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

Form 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2006

or

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

Commission File Number: 000-29959

Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**91-1911336**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

Remi Barbier
President and Chief Executive Officer
416 Browning Way
South San Francisco, CA 94080
(650) 624-8200
(Address, including zip code, or registrant's principal executive offices and telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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 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 "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $274,666,729 computed by reference to the last sales price of $8.35 as reported by the Nasdaq National Market System, as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2006.

The number of shares outstanding of the Registrant's common stock on February 1, 2007 was 44,332,503.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2007 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the Securities and Exchange Commission, are incorporated by reference to Part III of this Form 10-K Report.

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PART I

This document contains forward-looking statements that are based upon current expectations that are within the meaning of the Private Securities Reform Act of 1995. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to statements about:

- increases in collaboration revenue to be received from King Pharmaceuticals, Inc., or King, and other payments we may receive from our strategic alliances;
- the duration of the development period for all four expected drug candidates under our collaboration with King;
- anticipated clinical trials and number of patients to be enrolled in clinical trials;
- potential sources of clinical and commercial supply of Remoxy™ and its components;
- expansion of our potential product line, including the formulation of additional dosage forms of Remoxy and Oxytrex™;
- future operating losses and anticipated operating and capital expenditures;
- uses of proceeds from our securities offerings;
- the potential benefits of our drug candidates;
- the sufficiency of materials required for the clinical development of our drug candidates;
- the size of the potential market for our products;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital or increasing cash needs;
- potential competitors or competitive products;
- future market acceptance of our drug candidates and potential drug candidates;
- expenses increasing substantially or fluctuations in our operating results;
- future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- anticipated hiring and development of our internal systems and infrastructure;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- assumptions and estimates used for our disclosures regarding stock-based compensation in connection with Financial Accounting Standards Board Statement No. 123 (revised 2004), Share-based Payment, or SFAS 123R; and
- estimates concerning the provision for taxes and realization of deferred tax assets.

Such forward-looking statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to:

- the successful development of drug candidates pursuant to our collaboration agreements, including our collaboration agreement with King, and the continuation of such agreements;
- difficulties or delays in development, testing, clinical trials (including patient enrollment), regulatory approval, production and commercialization of our drug candidates;
- unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials) or potential post-approval market acceptance;

- the uncertainty of patent protection for our intellectual property or trade secrets;
- potential infringement of the intellectual property rights or trade secrets of third parties;
- pursuing in-license and acquisition opportunities;
- hiring and retaining personnel; and
- our financial position and our ability to obtain additional financing if necessary.

In addition, such statements are subject to the risks and uncertainties discussed in the “Risk Factors” section and elsewhere in this document.

Item 1. *Business*

Overview

We are a biopharmaceutical company that develops novel drugs for pain management and oncology. We have three investigational drug candidates in clinical programs. Remoxy and PTI-202 are proprietary, abuse-resistant forms of opioid drugs. Oxytrex is a novel, next-generation painkiller that potentially offers less physical dependence than currently marketed opioid painkillers. We are also developing a novel radio-labeled monoclonal antibody to treat metastatic melanoma, a rare but deadly form of skin cancer. We were incorporated in Delaware in May 1998.

Two of our novel drug candidates are currently in Phase III clinical programs:

- Remoxy, an abuse-resistant version of long-acting oxycodone, and
- Oxytrex, a novel oral opioid painkiller for the treatment of severe chronic pain.

We and King are engaged in a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150.0 million to us at the closing of this strategic alliance in December 2005.

In February 2006, we and King announced the completion of a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, in connection with the clinical development of Remoxy. We are conducting a pivotal Phase III clinical trial with Remoxy in approximately 400 patients with moderate to severe chronic pain, pursuant to the SPA.

In August 2006, we and King announced the initiation of a Phase I clinical trial program of a second abuse-resistant drug candidate, called PTI-202. In connection with the acceptance by the FDA of the investigational new drug application, or IND, for PTI-202, King made a milestone payment to us of $5.0 million.

We could also receive from King up to $145.0 million in additional milestone payments in the course of clinical development of Remoxy, PTI-202 and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1.0 billion in net sales of such drugs, for which the royalty is set at 15%.

Remoxy and PTI-202

Remoxy

Remoxy is being developed as an abuse-resistant long-acting oral oxycodone. Sales of controlled-release oxycodone were nearly $2.0 billion for the 12 months ended August 2005.

The active drug ingredient in Remoxy is oxycodone. Oxycodone is a strong narcotic painkiller that was developed around 1920 as a substitute for morphine. When used as prescribed, oxycodone can relieve severe chronic pain. The U.S. Drug Enforcement Administration, or DEA, and the national media have linked illicit oxycodone use to widespread patterns of drug abuse, addiction, diversion and drug overdose. In the United States, drug related emergency room visits are reported by the Department of Health and Human Service's Drug Abuse Warning Network, or DAWN. DAWN reports 22,000 oxycodone mentions in emergency room visits in 2002, a 450% increase from 4,000 oxycodone mentions in emergency room visits in 1994.

Remoxy is intended to meet the needs of physicians who appropriately prescribe opioid painkillers and who seek to minimize the risks of drug diversion, abuse or accidental patient misuse. Our clinical results to date demonstrate Remoxy is significantly less abusable than Oxycontin®, a brand of controlled-release oxycodone. In a variety of clinical comparisons of the abuse-resistant characteristics of Remoxy and Oxycontin, Oxycontin released significantly more active ingredient than Remoxy during the time when abusers presumably expect to get high.

We expect to conduct additional clinical trials or non-clinical studies of Remoxy in 2007, including additional abuse-resistance studies and other registration-enabling studies.

We believe the abuse-resistant technology used in Remoxy is applicable to different oral opioid painkillers. Pursuant to our agreement with King, we plan to develop abuse-resistant versions of additional opioid painkillers using this platform technology. We plan to formulate and scale-up a range of dosage forms of Remoxy.

PTI-202

In August 2006, we announced the initiation of a Phase I clinical trial program of a second abuse-resistant drug candidate, called PTI-202. Like Remoxy, PTI-202 is intended to meet the needs of physicians who appropriately prescribe opioid painkillers and who seek to minimize the risks of drug diversion, abuse or accidental patient misuse.

In November 2006, we announced positive results from a Phase I clinical trial evaluating PTI-202. This clinical trial was designed to investigate the safety, tolerability, pharmacokinetics and pharmacodynamic profile of a single, oral dose of PTI-202 in healthy volunteers. We believe results also indicate PTI-202 is safe and well-tolerated and its release profile appears well-suited to use with a chronic pain population.

We formulate Remoxy and PTI-202 using, in part, proprietary technology licensed from Durect Corporation. Under the terms of this agreement, we have exclusive worldwide rights to develop and to commercialize Remoxy and certain other opioid drugs that use Durect's technology. We reimburse Durect for certain formulation and related work, and are responsible to make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. We are responsible to pay Durect royalties on related drug sales. King is obligated to reimburse us for costs we incur pursuant to the agreement with Durect, including royalties.

We plan to have produced on our behalf additional clinical materials necessary to complete our Phase III program for Remoxy. We rely on Durect Corporation and other third-party manufacturers to formulate, manufacture, fill, label, ship or store Remoxy and other abuse-resistant drug candidates and their components.

Oxytrex

Oxytrex is an oral opioid painkiller with a novel mechanism of action. We believe Oxytrex could be an effective substitute for oxycodone, a narcotic painkiller widely used today to treat severe chronic pain. Sales of controlled-release oxycodone were nearly $2.0 billion for the twelve months ended August 2005. We have worldwide commercial rights to Oxytrex.

Our clinical results to date have shown that Oxytrex can reduce physical dependence and provides superior and prolonged pain relief compared to oxycodone. Published preclinical results also demonstrate that the technology used in Oxytrex results in a lack of opioid addiction or tolerance in animals.

In December 2006, we announced initiation of a Phase III study of Oxytrex. This clinical study is randomized, double-blinded, multi-center and placebo-controlled. The study will enroll approximately 120 patients who have each been taking greater than or equal to 120 mg of oxycodone per day for over a year. Patients who meet all eligibility requirements are randomized to receive twice-daily doses of 100 nanograms, or 0.0001 mg, ultra-low-dose naltrexone or matching placebo for two weeks. At the conclusion of this two-week period, patients check into a clinic and receive an injection of a high-dose opioid antagonist to precipitate withdrawal. During the withdrawal phase of the study, patients are closely monitored and measured for signs and symptoms of physical dependence or withdrawal. The study's primary endpoint is physical dependence/withdrawal scores in patients in the treatment arm compared to patients receiving placebo. For ethical and other reasons, the study protocol allows an interim analysis.

Oxytrex is formulated with two active drug ingredients: oxycodone and ultra-low-dose naltrexone. We rely on a limited number of third-party manufacturers to manufacture, fill, label, ship and store Oxytrex. We plan to have produced on our behalf additional clinical materials necessary to complete our Phase III program for Oxytrex.

Metastatic Melanoma

In November 2006, we announced a new antibody technology that we believe may enable clinicians to provide effective medical treatment for metastatic melanoma, a rare but deadly form of skin cancer.

Scientists at Albert Einstein College of Medicine have developed novel radio-labeled monoclonal antibodies that target melanoma tumor sites and deliver a short burst of lethal radiation to melanoma tumors. We believe the specificity of this treatment may be effective against tumors without harming normal tissue. The technology may also have therapeutic uses outside of oncology. We plan to initiate a clinical program in metastatic melanoma in 2007.

Strategy

Our goal is to continue to develop novel drugs that are more effective or safer than drugs used in the clinic today. Our strategy includes the following elements:

Focus on Clinical Development Stage Products. We believe this focus will enable us to generate product revenues earlier than if we were focused on early-stage research and discovery activities.

Retain Significant Rights to Our Drugs. We currently retain worldwide commercialization rights to all of our technology and drug candidates in all markets and indications, except for Remoxy and certain other abuse-resistant drugs that are subject to our strategic alliance with King. In general, we intend to independently develop our drug candidates through late-stage clinical trials. In market segments that require large or specialized sales forces, we may seek sales and marketing alliances with third parties.

Outsource Key Functions. We intend to continue to outsource preclinical studies, clinical trials and formulation and manufacturing activities. We believe outsourcing permits significant time savings and allows for more efficient deployment of our resources.

Pursue In-licensing or Acquisition Opportunities. We intend to evaluate promising drug candidates or technologies to further expand our product pipeline. Our in-licensing strategy consists of evaluating clinical or preclinical stage opportunities in therapeutic areas that can benefit from our core expertise in drug development. Such in-licensing or acquisition opportunities may be in pain management or in other therapeutic areas outside of pain management. We believe this element of our corporate strategy could diversify some of the risks inherent in focusing on a single therapeutic area and could also increase our probability of commercial success.

We also conduct basic research in collaboration with academic and other partners. Research and development expenditures totaled $35.1 million, $32.9 million and $46.8 million in 2004, 2005, and 2006 respectively, and include the costs of company-sponsored research and research and development services provided under the strategic alliance with King. We recorded contract revenue of $1.4 million and $22.7 million in 2005 and 2006, respectively, related to customer-sponsored research activities under our collaboration with King.

Oxytrex Science and Technology

The science behind Oxytrex was initially discovered by scientists at Albert Einstein College of Medicine. These scientists published results showing that opioid painkillers activate an excitatory signaling pathway linked to opioid receptors.

We believe that the excitatory pathway of opioid receptors contributes greatly to the adverse effects of chronic opioid use, such as tolerance, physical dependence and addiction. After repeated administration of morphine, oxycodone or other opioid painkillers, increasing doses of opioids are required in order to obtain the same level of pain relief, a process that leads to tolerance. If chronic opioid treatment is terminated abruptly, withdrawal symptoms rapidly appear. Continued administration of opioids prevents the appearance of withdrawal symptoms, at which point a patient is considered physically dependent. Published results in rodents also show that tolerance and physical dependence can be prevented by co-administration of ultra-low-dose naltrexone, an opioid antagonist. We believe ultra-low-dose naltrexone prevents activation of the excitatory pathway, but not the inhibitory pathway of opioid drugs. In addition, preclinical work using animal models of addiction suggests that very low doses of opioid antagonists decrease the pleasurable effects and addictive potential of opioid drugs such as morphine or oxycodone.

Optimal dose ratios of ultra-low-dose opioid antagonist to opioid painkillers depend on specific pharmacology and the mode of administration. Published preclinical and clinical dose response studies provide guidance in formulating optimal ratios of ultra-low-dose opioid antagonist to opioid painkillers for clinical development.

Oxytrex is a proprietary combination of two active drug ingredients. The first component is the opioid agonist oxycodone. The second component is an ultra-low-dose of the opioid antagonist naltrexone. Adding an antagonist to an agonist at usual clinical doses blocks the action of the agonist. This effect is clinically useful, for example, to reverse heroin overdose. At an ultra-low-dose, however, studies indicate that this effect is different: an ultra-low-dose of an opioid antagonist can enhance pain relief and attenuate the development of tolerance or addiction. Oxytrex takes advantage of this effect by combining an opioid agonist with an ultra-low-dose of an opioid antagonist.

License of Technology from Albert Einstein College of Medicine

We have licensed certain technology from Albert Einstein College of Medicine. We have a worldwide exclusive license to the technology and all intellectual rights arising from the technology. Pursuant to the agreements for the licensed technology, we are required to pay Albert Einstein College of Medicine clinical milestone payments and royalties based on a percentage of net drug sales. If a product is combined with a drug or other substance for which we are paying an additional royalty, the royalty that we pay to Albert Einstein College of Medicine will be reduced by up to one-half of the amount of such additional royalty.

Albert Einstein College of Medicine originally received grants from the U.S. federal government to research some of the technology that we license. The terms of these grants provide the U.S. federal government with a non-exclusive, non-transferable paid-up license to practice inventions made with federal funds. Thus, our licenses are non-exclusive to the extent of the U.S. federal government’s license. If the U.S. federal government exercises its rights under this license, it could make use of the same technology that we license and the size of our potential market could thereby be reduced.

Our Intellectual Property

We seek to protect our technology by, among other methods, filing and prosecuting U.S. and foreign patents and patent applications with respect to our technology and products and their uses. The focus of our patent strategy is to secure and maintain intellectual property rights to technology for the following categories of our business:

- the clinical use of an ultra-low-dose opioid antagonist, either alone or in combination with an opioid painkiller, for pain management and opioid and other addiction;
- the use of an ultra-low-dose opioid antagonist to render opioid-based products more effective;
- the clinical use of an ultra-low-dose opioid antagonist, either alone or in combination with any opioid painkiller, for the treatment of other conditions;
- the clinical use of radio-labeled monoclonal antibodies for the treatment of metastatic melanoma and certain therapeutic uses outside of oncology; and
- the manufacture and use of our drug candidates.

We plan to prosecute and defend our patent applications, issued patents and proprietary information. Our competitive position and potential future revenues will depend in large part upon our ability to protect our intellectual property from challenges and to enforce our patent rights against potential infringements.

We and our collaborators have filed patent applications with the U.S. Patent Office to further protect our technologies. Certain patents are issued and a number of patent applications are pending. If issued, we believe these applications would protect our technologies through at least 2020. If these patent applications do not result in issued patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

If our competitors are able to successfully challenge the validity or scope of our patent rights, based on the existence of prior art or otherwise, they might be able to market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result.

We may be involved in additional challenges to our intellectual property. An adverse outcome of any challenges to our intellectual property could result in loss of claims of these patents that pertain to certain drugs we currently have under development and could have a material adverse impact on our future revenues.

Strategic Alliance with King Pharmaceuticals, Inc.

We have a collaboration agreement and a license agreement with King to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150.0 million to us at the closing of this strategic alliance in December 2005. We could also receive from King up to $150.0 million in milestone payments in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance, of which we have received $5.0 million to date. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement.

We formed a joint oversight committee, or JOC, with King to oversee drug development and commercialization strategies for the strategic alliance. Pursuant to the collaboration agreement in the strategic alliance, we retain sole control of drug development activities in the United States through Phase II clinical trials. We and King will jointly manage Phase III clinical trials and New Drug Applications, or NDA, submissions in the United States. King has responsibility for these development activities outside the United States. Upon regulatory approval, King will assume sole control and worldwide responsibility to exclusively commercialize Remoxy and other abuse-resistant opioid drugs developed pursuant to the strategic alliance. We retain all development and commercial rights in Australia and New Zealand.

Pursuant to the license agreement, King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed pursuant to the strategic alliance, and is obligated to pay us a 20% royalty on net sales, except as to the first $1.0 billion in cumulative net sales, for which the royalty is set at 15%. King is also obligated to reimburse us for our payment of third-party royalty obligations related to this strategic alliance.

The collaboration agreement continues until the later of the expiration of any patent rights licensed under the license agreement or developed under the collaboration agreement and the expiration of all periods of market exclusivity with respect to Remoxy and other abuse-resistant opioid drug candidates being developed under the strategic alliance. We and King can terminate the collaboration agreement under certain circumstances, including material breach and insolvency. King can terminate the collaboration agreement six months after the third anniversary of the effective date of the collaboration agreement, or sooner if the JOC determines that the development program under the collaboration agreement is unlikely to generate any marketable products. Our license agreement with King terminates at the time that the collaboration agreement terminates.

Formulation Agreement

We have an exclusive, worldwide licensing agreement with Durect Corporation to use a patented technology that forms the basis for a number of oral gel-cap drug candidates, including Remoxy. We have sub-licensed to King certain rights to develop and to commercialize Remoxy and certain other opioid drugs formulated in part with technology we licensed from Durect. Under the agreement with Durect, we control all of the preclinical, clinical, commercial manufacturing and sales/marketing activities for Remoxy and other abuse-resistant opioid painkillers. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. Durect will supply us with certain components of Remoxy and other abuse-resistant opioid painkillers on a cost-plus basis. We also are obligated to pay Durect royalties on any related drug sales.

King is obligated to reimburse us for costs we incur under the agreement with Durect, including royalties. Under our license agreement with King, we are obligated not to amend or terminate our agreement with Durect if an amendment or termination would alter the rights or obligations of King under the collaboration agreement or license agreement.

Manufacturing

We have no manufacturing facilities. We rely on a limited number of third-party manufacturers to formulate, manufacture, fill, label, ship or store all of our drug candidates. We have entered into agreements with and rely upon qualified third parties for the formulation or manufacture of our clinical supplies. These supplies and the manufacturing facilities must comply with DEA regulations and current good manufacturing practices, or GMPs, enforced by the FDA and other government agencies. We plan to manufacture Remoxy with Mallinckrodt Pharmaceutical Outsourcing, a unit of Tyco Healthcare. Remoxy uses bulk oxycodone supplied by Noramco, Inc. We plan to continue to outsource formulation, manufacturing and related activities.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state, statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record keeping and marketing of our products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require us to spend

substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which our products may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Applicable FDA regulations require the filing of an NDA and approval by the FDA prior to commercialization of any of our drug candidates in the United States.

The Drug Approval Process

We will be required to complete several activities before we can market any of our drug candidates for human use in the United States, including:

- preclinical studies;
- submission to the FDA of an IND which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate;
- submission to the FDA of an NDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety of the product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practice. We submitted the results of preclinical tests to the FDA as part of our INDs prior to commencing clinical trials. We may be required to conduct additional toxicology studies concurrently with the clinical trials.

Based on preclinical testing, an IND is filed with the FDA to begin human testing of the drug in the United States. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new clinical trials will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted in accordance with Good Clinical Practice. In addition, an Institutional Review Board, or IRB, generally comprised of physicians at the hospital or clinic where the proposed clinical trials will be conducted, must review and approve the IND. The IRB also continues to monitor the clinical trial. We must submit progress reports detailing the results of the clinical trials to the FDA at least annually. In addition, the FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials under the IND cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. An FDA imposed clinical hold on an IND application can result in substantial delay and large, unforeseen expenses, and it may cancel the viability of developing a new drug candidate in the United States.

Clinical trials are typically conducted in three sequential phases that may overlap. Phase I clinical trials typically study a drug’s safety profile, and may include the safe dosage range. Phase I clinical trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. In addition, we may, to the extent feasible, assess early indicators of a drug’s efficacy in our Phase I clinical trials. In Phase II clinical trials, controlled studies are conducted on volunteer patients with the targeted disease or condition. The primary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine a drug’s side effect profile. These clinical trials may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety. During Phase III clinical trials, the drug is studied in an expanded patient population and in multiple sites. Physicians monitor the patients to determine efficacy and to observe and report adverse events that may result from use of the drug.

Our clinical trials are designed to produce clinical information about how our drugs perform compared to placebo or compared to existing opioid drugs where appropriate. We have designed most Phase II and Phase III clinical trials to date as randomized, double-blind, placebo-controlled, dose-ranging studies. A randomized clinical trial is one in which patients are randomly assigned to the various study treatment arms. A double-blind clinical trial is one in which the patient, the physician and our trial monitor are unaware if the patient is receiving placebo or study drug in order to preserve the integrity of the clinical trial and reduce bias. A placebo-controlled clinical trial is one in which a subset of patients is purposefully given inactive medication.

The FDA publishes industry guidelines specifically for the clinical evaluation of painkillers. We rely in part on these guidelines to design a clinical strategy for the approval of each of our drug candidates. In particular, FDA guidelines recommend that we demonstrate efficacy of our new painkillers in more than one clinical model of pain. Acceptable clinical models of pain include low-back pain and arthritis pain. Upon a clear demonstration of the safety and efficacy of painkillers in multiple clinical models of pain, the FDA has historically approved painkillers with broad indications. Such general purpose labeling often takes the form of “for the management of moderate to severe pain.” We have tested Oxytrex in several clinical settings of pain in order to support a broad approval by the FDA for use of Oxytrex for the relief of moderate to severe pain.

We may not successfully complete Phase I, Phase II or Phase III clinical trials within any specified time period, or at all, with respect to any of our drug candidates. Furthermore, we or the FDA may suspend clinical trials at any time in response to concerns that participants are exposed to an unacceptable health risk.

After the completion of clinical trials, if there is substantial evidence that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has 180 days in which to review the NDA and respond to the applicant. The review process is typically extended for significant amounts of time by the FDA’s requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If the FDA’s evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter, or an approvable letter which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA’s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA’s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional post marketing studies, or Phase IV clinical trials, to evaluate long-term effects of the approved drug.

Other Regulatory Requirements

The FDA mandates that drugs be manufactured in conformity with current GMP. If the FDA approves any of our drug candidates we will be subject to requirements for labeling, advertising, record keeping and adverse experience reporting. Failure to comply with these requirements could result, among other things, in suspension of regulatory approval, recalls, injunctions or civil or criminal sanctions. We may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental

Protection Act, the Clean Air Act, national restrictions on technology transfer, and import, export, and customs regulations. In addition, any of our products that contain narcotics will be subject to DEA regulations relating to manufacturing, storage, distribution and physician prescribing procedures. It is possible that any portion of the regulatory framework under which we operate may change and that such change could have a negative impact on our current and anticipated operations.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Any of our drug candidates that contain a scheduled substance will be subject to regulation by the DEA.

Competition

Our success will depend, in part, upon our ability to achieve market share at the expense of existing and established and future products in the relevant target markets. Existing and future products, therapies, technological approaches or delivery systems will compete directly with our products. Competing products may provide greater therapeutic benefits for a specific indication, or may offer comparable performance at a lower cost. Companies that currently sell generic or proprietary opioid formulations include, but are not limited to, Roxane Laboratories, Purdue Pharma, Abbott Laboratories, Cephalon, Endo Pharmaceuticals, Teva Pharmaceuticals, Elkins-Sinn, Watson Laboratories, Ortho-McNeil Pharmaceutical and Forest Pharmaceuticals. Alternative technologies are being developed to increase opioid potency, as well as alternatives to opioid therapy for pain management, several of which are in clinical trials or are awaiting approval from the FDA.

We compete with fully integrated pharmaceutical companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have opioid drugs already approved by the FDA or in development and operate larger research and development programs in these fields than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

We will also face competition to our potential product candidates outside of pain management, including oncology. Developments by competitors may render our drug candidates or technologies obsolete or non-competitive.

Employees

As of December 31, 2006, we had 41 employees. We engage consultants from time to time to perform services on a per diem or hourly basis.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d)

of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at http://www.paintrials.com, by contacting the Investor Relations Department at our corporate offices by calling 650-624-8200 or by sending an e-mail message to cwaarich@paintrials.com.

Item 1A. *Risk Factors*

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. You should carefully consider these factors before making an investment decision. If any of the following factors actually occur, our business, financial condition or results of operations could be harmed. In that case, the price of our common stock could decline, and you could experience losses on your investment in our common stock.

Risks Relating to our Financial Position and Need for Financing

Our operating history may make it difficult for you to evaluate our business to date and to assess its future viability.

We were founded in May 1998. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking preclinical studies and clinical trials of our drug candidates and forming collaborations. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture our drug candidates on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future.

Although we were profitable in 2006 based principally on revenues recognized from King and interest income, we have yet to generate any revenues from product sales. We had an accumulated deficit of $136.5 million as of December 31, 2006. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to conduct preclinical and clinical trials for our drug candidates;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates, we will not be able to generate such revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would have a material adverse impact on the market price of our common stock.

If we cannot raise additional capital on acceptable terms, we may be unable to complete planned clinical trials of any or some of our drug candidates or to pursue attractive business opportunities.

We have funded all of our operations and capital expenditures with the proceeds from our public and private stock offerings. We expect that our current cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, we may need to raise additional funds within such twelve-month period or thereafter and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional securities to raise funds, our existing stockholders' ownership percentage would be reduced and new investors may demand rights, preferences or privileges senior to those of existing stockholders. If we raise additional capital through debt financing, if available, such financings may involve covenants that restrict our business activities. If we raise additional capital through strategic alliance and license arrangements such as our strategic alliance with King, we may have to trade our rights to our technology, intellectual property or drug candidates to others in such arrangements on terms that may not be favorable to us.

If we determine that we need to raise additional funds and we are not successful in doing so, we may be unable to complete the clinical development of some or all of our drug candidates or to seek or obtain FDA approval of our drug candidates. We then could be forced to discontinue product development, enter into a relationship with an additional strategic partner earlier than currently intended, reduce sales and marketing efforts or forego attractive business opportunities.

Clinical and Regulatory Risks

If we are unable to design, conduct and complete clinical trials successfully, we will not be able to obtain regulatory approval for our drug candidates.

In order to obtain FDA approval for any of our drug candidates, we must submit to the FDA an NDA that demonstrates with substantive evidence that the drug candidate is both safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Our Phase III clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and preclinical studies. FDA guidelines recommend that the efficacy of new painkillers be demonstrated in more than one clinical model of pain. This means that even if one of our Phase III clinical trials demonstrates positive results for our drug candidates, we are likely to have to demonstrate positive results in one or more additional Phase III clinical trials prior to receiving FDA approval for broad indication of severe chronic pain. Even if the results of our Phase III clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before we can submit an NDA or obtain FDA approval for any of our drug candidates.

In February 2006, we completed an SPA with the FDA for a pivotal Phase III clinical trial with Remoxy in approximately 400 patients with moderate to severe chronic pain. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an efficacy claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful,

the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness. Under our SPA, if the outcome of our Phase III clinical trial is successful, we expect to use the data from the Phase III clinical trial as part of a basis of approval with respect to efficacy. While we received the SPA for this Phase III clinical trial assessing Remoxy, there can be no assurance that this clinical trial will have a successful outcome or that we will ultimately receive approval for this drug candidate. Furthermore, there can be no assurance that other events will not occur that would allow the FDA to disregard our SPA.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process also consumes a significant amount of time. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials.

Our clinical trials with Remoxy and Oxytrex measure clinical symptoms, such as pain and physical dependence, respectively, that are not biologically measurable. The success of Remoxy and Oxytrex in clinical trials depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. Due in part to a lack of consensus on standardized processes for assessing clinical outcomes, these scores may or may not be reliable, useful or acceptable to regulatory agencies.

In addition, completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- increases in time required to complete monitoring of patients during or after participation in a clinical trial; and
- unexpected need for additional patient-related data.

Any of these delays could significantly impact the timing, approval and commercialization of our drug candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our drug candidates are safe and effective for indicated uses. Such failure would cause us to abandon a drug candidate and could delay development of other drug candidates.

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drug candidates, and we will not generate product revenues.

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the drug candidate, and requires the expenditure of substantial resources for research and development and studies. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require us to conduct additional clinical studies, in which case we would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. In particular, the FDA may require additional toxicology studies for certain excipients used in Remoxy or any of our other drug candidates. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals would:

- delay commercialization of, and product revenues from, our drug candidates; and
- diminish the competitive advantages that we may have otherwise enjoyed, which would have an adverse effect on our operating results and financial condition.

Even if we comply with all FDA regulatory requirements, we may never obtain regulatory approval for any of our drug candidates. If we fail to obtain regulatory approval for any of our drug candidates we will have fewer saleable products, if any, and corresponding lower product revenues, if any. Even if we receive regulatory approval of our drug candidates, such approval may involve limitations on the indications and conditions of use or marketing claims we may make for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy Phase IV post-approval clinical trials, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before we can commercialize our drugs. Regulatory approval processes outside the United States generally include all of the aforementioned requirements and risks associated with FDA approval.

Clinical trial designs that were discussed with authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval.

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. With the exception of our SPA with the FDA for our Phase III clinical trial with Remoxy, these discussions are not binding obligations on the part of regulatory authorities. Regulatory authorities may revise previous guidance or decide to ignore previous guidance at any time during the course of our clinical activities or after the completion of our clinical trials. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

Developments by competitors may establish standards of care that affect our ability to conduct our clinical trials as planned.

We have conducted clinical trials of our drug candidates comparing our drug candidates to both placebo and other approved drugs. Changes in standards related to clinical trial design could affect our ability to design and conduct clinical trials as planned. For example, regulatory authorities may not allow us to compare our drug candidates to placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase.

The Drug Enforcement Administration, or DEA, limits the availability of the active ingredients in certain of our current drug candidates and, as a result, our quotas may not be sufficient to complete clinical trials, or to meet commercial demand or may result in clinical delays.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients in our current drug candidates, such as oxycodone, are listed by the DEA as Schedule II under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the drugs used in our clinical trials, and, in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Government agencies may establish and promulgate usage guidelines that could limit the use of our drug candidates.

Government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our drug candidates. These guidelines could address such matters as usage and dose, among other factors. Application of such guidelines could limit the use of our drug candidates.

Conducting clinical trials of our drug candidates or potential commercial sales of a drug candidate may expose us to expensive product liability claims and we may not be able to maintain product liability insurance on reasonable terms or at all.

The risk of product liability is inherent in the testing of pharmaceutical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We currently carry clinical trial insurance but do not carry product liability insurance. If we successfully commercialize one or more of our drug candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. We may not be able to obtain such insurance at a reasonable cost, if at all. Even if our agreements with any current or future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

If we receive regulatory approval for our drug candidates, we and our collaborators will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our ability to commercialize our potential drugs.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including but not limited to adverse events of unanticipated severity or frequency, or the discovery that adverse events previously observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our drugs and our business could suffer.

Risks Relating to our Collaboration Agreements

If King or other outside collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, our regulatory submissions and our product introductions may be delayed.

Pursuant to our strategic alliance with King, we will jointly manage and prepare Phase III clinical trials and NDA submissions in the United States for Remoxy and other abuse-resistant drug candidates with King. We rely on King to devote time and resources to the development and commercialization of Remoxy and other abuse-resistant drug candidates. If King limits its time and resources devoted to the strategic alliance, or otherwise fails to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected.

We depend on independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. These investigators and collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such activities ourselves. If these investigators or collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our regulatory submissions and our introductions of new drugs will be delayed or prevented.

Our collaborators may also have relationships with other commercial entities, some of which may compete with us. If outside collaborators assist our competitors to our detriment, the approval of our regulatory submissions will be delayed and the sales from our products, if any are commercialized, will be less than expected.

If we fail to maintain our strategic alliance for Remoxy and other abuse-resistant drugs, we may have to reduce or delay our drug candidate development.

Our plan for developing, manufacturing and commercializing Remoxy and other abuse-resistant drugs currently requires us to successfully maintain our strategic alliance with King to advance our programs and provide funding to support our expenditures on Remoxy and other drug candidates. If we are not able to maintain our existing strategic alliance with King, we may have to limit the size or scope of, or delay or abandon the development of Remoxy and other abuse-resistant drug candidates or undertake and fund development of these drug candidates ourselves. If we elect to fund drug development efforts with respect to Remoxy and other abuse-resistant drug candidates on our own, we may need to obtain additional capital, which may not be available on acceptable terms, or at all.

We may not succeed at in-licensing drug candidates or technologies to expand our product pipeline.

We may not successfully in-license drug candidates or technologies to expand our product pipeline. The number of such candidates or technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates or technologies is intense because such companies generally desire to expand their product pipelines through in-licensing.

Our collaborative agreements may not succeed or may give rise to disputes over intellectual property, disputes concerning the scope of collaboration activities or other issues.

Our strategy to focus on development of novel drug candidates discovered by third parties requires us to enter into license agreements with such third parties. In addition, we may enter into collaborative agreements to commercialize our products, such as our strategic alliance with King. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations or disputes concerning the scope of collaboration activities. Such disputes can delay or prevent the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Other factors relating to collaborative agreements may adversely affect the success of our drug candidates, including:

- the development of parallel products by our collaborators or by a competitor;
- arrangements with collaborative partners that limit or preclude us from developing certain products or technologies;
- premature termination of a collaborative agreement; or
- failure by a collaborative partner to devote sufficient resources to the development of our potential products.

Risks Relating to Commercialization

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves our drugs, physicians and patients may not accept and use them. Acceptance and use of our drugs will depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs;
- published studies demonstrating the cost-effectiveness of our drugs relative to competing products;
- availability of reimbursement for our products from government or healthcare payers;
- our ability to implement a risk management plan prior to the distribution of any Schedule II drug; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors.

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

If King is not successful in commercializing Remoxy and other abuse-resistant drugs, our revenues and our business will suffer.

Our ability to commercialize Remoxy and other abuse-resistant drugs and generate royalties from product sales of such drugs will depend on King's abilities in assisting us in developing such drugs and in maintaining regulatory approval and achieving market acceptance of such drugs once commercialized. King may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of Remoxy and other abuse-resistant drugs developed under our strategic alliance. King may not proceed with the commercialization of Remoxy and other abuse-resistant drugs developed under our strategic alliance with the same degree of urgency as we would because of other priorities they face. If King is not successful in commercializing Remoxy for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if King fails to perform as we expect, our potential for revenue from drugs developed in connection with our strategic alliance with King, if any, could be dramatically reduced and our business would suffer.

If we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, our product revenues could be disappointing.

We currently have no sales, marketing or distribution capabilities. Except with regard to products developed under our strategic alliance with King, in order to commercialize our products, if any are approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any of our drugs ourselves, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new drugs and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

If we decide to enter into new co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the number of potential collaborators is limited and because of competition from others for similar alliances with potential collaborators. Even if we are able to identify one or more acceptable new collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

In addition, due to the nature of the market for pain management products, it may be necessary for us to license all or substantially all of our drug candidates not covered by our strategic alliance with King to a single collaborator, thereby eliminating our opportunity to commercialize these other pain management products independently. If we enter into any such new collaborative arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

In addition, any revenues we receive would depend upon our collaborators' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, business combinations or other factors outside of our control. Depending upon the terms of our collaboration, the remedies we have against an under-performing collaborator may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, or at all.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our drug candidates is characterized by intense competition and rapid technological advances. If our drug candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete for market share against fully integrated pharmaceutical companies or other companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved or drug candidates in development that will or may compete against our approved drug candidates. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

Our ability to generate product revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from healthcare payers.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products and services and/or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic

data on any of our products. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Adequate third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of our drug candidates could be limited.

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation will be costly and time consuming and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Intellectual property rights in the areas of controlled-release oxycodone, antibodies, and more generally, in oncology, neurology and radiopharmaceutical technologies are complicated and are continuously evolving. Holders of patent rights in these areas may allege that the commercialization of Remoxy or our other drug candidates infringes such patent rights. While we believe that we would have valid defenses to any claim of infringement, there can be no assurance that these or other third party patents will not limit our ability to commercialize Remoxy or our other drug candidates.

In addition, because patent applications are published 18 months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management’s attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor’s patent or other proprietary rights;
- a court order prohibiting us from commercializing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market. Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

Risks Relating to our Intellectual Property

If we are unable to protect our intellectual property our competitors could develop and market products with similar features that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in part on our ability to protect our intellectual property. If we or our collaborators fail to file, prosecute, obtain or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result.

We and our collaborators have filed patent applications with the U.S. Patent Office to further protect our technologies. If these patent applications do not result in issued patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

We may be involved in challenges to our intellectual property. An adverse outcome of a challenge to our intellectual property could result in loss of claims of patents or other intellectual property rights that pertain to certain drugs we currently have under development and could have a material adverse impact on our future revenues.

We intend to file additional patent applications relating to our technology, products and processes. We may direct our collaborators to file additional patent applications relating to the licensed technology or we may do so ourselves. However, our competitors may challenge, invalidate or circumvent any of our current or future patents. These patents may also fail to provide us with meaningful competitive advantages.

We may become involved in expensive litigation or other legal proceedings related to our existing intellectual property rights, including patents.

We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our products or know-how or require us to license such information and pay significant fees or royalties in order to produce our products.

Our technology could infringe upon claims of patents owned by others. If we were found to be infringing on a patent held by another, we might have to seek a license to use the patented technology. In that case, we might not be able to obtain such a license on terms acceptable to us, or at all. If a legal action were to be brought against us or our licensors, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute were to be resolved against us, we could have to pay the other party large sums of money and our use of our technology and the testing, manufacture, marketing or sale of one or more of our proposed products could be restricted or prohibited.

Risks Relating to our Business and Strategy

Competition for qualified personnel in the pharmaceutical industry is intense, and if we are not successful in attracting and retaining qualified personnel, we could experience delays in completing necessary clinical trials, in the regulatory approval process or in formulating, manufacturing, marketing and selling our potential products.

We will need to hire additional qualified personnel with expertise in clinical research, preclinical testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the San Francisco Bay area, is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel is critical to our success.

If third-party manufacturers of our drug candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may be higher than expected.

We have no manufacturing facilities and have limited experience in drug product development and commercial manufacturing. We lack the resources and expertise to formulate, manufacture or test the technical performance of our drug candidates. We currently rely on a limited number of experienced personnel and a small number of contract manufacturers and other vendors to formulate, test, supply, store and distribute drug supplies

for our clinical trials. Our reliance on a limited number of vendors exposes us to the following risks, any of which could delay our clinical trials, and, consequently, FDA approval of our drug candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products before we may use the alternative manufacturer to produce our supplies.
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.
- If any contract manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

We recently announced our intentions to expand our research and development activities to include development of potential drug candidates for indications other than pain, and we may not be able to successfully develop or commercialize these potential new product candidates.

In November 2006, we announced our intentions to expand our research and development activities to include development of potential drug candidates for indications other than pain, such as oncology. We have no history of developing oncology drugs or manufacturing radiopharmaceuticals. We do not know whether any of our planned clinical trials in oncology will result in marketable products. We do not anticipate that any additional drug candidates will reach the market for at least several years, if at all.

Our employees and consultants are generally subject to confidentiality or other agreements with their former employers and they may inadvertently or otherwise violate those agreements.

Many of our employees and consultants were previously employed at universities or biotechnology or pharmaceutical companies. While we require our employees and consultants to honor any agreements they may have entered into prior to working with us, we may be subject to claims that we inadvertently or otherwise used or disclosed trade secrets or other confidential information belonging to former employers. Failure to defend such claims could result in loss of valuable rights or personnel, which in turn could harm or prevent commercialization of our drug candidates. Successful defense against such claims can be expensive and might distract us from executing our strategies.

Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process and commercialization of our drug candidates very difficult.

Media stories regarding the diversion of opioids and other controlled substances are commonplace. Law enforcement agencies or regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may adversely affect the regulatory approval and commercialization of our drug candidates.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In addition, the active ingredients in nearly all opioid drugs are available in generic form. Drug companies that sell generic opioid drugs represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. Our competitors may market less expensive or more effective drugs that would compete with our drug candidates or reach market with competing drugs before we are able to reach market with our drug candidates. These organizations also compete with us to attract qualified personnel and partners for acquisitions, joint ventures or other collaborations.

Business interruptions could limit our ability to operate our business.

Our operations as well as those of our collaborators on which we depend are vulnerable to damage or interruption from computer viruses, human error, natural disasters, electrical and telecommunication failures, international acts of terror and similar events. We have not established a formal disaster recovery plan and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Risks Relating to Manufacturing

We rely on third-party commercial drug manufacturers for drug supply.

Approved third-party commercial drug manufacturers may subsequently be stopped from producing, storing, shipping or testing our drug products due to their non-compliance with federal, state or local regulations. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state and foreign government agencies to ensure strict compliance with GMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

In addition, even if we enter into long-term supply arrangements with third-party suppliers, we cannot control changes in strategy by third-party suppliers that affect their ability or willingness to continue to supply our drug products on acceptable terms.

If our drug supply for one of our drug candidates was interrupted, our operations could be negatively affected.

If we cannot formulate and scale-up a wide range of dosage forms of Remoxy and other abuse-resistant drug candidates, we and King might determine that the commercial opportunity for Remoxy is too limited to warrant further investment in clinical testing and development.

We plan to formulate and scale-up a wide range of commercial dosage forms of Remoxy and other abuse resistant drug candidates. We may not be able to successfully complete our formulation or scale-up activities or we may determine that the commercial opportunity for Remoxy and other abuse-resistant drug candidates in certain dosage forms is too limited to warrant further investment. If we are unsuccessful in our formulation or scale-up activities with Remoxy and other abuse-resistant drug candidates, our future revenue from milestones and royalties under our strategic alliance with King may be less than expected and our operations may suffer.

We rely solely on Durect to provide us with certain components of Remoxy and other abuse-resistant drug candidates, to produce Remoxy and other abuse-resistant drug candidates for clinical supplies and will rely on Durect to produce commercial supplies of these components.

We rely on Durect as our sole source provider of certain components of Remoxy and other abuse-resistant drug candidates, and will rely solely on Durect to produce commercial supplies of these components. Durect's failure to achieve and maintain satisfactory manufacturing standards could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially harm our business. Durect may encounter manufacturing difficulties involving production yields, quality control and quality assurance. Durect is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with government regulations and corresponding foreign standards. We cannot control Durect's compliance with these regulations and standards.

To date, Durect has not produced commercial-scale supply of these components. If we and King receive marketing approval for and commercially launch Remoxy or other abuse resistant candidates, we anticipate that Durect will need to materially expand its manufacturing capacity. Durect may not be able to increase its manufacturing capacity for Remoxy and other abuse-resistant drug candidates in a timely or economic manner, or at all. Moreover, significant scale up of manufacturing will require additional validation studies, which are subject to FDA review and approval. If Durect is unable to successfully increase the manufacturing capacity for such components of Remoxy and other abuse-resistant drugs, at an acceptable cost or otherwise, and we are unable to establish alternative manufacturing capabilities, the commercial launch or continued commercialization after a commercial launch of Remoxy and other abuse-resistant drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our revenues and cause our business to suffer.

Risks Relating to an Investment in our Common Stock

Our stock price has been volatile and could experience a sudden decline in value.

Our common stock has experienced significant price and volume fluctuations and may continue to experience volatility in the future. You may not be able to sell your shares quickly or at the latest market price if trading in our stock is not active or the volume is low. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- results of or delays in our preclinical studies and clinical trials;
- the success of our collaboration agreements;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- announcements of technological innovations or new commercial products by us or others;
- developments in patent or other proprietary rights by us or others;
- comments or opinions by securities analysts or major stockholders;
- future sales of our common stock by existing stockholders;
- regulatory developments or changes in regulatory guidance;
- litigation or threats of litigation;
- economic and other external factors or other disaster or crises;
- the departure of any of our officers, directors or key employees;
- period-to-period fluctuations in financial results; and
- limited daily trading volume.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted certain new rules. If we were unable to continue to comply with the new rules, we could be delisted from trading on the NASDAQ Global Market, or Nasdaq, and thereafter trading in our common stock, if any, would be conducted through the over-the-counter market or on the Electronic Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

Anti-takeover provisions in our charter documents, our Stockholder Rights Plan and Delaware law may prevent or delay removal of incumbent management or a change of control.

Anti-takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws, our Stockholder Rights Plan and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

- a classified board so that only one of the three classes of directors on our board of directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our board of directors to amend our bylaws without stockholder approval; and
- the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

The rights issued pursuant to our Stockholder Rights Plan will become exercisable, subject to certain exceptions, the tenth day after a person or group announces acquisition of 15% or more of our common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203.

These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

Volatility in the stock prices of other companies may contribute to volatility in our stock price.

The stock market in general, Nasdaq and the market for technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of early stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company’s securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management’s attention and resources.

Our share ownership is concentrated, and our officers, directors and principal stockholders can exert significant control over matters requiring stockholder approval.

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of the Company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

Publicly available information regarding stockholders' ownership may not be comprehensive because the SEC does not require certain large stockholders to publicly disclose their stock ownership positions.

Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, our need for clinical supplies, the time it takes for us to respond to questions raised by King regarding any invoices we submit to them, and the valuation of stock-based compensation. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our clinical, financial or operating results may not meet the expectations of securities analysts and investors that could result in a decline in the price of our stock.

There may not be an active, liquid trading market for our common stock.

There is no guarantee that an active trading market for our common stock will be maintained on Nasdaq. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

We currently lease approximately 10,500 square feet of space in South San Francisco, California, which is used as general office space. We believe that this facility is adequate and suitable for our current needs.

Item 3. *Legal Proceedings*

We are not a party to any legal proceedings.

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

There were no matters submitted to a vote of the security holders during the fourth quarter of 2006.

PART II

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

Our common stock is quoted on the Nasdaq National Market under the symbol "PTIE." The following table sets forth the high and low sales prices per share of our common stock as reported on the Nasdaq National Market for the periods indicated.

	Sale Price	
	High	Low
Fiscal 2006:		
First Quarter	$11.80	$6.86
Second Quarter	$10.86	$7.70
Third Quarter	$ 9.04	$7.50
Fourth Quarter	$ 9.78	$7.90
Fiscal 2005:		
First Quarter	$ 7.48	$4.99
Second Quarter	$ 7.24	$4.78
Third Quarter	$ 7.22	$5.79
Fourth Quarter	$ 9.45	$5.46

We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and have not paid and do not anticipate paying any cash dividends in the foreseeable future. As of February 1, 2007, there were approximately 85 holders of record of our common stock.

The following table summarizes the securities authorized for issuance under our equity compensation plans as of December 31, 2006.

	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 stockholders	8,212,985	$ 7.12	1,823,394
Equity compensation plans not approved by stockholders	—	—	—
Total	8,212,985	$ 7.12	1,823,394

Item 6. ***Selected Financial Data (in thousands except per share data)***

	Years ended December 31,				
	2006	2005	2004	2003	2002
Statement of operations data:					
Program fee revenue	$ 26,201	$ 3,712	$ —	$ —	$ —
Collaboration revenue	22,717	1,368	—	—	—
Milestone revenue	5,000	—	—	—	—
Total revenues	53,918	5,080	—	—	—
Research and development expense	46,803	32,938	35,093	18,913	11,396
General and administrative expense	7,668	4,859	3,868	3,338	5,523
Total operating expenses	54,471	37,797	38,961	22,251	16,919
Operating loss	(553)	(32,717)	(38,961)	(22,251)	(16,919)
Interest and other income	9,668	2,047	1,185	634	994
Income (loss) before provision for income taxes	9,115	(30,670)	(37,776)	(21,617)	(15,925)
Provision for income taxes	2,927	—	—	—	—
Net income (loss)	$ 6,188	$ (30,670)	$ (37,776)	$ (21,617)	$ (15,925)
Earnings (loss) per share:					
Basic	$ 0.14	$ (0.70)	$ (1.01)	$ (0.73)	$ (0.59)
Diluted	$0.14	$ (0.70)	$ (1.01)	$ (0.73)	$ (0.59)
Weighted average shares used to compute earning (loss) per share:					
Basic	44,146	43,795	37,267	29,483	27,039
Diluted	45,475	43,795	37,267	29,483	27,039

	December 31,				
	2006	2005	2004	2003	2002
Balance sheet data:					
Cash and cash equivalents	$16,386	$ 95,651	$ 1,379	$ 12,027	$ 50,091
Marketable securities	188,014	117,001	98,018	65,402	55
Working capital	170,460	181,817	91,860	74,799	48,146
Total assets	208,456	215,795	101,192	80,513	53,325
Deferred program fee revenue	120,087	146,288	—	—	—
Total liabilities	130,541	152,435	7,796	3,951	3,101
Total stockholders' equity	77,915	63,360	93,396	76,562	50,224

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

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this report. Operating results are not necessarily indicative of results that may occur in future periods.

Overview

We are a biopharmaceutical company that develops novel drugs for pain management and oncology. We have three investigational drug candidates in clinical programs. Remoxy and PTI-202 are proprietary, abuse-resistant forms of opioid drugs. Oxytrex is a novel, next-generation painkiller that potentially offers less physical dependence than currently marketed opioid painkillers. We are also developing a novel radio-labeled monoclonal antibody to treat metastatic melanoma, a rare but deadly form of skin cancer.

Two of our novel drug candidates are currently in Phase III clinical programs:

- Remoxy, an abuse-resistant version of long-acting oxycodone, and
- Oxytrex, a novel oral opioid painkiller for the treatment of severe chronic pain.

We and King Pharmaceuticals, Inc., or King, are engaged in a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150.0 million to us at the closing of this strategic alliance in December 2005.

In February 2006, we and King announced the completion of a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, in connection with the clinical development of Remoxy. We are conducting a pivotal Phase III clinical trial with Remoxy in approximately 400 patients with moderate to severe chronic pain, pursuant to the SPA.

In August 2006, we and King announced the initiation of a Phase I clinical trial program of a second abuse-resistant drug candidate, called PTI-202. In connection with the acceptance by the FDA of the investigational new drug application, or IND, for PTI-202, King made a milestone payment to us of $5.0 million.

We could also receive from King up to $145.0 million in additional milestone payments in the course of clinical development of Remoxy, PTI-202 and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1.0 billion in net sales of such drugs, for which the royalty is set at 15%.

Although we were profitable in 2006 based principally on revenues recognized from King and interest income, we have yet to generate any revenues from product sales. Through December 31, 2006, we have recorded an accumulated deficit of approximately $136.5 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

We expect to continue to use significant cash resources in our operations for the next several years. Our cash requirements for operating activities and capital expenditures will increase substantially in the future as we:

- continue to conduct preclinical and clinical trials for our drug candidates;

- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional personnel.

Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. If our development efforts result in regulatory approval and successful commercialization of our drug candidates, we will generate revenue from direct sales of our drugs and/or, if we license our drugs to future collaborators, from the receipt of license fees and royalties from sales of licensed products. We conduct our research and development programs through a combination of internal and collaborative programs. We rely on arrangements with universities, our collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

We focus substantially all our research and development efforts on the research and development of opioid drugs for the treatment of pain. The following table summarizes expenses by category for research and development efforts (in thousands):

	Years Ended December 31,		
	2006	2005	2004
Compensation	$ 9,746	$ 4,717	$ 3,769
Contractor fees (1)	30,367	23,642	26,605
Supplies (2)	4,317	2,351	2,575
Other common costs (3)	2,373	2,228	2,144
	$46,803	$32,938	$35,093

(1) Contractor fees generally include expenses for preclinical studies and clinical trials.
(2) Supplies generally include costs for formulation and manufacturing activities.
(3) Other generally includes the allocation of common costs such as facilities.

Our technology has been applied across certain of our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates also relate to, and further the development of, our other drug candidates. For example, we expect that results of non-clinical studies, such as pharmacokinetics, toxicology and other studies, regarding certain components of our drug candidate Remoxy to be applicable to the other potential drug candidates that may arise out of our collaboration with King since all such potential drug candidates are expected to utilize such components. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing. In November 2006, we announced that we are developing a novel antibody technology that may transform how metastatic melanoma is treated. We spent approximately $3.0 million on this technology, primarily in contractor fees and supplies, during 2006.

Estimating the dates of completion of clinical development, and the costs to complete development of our drug candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical products take a significant amount of time to research, develop and commercialize. The clinical trial portion of the development of a new drug alone usually spans several years. We expect to reassess our future research and development plans based on our review of data we receive from our current research and development activities. The cost and pace of our future research and development activities are linked and subject to change.

Critical Accounting Policies

The preparation of our financial statements in accordance with United States generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and interest income in our financial statements and accompanying notes. We evaluate our estimates on an ongoing basis, including those estimates related to contract agreements, research collaborations and investments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our financial statements require significant estimates and judgments:

- *Expenses for clinical trials.* Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes enrollment. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Information about patient enrollment can become available significantly after we report our expenses for clinical trials, in which case we would change our estimate of the remaining cost of a trial. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.
- *Stock-based compensation.* In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. This statement requires companies to recognize expense in the income statement for the fair value all share-based payments to employees and directors, including grants of employee stock options. SFAS 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations, or APB 25, and amends FASB Statement No. 95, Statement of Cash Flows.

  We adopted SFAS 123R on January 1, 2006 using the modified-prospective transition method. We record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation expense recognized in the year ended December 31, 2006 includes $6.2 million in stock-based compensation cost for all outstanding stock-based awards. Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and directors in accordance with APB 25 and its interpretations. Accordingly, we did not recognize compensation cost in our financial statements prior to January 1, 2006 for these awards because stock options granted to employees and directors had exercise prices equal to or greater than the fair value of the underlying security at the time the stock option was granted.

  In adopting SFAS 123R, companies must choose among alternative valuation models and amortization assumptions. After assessing alternative valuation models and amortization assumptions, we continue to use the Black-Scholes option valuation model, or Black-Scholes and use the single-option award approach and straight-line attribution method for stock options granted since January 1, 2006. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

  Prior to adoption of SFAS 123R, we calculated the value of options granted to employees and directors for disclosure in the footnotes to our financial statements pursuant to Statement of Financial Accounting Standards No. 123, or SFAS 123, using Black-Scholes, the multiple-option award approach and the accelerated attribution method. This approach uses a graded vesting method over the vesting period of each respective stock option, generally four years. The accelerated attribution method results in recognizing as compensation cost more than 50% of the fair value of an option in year one, with the

remainder recognized in decreasing amounts from year two to year four. Under the modified-prospective transition method of SFAS 123R, we will continue to calculate compensation cost for options granted prior to January 1, 2006 using the multiple-option award approach and accelerated attribution method.

We estimate forfeitures when recognizing expense under SFAS 123R and adjust this estimate periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption.

- *Revenue recognition and deferred program fee revenue*. In connection with our strategic alliance with King we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from the upfront payment from King received in December 2005 and is recognized ratably over our estimate of the development period of four drug candidates expected to be developed under the strategic alliance with King. Of those drug candidates, Remoxy is in Phase III clinical trials, one drug candidate is in Phase I clinical trials and two potential drug candidates are at the pre-clinical stage. We currently estimate the development period for all four expected drug candidates to extend through July 2011. Collaboration revenues from reimbursement of development expenses, which are invoiced one month in arrears, are recognized when costs are incurred pursuant to the strategic alliance with King, unless we know that King has not completed to its satisfaction their review of our submitted invoices. Therefore, our Collaboration revenues may be impacted by the timeliness of our addressing any questions King may have on the invoices we submit to them as well as the length of time it takes King to complete its review once we have addressed their questions, and although we only invoice King for development expenses incurred by us that we believe qualify for reimbursement under our collaborative agreement, King may not ultimately agree with our determination of what constitutes a qualifying development expense. King is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the clinical development of Remoxy and the other abuse-resistant opioid painkillers under the strategic alliance. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King.
- *Income taxes.* We make estimates and judgments in determining our income tax expense. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of deferred tax assets is dependent upon future earnings, if any. We are uncertain of the timing and amount of any future earnings. Accordingly, we fully offset the total deferred tax assets by a valuation allowance. We may in the future determine that some, or all, of our deferred tax assets will likely be realized, in which case we will reduce our valuation allowance in the quarter in which such determination is made. If the valuation allowance is reduced, we may recognize a benefit from income taxes in our statement of operations in that period.

Results of Operations

Years Ended December 31, 2006 and 2005

Revenue—Program fee revenue

King paid us a $150.0 million upfront fee in connection with the closing of our strategic alliance with King in December 2005. Revenues recognized from amortization of this upfront fee were $26.2 and $3.7 million in the

years ended December 31, 2006 and 2005, respectively. We expect to recognize the remainder of the program fee ratably over our estimate of the development period under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through July 2011.

Revenue—Collaboration revenue

Collaboration revenues were $22.7 million and $1.4 million in the years ended December 31, 2006 and 2005, respectively. These revenues related to reimbursement of our development expenses incurred pursuant to the King strategic alliance.

We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses, as well as the timing of completion of King's review of submitted expenses. For example, we have not recognized collaboration revenue of approximately $10.4 million related to costs incurred by us between September and December 31, 2006 because King has informed us that they are still reviewing the invoice we submitted to them in the fourth quarter of 2006, and they have asked for additional supporting documentation and clarification in order to complete their review. We expect King's review to be completed in the first half of 2007.

Revenue—Milestone revenue

Milestone revenue was $5.0 million for the year end December 31, 2006. In connection with the acceptance by the FDA of the investigational new drug application for PTI-202, King made a non-refundable, non-creditable milestone payment to us of $5.0 million. We had no corresponding milestone revenue in 2005.

Research and Development Expense

Research and development expense consists primarily of costs of drug development work associated with our drug candidates, including:

- preclinical testing,
- clinical trials,
- clinical supplies and related formulation and design costs, and
- salaries and other personnel-related expenses.

Research and development expense increased to $46.8 million from $32.9 million in the years ended December 31, 2006 and 2005, respectively. The increase was primarily due to increases in clinical and development activities for Remoxy and PTI-202 and non-cash stock-related compensation costs associated with the adoption of SFAS 123R.

We expect research and development expenses to fluctuate over the next several years as we continue our development efforts. We expect our development efforts to result in our drug candidates progressing through various stages of clinical trials, including our Phase III clinical trial of Remoxy, and current and potential clinical trials for our other abuse-resistant drug candidates, as well as further clinical development of Oxytrex. King is obligated to reimburse development expenses for Remoxy and other abuse-resistant drug candidates pursuant to our collaboration. We expect to continue other development efforts on our drug candidates. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical trials and preclinical studies.

General and Administrative Expense

General and administrative expense consist primarily of compensation and other general corporate expenses. General and administrative expense increased to $7.7 million from $4.9 million in the years ended

December 31, 2006 and 2005, respectively. The increase was primarily due to increases in non-cash stock-related compensation costs associated with the adoption of SFAS 123R. We expect general and administrative expenses to increase over the next several years in connection with precommercialization and commercialization activities for our drug candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies.

Interest and Other Income

Interest and other income increased to $9.7 million from $2.0 million for the years ended December 31, 2006 and 2005, respectively, primarily due to increases in average balances of marketable securities and, to a lesser extent, increases in prevailing interest rates on investments in marketable securities. We expect our interest income to decrease in the future as we use cash to fund our operations.

Provision for Income Taxes

The provision for income taxes is comprised of $2.7 million for federal taxes and $0.2 million for state taxes. In 2005, King made an upfront cash payment of $150.0 million to us in connection with our strategic alliance. We have taxable income for 2006 primarily due to the recognition in 2006 of $146.3 million of the upfront cash payment for income tax purposes. We have reduced our taxable income for 2006 with deductions related to a combination of our net operating losses and tax credits from prior years. We do not expect to provide for income taxes in 2007 because we expect to incur net losses in 2007.

Years Ended December 31, 2005 and 2004

Revenues—Program fee revenue

King paid us a $150.0 million upfront fee in connection with the closing of our strategic alliance with King in December 2005. Revenues recognized from amortization of the upfront fee were $3.7 million in the fourth quarter of 2005 for recognition of the revenue for the period from the execution of the agreement in November 2005 to the end of 2005.

Revenues—Collaboration revenue

Collaboration revenues were $1.4 million in the fourth quarter of 2005, related to reimbursement of our development expenses incurred pursuant to the King strategic alliance from the execution of the agreement in November 2005 to the end of 2005. We did not have any corresponding collaboration revenue in 2004.

Research and Development Expense

Research and development expense consists primarily of costs of drug development work associated with our drug candidates, including:

- preclinical testing,
- clinical trials,
- clinical supplies and related formulation and design costs, and
- salaries and other personnel-related expenses.

Research and development expense decreased to $32.9 million from $35.1 million in the years ended December 31, 2005 and 2004, respectively. The decrease was primarily due to lower clinical trial activity in 2005 as compared to 2004. This decrease was offset in part by increased formulation and development activities for Remoxy and other preclinical activities as well as increased compensation related expenses.

General and Administrative Expense

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense increased to $4.9 million from $3.9 million in the years ended December 31, 2005 and 2004, respectively, primarily due to an increases in headcount and general corporate activities, offset in part by decreased non-cash stock-based compensation expense in 2005 as compared to 2004.

Interest and Other Income

Interest and other income increased to $2.0 million from $1.2 million in the years ended December 31, 2005 and 2004, respectively, primarily due to increases in yields on our investments in marketable securities and, to a lesser extent, in average balances of marketable securities.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private securities offerings. Additionally, in December 2005, we received a $150.0 million program fee under our strategic alliance with King. We intend to continue to use the proceeds from these offerings and from this program fee to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2006, cash, cash equivalents and marketable securities were $204.4 million.

Net cash used in operating activities was $11.8 million for the years ended December 31, 2006 compared to net cash provided by operating activities of $113.2 million for the year ended December 31, 2005. In 2006, we incurred approximately $10.4 million of expenses related to development of our abuse-resistant drug candidates under our strategic alliance with King that remain subject to review by King, and King has requested additional supporting documentation and clarification of amounts that we have invoiced them. We expect that King will complete this review in the first half of 2007.

Our investing activities to purchase property, equipment and leasehold improvements used cash of $0.1 million for the year ended December 31, 2006 and $0.5 million for the year ended December 31, 2005. Other investing activities for both these years consisted primarily of the purchase and sale of marketable securities. We expect to continue to invest in our infrastructure to support our operations.

Net cash provided by financing increased to $1.7 million in the year ended December 31, 2006 from $0.3 million in the year ended December 31, 2005. The increase was primarily due to an increase in issuances of common stock from our 1998 Stock Plan and our 2000 Employee Stock Purchase Plan.

We have $57.3 million of total deferred tax assets at December 31, 2006. Realization of these deferred tax assets is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. We have concluded that it was more likely than not that such deferred tax assets would not be realized. Accordingly, we fully offset the deferred tax asset with a valuation allowance.

We lease approximately 10,500 square feet of general office space. Our lease expires in 2010. Under the terms of our real property lease, annual minimum lease payments are as follows as of December 31, 2006 (in thousands):

	2007	2008	2009	2010	Total
Future minimum lease payments	$187	$196	$206	$160	$749

In 2007, we expect to increase the amount of office space we lease.

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our

licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of December 31, 2006. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. King is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

We have an accumulated deficit of $136.5 million at December 31, 2006. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next 12 months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

Recent Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement No. 109, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company in the first quarter of 2007. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition and is not yet in a position to determine such effects.

In fiscal 2006, we adopted FSP No. FAS 115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." This adoption did not have a material impact on the Company's results of operations or financial condition.

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

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2006 by approximately $0.9 million. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments. As of December 31, 2006, our investments consisted of short-term investments in corporate and government notes and obligations or in money market accounts and checking funds with variable, market rates of interest. We believe our credit risk is immaterial.

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

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited the accompanying balance sheets of Pain Therapeutics, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. 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 Pain Therapeutics, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Notes 1 and 6 to the financial statements, in 2006, Pain Therapeutics, Inc. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payments".

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Pain Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2006, 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 10, 2007 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Palo Alto, California
February 10, 2007

PAIN THERAPEUTICS, INC.

BALANCE SHEETS

(in thousands except share and per share data)

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,386	$ 95,651
Marketable securities	188,014	117,001
Other current assets	2,714	1,512
Total current assets	207,114	214,164
Property and equipment, net	1,267	1,556
Other assets	75	75
Total assets	$ 208,456	$ 215,795
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 985	$ 998
Accrued development expense	5,777	4,461
Deferred program fee revenue—current portion	26,200	26,200
Income taxes payable	2,779	—
Other accrued liabilities	913	688
Total current liabilities	36,654	32,347
Non-current liabilities:		
Deferred program fee revenue—noncurrent portion	93,887	120,088
Total liabilities	130,541	152,435
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value; 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $.001 par value; 120,000,000 shares authorized; 44,314,003 and 43,936,088 shares issued and outstanding in 2006 and 2005, respectively	44	44
Additional paid-in-capital	214,749	206,489
Accumulated other comprehensive loss	(372)	(479)
Accumulated deficit	(136,506)	(142,694)
Total stockholders' equity	77,915	63,360
Total liabilities and stockholders' equity	$ 208,456	$ 215,795

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(in thousands except per share data)

	Years ended December 31,		
	2006	2005	2004
Revenue:			
Program fee revenue	$26,201	$ 3,712	$ —
Collaboration revenue	22,717	1,368	—
Milestone revenue	5,000	—	—
Total revenue	53,918	5,080	—
Operating expenses:			
Research and development	46,803	32,938	35,093
General and administrative	7,668	4,859	3,868
Total operating expenses	54,471	37,797	38,961
Operating loss	(553)	(32,717)	(38,961)
Interest and other income	9,668	2,047	1,185
Income (loss) before provision for income taxes	9,115	(30,670)	(37,776)
Provision for income taxes	2,927	—	—
Net income (loss)	$ 6,188	$(30,670)	$(37,776)
Earnings (loss) per share:			
Basic	$ 0.14	$ (0.70)	$ (1.01)
Diluted	$ 0.14	$ (0.70)	$ (1.01)
Weighted-average shares used to compute earnings (loss) per share:			
Basic	44,146	43,795	37,267
Diluted	45,475	43,795	37,267

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENT OF STOCKHOLDERS' EQUITY
(in thousands except share data)

	Common and Preferred stock		Additional paid-in capital and deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Par value				
Balance at December 31, 2003	35,381,309	$ 35	$ 150,725	$ 50	$ (74,248)	$ 76,562
Issuance of common stock pursuant to exercise of stock options	184,257	1	473	—	—	474
Issuance of common stock pursuant to follow-on offering, net of expenses	8,000,000	8	54,074	—	—	54,082
Amortization of employee deferred compensation, net of reversals	—	—	7	—	—	7
Compensation with respect to non-employee option grants	—	—	394	—	—	394
Issuance of common stock related to employee stock purchase plan	86,550	—	247	—	—	247
Net unrealized losses on investment in marketable securities	—	—	—	(594)	—	(594)
Net loss	—	—	—	—	(37,776)	(37,776)
Comprehensive loss						(38,370)
Balance at December 31, 2004	43,652,116	44	205,920	(544)	(112,024)	93,396
Issuance of common stock pursuant to exercise of stock options	148,136	—	159	—	—	159
Issuance of common stock pursuant to exercise of warrants	60,450	—	6	—	—	6
Expenses pursuant to filing registration statements	—	—	(116)	—	—	(116)
Compensation with respect to non-employee option grants	—	—	248	—	—	248
Issuance of common stock related to employee stock purchase plan	75,386	—	272	—	—	272
Net unrealized gains on investment in marketable securities	—	—	—	65	—	65
Net loss	—	—	—	—	(30,670)	(30,670)
Comprehensive loss						(30,605)
Balance at December 31, 2005	43,936,088	44	206,489	(479)	(142,694)	63,360
Issuance of common stock pursuant to exercise of stock options	304,180	—	1,312	—	—	1,312
Issuance of common stock related to employee stock purchase plan	73,735	—	330	—	—	330
Compensation with respect to non-employee option grants	—	—	242	—	—	242
Compensation with respect to employee option grants	—	—	6,228	—	—	6,228
Tax benefits and excess tax benefits from the exercise of options	—	—	148	—	—	148
Net unrealized gains on investment in marketable securities	—	—	—	107	—	107
Net income	—	—	—	—	6,188	6,188
Comprehensive income						6,295
Balance at December 31, 2006	44,314,003	$ 44	$ 214,749	$ (372)	$ (136,506)	$ 77,915

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC

STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,		
	2006	2005	2004
Cash flows used in operating activities:			
Net income (loss)	$ 6,188	$ (30,670)	$ (37,776)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	345	368	383
Amortization of program fees	(26,201)	(3,712)	—
Non-cash net interest income	(1,858)	(100)	(484)
Non-cash stock based compensation	6,470	248	401
Loss on disposal of property and equipment	38	—	—
Changes in operating assets and liabilities:			
Other current assets	(1,202)	(1,253)	1,062
Accounts payable	(13)	121	(1,354)
Accrued development expense	1,316	(1,897)	5,148
Deferred program fee revenue	—	150,000	—
Income taxes payable	2,779	—	—
Tax benefits from equity-based compensation plans	148	—	—
Excess tax benefits from equity-based compensation plans	(62)	—	—
Other accrued liabilities	225	127	51
Net cash provided by (used in) operating activities	(11,827)	113,232	(32,569)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(94)	(463)	(156)
Purchase of marketable securities	(136,119)	(93,591)	(114,067)
Sales of marketable securities	27,261	74,773	81,341
Maturities of marketable securities	39,810	—	—
Net cash used in investing activities	(69,142)	(19,281)	(32,882)
Cash flows from financing activities:			
Excess tax benefits from equity-based compensation plans	62	—	—
Proceeds from issuance of common stock, net	1,642	321	54,803
Net cash provided by financing activities	1,704	321	54,803
Net increase (decrease) in cash and cash equivalents	(79,265)	94,272	(10,648)
Cash and cash equivalents at beginning of period	95,651	1,379	12,027
Cash and cash equivalents at end of period	$ 16,386	$ 95,651	$ 1,379
Supplemental cash flow information:			
Cash paid for income taxes	$ —	$ —	$ —

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Business

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs for pain management and oncology.

Although we were profitable in 2006 principally based on revenue recognized from King and interest income, in the course of our development activities, we have sustained cumulative operating losses. There are no assurances that additional financing will be available on favorable terms, or at all.

Our development activities involve inherent risks. These risks include, among others, dependence on our collaboration partners, key personnel and determination of patentability and protection of our products and processes. In addition, we have drug candidates that have not yet obtained FDA approval. Successful future operations depend on our ability to obtain approval for and commercialize these products.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Revenue Recognition and Deferred Program Fee Revenue

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition in Financial Statements” (“SAB 104”). We have also adopted the provisions of Emerging Issues Task Force, Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables” (“EITF 00-21”).

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Allowances are established for uncollectible amounts.

In November 2005, we and King Pharmaceuticals, Inc., or King, announced a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. In connection with the strategic alliance, we recognize program fee revenue and collaboration revenue. Program fee revenue is derived from the upfront payment from King and is recognized ratably over our estimate of the development period under the strategic alliance with King. Deferred program fee revenue represents the amount of the up front payment that has not been recognized as revenue to date. Collaboration revenues from reimbursement of development expenses, which are invoiced one month in arrears, are recognized when costs are incurred pursuant to the strategic alliance with King. We recognize milestone payments as revenue when the milestone payments are substantive and non-refundable and we achieve the underlying developmental milestone.

Cash, Cash Equivalents and Concentration of Cash Risk

We consider all highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist of cash maintained at two financial institutions and money market funds.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Marketable Securities

In accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," we consider our investments to be held as "available-for-sale." We classify these investments as current assets and carry them at fair value. Unrealized gains and losses are recorded as a separate component of stockholders' equity as accumulated other comprehensive income (loss). All realized gains and losses on our available-for-sale securities are recognized in our results of operations. Our investments are maintained at one financial institution and are governed by our investment policy as approved by our Board of Directors. We believe our credit risk is immaterial.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets (generally two to five years). Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or the lease term.

Impairment of Long-Lived Assets

We regularly perform reviews to determine if the carrying value of our long-lived assets is impaired. We consider facts or circumstances, either internal, or external that indicate that we may not recover the carrying value of the asset.

We evaluate long-lived assets, such as property, plant and equipment and purchased intangible assets with finite lives, for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." We measure impairment loss related to long-lived assets based on the amount by which the carrying amounts of such assets exceed their fair values. Our measurement of fair value is generally based on an analysis of the present value of estimated future discounted cash flows. We use available information and reasonable and supportable assumptions and projections. We consider the likelihood of possible outcomes and our best estimates of projected future cash flows. If necessary, we perform subsequent calculations to measure the amount of the impairment loss based on the excess of the carrying value over the measurement of fair value of the impaired asset. No events or changes in circumstances have occurred with respect to our long-lived assets that would indicate that an impairment analysis should have been performed.

Business Segments

Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires an enterprise to report segment information based on how management internally evaluates the operating performance of its business units (segments). Our operations are confined to one business segment: the development of novel drugs.

Expenses for Clinical Trials

Research and development expense includes the cost of clinical trials. Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes enrollment. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Information about patient enrollment can become available significantly after we report

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

our expenses for clinical trials, in which case we would change our estimate of the remaining cost of a trial. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. This statement requires companies to recognize expense in the income statement for the fair value all share-based payments to employees and directors, including grants of employee stock options. SFAS 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations, or APB 25, and amends FASB Statement No. 95, *Statement of Cash Flows*.

We adopted SFAS 123R on January 1, 2006 using the modified prospective transition method. We record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation expense recognized in the year ended December 31, 2006 includes compensation cost for all outstanding stock-based awards. Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and directors in accordance with APB 25 and its interpretations. Accordingly, we did not recognize compensation cost in our financial statements prior to January 1, 2006 for these awards because stock options granted to employees and directors had exercise prices equal to or greater than the fair value of the underlying security at the time the stock option was granted. We have adopted the alternative transition method to use to calculate the pool of windfall tax benefits under SFAS 123R.

In adopting SFAS 123R, companies must choose among alternative valuation models and amortization assumptions. After assessing alternative valuation models and amortization assumptions, we continue to use the Black-Scholes option valuation model, or Black-Scholes and use the single-option award approach and straight-line attribution method for stock options granted since January 1, 2006. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

Prior to adoption of SFAS 123R, we calculated the value of options granted to employees and directors for disclosure in the footnotes to our financial statements pursuant to Statement of Financial Accounting Standards No. 123, or SFAS 123, using Black-Scholes, the multiple-option award approach and the accelerated attribution method. This approach uses a graded vesting method over the vesting period of each respective stock option, generally four years. The accelerated attribution method results in recognizing as compensation cost more than 50% of the fair value of an option in year one, with the remainder recognized in decreasing amounts from year two to year four. Under the modified-prospective transition method of SFAS 123R, we will continue to calculate compensation cost for options granted prior to January 1, 2006 using the multiple-option award approach and accelerated attribution method.

We estimate forfeitures when recognizing expense under SFAS 123R and adjust this estimate periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption.

Net Income (Loss) per Share

Basic net income (loss) per share is computed on the basis of the weighted-average number of shares outstanding for the reporting period. Diluted net income (loss) per share is computed on the basis of the

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

weighted-average number of common share outstanding plus dilutive potential common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of convertible preferred stock, outstanding stock options and outstanding warrants.

The numerators and denominators in the calculation of basic and diluted net income (loss) per share were as follows (in thousands):

	Years Ended December 31,		
	2006	2005	2004
Numerators:			
Net income (loss)	$ 6,188	$(30,670)	$(37,776)
Denominators:			
Weighted average shares used to compute basic net income (loss) per share	44,146	43,795	37,267
Effect of dilutive securities:			
Dilution from employee stock plans	1,196	—	—
Dilution from warrants	133	—	—
Dilutive potential common shares	1,329	—	—
Weighted average shares used to compute diluted net income (loss) per share	45,475	43,795	37,267

In 2006, 2.2 million shares related to stock options were excluded from diluted net income per shares as the share price was greater than the average price per share and the effect would be anti-dilutive. In 2005 and 2004 we reported a loss and therefore all common shares related to potentially dilutive securities have been excluded from the calculation of diluted loss per share because they are anti-dilutive.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and unrealized holding gains and losses on available-for-sale securities as follows (in thousands):

	Years Ended December 31,		
	2006	2005	2004
Net income (loss)	$6,188	$(30,670)	$(37,776)
Other comprehensive income (loss)	107	65	(594)
Comprehensive income (loss)	$6,295	$(30,605)	$(38,370)

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized. Management performs assessments of the realization of deferred tax assets considering all available evidence, both positive and negative. These assessments require that management make significant judgments about many factors, including the amount and likelihood of future taxable income.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Recent Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement No. 109, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company in the first quarter of 2007. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition and is not yet in a position to determine such effects.

In fiscal 2006, we adopted FSP No. FAS 115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." This adoption did not have a material impact on the Company's results of operations or financial condition.

3. Collaboration Agreements

King Pharmaceuticals, Inc.

In November 2005, we and King announced a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150.0 million to us at the closing of this strategic alliance in December 2005, of which $26.2 million and $3.7 million were recorded as program fee revenue for the year ended December 31, 2006 and 2005, respectively. We could also receive from King up to $150.0 million in milestone payments in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance, of which we received $5.0 million in milestone revenue in the year ended December 31, 2006. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement, of which $22.7 and $1.4 million was recorded as collaboration revenue for the years ended December 31, 2006 and 2005, respectively. We have incurred and invoiced an additional $6.4 million in development expenses during the period from September to November 2006; King has informed us that it is still reviewing this invoice and has asked for additional supporting documentation and clarification in order for them to complete their review. We have therefore excluded these amounts from our Collaboration revenues in 2006. Further, we have also excluded from revenue an additional $4.0 million in development expenses incurred in December 2006 due to the open issues with King on our most recent invoice. We expect to fully respond to King's request and for King to complete their review in the first half of 2007. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1.0 billion in net sales of such drugs, for which the royalty is set at 15%.

Durect Corporation

We have an exclusive, worldwide licensing agreement with Durect Corporation to use a patented technology that forms the basis for a number of oral gel-cap drug candidates, including Remoxy. We have sub-licensed to King certain rights to develop and to commercialize Remoxy and certain other opioid drugs formulated in part with technology we licensed from Durect. Under the agreement with Durect, we control all of the preclinical, clinical, commercial manufacturing and sales/marketing activities for Remoxy and other abuse-resistant opioid painkillers. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. Durect will supply us with certain

components of Remoxy and other abuse-resistant opioid painkillers on a cost-plus basis. We also are responsible to pay Durect royalties on any related drug sales. King is obligated to reimburse us for costs we incur under the agreement with Durect, including royalties.

4. Cash and Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities held as available-for-sale consisted of the following (in thousands):

	Cash, Cash Equivalents and Investments				
	Amortized Cost	Accrued Interest	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2006					
Cash and cash equivalents:					
Money market securities	$ 16,350	$ 34	$ 2	$ —	$ 16,386
	16,350	34	2	—	16,386
Marketable securities available-for-sale:					
U.S. government and agency obligations	54,563	554	13	(90)	55,040
Corporate obligations	71,213	932	2	(295)	71,852
Mortgage/asset-backed securities	60,960	166	82	(86)	61,122
	186,736	1,652	97	(471)	188,014
	$203,086	$1,686	$ 99	$ (471)	$204,400
December 31, 2005					
Cash and cash equivalents:					
Money market securities	$ 95,599	$ 52	$ —	$ —	$ 95,651
	95,599	52	—	—	95,651
Marketable securities available-for-sale:					
U.S. government and agency obligations	40,785	255	—	(119)	40,921
Corporate obligations	65,644	854	7	(300)	66,205
Mortgage/asset-backed securities	9,928	14	—	(67)	9,875
	116,357	1,123	7	(486)	117,001
	$211,956	$1,175	$ 7	$ (486)	$212,652

The amount of unrealized losses on investments at December 31, 2006 and 2005 that were in an unrealized loss position for a continuous period of more than one year was immaterial. To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. We would recognize an impairment charge when the decline in the estimated fair value of a marketable security below the amortized cost is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost, any adverse changes in the investees' financial condition as well as our intent and ability to hold the marketable security for a period of time sufficient to allow for any anticipated recovery in market value.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The gross realized losses and gains on the sale of available-for-sale securities during the years ended December 31, 2006, 2005 and 2004 were not material.

The contractual maturities of our marketable securities at December 31, 2006, consisted of the following (in thousands):

Less than one year	$ 143,342
Greater than one year	44,672
	$ 188,014

5. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,		
	2006	2005	2004
Furniture and fixtures	$ 1,145	$ 1,089	$ 630
Computers and software	94	128	224
Leasehold improvement	1,887	1,887	1,887
	3,126	3,104	2,741
Accumulated depreciation and amortization	(1,859)	(1,548)	(1,280)
Total	$ 1,267	$ 1,556	$ 1,461

Depreciation expense was $345,000, $368,000 and $383,000 in 2006, 2005 and 2004, respectively.

6. Stockholders' Equity and Stock-Based Compensation

Common Stock

In 2004, we filed with the Securities and Exchange Commission a registration statement, using a shelf registration process, and reserved 15,000,000 shares of common stock to be offered via prospectus in amounts, at prices and at terms determined at the time of an offering and that may be sold directly by us to investors, through agents designated from time to time, or to or through underwriters or dealers. In 2004, we issued 8,000,000 shares of common stock at $7.25 per share in a follow-on public offering pursuant to this shelf registration statement and received net proceeds of approximately $54.5 million after deducting underwriting discounts and related expenses.

In 2005, we filed with the Securities and Exchange Commission a registration statement, using a shelf registration process under which we may offer to sell any combination of securities described in the registration statement in one or more offerings, up to a total dollar amount of $150.0 million. We have not sold any securities under this registration statement.

Preferred Stock

Our Board of Directors has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges, restrictions and the number of shares constituting any series or the designation of the series.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

In 2005, our Board of Directors adopted a stockholder rights plan designed to guard against partial tender offers and other coercive tactics to gain control of the Company without offering a fair and adequate price and terms to all of Pain Therapeutics' stockholders. Pursuant to the stockholder rights plan, our Board of Directors declared and paid a dividend of one right to purchase one one-thousandth share of the Company's Series A Participating Preferred Stock for each outstanding share of our common stock. Each of these rights entitles the registered holder to purchase from us one one-thousandth of a share of Series A Preferred at an exercise price of $40.00, subject to adjustment at any time.

Stock-Based Compensation

On January 1, 2006 we adopted SFAS 123R using the modified-prospective transition method. Under this transition method, we record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation expense recognized for the year ended December 31, 2006 includes compensation cost for all outstanding stock-based awards.

Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and directors in accordance with APB 25 and its interpretations. Accordingly, we did not recognize compensation cost in our financial statements prior to January 1, 2006 for these awards because stock options granted to employees and directors had exercise prices equal to or greater than the fair value of the underlying security at the time the stock option was granted.

Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2006 of $10.1 million over the weighted average remaining recognition period of 2.14 years.

We did not retroactively apply SFAS 123R to periods prior to January 1, 2006. If we had recorded compensation expense for our stock-based plans in a manner consistent with the fair value approach of SFAS 123R, our net loss and net loss per share for the years ended December 31, 2005 and 2004 would have been as follows (in thousands, except per share data):

	Years ended December 31,	
	2005	2004
Net loss, as reported	$ (30,670)	$ (37,776)
Deduct: Total stock based employee compensation expense determined under the fair value based method for all awards	(7,772)	(6,188)
Add (deduct): Total stock based employee compensation expense (reduction in expense)	—	7
Adjusted net loss	$ (38,442)	$ (43,957)
Net loss per common share basic and diluted, as reported	$ (0.70)	$ (1.01)
Adjusted net loss per common share basic and diluted	$ (0.88)	$ (1.18)

1998 Stock Plan

Under the 1998 Stock Plan, our employees, directors and consultants may be granted options that allow for the purchase of shares of our common stock. Incentive stock options may only be granted to employees. Through December 31, 2006 a total of 12,600,000 shares of common stock were authorized for issuance under the 1998

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Stock Plan. The 1998 Stock Plan allows for annual increases in the number of common shares authorized for issuance equal to the lesser of (i) 2,000,000 shares, (ii) 5% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by our Board of Directors.

Our Board of Directors or a designated Committee of the Board is responsible for administration of the 1998 Stock Plan and determines the terms and conditions of each option granted, consistent with the terms of the plan. Incentive stock options may be granted under the 1998 Stock Plan at a price not less than 100% of the fair market value of the stock on the date of grant (not less than 110% of the fair market value on the date of grant in the case of holders of more than 10% of our voting stock). Options granted under the 1998 Stock Plan generally expire ten years from the date of grant (five years for incentive stock options granted to holders of more than 10% of our voting stock). Forfeited options become available for reissuance under the 1998 Stock Plan.

The 1998 Stock Plan also provides for the automatic grant of options to purchase shares of common stock to outside directors. On the date of each annual stockholders' meeting, each outside director is automatically granted an option to purchase 25,000 shares of common stock. The term of the option is ten years, the exercise price is 100% of the fair market value of the stock on the date of grant, and the option becomes exercisable as to 25% of the shares on the anniversary of its date of grant provided the optionee continues to serve as a director on such dates.

The following summarizes stock option activity for the years ended December 31, 2006, 2005 and 2004:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In years	Aggregate Intrinsic Value In millions
Options outstanding as of December 31, 2003	4,368,509	$ 6.53		
Granted	1,373,100	$ 7.56		
Exercised	(184,257)	$ 2.57		
Forfeited	(222,618)	$ 6.28		
Options outstanding as of December 31, 2004	5,334,734	$ 6.94		
Granted	1,880,300	$ 5.75		
Exercised	(148,136)	$ 1.08		
Forfeited	(73,406)	$ 7.90		
Options outstanding as of December 31, 2005	6,993,492	$ 6.74		
Granted	1,617,200	$ 8.35		
Exercised	(304,180)	$ 4.31		
Forfeited	(93,527)	$ 8.56		
Options outstanding as of December 31, 2006	8,212,985	$ 7.12	7.20	$ 15.9
Vested and expected to vest at December 31, 2006	7,918,924	$ 7.11	7.13	$ 15.5
Exercisable at December 31, 2006	4,869,925	$ 7.03	6.17	$ 10.4

The pre-tax intrinsic value of options exercised in 2006 was $1.4 million (calculated by multiplying the number of shares exercised by the difference between the closing stock price on the last trading day of 2006 and the weighted average exercise price for shares exercised in 2006). Shares reserved for issuance and available for grant under the 1998 Stock Plan were 1,673,639 as of December 31, 2006.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The following summarizes information about stock options outstanding at December 31, 2006:

	Options outstanding			Options exercisable	
Range of exercise prices	Number of options	Weighted average remaining contractual life (years)	Weighted average exercise price	Number of vested options	Weighted average exercise price
$0.10—$ 5.25	1,489,177	7.41	$ 4.44	819,374	$ 3.81
5.34— 6.85	1,453,938	6.67	6.42	1,016,889	6.52
6.90— 7.16	1,527,100	6.02	7.02	1,380,048	7.01
7.17— 7.78	1,440,146	7.55	7.63	791,267	7.65
8.00— 8.49	1,429,424	8.76	8.30	339,952	8.25
8.51— 18.63	873,200	6.63	10.27	522,395	11.38
$0.10—$18.63	8,212,985	7.20	$ 7.12	4,869,925	$ 7.03

Determining the Fair Value of Options

We use Black-Scholes to estimate the fair value of options granted. Black-Scholes considers a number of factors, including the market price and volatility of our common stock. We used the following forward-looking range of assumptions to value each stock option granted to employees during the years ended December 31, 2006, 2005 and 2004:

	2006	2005	2004
Factors:			
Volatility	68% to 74%	78% to 86%	89% to 95%
Risk-free interest rates	5%	4%	4%
Expected life of option	5 years	5 years	5 years
Forfeiture rate	5%	—	—
Dividend yield	—	—	—

Our volatility assumption is based on reviews of the historical volatility of our common stock. Our risk-free interest rate assumption is based on yields of US treasury notes in effect at the date of grant. Our expected life of options granted assumption is based on actual historical option exercises. Our forfeiture rate assumption is based on historical cancellations of options. Our dividend yield assumption is based on the fact that we have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $5.16, $4.47 and $6.25 per share for the years ended December 31, 2006, 2005 and 2004, respectively.

We estimate the fair value of stock options granted to non-employees using forward-looking assumptions similar to those used for stock options granted to employees and appropriate for the terms underlying the stock options granted to non-employees. We re-measure the compensation expense for options granted to non-employees over the related vesting period. The expense related to stock options granted to non-employees was approximately $0.2, $0.2, and $0.4 million for the years ended December 31, 2006, 2005 and 2004, respectively.

2000 Employee Stock Purchase Plan

Under the 2000 Employee Stock Purchase Plan, or the Purchase Plan, eligible employees may purchase common stock through payroll deductions of up to 15% of the employee's compensation. The purchase price of the stock is generally 85% of the lower of the fair market value of the common stock at the beginning of the

offering period or at the end of the purchase period. A total of 500,000 shares of common stock have been reserved for issuance under the Purchase Plan. Shares reserved for issuance under the Purchase Plan may be automatically increased each year by the amount equal to the lesser of (i) 500,000 shares, (ii) 1% of the initially outstanding shares of common stock on such date, or (iii) an amount determined by our Board of Directors. We have issued 350,245 shares of common stock pursuant to the Purchase Plan through December 31, 2006, leaving 149,755 shares reserved for issuance.

We estimate the fair value of stock purchase rights under our 2000 Employee Stock Purchase Plan using forward looking assumptions similar to those used for stock options granted to employees. The weighted-average fair value of purchase rights granted was $2.15, $2.14, and $2.85 in 2006, 2005 and 2004, respectively, calculated using Black-Scholes with an expected life of 1 year in 2006 and 2005 and 2 years in 2004 with no dividend yield. We assumed volatility was 55% in 2006, 41% to 46% in 2005 and 89% to 94% in 2004. We used risk free interest rates of 5% in 2006, 3% to 4% in 2005 and 3% in 2004. The expense related to the Employee Stock Purchase Plan was $0.2, $0.2 and $0.1 million for the years ended December 31, 2006, 2005 and 2004, respectively.

Warrants

As of December 31, 2006, we have outstanding exercisable warrants to purchase 150,000 shares of common stock at $1.00 per share. These warrants were issued in connection with corporate activities. The value of these warrants was immaterial. These warrants expire in 2010.

7. Employee 401(k) Benefit Plan

We have a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. Employees are eligible to participate in the plan the first day of the month after hire and may elect to contribute the lesser of 20% of their annual compensation or the current statutory limits under Internal Revenue Service regulations. The 401(k) plan permits us to make additional matching contributions on behalf of all employees. Through December 31, 2006, we have not made any matching contributions.

8. Income Taxes

In 2005, King made an upfront cash payment of $150.0 million to us in connection with our strategic alliance. We have taxable income for 2006 primarily due to the recognition in 2006 of $146.3 million of the upfront cash payment for income tax purposes. We have reduced our taxes payable for 2006 with our net operating losses and tax credit carryforwards from prior years.

Our provision for income taxes for 2006 is $2.9 million, of which $2.7 million is provided for federal tax and $0.2 million is provided for state tax. We do not have any deferred components in our provision for income taxes. All of our net income (loss) is domestic. A reconciliation between our provision for income taxes and the amount computed by multiplying income before provision for income taxes by the U.S. statutory tax rate follows (in thousands):

	2006
Tax at U.S. statutory tax rate of 35%	$3,190
State taxes	188
Research credits	(481)
Equity-based compensation	699
Change in valuation allowance	(679)
Other	10
Provision for income taxes	$2,927

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Deferred tax assets reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,		
	2006	2005	2004
Deferred tax assets:			
Net operating loss carryforwards	$ —	$ 51,300	$ 38,300
Deferred license fee revenue	48,800	—	—
Research and development credits	3,100	7,200	7,700
Stock-related compensation	2,500	800	900
Other	2,900	2,400	3,000
Total deferred tax assets	57,300	61,700	49,900
Valuation allowance	(57,300)	(61,700)	(49,900)
Net deferred tax assets	$ —	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which we are uncertain. We have concluded that it was more likely than not that our deferred tax assets would not be realized. Accordingly, the total deferred tax assets have been fully offset by a valuation allowance. We will continue to assess the realizability of deferred tax assets based on actual and forecasted operating results. Approximately $0.2 million of the valuation allowance at December 31, 2006 relates to the tax benefits associated with excess tax deductions resulting from stock option transactions. This amount will be credited to additional paid-in capital when realized in a reduction to income taxes payable. The valuation allowance decreased by $4.4 million in 2006 and increased by $11.8 million and $14.3 during 2005 and 2004, respectively.

As of December 31, 2006, we had federal research and development tax credits of approximately $3.1 million, which expire in the years 2018 through 2026.

9. Leases and Commitments

We conduct our product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. We have contractual arrangements with these organizations. However these arrangements are cancelable and our obligations under these arrangements are largely based on services performed.

We currently lease office space pursuant to a non-cancelable operating lease that will expire in 2010. Future minimum lease payments for this lease is as follows for the years ended December 31, (in thousands):

	2007	2008	2009	2010	Total
Future minimum lease payments	$187	$196	$206	$160	$749

Rent expense was $178,000, $178,000, and $178,000 for the years ended December 31, 2006, 2005, and 2004 respectively.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

10. Selected Quarterly Financial Data (Unaudited) (in thousands except per share data)

	Quarters Ended			
	March 31	June 30	September 30	December 31
2006				
Total revenues	$15,326	$ 13,746	$ 18,510	$ 6,336
Net Income (loss)	$ 877	$ 1,367	$ 9,656	$ (5,712)
Basic income (loss) per common share	$ 0.02	$ 0.03	$ 0.22	$ (0.13)
Diluted income (loss) per common share	$ 0.02	$ 0.03	$ 0.21	$ (0.13)
2005				
Total revenues	$ —	$ —	$ —	$ 5,080
Net loss	$ (8,589)	$ (10,182)	$ (8,767)	$ (3,132)
Basic and diluted (loss) per common share	$ (0.20)	$ (0.23)	$ (0.20)	$ (0.07)

The sum of each quarter may not equal the annual total due to rounding.

Total revenues during the quarter ended December 31, 2006 exclude approximately $10.4 million of incurred development expenses not recognized as collaboration revenues pending completion of King's review and acceptance of such amounts.

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

Not applicable.

Item 9A. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

We are responsible for establishing and maintaining adequate internal control over our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2006. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

Our 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. Our 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 our transactions and dispositions of our assets;

(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 our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our 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.

Based on using the COSO criteria, we believe our internal control over financial reporting as of December 31, 2006 was effective.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our independent registered public accounting firm, Ernst & Young LLP has audited the financial statements included in this Annual Report on Form 10-K and has issued a report on management’s assessment of our internal control over financial reporting as well as on the effectiveness of our internal control over financial reporting. The attestation report of Ernst & Young LLP, our registered public accounting firm, is included below.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited management's assessment, included in the accompanying evaluation of disclosure controls and procedures, that Pain Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Pain Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Pain Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Pain Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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 Pain Therapeutics, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 of Pain Therapeutics, Inc. and our report dated February 10**,** 2007 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Palo Alto, California
February 10, 2007

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information regarding our directors, executive officers and the audit committee of our board of directors is incorporated by reference from "Directors and Executive Officers" in our Proxy Statement for our 2007 Annual Meeting of Stockholders.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended requires our executive officers and directors and persons who own more than ten percent (10%) of a registered class of our equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission, or SEC, and the National Association of Securities Dealers, Inc. Executive officers, directors and greater than ten percent (10%) stockholders are required by Commission regulation to furnish us with copies of all Section 16(a) forms they file. We believe all of our executive officers and directors complied with all applicable filing requirements during the fiscal year ended December 31, 2006.

Code of Ethics

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. We publicize the Code of Ethics through posting the policy on our website, http://www.paintrials.com. We will disclose on our website any waivers of, or amendments to, our Code of Ethics.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Executive Compensation and Other Matters."

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

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Security Ownership of Certain Beneficial Owners and Management." The table required by this Item regarding equity compensation plans is incorporated by reference from Item 5 above of this Annual Report on Form 10-K.

Item 13. ***Certain Relationships and Related Transactions and Director Independence***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Certain Relationships and Related Transactions."

Item 14. ***Principal Accounting Fees and Services***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading **"**Principal Accounting Fees and Services."

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this Form 10-K:

(1) *Financial Statements (included in Part II of this report):*

Reports of Independent Registered Public Accounting Firm

Balance Sheets

Statements of Operations

Statement of Stockholders' Equity

Statements of Cash Flows

Notes to Financial Statements

(2) *Financial Statement Schedules:*

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

(3) *Exhibits:*

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(2)	Specimen Common Stock Certificate.
4.2(3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the Company and Mellon Investor Services LLC, including the Certificate of Designation, the form of Rights Certificate and Summary of Rights attached thereto as Exhibits A, B and C, respectively.
10.1(4)	Form of Indemnification Agreement between Pain Therapeutics and each of its directors and officers.
10.2(4)	1998 Stock Plan and form of agreements thereunder.
10.3(4)	2000 Employee Stock Purchase Plan and form of agreements thereunder.
10.4(5)	Employment Agreement dated August 29, 2000, between Registrant and Grant L. Schoenhard, Ph.D.
10.5(5)	Employment Agreement dated October 23, 2001, between Registrant and Nadav Friedmann, Ph.D., M.D.
10.6(4)	Second Amended and Restated Investors' Rights Agreement dated as of February 1, 2000 between Registrant and the holders of its series B and series C redeemable convertible preferred stock.
10.7(6)	Lease Agreement dated July 21, 2000 between Registrant and Goss-Jewett Company of Northern California.
10.8(7)	Collaboration Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.9(7)	License Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.10(7)	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
10.11(7)	Amendment dated December 15, 2005 to Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.

Exhibit Number	Description of Document
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page 60).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending June 30, 2005.
(2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending March 31, 2005.
(3) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
(4) Incorporated by reference from our registration statement on Form S-1, registration number 333-32370, declared effective by the Securities and Exchange Commission on July 13, 2000.
(5) Incorporated by reference from exhibits to our report on Form 10-K for the period ending December 31, 2001.
(6) Incorporated by reference from Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000.
(7) Incorporated by reference from exhibits to our report on Form 10-K for the period ending December 31, 2005.

(b) *Exhibits*

The exhibits listed under Item 15(a)(3) hereof are filed as part of this Form 10-K other than Exhibit 32.1, which shall be deemed furnished.

(c) *Financial Statement Schedules*

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

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.

PAIN THERAPEUTICS, INC.

By: /s/ REMI BARBIER
Remi Barbier
President, Chief Executive Officer and Chairman of the Board of Directors

Dated: February 23, 2007

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Remi Barbier and Peter S. Roddy, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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/ REMI BARBIER **Remi Barbier**	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 23, 2007
/s/ PETER S. RODDY **Peter S. Roddy**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2007
/s/ NADAV FRIEDMANN, PH.D., M.D. **Nadav Friedmann, Ph.D., M.D.**	Chief Operating and Medical Officer and Director	February 23, 2007
/s/ ROBERT Z. GUSSIN, PH.D. **Robert Z. Gussin, Ph.D.**	Director	February 23, 2007
/s/ VERNON R. LOUCKS, JR. **Vernon R. Loucks, Jr.**	Director	February 23, 2007
/s/ MICHAEL J. O'DONNELL, ESQ. **Michael J. O'Donnell, Esq.**	Director and Secretary	February 23, 2007
/s/ SANFORD R. ROBERTSON **Sanford R. Robertson**	Director	February 23, 2007

EXHIBIT INDEX

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(6) Incorporated by reference from Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000.
(7) Incorporated by reference from exhibits to our report on Form 10-K for the period ending December 31, 2005.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-115362 and 333-127882) of Pain Therapeutics, Inc. and in the related Prospectuses, and in the Registration Statements (Form S-8 Nos. 333-134364, 333-115361, 333-105138, 333-68118, and 333-41660) pertaining to the 1998 Stock Plan of Pain Therapeutics, Inc. of our reports dated February 10, 2007, with respect to the financial statements of Pain Therapeutics, Inc., Pain Therapeutics, Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Pain Therapeutics, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2006.

Ernst & Young LLP

Palo Alto, California
February 20, 2007

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Remi Barbier, certify that:

1. I have reviewed this Report on Form 10-K of Pain Therapeutics, 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(s) 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(s) 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.

/s/ REMI BARBIER

Remi Barbier,
Chairman of the Board of Directors,
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 21, 2007

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter S. Roddy, certify that:

1. I have reviewed this Report on Form 10-K of Pain Therapeutics, 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(s) 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(s) 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.

/s/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: February 21, 2007

EXHIBIT 32.1

CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND THE CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Remi Barbier, Chairman of the Board of Directors, President and Chief Executive Officer and Peter S. Roddy, Vice President and Chief Financial Officer of Pain Therapeutics, Inc. (the "Company"), hereby certify that to the best of our knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and to which this certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, and
2. The information contained in this Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 21, 2007

/s/ REMI BARBIER

Remi Barbier,
Chairman of the Board of Directors,
President and Chief Executive Officer

/s/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer