 2, 2007, we filed an IND with the FDA for PN 400 and in April 2007, the first Phase 1 study was initiated.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and PN 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for chronic use of naproxen in adults would accrue to the PN product, if clinical trials successfully demonstrated improved safety (lower incidence of gastric ulcers) of the PN product compared with naproxen alone and the PN formulation was shown to be bioequivalent to marketed formulations of enteric coated, or EC, naproxen. Prior to entering into our collaboration agreement with AstraZeneca, we completed a study designed to demonstrate the bioequivalence of the naproxen component of our PN 200 product candidate development formulation to EC naproxen. This study demonstrated that the PN 200 product was bioequivalent to the reference drug, EC Naprosyn®, with respect to the naproxen component.

In early 2006, we submitted a SPA to the FDA for our pivotal Phase 3 clinical trials for PN 200. The SPA is a process in which the FDA provides evaluations and guidance on clinical trial protocols for pivotal Phase 3 clinical trials. In April 2006, we announced that we had reached an agreement with the FDA on the Phase 3 pivotal clinical trials for PN 200 for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. We also reached agreement with the FDA that the development program and study design proposed for PN 200 would be applicable to a product that contained an isomer of omeprazole combined with naproxen. In light of our collaboration agreement with AstraZeneca, we, along with AstraZeneca have met with the FDA and confirmed the core development program and the principles in the SPA already agreed upon do apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen.

In the third quarter of 2006, we began recruiting subjects for a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy. The primary endpoint for the trial was the cumulative incidence of gastric ulcers over six months of treatment. Because we did not have final results until the fourth quarter of 2007, we, together with AstraZeneca reviewed the interim results of this trial prior to commencing Phase 3 studies of PN 400 in September 2007. This study has now been completed and the results which have been presented publicly, indicated significantly fewer endoscopically confirmed gastric ulcers during the six month treatment period in subjects on PN 200 compared to subjects receiving enteric coated naproxen alone. We have completed two PN 400 Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which is the reduction in endoscopic gastric ulcers. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition, we are conducting a long-term, open label safety study for PN 400. We have terminated a non-pivotal smaller study in patients at high risk (i.e., previous bleeding from a gastric ulcer) of gastrointestinal related events from NSAIDs which is not required for approval. We are also conducting additional studies at AstraZeneca's expense.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID-containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen safety concerns becomes available, long-term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN product candidates.

Additionally, we have met with four national European regulatory agencies to discuss the proposed development program for PN. Under our agreement with AstraZeneca, AstraZeneca has responsibility for the development program for PN outside the U.S., including interactions with regulatory agencies. It is our understanding that AstraZeneca intends to file marketing applications for PN 400 in certain ex-U.S. countries based upon clinical data being generated for the NDA soon after the NDA is filed.

We cannot reasonably estimate or know the amount or timing of the costs necessary to obtain regulatory approval of PN 400. Nor can we reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PN product candidates we may seek to develop or when, if and to what

extent we will receive cash inflows from any PN products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN program of $45.4 million for the fiscal year ended December 31, 2008, $28.7 million of which was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PA Program. As part of our PA program, we are exploring the development of a combination of a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program.

Our initial PA product candidate, PA32540, is currently in early-stage clinical development. We completed a Phase 1 proof of concept study in Canada of an earlier formulation of PA containing 325 mg of aspirin and 20 mg of omeprazole (PA32520) in the first quarter of 2007. The primary endpoint was gastrointestinal damage as measured by the Lanza scoring system used in our previous PN studies. The results were highly significant ($p<0.001$) with 10 percent of the PA group having Lanza 3 or 4 gastrointestinal damage, whereas 57.5% of the EC aspirin group had this level of gastrointestinal damage during the 28 day study. We also completed a second proof of concept study with PA32520 as compared to 81 mg of EC aspirin. These results confirmed the earlier levels of gastric damage as measured by Lanza scoring at about 10% for PA32520. While these results in the second study were numerically different between treatment groups, they did not achieve statistical significance from the results obtained with 81mg EC aspirin (21%). After reviewing these data, we decided to increase the dose of omeprazole to 40 mg per tablet and conduct an additional 28 day Phase 1 study using the formulation containing 40 mg of immediate release of omeprazole and 325 mg of aspirin (PA32540) compared to 325 mg EC aspirin. Topline results from this study indicate a highly significant ($P=0.003$) reduction in gastrointestinal damage with the higher strength PA32540 tablet as compared with 325 mg EC aspirin (2.5% vs. 27.5% grade 3 or 4 Lanza scores, respectively). In this last study, 75% of subjects treated with the PA32540 tablet showed no gastrointestinal damage at all as compared to < 50% with the PA32520 tablet. An IND for the product was filed in the fourth quarter of 2007 and we met with the FDA in July 2007 to discuss the overall development program requirements. We completed a study which demonstrated that the salicylic acid component of PA32540 was bioequivalent to the reference drug, EC aspirin, with respect to the aspirin component, and which we believe will allow our PA product to receive all the cardio- and cerebrovascular secondary prevention claims of aspirin. In June 2008, we filed an SPA with the FDA for our pivotal Phase 3 trials for PA32540, the primary endpoint for which is the reduction in endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs and in February 2009, we received written confirmation from FDA that endoscopic gastric ulcer incidence was an acceptable endpoint for the Phase 3 clinical studies we proposed in our SPA for PA32540. We are also conducting both formulation development and early stage clinical studies with other PA product candidates for indications in addition to cardiovascular protection.

Additionally, we have met with three national European regulatory agencies to discuss the proposed development program for PA. Each of these regulatory agencies has indicated that reduction in gastric ulcers is an appropriate endpoint for the pivotal trials, along with demonstrating bioequivalence to the reference drug, EC aspirin, with respect to the aspirin component. Dose ranging studies may also be required.

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

We incurred direct development costs associated with the development of our PA program of $5.0 million during the fiscal year ended December 31, 2008. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300. In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300, which we had submitted in December 2002. We are not currently conducting any clinical trials for MT 300 and do not expect to incur any additional significant development costs related to MT 300, nor do we believe that we will receive any future cash inflows from MT 300. We incurred $0.1 million direct development costs associated with the development of MT 300 for the fiscal

year ended December 31, 2008. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

In July 2005, we received a letter from Valeant NA, seeking payment of a $1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable under the circumstances of receipt of the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement, although the last written communication from Valeant NA was received in March 2006. In 2008, based upon our evaluation of the facts and circumstances, we recognized the remaining $1.0 million licensing fee for MT 300. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We record revenue under two categories: licensing revenues and development revenues. With regard to the licensing revenues, the licensing and other collaborative agreements have terms that include up-front payments upon contract signing, additional payments if and when certain milestones in the product's development are reached, royalty payments based on future product sales and withdrawal fees if certain conditions are met. We recognize revenue under these agreements in accordance with SEC Staff Accounting Bulletin 101, "Revenue Recognition" as amended by SAB 104 "Revenue Recognition" ("SAB 104"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables."

Under SAB 104 recognition of revenue from non-refundable up-front payments is deferred by us upon receipt and recognized over the period ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. If regulatory approvals or other events relating to our product candidates are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products would prospectively be accelerated or reduced accordingly.

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

Treximet royalty revenue is recognized when earned as will future royalty revenues with respect to the manufacture, sale or use of our products or technology. For Treximet or those future arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. During the year ended December 31, 2008, we recognized $2.4 million of royalty revenue which is included within licensing revenue in the accompanying statements of operations.

With regard to the development revenues, our licensing agreements may include payment for services provided by us on an hourly rate and direct expense basis. We record such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project. In accordance with EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent", under the AstraZeneca and GSK agreements, we will recognize as revenue the direct costs and certain personnel-related expense incurred in performing additional development activities described within the related agreement.

Management believes that its current assumptions and other considerations used to estimate the periods for revenue recognition described above are appropriate, and historical changes in our estimates of these periods have not resulted in

material changes in the revenue we recognized. However, we continually review these estimates, which could result in a change in the deferral period and might impact the timing and amount of revenue recognition. Further, if regulatory approval for Treximet is accelerated, delayed or not ultimately obtained, then the amortization of revenues for this product would prospectively be accelerated or reduced accordingly.

As of December 31, 2008, we had deferred revenue on our balance sheet totaling $19.5 million. The current portion of deferred revenue, totaling $12.3 million, is expected to be earned in the next twelve months. We recognized licensing revenue of $37.2 million for the fiscal year ended December 31, 2008, $34.4 million for the fiscal year ended December 31, 2007, and $8.7 million for the fiscal year ended December 31, 2006. Of the licensing revenue we recognized $20.0 million in milestone revenue related to the approval of, and GSK's intent to commercialize, Treximet and $2.4 million in royalty revenue during the fiscal year ended December 31, 2008. A $20.0 million milestone payment from AstraZeneca for the PN 400 program was recognized in the fiscal year ended December 31, 2007. We recognized development revenue of $28.9 million for the fiscal year ended December 31, 2008, $19.0 million for the fiscal year ended December 31, 2007, and $4.8 million for the fiscal year ended December 31, 2006. There was no milestone revenue recognized for the fiscal year ended December 31, 2006.

Accrued expenses, including contracted costs

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

Our management believes that its current assumptions and other considerations used to estimate accrued expenses for the period are appropriate. However, determining the date on which certain contract services commence, the extent of services performed on or before a given date and the cost of such services involves subjective judgments and estimates and often must be based upon information provided by third parties. In the event that we do not identify certain contract costs which have begun to be incurred or we under- or over-estimate the extent of services performed or the costs of such services, we adjust our annuals during the period in which the information becomes available.

Accrued costs related to product development and operating activities, including clinical trials, based upon the progress of these activities covered by the related contracts, invoices received and estimated costs totaled $5.7 million at December 31, 2008 and $3.6 million at December 31, 2007. The variance, at each of these ending periods, between the actual expenses incurred and the estimated expenses accrued has been less than $125,000.

Stock-based compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment," which requires us to account for share-based payment transactions using a fair value-based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share-based payments to employees using the Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees," intrinsic value method. Therefore, prior to January 1, 2006 we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options, as all such options had an exercise price equal to the market value of the underlying common stock on the date of the grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. Under this transition method, our compensation cost recognized includes compensation costs for all share-based payments granted prior to, but not yet vested as of, January 1, 2006 based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and compensation cost for all share-based payments granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Accordingly, we have not restated our financial results for prior periods.

Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure-only purposes under the provisions of SFAS No. 123, we use the Black-Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance or market conditions granted subsequent to our adoption of SFAS

No. 123(R), we intend to recognize compensation cost over the expected period to achieve the performance or market condition, provided achievement of the performance condition is deemed probable.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. Our expected volatility rate was estimated based on an equal weighting of the historical volatility of our common stock over a six year period. The expected term we use was estimated based on average historical terms to exercise. The risk-free interest rate for periods within the contractual life of the option is based on seven year U.S. Treasury securities. The pre-vesting forfeiture rate used for the year ended December 31, 2008 was based on actual historical rates.

Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

Fair Value Measurement

On January 1, 2008, we adopted the provisions of SFAS 157 "Fair Value Measurements" ("SFAS 157"). SFAS 157 was issued in September 2006 and is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the Financial Accounting Standards Board ("FASB") released FSP No. FAS 157-2 which deferred the effective date of SFAS 157 for one year for nonfinancial assets and nonfinancial liabilities. It did not defer recognition and disclosure requirements for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. Accordingly, as of January 1, 2008, we have applied the provisions of SFAS 157 only to financial assets and liabilities as discussed below. Our adoption of SFAS 157 did not result in our recording any cumulative effect adjustments to retained earnings.

Under SFAS 157, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e. "the exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, we use various valuation approaches, including quoted market prices and discounted cash flows. SFAS No. 157 also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from independent sources. Unobservable inputs are inputs that reflect a company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed based on the best information available under the circumstances. The fair value hierarchy is broken down into three levels based on the reliability of inputs as follows:

- Level 1 - Valuations based on quoted prices in active markets for *identical* instruments that the Company is able to access. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

- Level 2 - Valuations based on quoted prices in active markets for instruments that are *similar*, or quoted prices in markets that are not active for identical or similar instruments, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

- Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The financial assets for which we perform recurring remeasurements are cash equivalents and short-term investments. As of December 31, 2008, financial assets utilizing Level 1 inputs included cash equivalents and short-term investments. Financial assets utilizing Level 2 inputs included short-term investments in government agency obligations and corporate fixed income securities.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation, such as the recent illiquidity in the auction rate securities market. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition has caused, and in the future may cause, our financial instruments to be reclassified from Level 1 to Level 2 or from Level 2 to Level 3.

SFAS 157 requires that the valuation techniques used by us are consistent with at least one of the three possible approaches: the market approach, income approach, and/or cost approach. Our Level 1 valuations are based on the market approach and consist primarily of quoted prices for identical items on active securities exchanges. Our Level 2 valuations also use the market approach and are based on significant other observable inputs such as quoted prices for financial instruments not traded on a daily basis. We did not rely on Level 3 input for valuation of our securities at December 31, 2008.

Income Taxes

We estimate an annual effective tax rate of 0% for the year ended December 31, 2008. Our effective tax rate was 0% for the twelve month period ended December 31, 2008. However, the actual effective rate may vary depending upon actual licensing fees and milestone payments received, specifically the pre-tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with SFAS 109, "Accounting for Income Taxes." Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Act) that could limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because tax laws limit the time during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal and state income tax purposes.

We currently file income tax returns in the U.S. federal jurisdiction, and the state of North Carolina. We are no longer subject to federal or North Carolina income tax examinations by tax authorities for years before 2005. However, the loss carryforwards generated prior to 2005 may still be subject to change, if we subsequently begin utilizing these losses in a year that is open under statute and subject to federal or North Carolina income tax examinations by tax authorities.

We adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), on January 1, 2007 and as a result, there were no material impacts to the financial statements.

We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the fiscal years ended December 31, 2008 and 2007, there were no such interest and penalties.

Historical Results of Operations

Year ended December 31, 2008 compared to the year ended December 31, 2007

Net (loss) / income per share: Net loss attributable to common stockholders for the fiscal year ended December 31, 2008 was $(6.0) million or $(0.20) per share, on a basic and diluted basis, as compared to a net income of $4.7 million, or $0.15 per share, on a diluted basis, for the fiscal year ended December 31, 2007. The net loss for the fiscal year ended December 31, 2008 included a $(6.0) million or $(0.20) per share charge for non-cash stock-based compensation expense as compared to $4.3 million or $0.15 per share for the same period of 2007.

Revenue: We recognized total revenue of $66.1 million for the fiscal year ended December 31, 2008 as compared to total revenue of $53.4 million for the fiscal year ended December 31, 2007. The increase in revenue was primarily due to $2.4 million of Treximet royalty revenue and an increase of $9.9 million in development revenue for the fiscal year ended December 31, 2008 compared to 2007. Licensing revenue for the fiscal year ended December 31, 2008 was $37.2 million compared to $34.4 million for 2007. Development revenue was $28.9 million for the fiscal year ended December 31, 2008 compared to $19.0 million for 2007. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $19.5 million remains in deferred revenue at December 31, 2008. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled $25.9 million and $16.1 million for the fiscal year ended December 31, 2008 and 2007, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses increased by $22.0 million to $61.9 million for the fiscal year ended December 31, 2008, as compared to the same period of 2007. The increase was due primarily to an increase in direct development costs for our PN program and exploratory programs, partially offset by a decrease in direct development costs for our PA program, as compared to the same period of 2007. Direct development costs for the PN program increased by $20.2 million to $45.4 million, primarily due to clinical trial activities and other product development activities during the fiscal year ended December 31, 2008, as compared to the same period of 2007. Direct development costs for the exploratory programs increased by $1.4 million to $3.1 million, offset by a decrease of $0.7 million in the PA program, as compared to the same period of 2007. Other direct development costs and departmental expenses increased by $1.0 million primarily due to increased personnel costs, as compared to the same period of 2007. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

General and administrative: General and administrative expenses increased by $0.8 million to $12.3 million for the fiscal year ended December 31, 2008, as compared to the same period of 2007. The increase was due primarily to increased personnel costs and marketing research expenses, as compared to the same period of 2007. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $1.2 and $1.5 million for the fiscal years ended December 31, 2008 and 2007, respectively. Investment income from bond amortization for the fiscal year ended December 31, 2008 totaled $0.9 million as compared to $1.8 million during the same period of 2007.

Year ended December 31, 2007 compared to the year ended December 31, 2006

Net income/(loss) per share: Net income attributable to common stockholders for the fiscal year ended December 31, 2007 was $4.7 million or $0.15 per share as compared to a net loss of $(19.3) million, or $(0.66) per share, on a diluted basis, for the fiscal year ended December 31, 2006. The net income for the fiscal year ended December 31, 2007 included a $4.3 million or $0.15 per share charge for non-cash stock-based compensation expense, as compared to $5.5 million or $0.19 per share for the same period of 2006.

Revenue: We recognized total revenue of $53.4 million for the fiscal year ended December 31, 2007 as compared to total revenue of $13.5 million for the fiscal year ended December 31, 2006. Licensing revenue for fiscal year ended December 31, 2007 was $34.4 million compared to $8.7 million for 2006. Development revenue for fiscal year ended December 31, 2007 was $19.0 million compared to $4.8 million for 2006. The $25.8 million increase in licensing revenue was primarily due to receipt of a $20.0 million milestone payment from AstraZeneca for the PN 400 program, and a $5.8 million increase in the amortization of upfront payments we received. The $14.2 million increase in development revenue relates to increased billings to AstraZeneca and GSK for direct and certain personnel-related costs. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are recognized and being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $34.4 million remains in deferred revenue at December 31, 2007. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled $16.1 million and $4.4 million for the fiscal years ended December 31, 2007 and 2006, respectively. All costs associated with our development revenues are included in Research and Development expenses in our Statement of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses increased by $17.6 million to $40.0 million for the fiscal year ended December 31, 2007, as compared to the same period of 2006. The increase was due primarily to an increase in direct development costs for our PN, PA and Treximet programs, partially offset by a decrease in direct development costs for Lornoxicam, as compared to the same period of 2006. Direct development costs for the PN program increased by $15.5 million to $25.2 million, primarily due to clinical trial activities and other product development activities during 2007, as compared to the same period of 2006. Direct development costs for the PA program increased by $4.5 million to $5.8 million, primarily due to Phase 1 clinical trial activities and other product development activities during 2007, as compared to the same period of 2006. Direct development costs for Treximet increased by $0.7 million to $0.9 million, as compared to the same period of 2006 primarily due to the receipt of a second approvable letter from the FDA requesting we further address the FDA's concern about the product's potential for genotoxicity. We have included in our research and development total

expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

General and administrative: General and administrative expenses decreased by $1.3 million to $11.5 million for the fiscal year ended December 31, 2007, as compared to the same period of 2006. The decrease was due primarily to a reduction in non-cash stock based compensation expense as a result of previously expensed stock-based compensation expense related to the Treximet incentive program, and a decrease in public company legal expenses as compared to the same period of 2006. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $1.5 million for the fiscal year ended December 31, 2007 as compared to $1.1 million for the fiscal year ended December 31, 2006. Investment income from bond amortization for the fiscal year ended December 31, 2007 totaled $1.8 million as compared to $1.1 million during the same period of 2006.

Income Taxes

At December 31, 2008 and 2007, we had federal net operating loss carryforwards of approximately $80.8 million and $75.6 million respectively, state net economic loss carryforwards of approximately $68.7 million and $74.2 million respectively, and research and development credit carryforwards of approximately $11.7 million and $10.3 million, respectively. The amount of the NOL related to excess tax based stock compensation is $4.8 million and $4.8 million at December 31, 2008 and 2007, respectively. The federal and state net operating loss carryforwards begin to expire in 2014 and the research and development credit carryforwards begin to expire in 2012. For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards. Of the total increase in valuation allowance of $2.7 million, $2.4 million was allocable to current operating activities and $0.3 million was allocable to a change in the state tax rate. When the valuation allowance is realized, a portion related to excess stock option compensation will be realized as an increase in additional paid-in capital. Our effective tax rate was 0.0% for the twelve-month period ended December 31, 2008. Based upon our historic losses, management has recorded a valuation allowance on the net deferred tax assets. Accordingly, we have not recognized a deferred tax benefit in the current year associated with the projected NOL generated. The actual effective rate may vary depending upon actual licensing fees and milestone payments received, specifically the pre-tax book income for the year, and other factors. Income taxes are computed using the asset and liability approach, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in our financial statements or tax returns, in accordance with SFAS 109, “Accounting for Income Taxes.” Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986 (the “Tax Reform Act”) limits the annual use of net operating loss and research and development tax credit carry-forwards following certain ownership changes, as defined by the Tax Reform Act. We have experienced various ownership changes, as defined by the Tax Reform Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal income tax purposes.

Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth through private placements of preferred stock and our initial public offering, resulting in cash inflows of $135.3 million. Since 2003, we have received $152.5 million from upfront and milestone payments from our collaborators. Additionally, since 2004, we have received $45.4 million of development revenue payments associated with development activities pursuant to the terms of our agreements with AstraZeneca and GSK. At December 31, 2008, cash and cash equivalents, along with short-term investments, totaled $61.7 million, a decrease of $12.3 million compared to December 31, 2007. The decrease in cash was primarily due to increased operating expenses for the period offset in part by cash receipts for development activities and milestone payments received pursuant to the terms of our agreements with AstraZeneca and GSK. Our cash is 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 and short-term corporate fixed income obligations and U.S. Government agency obligations.

Short-term investments are held in a managed investment account designed to increase the return on our cash. This account, which is invested as described above, is managed within our Board approved investment policy, which restricts investments to maturities of less than twelve months, limits concentration to 5% or less and requires minimum credit ratings of A1/P1, among other requirements. We have considered the impact of the current economic environment in evaluating the fair value of our investments. We believe we are adhering to a conservative investment policy. Nonetheless, given the current credit crisis and other market risks, were any of our A1/P1 investments downgraded such that action is required under our investment policy, such an action may result in an investment loss.

Because certain holdings in the managed account have maturities longer than three months, we have classified these holdings as short-term investments in our balance sheet and accounting principles require reporting such investments at market value. Any difference in market value and cost is reported in the stockholder's equity section of our financial statements as comprehensive income or loss.

We received $45.0 million in operating cash during the fiscal year ended December 31, 2008 pursuant to the terms of our collaboration agreements with AstraZeneca and GSK. In addition, our balance sheet included an $8.1 million accounts receivable for invoiced development activities under the terms of the AstraZeneca and GSK agreements. Cash received from financing activities during the period totaled $166,888 reflecting net proceeds from the exercise of stock options.

Based upon the indirect method of presenting cash flow, cash used in operating activities totaled $13.5 million for the fiscal year ended December 31, 2008. Cash provided by operating activities was $7.4 million for the fiscal year ended December 31, 2007. Net cash provided by investing activities during the fiscal year ended December 31, 2008 totaled $1.8 million, and net cash provided by investing activities for the fiscal year ended December 31, 2007 totaled $1.8 million reflecting investing activities associated with the purchase and sale of short-term securities. Cash required for our operating activities during 2009 is projected to increase from our 2008 requirements as a result of decreased milestone payments. During the fiscal years ended December 31, 2008 and December 31, 2007 we recorded non-cash stock-based compensation expense of $6.0 million and $4.3 million, respectively, associated with the grant of stock options and restricted stock.

As of December 31, 2008, we had $26.1 million in cash and cash equivalents and $35.6 million in short-term investments. Our operating expenses for 2009 and 2010 are expected to approximate the net level of our operating expenses in 2008. We believe that we will have sufficient cash reserves to maintain our planned level of business activities through 2010.

As part of our ongoing assessment of our business and liquidity needs, we regularly assess available funding options and will consider available funding opportunities as they arise. We may sell shares of common stock in the future to fund additional development activities and increase our working capital. We have filed with the Securities and Exchange Commission, or SEC, and the SEC has declared effective, a shelf registration statement on Form S-3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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

- the number and progress of our clinical trials and other trials and studies;
- our success, or any delays, in obtaining, and any delays in obtaining, regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights;
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies;
- costs incurred in the defense of the class action lawsuit that is pending against us and our president and chief executive officer and certain executive officers relating to Treximet; and
- costs incurred in the defense of our Treximet patents against generic companies that have filed ANDAs with the FDA to market the product prior to the expiration of our patents.

Obligations and Commitments

The following summarizes our contractual obligations as of December 31, 2008, and the expected timing of maturities of those contractual obligations. This table should be read in conjunction with the notes accompanying our financial statements included elsewhere in this Annual Report on Form 10-K.

	Payments Due by Period			
Contractual Obligations	Total	2009	2010-2011	2012-after
	($ in thousands)			
Operating leases[1]	$ 479	$ 410	$ 69	$ 0
Product development agreements[2]	7,037	6,841	196	—
Total contractual obligations	$ 7,516	$ 7,251	$ 265	$ 0

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

[2] Amounts represent open purchase orders for ongoing pharmaceutical development activities for our product candidates as of December 31, 2008. These agreements may be terminated by us at any time without incurring a termination fee.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides a common definition of fair value and establishes a framework to make the measurement of fair value in generally accepted accounting principles more consistent and comparable. SFAS 157 also requires expanded disclosure to provide information about the extent to which fair value is used to measure assets and liabilities, the methods and assumptions used to measure fair value, and the effect of fair value measures on earnings. SFAS 157 was adopted effective January 1, 2008.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 gives companies the irrevocable option to carry most financial assets and liabilities at fair value, with changes in fair value recognized in earnings. SFAS 159 was adopted effective January 1, 2008.

In February 2008, the Financial Accounting Standards Board ("FASB") released FSP No. FAS 157-2 which deferred the effective date of SFAS 157 for one year for nonfinancial assets and nonfinancial liabilities. It did not defer recognition and disclosure requirements for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. Accordingly, as of January 1, 2008, we have applied the provisions of SFAS 157 only to financial assets and liabilities. Our adoption of SFAS 157 did not result in our recording any cumulative effect adjustments to retained earnings.

In June 2007, the FASB issued Emerging Issues Task Force ("EITF") on EITF Issue No. 07-3, *"Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"* ("EITF 07-3"). EITF 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties, and amortize them over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We adopted EITF 07-3 effective January 1, 2008.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Our management's report on internal control over financial reporting procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) is included with the financial statements reflected in Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Information required to be disclosed by this Item with respect to our executive officers is set forth under the caption "Officers and Key Employees" contained in Part I, Item 1of this annual report on Form 10-K.

Information required to be disclosed by this Item about our board of directors is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Nomination and Election of Directors" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in this annual report on Form 10-K by reference from the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about our board of directors, the audit committee of our board of directors, our audit committee financial expert, our Code of Business Conduct and Ethics, and other corporate governance matters is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Board of Directors and Corporate Governance Matters" contained in our definitive proxy statement related to our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) is posted in the "Corporate Governance" section of our website, www.pozen.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and The NASDAQ Stock Market.

Item 11. Executive Compensation

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Compensation for Executive Officers and Directors" and "Board of Directors and Corporate Governance Matters" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

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

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Principal Stockholders," "Stock Ownership of Directors, Nominees for Director, and Executive Officers" and "Compensation for Executive Officers and Directors" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section(s) entitled "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance Matters," "Compensation for Executive Officers and Directors, "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

Item 14. Principal Accounting Fees and Services

This information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Audit and Other Fees" contained in our definitive proxy statement for our 2009 annual meeting of stockholders scheduled to be held on June 3, 2009, which we intend to file within 120 days of the end of our fiscal year.

PART IV

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

(a) Financial Statements and Schedules:

1. Financial Statements

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

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.1	Stock Option Plan of the Registrant.*
10.2	First Amendment to Stock Option Plan dated February 14, 1997.*
10.3	Second Amended and Restated 2000 Equity Compensation Plan of the Registrant (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.4	Form of Incentive Stock Option Agreement under Registrant's Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.5	Form of Nonqualified Stock Option Agreement under Registrant's Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.6	Form of Non-Employee Director Nonqualified Stock Option Agreement under Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***.
10.7	Form of Non-Employee Director Restricted Stock Unit Agreement under Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.9	Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 16, 2006).***
10.10	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-

Exhibit No.	Description
	Q filed November 5, 2007).***
10.11	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.12	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007 (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.13	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed October 27, 2004).***
10.14	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.15	Executive Employment Agreement with Marshall E. Reese dated November 8, 2004 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 12, 2004).***
10.16	First Amendment to Executive Employment Agreement with Marshall E. Reese, Ph.D., dated September 28, 2007 (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***.
10.17	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.18	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.19	Summary of Non-Employee Director Compensation (filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed March 8, 2007).***
10.20	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).†
10.21	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).
10.22	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Form 10-Q/A filed November 8. 2004).†
10.23	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.24	Collaboration and License Agreement dated September 3, 2003 between the Registrant and Valeant Pharmaceuticals NA (formerly Xcel Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 6, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.25	Restricted Stock Unit Agreement dated May 4, 2004 between Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed July 30, 2004).***
10.26	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.27	Form of Non-Qualified Stock Option Agreement for Trexima grants issued pursuant Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***
10.28	Development, Option and License Agreement dated May 15, 2003 between the Registrant and Nycomed Danmark ApS (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 28, 2005, and Current Report on Form 8-K/A filed January 10, 2006).†
10.29	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB (filed as Exhibit 10.1 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.30	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca AB (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q

Exhibit No.	Description
	filed November 5, 2007). †
10.31	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between the Registrant and AstraZeneca AB (filed as 10.2 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.32	Side Letter Agreement, dated October 1, 2007, between the Registrant and AstraZeneca, AB (filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.33	Long-Term Cash Incentive Award Agreement between the Registrant and John R. Plachetka dated February 14, 2007 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.34	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.35	Restricted Stock Unit Agreement with John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.36	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.37	Nonqualified Stock Option Grant issued to John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.38	Form of Nonqualified Stock Option Agreement for PN 400 Incentive Program under Second Amended and Restated 200 Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on May 8, 2008).***
10.39	Amendment No. 2 to the Collaboration and License Agreement, dated October 1, 2008, between the registrant and AstraZeneca, AB (filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed November 4, 2008). †
10.40	Lease Modification Agreement No. 1, dated as of February 16, 2009, by and between the Registrant and The Exchange at Meadowmont LLC (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on February 17, 2009).
10.41	Consulting Agreement dated as of April 1, 2009, between the Registrant and Marshall E. Reese (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on February 24, 2009).***
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

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

** Filed herewith.

*** Compensation Related Contract.

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

(b) Exhibits.

See Item 15(a)(3) above.

(c) Financial Statement Schedules.

See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Registrant:

POZEN Inc.

Date: March 6, 2009

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 6, 2009
/s/ William L. Hodges William L. Hodges	Senior Vice President, Finance and Administration and Chief Financial Officer (Principal Financial Officer)	March 6, 2009
/s/ John E. Barnhardt John E. Barnhardt	Vice President, Finance and Administration (Principal Accounting Officer)	March 6, 2009
/s/ Arthur S. Kirsch Arthur S. Kirsch	Director	March 6, 2009
/s/ Kenneth B. Lee, Jr. Kenneth B. Lee Jr.	Director	March 6, 2009
/s/ James J. Mauzey James J. Mauzey	Director	March 6, 2009
/s/ Jacques F. Rejeange Jacques F. Rejeange	Director	March 6, 2009
/s/ Paul J. Rizzo Paul J. Rizzo	Director	March 6, 2009
/s/ Peter J. Wise Peter J. Wise	Director	March 6, 2009

POZEN Inc.

Audited Financial Statements

Contents

Management's Report on Internal Control Over Financial Reporting

Management of POZEN Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management evaluated the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (COSO). As a result of this assessment and based on the criteria in the COSO framework, management has concluded that, as of December 31, 2008, the Company's internal control over financial reporting was effective.

The registered public accounting firm that audited the financial statements included in this report has issued an attestation report on our internal controls over financial reporting.

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

March 6, 2009

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of POZEN Inc.

We have audited the accompanying balance sheets of POZEN Inc. as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of POZEN Inc. at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), POZEN Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 17, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 17, 2009

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of POZEN Inc.

We have audited POZEN Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). POZEN Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, POZEN Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of POZEN Inc. as of December 31, 2008 and 2007, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008 and our report dated February 17, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 17, 2009

POZEN Inc.

Balance Sheets

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,119,249	$ 37,660,068
Short-term investments	35,562,723	36,282,108
Accounts receivable	8,119,435	2,129,003
Prepaid expenses and other current assets	562,161	1,198,397
Total current assets	70,363,568	77,269,576
Property and equipment, net of accumulated depreciation	72,563	117,485
Total assets	$ 70,436,131	$ 77,387,061
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,328,428	$ 2,536,040
Accrued compensation	2,172,314	1,392,849
Accrued expenses	5,737,254	3,796,164
Deferred revenue	12,344,708	15,936,125
Total current liabilities	27,582,704	23,661,178
Long-term liabilities:		
Deferred revenue	7,201,080	18,475,074
Total liabilities	34,783,784	42,136,252
Preferred stock, $0.001 par value; 10,000,000 shares authorized, issuable in series, of which 90,000 shares are designated Series A Junior Participating Preferred Stock, none outstanding	—	—
Common stock, $0.001 par value, 90,000,000 shares authorized; 29,778,310 and 29,704,760 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	29,778	29,705
Additional paid-in capital	168,541,451	162,371,437
Accumulated other comprehensive income	221,520	14,540
Accumulated deficit	(133,140,402)	(127,164,873)
Total stockholders' equity	35,652,347	35,250,809
Total liabilities and stockholders' equity	$ 70,436,131	$ 77,387,061

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Operations

	Year ended December 31,		
	2008	2007	2006
Revenue:			
Licensing revenue	$ 37,221,242	$ 34,459,001	$ 8,681,800
Development revenue	28,912,399	18,985,344	4,834,972
Total revenue	66,133,641	53,444,345	13,516,772
Operating expenses:			
General and administrative	12,314,574	11,474,608	12,822,050
Research and development	61,934,337	39,962,688	22,358,715
Total operating expenses	74,248,911	51,437,296	35,180,765
Interest and other income	2,139,741	3,326,043	2,354,173
Income (loss) before income tax expense	(5,975,529)	5,333,092	(19,309,820)
Income tax expense	—	(667,000)	—
Net income (loss) attributable to common stockholders	$ (5,975,529)	$ 4,666,092	$(19,309,820)
Basic net income (loss) per common share	$ (0.20)	$ 0.16	$ (0.66)
Shares used in computing basic net income (loss) per common share	29,761,847	29,592,890	29,224,699
Diluted net income (loss) per common share	$ (0.20)	$ 0.15	$ (0.66)
Shares used in computing diluted net income (loss) per common share	29,761,847	30,581,326	29,224,699

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Stockholders' Equity

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2005	$ 29,002	146,399,373	(112,521,145)	(8,551)	33,898,679
Exercise of common stock options	446	2,658,520	-	-	2,658,966
Unrealized loss on investments	-	-	-	4,459	4,459
Stock-based compensation	-	6,862,175	-	-	6,862,175
Net Loss	-	-	(19,309,820)	-	(19,309,820)
Balance at December 31, 2006	29,448	155,920,068	(131,830,965)	(4,092)	24,114,459
Exercise of common stock options	257	2,138,995	-	-	2,139,252
Unrealized gain on investments	-	-	-	18,632	18,632
Stock-based compensation	-	4,312,374	-	-	4,312,374
Net Income	-	-	4,666,092	-	4,666,092
Balance at December 31, 2007	29,705	162,371,437	(127,164,873)	14,540	35,250,809
Exercise of common stock options	73	166,815	-	-	166,888
Unrealized gain on investments	-	-	-	206,980	206,980
Stock-based compensation	-	6,003,199	-	-	6,003,199
Net Loss	-	-	(5,975,529)	-	(5,975,529)
Balance at December 31, 2008	$ 29,778	$ 168,541,451	$ (133,140,402)	$ 221,520	$ 35,652,347

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Cash Flows

	Year ended December 31,		
	2008	2007	2006
Operating activities			
Net (loss) income	$ (5,975,529)	$ 4,666,092	$(19,309,820)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation	81,665	89,678	96,379
Bond amortization income	(910,839)	(1,850,403)	(1,071,549)
Noncash compensation expense	6,003,199	4,312,374	5,500,479
Changes in operating assets and liabilities:			
Accounts receivable	(5,990,432)	1,138,150	(3,267,153)
Prepaid expenses and other current assets	636,236	(89,891)	(494,824)
Accounts payable and accrued expenses	7,512,943	3,568,599	281,818
Deferred revenue	(14,865,411)	(4,459,001)	31,318,200
Net cash (used in) provided by operating activities	(13,508,168)	7,375,598	13,053,530
Investment activities			
Purchase of equipment	(36,744)	(23,695)	(45,008)
Purchase of investments	(64,382,222)	(72,301,799)	(54,138,393)
Sale of investments	66,219,427	74,173,828	37,300,000
Net cash provided by (used in) investing activities	1,800,461	1,848,334	(16,883,401)
Financing activities			
Proceeds from issuance of common stock	166,888	2,139,252	2,658,966
Net cash provided by financing activities	166,888	2,139,252	2,658,966
Net (decrease) increase in cash and cash equivalents	(11,540,819)	11,363,184	(1,170,905)
Cash and cash equivalents at beginning of period	37,660,068	26,296,884	27,467,789
Cash and cash equivalents at end of period	$ 26,119,249	$ 37,660,068	$ 26,296,884

See accompanying Notes to Financial Statements.

1. Significant Accounting Policies

General

POZEN Inc. ("we" or "POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996 and is operating in a single reportable segment. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain-related conditions. Since inception, the Company has focused its efforts on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. The Company may enter into collaboration agreements to commercialize its product candidates, and has entered into, and may continue to enter into such collaborations. The Company's licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the eventual royalty payments based on product sales. Additionally, the Company's development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under its collaboration agreements.

Through December 31, 2007, the Company was a development stage company as defined in Statement of Financial Accounting Standards Board No. 7, "Accounting and Reporting by Development Stage Enterprises" ("SFAS 7"). In connection with the receipt of FDA approval of Treximet in 2008, we have considered the guidance outlined in SFAS 7 and have concluded that the Company has emerged from the development stage.

Use of Estimates

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

Revenue Recognition

The Company records revenue under two categories: licensing revenues and development revenues. With regard to the licensing revenues, the Company's licensing agreements have terms that include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and royalty payments based on product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition", as amended by SAB 104, "Revenue Recognition" ("SAB 104"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables." The non-refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a straightline basis over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on the part of the Company. For the Company's current agreements, these periods are estimated to be as follows:

- The September 2006 $40.0 million licensing fee received from AstraZeneca related to the August 2006 Collaboration and License Agreement with AstraZeneca has been deferred and was being amortized over 40 months. The AstraZeneca licensing fee relates to the Company's proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the non-steroidal anti-inflammatory drug (NSAID) naproxen, in a single tablet. As a result of the revised development timeline agreed upon in the September 2007 amendment, we extended the amortization period to 43 months. In 2008, we subsequently increased the estimated amortization period to 47 months, as a result of revisions to the development timeline. We recognized $10.1 million, $11.4 million and $4.0 million of licensing revenue from the amortization of the AstraZeneca licensing fee for the fiscal years ended December 31, 2008, 2007 and 2006, respectively. The September 2007 amendment to the AstraZeneca agreement included a $10 million payment in connection with execution of the amendment. This payment was deferred to be amortized over 31 months. In 2008, we increased the estimated amortization period to 35 months, as a result of revisions to the development timeline. We recognized $3.6 million and $1.3 million of licensing revenue from this amortization in the fiscal years ended December 31, 2008 and 2007, respectively. The 2007 and 2008 changes in accounting estimates were prospective adjustments beginning in the third quarters of 2007 and 2008, respectively. The 2008 change in the estimated amortization periods resulted in a $1.1 million decrease in the 2008 full-year amortization.

Under the terms of the agreement, our representatives are members of both the Global Product Team and the Joint Steering Committee. The Global Product Team's only commercialization responsibilities are to develop AstraZeneca's commercial launch and marketing plans. The Joint Steering Committee reviews recommendations from the Global Product Team regarding the U.S. development plan and resolves disputes of the Global Product Team. In the event of a Joint Steering Committee dispute, our chief executive officer or designee will have the final decision-making authority only with respect to any such disagreement arising out of either (i) core development activities (other than decisions pertaining to dose selection or initial product labeling) or (ii) additional development activities, but only to the extent that such activities are required by the FDA to obtain NDA approval in the U.S. of the initial product. The chief executive officer or designee of AstraZeneca will have the final decision-making authority with respect to disagreements relating to all other matters.

In reviewing the terms of the executed agreement and considering the provisions of EITF 00-21, "Revenue Arrangements with Multiple Deliverables", we concluded that our involvement in the Global Product Team and the Joint Steering Committee during the development phase of the collaboration represents a substantive performance obligation or deliverable as defined in EITF 00-21. Following FDA approval of the NDA, we believe that participation on the Global Product Team and the Joint Steering Committee represents a right and a governance role only, rather than a substantive performance obligation. Given that the participation on the Global Product Team and Joint Steering Committee during the development phase do not meet criteria in paragraph 9 of EITF 00-21 for separation (e.g., no separate identifiable fair value), we concluded that this deliverable would be combined with the upfront payments received and treated as a single unit-of-accounting for purposes of revenue recognition. We recognize the combined unit of accounting over the estimated period of obligation, involvement and responsibility – through the estimated NDA approval / transfer date, which coincides with our substantive obligation to serve on the Global Product Team and the Joint Steering Committee.

- The June 2003 initial licensing and patent-issuance milestone payments totaling $25.0 million for MT 400 received from GlaxoSmithKline, or GSK, have been deferred and were amortized over the expected period of development. During 2005 the amortization period was decreased to 39 months based upon the August 2005 submission to the FDA of the Treximet NDA which occurred earlier than previously anticipated. The 2005 change in the amortization period resulted in a $0.7 million increase in the 2005 full-year amortization. During 2006, based upon the June 2006 receipt of an approvable letter from the FDA related to the Treximet NDA and the December 2006 receipt of a notice from the FDA that it had requested additional analyses and supporting information relating to submitted data, $1.9 million of the $25 million initial licensing and patent-issuance milestone payments was deferred to 2007. With the receipt of a second approvable letter in August 2007, unamortized deferred revenue was amortized through March 2008. We recognized $0.2 million and $1.7 million of licensing revenue from the amortization of GSK milestone payments during the fiscal years ended December 31, 2008 and 2007, respectively. The GSK upfront payments are now fully amortized.

- The September 2003 $1.0 million licensing fee for MT 300 ($2.0 million non-refundable upfront licensing fee net of a potential termination fee of $1.0 million) received from Valeant Pharmaceuticals North America (Valeant NA), a subsidiary of Valeant Pharmaceuticals International (formerly Xcel Pharmaceuticals Inc.), has been amortized over 32 months. As the result of the receipt in October 2003 of a not-approvable letter from the FDA relating to the NDA for MT 300, after three months of amortization, this estimated deferral period was increased from an original estimate of 20 months to 32 months ending in April 2006. In July 2005, we received a letter from Valeant NA, seeking payment of a $1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable under the circumstances of receipt of the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement although the last written communication from Valeant NA was received in March 2006. In 2008, based upon our evaluation of the facts and circumstances, we recognized the remaining $1.0 million licensing fee for MT 300. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. During the year ended December 31, 2008, a $20.0 million milestone was recognized related to the approval of, and GSK's intent to commercialize, Treximet.

Treximet royalty revenue is recognized when earned as will any future royalty revenues with respect to the manufacture, sale or use of the Company's products or technology. For Treximet or those future arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. During the year ended December 31, 2008, the Company recognized $2.4 million of royalty revenue which is included within licensing revenue in the accompanying statements of operations.

With regards to the development revenues, the Company's licensing agreements may include payment for development services provided by the Company on an hourly rate and direct expense basis. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project. In accordance with EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent", under the collaboration agreements with AstraZeneca and GSK, the Company recognizes as development revenue the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described within the related agreements. We recognize development revenue for development activities performed pursuant to the AstraZeneca and GSK agreements. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Development revenue and direct billed costs for the twelve months ended December 31, 2008, 2007 and 2006 were the following:

	Twelve months ended December 31,		
	2008	2007	2006
Development Revenue	$ 28,912,399	$ 18,985,344	$ 4,834,972
Direct Costs	$ 25,934,849	$ 16,128,985	$ 4,364,287

Investments

Investments consist primarily of United States government and government agency obligations, and corporate fixed income securities. The Company invests in high-credit quality investments in accordance with its investment policy, which minimizes the possibility of loss, however, given the recent disruption in the credit markets and the downgrades of previous high-credit companies, the possibility of a loss is increased. Under the Company's investment policy, investments that have a maturity of greater than three months and less than one year are classified as short-term, are considered to be available-for-sale and are carried at fair value with unrealized gains and losses recognized in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis. Generally, investments with maturities beyond twelve months are classified as long-term. Marketable and non-marketable equity investments are evaluated, on an on-going basis, for market impairment. If it is determined that a decline of any investment is other than temporary, the investment would be written down to fair value and the write-down would be permanent. For the twelve month period ended December 31, 2008, 2007 and 2006, the Company had $1.2 million, $1.5 million and $1.3 million, respectively, of interest income and $0.9 million, $1.8 million and $1.1 million, respectively, of bond amortization income included in other income for the period. The Company has considered the impact of the current economic environment on its evaluation of the fair value of its investments. We have no investments in debt securities with maturities of greater than one year.

Cash and cash equivalents and short-term investments consisted of the following as of December 31, 2008:

	Amortized Costs	Loss	Gain	Market
Cash and cash equivalents:				
Cash	$ 4,959,331	$ -	$ -	$ 4,959,331
Money market securities	19,272,396	-	-	19,272,396
Corporate notes	1,887,522	-	-	1,887,522
Total cash and cash equivalents	$ 26,119,249	$ -	$ -	$ 26,119,249
Short-term investments:				
U.S. treasury and agency securities	$ 30,429,208	$ -	$ 213,830	$ 30,643,038
Corporate notes	4,911,995	(4,894)	12,584	4,919,685
Total short-term investments	$ 35,341,203	$ (4,894)	$ 226,414	$ 35,562,723

Cash and cash equivalents and short-term investments consisted of the following as of December 31, 2007:

	Amortized Costs	Loss	Gain	Market
Cash and cash equivalents:				
Cash	$ 2,228,028	$ -	$ -	$ 2,228,028
Money market securities	19,270,455	-	-	19,270,455
Corporate notes	16,161,585	-	-	16,161,585
Total cash and cash equivalents	$ 37,660,068	$ -	$ -	$ 37,660,068
Short-term investments:				
U.S. treasury and agency securities	$ 3,600,000	$ (252)	$ -	$ 3,599,748
Corporate notes	32,667,568	(7,442)	22,234	32,682,360
Total short-term investments	$ 36,267,568	$ (7,694)	$ 22,234	$ 36,282,108

Cash and Cash Equivalents and Concentration of Credit Risk

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash is invested in interest-bearing investment-grade securities. Cash is restricted to the extent of a $94,684 letter of credit, maintained in compliance with the terms of the Company's office lease.

Cash and cash equivalents include financial instruments that potentially subject the Company to a concentration of credit risk. Cash and cash equivalents are of a highly liquid nature and are insured by the respective financial institutions up to $250,000 per account. Additionally, approximately $5.6 million in a money market account at September 18, 2008 participates in the U.S. Treasury Department's Temporary Guarantee Program for Money Market Funds thru April 30, 2009. Any excess amounts are uninsured. 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.

Fair Value Measurement

On January 1, 2008, we adopted the provisions of SFAS 157 "Fair Value Measurements" ("SFAS 157"). SFAS 157 was issued in September 2006 and is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the Financial Accounting Standards Board ("FASB") released FSP No. FAS 157-2 which deferred the effective date of SFAS 157 for one year for nonfinancial assets and nonfinancial liabilities. It did not defer recognition and disclosure requirements for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. Accordingly, as of January 1, 2008, we have applied the provisions of SFAS 157 only to financial assets and liabilities as discussed below. Our adoption of SFAS 157 did not result in our recording any cumulative effect adjustments to retained earnings.

Under SFAS 157, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e. "the exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, we use various valuation approaches, including quoted market prices and discounted cash flows. SFAS No. 157 also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from independent sources. Unobservable inputs are inputs that reflect a company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed based on the best information available under the circumstances. The fair value hierarchy is broken down into three levels based on the reliability of inputs as follows:

- Level 1 - Valuations based on quoted prices in active markets for *identical* instruments that the Company is able to access. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

- Level 2 - Valuations based on quoted prices in active markets for instruments that are *similar*, or quoted prices in markets that are not active for identical or similar instruments, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

- Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The financial assets for which we perform recurring remeasurements are cash equivalents and short-term investments. As of December 31, 2008, financial assets utilizing Level 1 inputs included cash equivalents and short-term investments. Financial assets utilizing Level 2 inputs included short-term investments in government agency obligations and corporate fixed income securities.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation, such as the recent illiquidity in the auction rate securities market. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition has caused, and in the future may cause, our financial instruments to be reclassified from Level 1 to Level 2 or from Level 2 to Level 3.

SFAS 157 requires that the valuation techniques used by us are consistent with at least one of the three possible approaches: the market approach, income approach, and/or cost approach. Our Level 1 valuations are based on the market approach and consist primarily of quoted prices for identical items on active securities exchanges. Our Level 2 valuations also use the market approach and are based on significant other observable inputs such as quoted prices for financial instruments not traded on a daily basis. We did not rely on Level 3 input for valuation of our securities at December 31, 2008.

The following table sets forth our financial instruments carried at fair value as of December 31, 2008:

	Financial Instruments Carried at Fair Value	
	December 31,	
	2008	2007
Assets:		
Cash equivalents	$ 26,119,249	$ 37,660,068
Short-term investments	35,562,723	36,282,108
Total assets	$ 61,681,972	$ 73,942,176

The following table sets forth our financial instruments carried at fair value within the SFAS 157 hierarchy and using the lowest level of input as of December 31, 2008:

	Financial Instruments Carried at Fair Value			
	Quoted prices in active Markets for identical items (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Cash equivalents	$ 24,231,727	1,887,552	—	26,119,249
Short-term investments	—	35,562,723	—	35,562,723
Total assets	$ 24,231,727	37,450,245	—	61,681,972

Realized gains and losses from sales of our investments are included in "Other income (expense), net" and unrealized gains and losses are included as a separate component of equity, net of tax, unless the loss is determined to be "other-than-temporary."

In determining whether a decline in fair value below the original cost is other-than-temporary, we use a systematic methodology that considers all available evidence, including the credit rating of the relevant trust, the parity score (a measure of the trust's ability to meet its obligations as they come due), general market conditions, and industry and sector performance, among other factors. We also consider the duration and extent to which the fair value is less than cost, as well as our intent and ability to hold the investment until recovery or, if necessary, to the instrument's maturity. When determining whether an impairment is other-than-temporary we also consider the following information: (i) if the market value of the investment is below its current carrying value for an extended period, which we generally define as nine to twelve months; (ii) if the issuer has experienced significant financial declines; or (iii) if the issuer has experienced significant changes in its credit quality, among other factors. The Company did not have any other-than-temporary impairments during the periods presented.

Accumulated Other Comprehensive Income

The Company follows the provisions of SFAS 130, "Reporting Comprehensive Income." SFAS 130 establishes standards for the reporting and display of comprehensive income (loss) and its components for general purpose financial statements. Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders' equity. The Company had $221,520 of unrealized gains on its investments that are classified as accumulated other comprehensive income (loss) at December 31, 2008 and $14,540 of unrealized gains for the same period of 2007.

Comprehensive income (loss) consists of the following components for the twelve months ended December 31, 2008, 2007 and 2006:

	Twelve Months Ended December 31,		
	2008	2007	2006
Net (loss) income	$ (5,975,529)	$ 4,666,092	$ (19,309,820)
Unrealized gain (loss) on marketable securities	206,980	18,632	4,459
Total comprehensive (loss) income	$ (5,768,549)	$ 4,684,724	$ (19,305,361)

Equipment

Equipment consists primarily of computer hardware and software and furniture and fixtures and is recorded at cost. Depreciation is computed using an accelerated method over the estimated useful lives of the assets ranging from five to seven years. Accumulated depreciation at December 31, 2008 and 2007 totaled $0.7 million and $0.6 million respectively.

Research and Development Costs, Including Clinical Trial Expenses

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

Income Taxes

Income taxes are computed using the asset and liability approach, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactment of changes in tax law or rates. If it is more likely than not that some or all of a deferred tax asset will not be realized, the Company records a valuation allowance.

Net Income (Loss) Per Share

Net Income and Net Loss Per Share—Basic and diluted net income and net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net income or loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the fiscal years ended December 31, 2008, 2007 and 2006. During the fiscal years ended December 31, 2008, 2007 and 2006, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for the fiscal years ended 2008 and 2006 because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share is the same for the fiscal years 2008 and 2006. In accordance with SFAS 128, the Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the EPS calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

The following table illustrates the calculation of dilutive shares outstanding:

	Years ended December 31,		
	2008	**2007**	**2006**
Weighted-average shares used in computing basic net income (loss) per share	29,761,847	29,592,890	29,224,699
Effect of dilutive securities	—	988,436	—
Weighted-average shares used in computing diluted net income (loss) per share	29,761,847	30,581,326	29,224,699

Fair Value of Financial Instruments

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

Patent Costs

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

Stock-Based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment," which requires us to account for share-based payment transactions using a fair value-based method and recognize the related expense in our results of operations.

Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure-only purposes under the provisions of SFAS No. 123, we use the Black-Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance conditions granted subsequent to our adoption of SFAS No. 123(R), we recognize compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable.

Contingencies

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed motions to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of the Company's directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs have stated that they intend to file objections to the Recommendation and, if plaintiffs do object, there can be no assurance that the Court will accept the Recommendation. If plaintiffs do file objections to the Recommendation, the Company and the individual defendants intend to continue to defend these claims vigorously.

The Company and GSK have received notices of paragraph IV certifications from Par Pharmaceuticals Inc., or Par, and Alphapharm Pty Ltd., or Alphapharm, and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm. We filed suit against Par on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

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

Under its commercialization collaboration with Valeant NA, related to MT 300, if the Company chooses to withdraw the MT 300 NDA for commercial or financial reasons under the conditions specified in the agreement, it could be required to pay a withdrawal fee of $1.0 million. As a result of this contingency, $1.0 million of the $2.0 million upfront payment received by the Company from Valeant NA pursuant to the agreement was not recognized as revenue prior to 2008.

In July 2005, we received a letter from Valeant NA, seeking payment of a $1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable under the circumstances of receipt of the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement although the last written communication from Valeant NA was received in March 2006. In 2008, based upon our evaluation of the facts and circumstances, we recognized the remaining $1.0 million licensing fee for MT 300. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

New Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides a common definition of fair value and establishes a framework to make the measurement of fair value in generally accepted accounting principles more consistent and comparable. SFAS 157 also requires expanded disclosure to provide information about the extent to which fair value is used to measure assets and liabilities, the methods and assumptions used to measure fair value, and the effect of fair value measures on earnings. SFAS 157 was adopted effective January 1, 2008.

In February 2008, the Financial Accounting Standards Board ("FASB") released FSP No. FAS 157-2 which deferred the effective date of SFAS 157 for one year for nonfinancial assets and nonfinancial liabilities. It did not defer recognition and disclosure requirements for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. Accordingly, as of January 1, 2008, we have applied the provisions of SFAS 157 only to financial assets and liabilities. Our adoption of SFAS 157 did not result in our recording any cumulative effect adjustments to retained earnings.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 gives the Company the irrevocable option to carry most financial assets and liabilities at fair value, with changes in fair value recognized in earnings. SFAS 159 was adopted effective January 1, 2008.

In June 2007, the FASB issued Emerging Issues Task Force ("EITF") on EITF Issue No. 07-3, *"Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"* ("EITF 07-3"). EITF 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties, and amortize them over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company believes EITF 07-3 does not have a material impact on its financial statements.

2. License Agreements

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

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the NDA for Treximet, the trade name for the product. On April 26, 2008 the Company received, from GSK, $20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, Treximet. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. At December 31, 2008, the Company accrued $1.2 million of Treximet royalty revenue and GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017) based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

The Company and GSK have received notices of paragraph IV certifications from Par and Alphapharm and its designated agent, Mylan Pharmaceuticals Inc., informing us that each company had filed an ANDA with the FDA seeking

approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par and Alphapharm have each indicated that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it elected not to exercise its first right to bring infringement suits against Par and Alphapharm. We filed suit against Par on November 14, 2008 in the federal court of the Eastern District of Texas. We filed suit against Alphapharm and Mylan on January 2, 2009, also in the federal court of the Eastern District of Texas. Both actions have been consolidated into one suit. Upon filing of a patent infringement lawsuit against the filer of an ANDA, approval of such ANDA would automatically be stayed, or barred, for 30 months, or until an adverse court decision is entered, whichever may occur earlier. Treximet currently has regulatory exclusivity through April 15, 2011 and such exclusivity can be extended by 6 months by completing pediatric studies.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca had the right, which has now expired, to elect to include Japan in the licensed territory within two years after the effective date of the agreement. Pursuant to the terms of the agreement, we received an upfront license fee of $40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

In September 2007, we agreed with AstraZeneca to amend our collaboration and license agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to $345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007 we received a $10.0 million payment upon execution of the amendment and a $20.0 million payment in recognition of the achievement of the primary endpoints for the PN 400-104 study, a study which compared acid suppression of different doses of PN 400, and achievement of the interim results of the PN 200-301 study, a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy, meeting mutually agreed success criteria. An additional $55.0 million will be paid upon achievement of certain development and regulatory milestones, and $260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved. Under the original agreement, we were to have received development and regulatory milestones totaling $160.0 million, of which $20.0 million was to be paid upon the successful completion of the proof of concept studies, and sales performance milestones totaling $175.0 million.

In addition, the amendment revised the royalty rates we were to have received under the original agreement. Under the original agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the amendment, we will now receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revises the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure.

Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We further amended the collaboration and license agreement effective October 1, 2008 to shorten the timing of AstraZeneca's reimbursement obligation for certain development expenses incurred by us under the agreement and to update the description of the target product profile studies (as defined in the agreement) for PN 400.

We retain responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We have agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote

with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

Valeant Pharmaceuticals North American (Valeant NA) (formerly Xcel Pharmaceuticals Inc.)

In September 2003, we signed an agreement with Valeant NA for the further development and commercialization of MT 300. In March 2005, Valeant Pharmaceuticals International (Valeant International) acquired Valeant NA. Under the terms of the agreement, Valeant NA would have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations. Pursuant to the terms of the agreement, Valeant NA paid us an upfront fee of $2.0 million. Upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300, potential milestone payments of up to $8.0 million would be due. Valeant NA is also obligated to pay us royalties on all combined net sales of MT 300 and Valeant NA's D.H.E. 45® (dihydroergotamine mesylate) Injection, upon commercialization of MT 300, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that Valeant NA pays royalties to one or more third parties to license rights from such third parties to commercialize MT 300. The agreement terminates on the date of expiration of all royalty obligations (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent) unless earlier terminated by either party for a material breach or in the event that either party determines not to pursue approval of MT 300, under the conditions described below. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non-terminating party. Generally, each party must indemnify the other for damages arising from such party's breach of its representations, warranties and obligations under the agreement, as well as for the gross negligence or willful misconduct by either party. Additionally, Valeant NA must indemnify us for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while we must indemnify Valeant NA for any damages arising from such development, manufacture or use prior to the effective date. We must also indemnify Valeant NA for any use by us or any sub licensee of certain technology owned by Valeant NA.

Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant of this situation and Valeant NA does not assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a withdrawal fee of $1.0 million. If Valeant decides to assume development, it would be credited $1.0 million in development expense. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300. In July 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. We do not believe that the withdrawal fee is payable based on our receipt of a not-approvable letter from the FDA with respect to our NDA for MT 300. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration.

Based upon the delays related to commercialization of MT 300 due to our receipt of the not-approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Valeant NA had previously agreed to extend the time for certain activities under our agreement with Valeant NA that are dependent on the FDA's actions with respect to MT 300. In the event of termination of the agreement, these obligations will not be relevant. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement although the last written communication from Valeant NA was received in March 2006. In 2008, based upon our evaluation of the facts and circumstances, we recognized the remaining $1.0 million licensing fee for MT 300. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

3. Stockholders' Equity

Shares Reserved for Future Issuance

In January 2005, the Company approved a stockholder rights plan (the "Rights Plan"), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Company declared a dividend of a right to acquire one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock, $0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Generally, the Rights only are triggered and become exercisable if a person or group acquires beneficial ownership of 15 percent or more of the Company's common stock or announces a tender offer for 15 percent or more of the Company's common stock. The Rights Plan is similar to plans adopted by many other publicly-traded companies. The effect of the Rights Plan is to discourage any potential acquirer from triggering the Rights without first convincing POZEN's Board of Directors that the proposed acquisition is fair to, and in the best interest of, the shareholders and the Company. The provisions of the Plan will substantially dilute the equity and voting interest of any potential acquirer unless the Board of Directors determines that the proposed acquisition is in the best interest of the shareholders. In connection with the Plan, the Company designated 90,000 shares of its authorized Preferred Stock as Series A Junior Participating Preferred Stock. Each Right, if and when exercisable, will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00 for each one one-thousandth of a share, subject to adjustment. Each holder of a Right (except for the Acquiring Person (as defined in the Rights Plan), whose Rights will be null and void upon such event) shall thereafter have the right to receive, upon exercise, that number of shares of Common Stock of the Company (or, in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of Common Stock at the date of the occurrence of such event. The Rights can be terminated by POZEN's Board of Directors and are subject to optional redemption by the Company at $0.001 per Right. The Rights Plan has a 10-year term and contains provisions requiring a periodic review and evaluation by the Board of Directors.

At December 31, 2008, shares of our common stock reserved for future issuance are as follows:

Common shares available for grant under stock option plans	1,392,316
Common shares issuable pursuant to options and restricted stock units granted under equity compensations plans	4,160,097
Rights Plan shares issuable as Series A Junior Participating Preferred Stock	90,000
Total reserved	5,642,413

4. Accrued Expenses

Accrued expenses consist of the following at December 31:

	2008	2007
Research and development costs	$ 5,481,698	$ 3,299,517
Other	255,556	496,647
	$ 5,737,254	$ 3,796,164

5. Income Taxes

At December 31, 2008 and 2007, we had federal net operating loss carryforwards of approximately $80.8 million and $75.6 million respectively, state net economic loss carryforwards of approximately $68.6 million and $74.2 million respectively, and research and development credit carryforwards of approximately $11.7 million and $10.3 million, respectively. The amount of the NOL related to excess tax based stock compensation is $4.8 million and $4.8 million at December 31, 2008 and 2007, respectively. The federal and state net operating loss carryforwards begin to expire in 2014 and the research and development credit carryforwards begin to expire in 2012. For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards. Of the total increase in valuation allowance of $2.7 million, $2.4 million was allocable to current operating activities and $0.3 million was allocable to a change in the state tax rate. When the valuation allowance is realized, a portion related to excess stock option compensation will be realized as an increase in additional paid-in capital. 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 loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

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

	($ in thousands) 2008	2007
Deferred tax assets:		
Net operating loss carryforwards	$ 31,371	$ 29,775
Research and development credits	11,781	10,320
Revenue recognition	7,279	9,330
Equity compensation and other	5,802	4,067
Total deferred tax assets	56,233	53,492
Valuation allowance	(56,233)	(53,492)
Net deferred tax asset	$ —	$ —

The components for the income tax provision were as follows:

	($ in thousands) 2008	2007	2006
State income taxes			
Current	$ 0	$ 0	$ 0
Deferred	0	0	0
Federal income taxes			
Current	0	667	0
Deferred	0	0	0
Provision for income taxes	$ 0	$ 667	$ 0

The actual income tax expense for the years ended December 31, 2008, 2007 and 2006, differed from the amounts computed by applying the U.S. federal tax rate of 35% to pretax earnings as a result of the following:

	($ in thousands) 2008	2007	2006
(Loss) income before income tax	$ (5,976)	$ 5,333	$ (19,310)
Federal tax rate	35 %	35 %	35%
Federal income tax provision at statutory rate	(2,091)	1,867	(6,758)
State tax provision	(36)	(405)	771
Increase (decrease) in income tax expense resulting from:			
Research and development credits	(1,461)	(1,551)	(602)
Non-deductible expenses and other	847	705	680
Change in state tax rate	—	(90)	—
Change in valuation allowance	2,741	141	5,909
Tax expense	$ —	$ 667	$ —

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109", or FIN 48, on January 1, 2007. As of December 31, 2006, the Company had not recorded a contingent tax liability.

The Company had gross unrecognized tax benefits of approximately $0.1 million as of January 1, 2008. As of December 31, 2008, the total gross unrecognized tax benefits were approximately $0.1 million and of this total, $21,000 is the amount that, if recognized, would reduce the Company's effective tax rate. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next 12 months.

The Company's policy for recording interest and penalties associated with tax audits is to record them as a component of provision for income taxes. In conjunction with the adoption of FIN 48, the Company has not recognized any amount for the

payment of interest or penalties at January 1, 2008. During 2008, the Company did not record any expense to the income statement for interest and penalties.

The Company has analyzed its filing positions in all significant federal, state and foreign jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to US Federal and state and local tax examinations by tax authorities for years before 2005, although carryforward attributes that were generated prior to 2005 may still be adjusted upon examination by the IRS if they either have been or will be used in a future period. No income tax returns are under examination by taxing authorities.

Rollforward of gross unrecognized tax positions:

Gross tax liability at January 1, 2008	$	122,000
Additions for tax positions of the current year		14,400
Reductions for tax positions of the prior years		0
Gross tax liability at December 31, 2008	$	136,400

6. Equity Compensation Plans

On November 20, 1996, the Company established a Stock Option Plan (the "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. In May 2000, the Board of Directors adopted, and in June 2000 the stockholders approved, the POZEN Inc. 2000 Equity Compensation Plan (the "Plan") which authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. In May 2004 an award of 98,135 restricted stock units was made to the Company's chief executive officer under the Plan. Those restricted stock units are not reflected as stock options in the charts below. In 2004, the Board of Directors adopted and the stockholders approved an amendment to and restatement of the Plan which provided for an increase in the number of shares of common stock authorized for issuance under the Plan, from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. On June 13, 2007, the stockholders approved the amendment and restatement of the Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan from 5,500,000 to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards under the Plan so as to qualify the compensation attributable to any such awards as performance-based compensation under Section 162(m) of the Internal Revenue Code.

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, 2007	3,445,417	$	9.60
Options granted	366,312		10.67
Exercised	(59,550)		2.80
Forfeited	(20,000)		10.64
Balance at December 31, 2008	3,732,179	$	9.86

The adoption of SFAS No. 123(R) had a significant impact on our results of operations. Our consolidated statement of operations for the years ended December 31, 2008, 2007 and 2006 includes the following stock-based compensation expense:

	Years ended December 31,		
	2008	2007	2006
Research and development	$ 2,180,018	$ 1,217,264	$ 1,760,153
General and administrative	3,823,181	3,095,110	3,740,326
Total expenses	$ 6,003,199	$ 4,312,374	$ 5,500,479

Unrecognized stock-based compensation expense, including time-based options, performance-based options and restricted stock awards, expected to be recognized over an estimated weighted-average amortization period of 1.17 years, was $9.6 million at December 31, 2008.

Stock Plans

On November 20, 1996, the Company established a Stock Option Plan (the "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 were permitted to be made under the Option Plan to eligible employees, officers, consultants and non-employee directors in the form of incentive or nonqualified stock options. Eligible participants under the Option Plan include executive and key employees of the Company. The vesting periods for options granted under the Option Plan range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. The exercise price for incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (110% with respect to incentive stock options granted to optionees who are holders of 10% or more of the Company's common stock).

In June 2000, the stockholders approved the POZEN Inc. 2000 Equity Compensation Plan (the "Plan"). The Plan became effective upon the completion of the Company's initial public offering in October 2000, after which time no further grants were made under the Option Plan. The Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units, and other stock-based awards, such as restricted stock units and stock appreciation rights, to employees, non-employee directors, advisors and consultants. At adoption, the Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The vesting periods for awards made under the Plan generally range from immediate vesting at issuance to four years, as described in and in accordance with the Plan, and upon a change of control as defined in the Plan. 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 awards granted under the Plan.

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

In June 2007, the stockholders approved the amendment and restatement of the Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan from 5,500,000 to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards under the Plan so as to qualify the compensation attributable to any such awards as performance-based compensation under Section 162(m) of the Internal Revenue Code.

Time-Based Stock Awards

The fair value of each time-based award is estimated on the date of grant using the Black-Scholes option valuation model, which uses the assumptions described below. Our weighted-average assumptions used in the Black-Scholes valuation model for equity awards with time-based vesting provisions granted for the years ended December 31, 2008, 2007 and 2006 are shown in the following table:

	2008	2007	2006
Expected volatility	71.3 – 74.5 %	76.0 – 79.2 %	76.0 – 90.3 %
Expected dividends	0 %	0 %	0 %
Expected terms	5.0 – 6.25 Years	6.25 Years	6.25 Years
Risk-free interest rate	2.6 – 4.4 %	4.4 – 5.1 %	4.3 – 5.1 %

For the years ended December 31, 2008, 2007 and 2006, the expected volatility rate was estimated based on an equal weighting of the historical volatility of POZEN common stock over approximately a six year period. For the year ended December 31, 2008, the expected term was based upon average historical terms to exercise. For the years ended December 31, 2007 and 2006, the expected term was estimated based on a simplified method, as allowed under SEC Staff Accounting Bulletin No. 107, "Share-Based Payment", averaging the vesting term and original contractual term. The risk-free interest rate for periods within the contractual life of the option is based on seven year U.S. Treasury securities. The pre-vesting forfeiture rate used for the years ended December 31, 2008, 2007 and 2006 was based on historical rates. As required under SFAS No. 123(R), we adjust the estimated forfeiture rate based upon actual experience.

A summary of the time-based stock awards as of December 31, 2008, and changes during the year ended December 31, 2008, is as follows:

Time-Based Stock Awards	Underlying Shares (000s)	Weighted-Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Outstanding at December 31, 2007	3,445	$ 9.60	6.4	$ 11,167
Granted	366	10.67		
Exercised	(59)	2.80		
Forfeited or expired	(20)	10.64		
Outstanding at December 31, 2008	3,732	9.86	5.2	$ 197
Exercisable at December 31, 2008	2,493	$ 8.56	4.8	$ 197

The aggregate intrinsic value of options outstanding represents the pretax value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period. The exercise price of stock options granted during the twelve month periods ended December 31, 2008, 2007 and 2006 was equal to the market price of the underlying common stock on the grant date. The total intrinsic value of stock options exercised during the year ended December 31, 2008, 2007 and 2006 was $0.6 million, $2.3 million and $3.2 million, respectively.

Restricted Stock and Restricted Stock Units

For the years ended December 31, 2008, 2007 and 2006, the Company recognized $0.2 million, $0.2 million and $0.4 million, respectively, in compensation expense related to restricted stock units. As of December 31, 2008, there was an aggregate $0.1 million of unrecognized compensation expense related to unvested restricted stock units. Of the aggregate amount, $46,000 unrecognized compensation expense related to unvested restricted stock units under the 2007 award of 20,200 restricted stock units with a grant-date per-share fair value of $16.89 and $61,000 unrecognized compensation expense related to unvested restricted stock units under the May 6, 2008 award of 14,000 restricted stock units with a grant-date per-share fair value of $14.45. During 2008, 2,000 restricted stock units, under the May 6, 2008 award, were forfeited. As of December 31, 2008, there was no unrecognized compensation expense related to the May 2004 award of 98,135 restricted stock units. There were 15,487 unvested restricted stock units outstanding at December 31, 2008.

Performance-Based Awards

In January 2005, pursuant to an incentive program (the "Treximet incentive program") approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 506,772 shares of common stock. Each performance-based option would vest in full upon the later to occur of (i) January 3, 2007 or (ii) the receipt by the Company of an action letter from the FDA indicating approval of the NDA for the product candidate Treximet, provided, however that 25% of each such option would be forfeited if receipt of the FDA approval letter for the Treximet NDA did not occur prior to June 30, 2007, and 100% of each such option would be forfeited if receipt of the FDA approval letter for the Treximet NDA did not occur on or before December 31, 2007. These performance-based options, which were granted under the Plan, as amended and restated, had a ten-year term and an exercise price of $7.06, which was equal to the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant. The grant date fair value of these performance-based options was $3.77 per share. The receipt of the FDA approval letter for the Treximet NDA had not occurred on or before December 31, 2007 as described under the terms of the initial grant, and therefore all options to purchase shares of common stock under the Treximet incentive program were forfeited during the 2007 year and the related compensation expense was reversed.

On May 6, 2008, pursuant to an incentive program (the "PN incentive program") approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 281,433 shares of common stock. On September 10, 2008, additional stock options were granted under the PN incentive program, to purchase 11,700 shares of common stock. Twenty-five percent (25%) of the PN incentive program options granted will vest upon the acceptance by the FDA of the NDA for PN 400. The remaining seventy-five (75%) of the options granted will vest upon the receipt by the Company of an action letter from the FDA indicating approval of the NDA for PN 400. The options have a ten-year term. The May 6, 2008 and September 10, 2008 option grants have exercise prices of $14.45 and $10.82, respectively, which was equal to the Nasdaq reported market closing price of the common stock on the date of grant. The weighted average grant-date fair value of these performance-based

options was $9.66 and $7.08 per share for the May 6, 2008 and September 1, 2008 option grants, respectively. The options also include provisions that require satisfactory employee performance prior to vesting. Additionally, 20,000 options were granted to an executive officer on May 6, 2008 under the PN incentive plan, with identical grant and exercise terms except that 100% of the options granted will vest upon the FDA indicating acceptance of the NDA for PN 400. The Company is recognizing compensation costs for these awards over the expected service period. Total expense related to these awards was $0.9 million for the fiscal year ended December 31, 2008.

As of December 31, 2008, there was $1.5 million in unrecognized compensation expense related to performance-based awards granted under the PN incentive program. The December 31, 2008 amount is expected to be recognized over the period ending July 31, 2010. There were 313,133 unvested performance-based options outstanding at December 31, 2008. In 2007, as a result of Treximet not receiving approval by the FDA by December 31, 2007, we reversed all remaining previously expensed stock-based compensation for the Treximet incentive program. The reversal reduced 2007 research and development expenses by $0.3 million and general and administrative expenses by $0.6 million. The grant-date fair value of these performance-based options was $3.77 per share. There were 375,251 awards forfeited during the year ended December 31, 2007. No performance-based awards were exercised during the twelve months ended December 31, 2008 and 2007; no awards were forfeited during the twelve months ended December 31, 2008. At December 31, 2008 the performance-based options had no intrinsic value and a remaining contractual life of 9.3 years.

The fair value of each performance-based option granted under the Plan, including those granted under the Treximet incentive program, was estimated as of the grant date using the Black-Scholes option valuation model without consideration of the performance measures.

7. Leases

The Company leases its office space and certain equipment under cancellable and noncancellable operating lease agreements. Rent expense incurred by the Company was approximately $431,000, $412,000 and $401,000, for the fiscal years ended December 31, 2008, 2007, and 2006, respectively. The following is a schedule of noncancellable future minimum lease payments for operating leases at December 31, 2008:

	($ in thousands)
2009	$ 410
2010	69
	$ 479

On February 16, 2009, the Company entered into a Lease Modification Agreement No. 1 (the "Modification Agreement") modifying certain terms to our existing lease. Under the terms of the Modification Agreement, the lease term is extended for an additional 5 years and 7 months, terminating on September 30, 2015. As a result of entering into the Modification Agreement, the Company's noncancellable future minimum lease payments for operating leases will increase by approximately $2.7 million over the lease term.

8. Retirement Savings Plan

In July 1997, the Company adopted a defined contribution 401(k) plan (the "Plan") covering substantially all employees who are at least 21 years of age. Based upon management's discretion, the Company may elect to make contributions to the Plan. During the years ended December 31, 2008, 2007, and 2006, the Company made contributions of $256,690, $242,358, and $216,641, respectively, to the Plan.

9. Subsequent Events

On February 16, 2009, the Company entered into a Lease Modification Agreement No. 1 (the "Modification Agreement) modifying certain terms to our existing lease, dated November 21, 2001, relating to approximately 17,009 square feet of office space located at Exchange Office Building, Chapel Hill, North Carolina. Under the terms of the Modification Agreement, the lease term is extended for an additional 5 years and 7 months, terminating on September 30, 2015. The Modification Agreement also provides the Company with a reduced notice period of 7 months for renewals of the lease. The Company is also entitled to a 3-year lease extension option available at the end of the term and a first offer right on available space located within the Exchange Office Building property. As a result of entering into the Modification Agreement, the Company's noncancellable future minimum lease payments for operating leases will increase by approximately $2.7 million over the lease term.

10. Summary of Operations by Quarters (Unaudited)

	2008			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue				
Licensed revenue	$ 3,851,082	$ 24,519,015	$ 3,603,100	$ 5,248,046
Development revenue	3,977,908	8,605,038	7,542,097	8,787,355
Total revenue	7,828,990	33,124,053	11,145,197	14,035,401
Operating expenses	15,961,507	20,287,090	19,456,674	18,543,640
Net (loss) income	(7,371,253)	13,334,103	(7,854,980)	(4,083,399)
Net (loss) income per share of common stock				
Basic	$ (0.25)	0.45	(0.26)	(0.14)
Net (loss) income per share of common stock				
Diluted	$ (0.25)	0.43	(0.26)	(0.14)
Number of shares used in per share calculation				
Basic	29,723,563	29,759,250	29,786,264	29,778,310
Number of shares used in per share calculation				
Diluted	29,723,563	30,707,710	29,786,264	29,778,310

	2007			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue				
Licensed revenue	$ 3,701,000	$ 3,701,000	$ 23,205,920	$ 3,851,082
Development revenue	3,955,004	8,233,383	4,423,556	2,373,400
Total revenue	7,656,004	11,934,383	27,629,476	6,224,482
Operating expenses	10,534,957	16,528,164	11,928,769	12,445,404
Income (loss) before income tax expense	(2,089,640)	(3,847,075)	16,482,223	(5,212,416)
Income tax expense	-	-	(1,645,099)	978,099
Net (loss) income	(2,089,640)	(3,847,075)	14,837,124	(4,234,317)
Net (loss) income per share of common stock				
Basic	$ (0.07)	(0.13)	0.50	(0.14)
Net (loss) income per share of common stock				
Diluted	$ (0.07)	(0.13)	0.48	(0.14)
Number of shares used in per share calculation				
Basic	29,469,392	29,502,372	29,695,596	29,704,198
Number of shares used in per share calculation				
Diluted	29,469,392	29,502,372	30,598,807	29,704,198

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.1	Stock Option Plan of the Registrant.*
10.2	First Amendment to Stock Option Plan dated February 14, 1997.*
10.3	Second Amended and Restated 2000 Equity Compensation Plan of the Registrant (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.4	Form of Incentive Stock Option Agreement under Registrant's Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.5	Form of Nonqualified Stock Option Agreement under Registrant's Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.6	Form of Non-Employee Director Nonqualified Stock Option Agreement under Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***.
10.7	Form of Non-Employee Director Restricted Stock Unit Agreement under Second Amended and Restated Equity Compensation Plan (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2007).***
10.9	Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 16, 2006).***
10.10	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.11	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.12	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007 (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.13	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed October 27, 2004).***
10.14	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.15	Executive Employment Agreement with Marshall E. Reese dated November 8, 2004 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 12, 2004).***
10.16	First Amendment to Executive Employment Agreement with Marshall E. Reese, Ph.D., dated September 28, 2007 (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***.
10.17	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.18	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***

Exhibit No.	Description
10.19	Summary of Non-Employee Director Compensation (filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed March 8, 2007).***
10.20	Commercial Supply Agreement dated October 2001 by and between Registrant and Lek Pharmaceuticals Inc. (filed as Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).†
10.21	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).
10.22	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Form 10-Q/A filed November 8. 2004).†
10.23	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.24	Collaboration and License Agreement dated September 3, 2003 between the Registrant and Valeant Pharmaceuticals NA (formerly Xcel Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 6, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.25	Restricted Stock Unit Agreement dated May 4, 2004 between Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed July 30, 2004).***
10.26	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.27	Form of Non-Qualified Stock Option Agreement for Trexima grants issued pursuant Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***
10.28	Development, Option and License Agreement dated May 15, 2003 between the Registrant and Nycomed Danmark ApS (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 28, 2005, and Current Report on Form 8-K/A filed January 10, 2006).†
10.29	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB (filed as Exhibit 10.1 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.30	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca AB (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.31	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between the Registrant and AstraZeneca AB (filed as 10.2 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.32	Side Letter Agreement, dated October 1, 2007, between the Registrant and AstraZeneca, AB (filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.33	Long-Term Cash Incentive Award Agreement between the Registrant and John R. Plachetka dated February 14, 2007 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.34	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.35	Restricted Stock Unit Agreement with John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.36	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.37	Nonqualified Stock Option Grant issued to John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***

Exhibit No.	Description
10.38	Form of Nonqualified Stock Option Agreement for PN 400 Incentive Program under Second Amended and Restated 200 Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on May 8, 2008).***
10.39	Amendment No. 2 to the Collaboration and License Agreement, dated October 1, 2008, between the registrant and AstraZeneca, AB (filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed November 4, 2008). †
10.40	Lease Modification Agreement No. 1, dated as of February 16, 2009, by and between the Registrant and The Exchange at Meadowmont LLC (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on February 17, 2009).
10.41	Consulting Agreement dated as of April 1, 2009, between the Registrant and Marshall E. Reese (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed on February 24, 2009).***
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Auditors.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

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

** Filed herewith.

*** Compensation Related Contract.

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

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EXHIBIT 21.1

POZEN UK Limited

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

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-3 No. 333-155928) as amended and restated, and Registration Statements (Forms S-8 No. 333-52446, No. 333-117962 and No. 333-144087) pertaining to the 2000 Equity Compensation Plan of POZEN Inc. and in the related Prospectus of our reports dated February 17, 2009 with respect to the financial statements of POZEN Inc., and the effectiveness of internal control over financial reporting of POZEN Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 3, 2009

EXHIBIT 31.1

Section 302 Certification

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

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

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2009

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

EXHIBIT 31.2

Section 302 Certification

I, William L. Hodges, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2009

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

EXHIBIT 32.1

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

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

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

Date: March 6, 2009

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

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

EXHIBIT 32.2

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

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

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

Date: March 6, 2009

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

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

CORPORATE INFORMATION

BOARD OF DIRECTORS

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

Peter J. Wise, M.D.
Retired Vice Chairman
POZEN Inc.

NOMINATING/CORPORATE
GOVERNANCE COMMITTEE

James J. Mauzey
Retired President and
Chief Executive Officer
Bertek Pharmaceuticals, Inc.

COMPENSATION COMMITTEE,
CHAIRMAN

Arthur S. Kirsch
Managing Director/Partner
GCA Savvian Advisors, LLC

AUDIT COMMITTEE, CHAIRMAN
COMPENSATION COMMITTEE

Jacques F. Rejeange
Retired President
Florham Consulting S.A.

NOMINATING/CORPORATE
GOVERNANCE COMMITTEE,
CHAIRMAN

Kenneth B. Lee, Jr.
General Partner
Hatteras BioCapital, LLC

LEAD INDEPENDENT DIRECTOR
AUDIT COMMITTEE
COMPENSATION COMMITTEE

Paul J. Rizzo
Chairman of the Board
and Partner
Franklin Street Partners

NOMINATING/CORPORATE
GOVERNANCE COMMITTEE
AUDIT COMMITTEE

CORPORATE HEADQUARTERS

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

STOCK TRANSFER AGENT AND REGISTRAR

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

INDEPENDENT ACCOUNTANTS

Ernst & Young LLP
4130 ParkLake Avenue
Suite 500
Raleigh, NC 27612

COMMON STOCK LISTING

Ticker Symbol: POZN
Nasdaq Global Market

ANNUAL MEETING

Wednesday, June 3, 2009

STOCKHOLDER INQUIRIES

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

FORWARD-LOOKING STATEMENTS

Statements included in this annual report that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval of our product candidates, including as a result of the need to conduct additional studies, or the failure to obtain such approval of our product candidates, including as a result of changes in regulatory standards or the regulatory environment during the development period of any of our product candidates; uncertainties in clinical trial results or the timing of such trials, resulting in, among other things, an extension in the period over which we recognize deferred revenue or our failure to achieve milestones that would have provided us with revenue; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products, including our dependence on GlaxoSmithKline for the sales and marketing of *Treximet;* competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third-party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events, including those discussed herein and in our Annual Report on Form 10-K for the period ended December 31, 2008. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

1414 Raleigh Road
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919.913.1030
www.pozen.com

POZEN® INC.

The Pharmaceutical Development Company