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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT UNDER SECTION 13 or 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2003

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $177,038,020 computed by reference to the last sales price of $6.45 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, 2003.

The number of shares outstanding of the Registrant's common stock on February 19, 2004 was 35,392,434 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2004 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. It is the Company's intent 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 future operating losses and anticipated operating and capital expenditures; statements about the potential benefits of our drug candidates; statements relating to the timing, substance, sufficiency of materials required for or anticipated results of our clinical development of our drug candidates; statements about the size of the potential market for our products, statements about upcoming announcements by the Company; statements relating to the utility of our intellectual property; statements about expected future sources of revenue and capital; statements about potential competitors or products; statements about future market acceptance of our drug candidates; statements about expenses increasing substantially or fluctuating; statements about future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions; statements about anticipated hiring; statements about the sufficiency of our current resources to fund our operations over the next twelve months; statements about increasing cash requirements; statements about fluctuations in our operating results; statements about potential future dividends and statements about development of our internal systems and infrastructure.

Such forward-looking statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's 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), the uncertainty of patent protection for the Company's intellectual property or trade secrets, potential infringement of the intellectual property rights or trade secrets of third parties and the Company's 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. Our drugs target severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or irritable bowel syndrome. We have three proprietary drug candidates in clinical development: Oxytrex™, Remoxy™ and PTI-901. Our two most advanced drugs, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom. We believe the target market for our three drug candidates exceeds $3 billion per year. We currently retain all commercial rights to our drug candidates. We incorporated in Delaware in May 1998.

Our Drug Candidates

Our pipeline consists of three proprietary drug candidates: Oxytrex, Remoxy and PTI-901. Oxytrex and PTI-901 are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom.

Oxytrex

Our lead candidate is a novel oral opioid called Oxytrex. Oxytrex is a small molecule drug that is currently in a Phase III clinical program. We are developing Oxytrex to treat severe chronic pain, such as low back, osteoarthritic pain or cancer pain.

If the Food and Drug Administration, or FDA, approves Oxytrex, we believe it could be an effective substitute for oxycodone. Oxycodone is widely used today to treat severe chronic pain. Sales of oxycodone exceed $1.5 billion a year. We own all commercial rights to Oxytrex.

Previous clinical results have shown that Oxytrex provides enhanced pain relief and prolonged pain relief. In a previously announced Phase II study with 350 patients suffering from severe osteoarthritic pain, Oxytrex reduced patients' pain scores by over 40% ($p<0.001$ vs. placebo and $p=0.006$ vs. oxycodone) over a 21-day treatment period. By comparison, oxycodone reduced patients' pain scores by 24%. Published pre-clinical results also demonstrate that the technology used in Oxytrex results in a lack of opioid addiction, tolerance, physical dependence or withdrawal symptoms in animals.

The FDA guidelines recommend that we demonstrate the efficacy of Oxytrex in more than one clinical model of pain. We plan to study Oxytrex in at least two Phase III efficacy studies.

In June 2003, we announced the initiation of our first Phase III efficacy study. This randomized, double-blinded study compares the analgesic efficacy of Oxytrex against placebo and oxycodone over a three-month treatment period in up to 700 patients with severe chronic low back pain.

In the first quarter of 2004, we expect to initiate a second Phase III clinical study of Oxytrex. This randomized, double-blinded study will compare the analgesic efficacy of Oxytrex against placebo and oxycodone over a three-month treatment period in up to 700 patients with severe chronic osteoarthritic pain.

Oxytrex is formulated with two active drug ingredients: oxycodone and low-dose naltrexone. We believe we have produced sufficient clinical materials necessary to complete two Phase III trials of Oxytrex. We rely on a limited number of third-party manufacturers to manufacture, fill, label, ship or store Oxytrex.

Remoxy

In November 2003, we announced our second novel drug candidate, which we named Remoxy. Remoxy is an abuse-deterrent, long-acting version of oxycodone. Sales of oxycodone exceed $1.5 billion a year. We own all commercial rights to Remoxy.

Oxycodone is a strong narcotic painkiller that is widely used today to treat patients suffering from severe chronic pain. However, oxycodone has an abuse potential similar to morphine. The U.S. Drug Enforcement Agency, or DEA, and the national media have linked illicit oxycodone use to widespread patterns of drug abuse, addiction, diversion and drug overdose. Oxycodone is also the active ingredient in OxyContin©, a branded controlled-release narcotic painkiller. Remoxy's novel capsule formulation is specifically designed to foil abusers who attempt to tamper with the drug in order to induce a powerful euphoric high. Given a choice between prescribing abuse-resistant Remoxy or more easily abusable forms of oxycodone, we believe physicians will choose a less abusable alternative, such as Remoxy.

In November 2003, we filed an Investigational New Drug Application for Remoxy with the FDA. The FDA has requested additional information on certain excipients used in formulations of Remoxy. We are responding to the FDA's requests for additional data prior to initiating any clinical studies in the United States.

In January 2004, we initiated a Phase I clinical program of Remoxy in the United Kingdom. Our phase I program is designed to assess the pharmacokinetics and pharmacological profile of several different formulations of Remoxy against placebo and active drug in healthy volunteers.

Remoxy is formulated with Durect Corporation's SABER™ technology under a joint development and license agreement. Under the terms of our license agreement with Durect, we have exclusive worldwide rights to develop and to commercialize Remoxy and certain other opioid drugs formulated with Durect's SABER

technology. We plan to formulate and scale-up a wide range of dosage forms of Remoxy. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. We will also pay Durect royalties on related drug sales.

We believe we can produce sufficient clinical materials necessary to complete our Phase I trials of Remoxy. We rely on Durect Corporation and a limited number of third-party manufacturers to formulate, manufacture, fill, label, ship or store Remoxy.

PTI-901

Our third drug candidate is called PTI-901 and treats Irritable Bowel Syndrome, or IBS. PTI-901 is a proprietary drug candidate that consists of an oral low-dose opioid antagonist. If approved by the FDA to treat men and women with IBS, we believe PTI-901 will target a market in excess of $1 billion per year. We own all commercial rights to PTI-901.

Chronic IBS is a painful abdominal disorder that leads to major changes in bowel habits. IBS causes some patients to have constipation, diarrhea or in some cases both. The causes of IBS are not known, and as yet there is no cure. People with chronic IBS may be unable to attend social events, hold a job, or travel away from home. Over 10 percent of the U.S. population suffers from IBS. For unknown reasons, IBS predominantly affects women.

There are no FDA-approved drugs to treat men with IBS. There are two FDA-approved drugs to treat women with IBS: Lotronex® (GlaxoSmithKline) and Zelnorm® (Novartis). The FDA approved Lotronex® in February 2000 for use in female patients with diarrhea-predominant IBS. The FDA approved Zelnorm® in July 2002 for short-term use by female patients who have constipation-predominant IBS.

We believe PTI-901 represents a novel approach to treat patients with IBS. We believe an appropriate dose of PTI-901 modulates aberrant neuronal communication within the gut, thus restoring proper bowel function and relieving pain in IBS patients.

Results from a 50-patient pilot study with PTI-901 in men and women were announced in May 2003 and presented at the American College of Gastroenterology meeting in October 2003. In this open-label study, patients with IBS reported a 76% response rate to PTI-901. This response rate was observed in both men and women and occurred without drug-related safety issues.

In November 2003, we announced the initiation of a Phase III program with PTI-901. The Phase III program consists of two clinical studies that are identical in all respects, except for gender. One study will enroll 600 women and the other will enroll 600 men, all of whom have been diagnosed with chronic IBS by a gastroenterologist according to clinically accepted criteria. Each Phase III study is randomized, double-blinded and will assess the clinical effect of PTI-901 against placebo during a three-month treatment period.

We believe we have produced sufficient clinical materials necessary to complete two Phase III trials with PTI-901. We rely on a limited number of third-party manufacturers to manufacture, fill, label, ship and store PTI-901.

Strategy

Our commercial goal is to build a franchise in pain management by developing novel drugs that target severe, chronic pain such as pain associated with advanced osteoarthritis, low-back pain or IBS. We intend to

achieve this goal by developing proprietary drugs that are more effective or safer than drugs used in the clinic today. Our strategy includes:

Focusing on Clinical Development and Late 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.

Retaining Significant Rights to Our Drugs. We currently retain worldwide commercialization rights to all of our technology and drug candidates in all markets and indications. In general, we intend to independently develop our drug candidates through late-stage clinical trials. As a result, we expect to capture a greater percentage of the profits from drug sales than we would if we outlicensed our drug candidates earlier in the development process. In market segments that require large or specialized sales forces, such as the market for oxycodone products, we may seek sales and marketing alliances with third parties.

Outsourcing Key Functions. We intend to continue to outsource pre-clinical studies, clinical trials and formulation and manufacturing activities. We believe outsourcing permits significant timesavings 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 pre-clinical stage opportunities in therapeutic areas that are related to our core expertise in drug development. We believe this strategy could diversify some of the risks inherent in drug development and increase our probability of commercial success.

Our Science and Technology

Our science was developed at Albert Einstein College of Medicine. It is well known that opioid painkillers produce their pain relieving effect by inhibiting the transmission of pain signals in certain nerve cells in the central nervous system. This inhibition of pain is achieved by inhibiting nerve cells that have opioid receptors on their membranes, via an inhibitory signaling pathway linked to the receptor. Scientists at Albert Einstein College of Medicine, however, have published results suggesting that opioid painkillers also activate an excitatory signaling pathway linked to opioid receptors, thereby stimulating the transmission of pain. This excitatory pathway counteracts pain inhibition and is believed to be a major cause of adverse side effects associated with opioid use, including the development of tolerance and addiction.

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 known as 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 coadministration of low-dose naltrexone, an opioid antagonist. We believe low-dose naltrexone blocks the excitatory pathway, thus minimizing tolerance, physical dependence and addiction. In addition, recent pre-clinical 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 low-dose opioid antagonist to opioid painkiller depend on their specific pharmacology and the mode of administration. Published pre-clinical and clinical dose response studies provide guidance in formulating optimal ratios of low-dose opioid antagonist to opioid painkiller 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 extremely 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 a very low dose, however, studies indicate that this effect is different: a very 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 opioid agonists with low doses of opioid antagonists.

PTI-901 is a proprietary drug candidate that consists of oral low-dose opioid antagonist. We use PTI-901 to treat IBS. The precise causes of IBS are unknown. The two FDA-approved drugs attempt to slow down the gastrointestinal tract for diarrhea-predominant IBS in the case of Lotronex®, or speed up the gastrointestinal tract for constipation-predominant IBS in the case of Zelnorm®.

Scientific evidence suggests IBS is a disorder of the nervous system. In this scenario, patients with IBS suffer from aberrant neuronal communication within the gut due to an imbalance of opioid peptides in the gut. Since opioid peptides contribute to the proper function of the gut, an imbalance results in a broad range of gastrointestinal problems, including abdominal pain, diarrhea or constipation. We believe PTI-901 modulates aberrant neuronal communication within the gut, thus restoring proper bowel function and relieving pain in IBS patients.

Company sponsored research and development expenditures were $11.7 million, $11.4 million, and $18.9 million in 2001, 2002 and 2003, respectively.

License from Albert Einstein College of Medicine

In May 1998, we 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. Our license rights terminate upon the expiration of the patents used to protect the technology, which are scheduled to expire no earlier than September 2012. Pursuant to the terms of the license, we paid Albert Einstein College of Medicine a one-time licensing fee and are required to pay 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. government’s license. If the U.S. 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. 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. If our competitors are able to successfully challenge the validity of our patent rights, based on the existence of prior art or otherwise, they would 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.

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 a low-dose opioid antagonist, either alone or in combination with an opioid painkiller, for pain management and opioid and other addiction;
- the use of a low-dose opioid antagonist to render opioid-based anesthesia products, such as fentanyl or fentanyl analogs, more effective;
- the clinical use of a low-dose opioid antagonist for the treatment of IBS; and
- the clinical use of a low-dose opioid antagonist, either alone or in combination with any opioid painkiller, for the treatment of other conditions.

In January 2003, the U.S. Patent and Trademark Office, or the PTO, disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. In each of the reexaminations, the PTO issued a first/initial office action and responses to those office actions were filed. In certain of the reexaminations, the PTO issued second/final office actions in which the PTO affirmed the patentability of certain claims related to uses of our drugs under development while maintaining rejections with respect to other claims, and responses to those office actions have been filed. A reexamination certificate has been issued in one of the proceedings confirming the patentability of the claims, and a notice of intent to issue a reexamination certificate confirming the patentability of the claims has been issued in another of the proceedings. We cannot provide any assurance as to the outcome of the remaining ongoing PTO proceedings. An adverse outcome of the reexamination process could result in loss of claims of these patents that pertain to certain drugs we currently have under development.

Formulation Agreement

In December 2002, we entered into an exclusive, worldwide licensing agreement with Durect Corporation. In November 2003, we disclosed that we were developing Remoxy. Remoxy is an abuse-deterrent, long-acting version of oxycodone. Remoxy is formulated with Durect's SABER technology under a joint development and license agreement entered into between us and Durect. SABER is a patented technology that forms the basis for a number of oral gel-cap drug candidates, including Remoxy. We plan to complete formulation and scale-up of higher dosage forms of Remoxy to use in late stage clinical trials and commercialization. Under the terms of the license agreement between us and Durect, we have exclusive worldwide rights to develop and to commercialize Remoxy and certain other opioid drugs formulated with Durect's SABER technology. We control all of Remoxy's pre-clinical, clinical, commercial manufacturing and sales/marketing activities. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. We will also pay Durect royalties on related drug sales. We can terminate the agreement without cause and Durect can terminate the agreement only if we do not cure defaults in our obligations under the agreement within a certain period of time.

Manufacturing

We have no manufacturing facilities. 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 continue to outsource formulation, manufacturing and related activities.

We believe we have produced sufficient clinical materials to complete two Phase III clinical trials of Oxytrex and two Phase III clinical trials of PTI-901. We rely on a limited number of third-party manufacturers to formulate, manufacture, fill, label, ship or store all of our drug candidates.

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 pre-clinical 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 treat Oxytrex and PTI-901 as new drugs and require the filing of a New Drug Application, or NDA, and approval by the FDA prior to commercialization in the United States.

The Drug Approval Process

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

- pre-clinical studies;
- submission to the FDA of an Investigational New Drug application, or 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.

Pre-clinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practice. We submitted the results of pre-clinical 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 pre-clinical 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 studies 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 studies will be conducted, must review and approve the IND. The IRB also continues to monitor the study. 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 cannot commence or recommence in the United States 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 tests typically study a drug's safety profile, and may include the safe dosage range. Phase I clinical studies 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 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 studies 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 trials are designed to produce clinical information about how our drugs perform compared to placebo or compared to existing opioid drugs where appropriate. We plan to test Oxytrex in several clinical settings of pain in order to support a broad approval by the FDA for use of the drug for the relief of moderate to severe pain. FDA guidelines recommend that we demonstrate Oxytrex's efficacy in more than one clinical presentation of pain, such as post-operative pain, arthritis pain or generalized lower back pain. Because clinical models differ in their sensitivity to detect pain, we expect to complete studies in multiple clinical models of pain.

We have designed most Phase II and Phase III clinical trials to date as randomized, double-blind, placebo- controlled, dose-ranging studies. A randomized study is one in which patients are randomly assigned to the various study treatment arms. A double-blind study is one in which the patient, the physician and the Company's study monitor are unaware if the patient is receiving placebo or study drug in order to preserve the integrity of the trial and reduce bias. A placebo-controlled study 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 post-operative pain, low-back pain or 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 may not successfully complete Phase I, Phase II or Phase III testing 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 a 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 365 days in which to review the NDA and respond to the applicant. The review process is typically extended for significant amounts of time by FDA 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 FDA 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 studies, to evaluate long-term effects of the approved drug.

Other Regulatory Requirements

The FDA mandates that drugs be manufactured in conformity with current GMPs. 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, Janssen Pharmaceutica, Abbott Laboratories, Cephalon, Endo 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. Companies that sell drugs to treat IBS include Novartis and GlaxoSmithKline. We believe that a number of other companies are developing new drug candidates to treat IBS.

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

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

Employees

As of December 31, 2003, we had approximately 30 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://paintrials.com, by contacting the Investor Relations Department at our corporate offices by calling 650-824-8200 or by sending an e-mail message.

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 2003.

PART II

Item 5. ***Market for Registrant's Common Equity and Related Stockholder Matters***

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 2003:		
First Quarter	$ 3.90	$1.68
Second Quarter	$ 8.11	$1.68
Third Quarter	$ 8.95	$5.90
Fourth Quarter	$ 7.71	$4.44
Fiscal 2002:		
First Quarter	$10.61	$7.46
Second Quarter	$12.12	$6.10
Third Quarter	$10.00	$3.86
Fourth Quarter	$ 4.76	$2.00

We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and have not and do not anticipate paying any cash dividends in the foreseeable future. As of February 19, 2004, there were 75 holders of record of our common stock. In 2003, we issued 7,730,500 shares of common stock at $6.50 per share in a follow-on public offering and received approximately $46.7 million in net proceeds after deducting underwriting discounts and related expenses. From the time of receipt through December 31, 2003, the net proceeds from our public offerings were used for research and development activities, capital expenditures, working capital and other general corporate purposes. As of December 31, 2003, $77.4 million of the proceeds from our public offerings remained available.

The following table summarizes the securities authorized for issuance under our equity compensation plans as of December 31, 2003.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders	4,368,509	$ 6.53	2,290,114
Equity compensation plans not approved by stockholders	—	—	—
Total	4,368,509	$ 6.53	2,290,114

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

	Years ended December 31,					May 4, 1998 (inception) through December 31, 2003
	2003	2002	2001	2000	1999	
Statement of operations data:						
Research and development expense	$ 18,913	$ 11,396	$ 11,668	$ 12,596	$ 3,967	$ 58,840
General and administrative expense	3,338	5,523	5,647	7,710	693	23,034
Total operating expenses	22,251	16,919	17,315	20,306	4,660	81,874
Operating loss	(22,251)	(16,919)	(17,315)	(20,306)	(4,660)	(81,874)
Interest income	634	994	2,978	2,826	160	7,626
Net loss	(21,617)	(15,925)	(14,337)	(17,480)	(4,500)	(74,248)
Return to series C preferred stockholders for beneficial conversion feature	—	—	—	(14,231)	—	(14,231)
Loss available to common stockholders	$ (21,617)	$ (15,925)	$ (14,337)	$ (31,711)	$ (4,500)	$ (88,479)
Basic and diluted loss per common share	$ (0.73)	$ (0.59)	$ (0.57)	$ (2.33)	$ (1.35)	
Weighted average shares used in computing basic and diluted loss per common share	29,483	27,039	25,332	13,635	3,345	

	2003	2002	2001	2000	1999
Balance sheet data:					
Cash and cash equivalents	$ 12,027	$ 50,091	$ 65,274	$ 78,927	$ 9,340
Marketable securities	65,402	55	—	—	—
Working capital	74,799	48,146	63,195	77,320	9,096
Total assets	80,513	53,325	68,136	81,147	9,441
Total liabilities	3,951	3,101	2,519	2,452	301
Series B redeemable convertible preferred stock	—	—	—	—	9,704
Series A convertible preferred stock	—	—	—	—	3
Stockholders' equity (deficit)	76,562	50,224	65,616	78,695	(563)

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 research company that develops novel drugs. Our drugs target severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or IBS. We have three proprietary drug candidates in clinical development: Oxytrex, Remoxy and PTI-901. Our two most advanced drugs, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom. We believe the target market for our three drug candidates exceeds $3 billion per year. We currently retain all commercial rights to our drug candidates.

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception on May 4, 1998 through December 31, 2003, we have incurred an accumulated deficit of

approximately $74.2 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 incur significant additional operating losses 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, including the Phase III trials of Oxytrex and PTI-901 and formulation activities and Phase I trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates and drugs;
- 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.

Recent Developments

Oxytrex and PTI-901 are in Phase III clinical trials. Remoxy is in Phase I clinical trials. In 2003, we:

- completed a 21-day Phase II clinical trial of Oxytrex in 350 patients with severe osteoarthritic pain;
- announced that the 350-patient Phase II study met its primary and secondary efficacy endpoints, showing a statistically significant reduction in chronic pain and in functional scores for patients on Oxytrex;
- initiated a 700-patient Phase III clinical trial of Oxytrex to demonstrate its safety and efficacy in patients with severe chronic low back pain;
- announced clinical results of a 50-patient pilot study using PTI-901, a proprietary new drug we are developing to treat IBS in both men and women;
- presented the final clinical results of the pilot study using PTI-901 at the Scientific Meeting of the American College of Gastroenterology, disclosing that PTI-901 significantly improved symptoms commonly associated with IBS without drug-related safety issues;
- initiated a 1,200-patient Phase III clinical program of PTI-901 in both men and women; and,
- announced a new drug candidate, Remoxy.

Critical Accounting Policies

The preparation of our financial statements in accordance with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and interest income in our financial statements and accompanying notes. On an on-going basis, we evaluate our estimates, including those 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 trial completes enrollment. 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 trial.
- *Stock based compensation.* We use the intrinsic-value method of accounting for stock based awards granted to employees in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Accordingly, we recognize compensation expense in our financial statements in connection with stock options granted to employees with exercise prices less than fair value at the time the stock option is granted. We record stock based compensation expense for non-employees at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123, or SFAS 123, and Emerging Issues Task Force No. 96-18, or EITF 96-18. The fair value of options granted to non-employees is estimated using a Black-Scholes option valuation model. The model considers a number of factors, including the market price and volatility of our common stock at the date of measurement. We periodically re-measure the compensation expense for options granted to non-employees as the underlying options vest. The compensation expense related to all grants is being amortized using the graded vesting method, in accordance with SFAS 123, EITF 96-18 and FASB Interpretation No. 28, over the vesting period of each respective stock option, generally four years. The graded vesting method results in expensing approximately 57% of the total award in year one, 26% in year two, 13% in year three and 4% in year four.

Results of Operations

Years Ended December 31, 2003 and 2002

Research and Development

Research and development expense consists primarily of drug development work associated with our drug candidates, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs and salaries and other personnel related expenses. Research and development expense increased to $18.9 million from $11.4 million in the years ended December 31, 2003 and 2002, respectively. The $7.5 million increase in expense was primarily due to the development costs related to our new drug candidate Remoxy as well as for the ongoing development and Phase III programs for Oxytrex and PTI-901.

We expect research and development expenses to increase significantly over the next several years as we expand our development efforts and as our drug candidates progress through various stages of clinical trials, including the Phase III trials of Oxytrex and PTI-901 as well as the continued development and clinical studies of

Remoxy. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and studies.

General and Administrative

General and administrative expense consists primarily of compensation and other general corporate expenses as well as non-cash stock based compensation. General and administrative expense decreased to $3.3 from $5.5 million for the year ended December 31, 2003 and 2002, respectively. The decrease in general and administrative expense resulted primarily from lower non-cash equity related expense as well as a reclassification of certain occupancy and other expenses to research and development.

Interest Income

Interest income decreased to $0.6 million from $1.0 million for the years ended December 31, 2003 and 2002, respectively. The decrease in interest income is primarily the result of lower average balances of cash and cash equivalents and marketable securities as well as lower returns on the investment of our cash and cash equivalents and marketable securities.

Years Ended December 31, 2002 and 2001

Research and Development

Research and development expense was $11.4 million for the year ended December 31, 2002 compared to $11.7 million in the year ended December 31, 2001. The $0.3 million decrease from year-to-year was primarily due to a decrease in non-cash stock based compensation. At December 31, 2002 our research and development activities were primarily related to Oxytrex.

General and Administrative

General and administrative expenses were $5.5 million for the year ended December 31, 2002 compared to $5.6 million for the year ended December 31, 2001. General and administrative expense consists primarily of compensation, facilities expenses and other general corporate expenses as well as non-cash stock based compensation. The year-to-year decrease of $0.1 million was primarily due to a decrease in non-cash stock based compensation, partially offset by increases in depreciation and general corporate expenses.

Interest Income

Interest income decreased to $1.0 million for the year ended December 31, 2002 from $3.0 million for the year ended December 31, 2001. This decrease resulted from the lower average balances of cash and cash equivalents and to a lesser extent from the decline in interest rates during 2002.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private securities offerings. We intend to continue to use the proceeds from these offerings to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2003, cash, cash equivalents and marketable securities were $77.4 million. During 2003, we issued 7,730,500 shares of common stock at $6.50 per share in a follow-on public offering and received approximately $46.7 million in net proceeds, after deducting underwriting discounts and related expenses.

Net cash used in operating activities was $20.5 million for the year ended December 31, 2003 compared to $15.6 million in 2002 and $12.7 million in 2001. Cash used in operating activities related primarily to the funding of operating losses.

Our investing activities to purchase property, equipment and leasehold improvements used cash of $26,000, $7,000 and $1.3 million in the years ended December 31, 2003, 2002 and 2001, respectively. Other investing activities in 2003 consisted primarily of the purchase and sale of marketable securities. We expect to continue to invest in our infrastructure to support our operations. At December 31, 2003, our investments consist of cash and cash equivalents as well as marketable securities that are held as short-term, available-for-sale securities.

Our financing activities provided cash of $47.8 million, $0.3 million and $0.1 million in the years ended December 31, 2003, 2002 and 2001, respectively. Financing activities in the 2003 period consisted primarily of the proceeds of $46.7 million from our follow-on public offering in September 2003 and $1.0 million from exercise of warrants and stock options from our stock plans. In the years ended December 31, 2002 and 2001, cash provided by financing activities was primarily from the exercise of stock options from our stock plans.

We lease approximately 10,500 square feet of general office space. In addition to office space we also lease equipment pursuant to operating leases. Our leases expire at various dates through 2010. Under the terms of all of our leases, future minimum lease payments are as follows: (in thousands).

	2004	2005	2006	2007	2008	2009 and Thereafter	Total
Future minimum lease payments	$ 183	$ 187	$ 191	$ 187	$ 196	$ 366	$ 1,310

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. These agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. None of these potential future payments are non-cancelable as of December 31, 2003.

Since our inception we have incurred a cumulative deficit of approximately $74.2 million, including a net loss of $21.6 million in 2003, and we expect to incur significant additional operating losses for the next several years. Since inception we have used $58.7 million of cash in operating activities. We expect our cash requirements to increase 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 drugs; 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. The amount and timing of cash requirements will depend on regulatory and market acceptance of our products 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 twelve 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.

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.

Risks Relating to our Financial Position and Need for Financing

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

We were founded in May 1998 and are in the development stage. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and undertaking

preclinical studies and clinical trials of our drug candidates. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture commercial-scale product 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.

We have incurred net losses each year since our inception. As a result of ongoing operating losses, we had an accumulated deficit of $74.2 million as of December 31, 2003. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. 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, including the Phase III trials of Oxytrex and PTI-901 and formulation activities and Phase I trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drugs;
- 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 and commercialize our products, we will not be able to generate such revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock.

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

We have funded all of our operations and capital expenditures with the proceeds from public and private stock offerings. We expect that our current cash, cash equivalent and marketable securities on hand will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months. However, we may need to raise additional funds sooner 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 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 obtain FDA approval of our drug candidates, and we could be forced to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts and forego attractive business opportunities.

Clinical and Regulatory Risks

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drugs, 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 testing. 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 testing, in which case we would have to expend additional time and resources. 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 will:

- delay commercialization of, and product revenues from, our drug candidates; and
- diminish the competitive advantages that we may have otherwise enjoyed.

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 of any of our drug candidates we will have fewer saleable products and corresponding lower product revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition.

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

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

In order to obtain FDA approval of any of our drug candidates, we must submit to the FDA a NDA that demonstrates that the drug candidate is 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. Two of our drug candidates, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials.

Our Phase III trials may not demonstrate the safety or efficacy of our drug candidates. Success in pre-clinical testing 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 pre-clinical testing. FDA guidelines recommend that the efficacy of new painkillers be demonstrated in more than one clinical model of pain. Even if the results of our Phase III trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical and clinical studies before we can submit NDAs or obtain FDA approvals for our drug candidates.

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

Even if our clinical trials are completed as planned, their results may not support our product 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 are unable to satisfy the FDA's request for additional information on Remoxy, we will not be allowed to conduct clinical testing of this product in the United States.

In November 2003, we filed an IND for Remoxy with the FDA. The FDA responded to our IND with a request for additional information on certain excipients used in formulations of Remoxy. We are not able to conduct human clinical studies with Remoxy in the United States until the FDA notifies us that their request for additional information is satisfied. If we are unable to conduct human clinical studies of Remoxy in the United States, we may determine that the commercial opportunity for Remoxy in certain dosage forms is too limited to warrant further investment.

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. 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 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 trial could increase.

The DEA limits the availability of the active ingredients in our current drug candidates and, as a result, our quota may not be sufficient to complete clinical trials, 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 or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of 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 directly apply to our products.

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

Conducting clinical trials of our drug candidates exposes 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. We may not be able to obtain such insurance at a reasonable cost, if at all. If our agreements with any future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

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;
- 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, if any.

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our product 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 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, our product revenues could be disappointing.

We currently have no sales, marketing or distribution capabilities. 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 co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the significant number of recent business combinations among pharmaceutical companies has resulted in a reduced number of potential future collaborators. Even if we are able to identify one or more acceptable 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 to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products independently. If we enter into any collaborative arrangements, our product 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, further 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 opioid painkillers already approved or in development. 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. 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. 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 them could be limited.

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, Albert Einstein College of Medicine or our other collaborators fail to file, prosecute 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. In January 2003, PTO disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. In each of the reexaminations, the PTO issued a first/initial office action and responses to those office actions were filed. In certain of the reexaminations, the PTO issued second/final office actions in which the PTO affirmed the patentability of certain claims related to uses of our drugs under development while maintaining rejections with respect to other claims, and responses to those office actions have been filed. A reexamination certificate has been issued in one of the proceedings confirming the patentability of the claims, and a notice of intent to issue a reexamination certificate confirming the patentability of the claims has been issued in another of the proceedings. We cannot provide any assurance as to the outcome of the remaining ongoing PTO proceedings. An adverse outcome of the reexamination process 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.

We intend to file additional patent applications relating to our technology, products and processes. We may direct Albert Einstein College of Medicine or 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 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 will be critical to our success.

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

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 process for 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. 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

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, 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 product 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 third-party 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 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 good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

If we cannot formulate and scale-up a wide range of dosage forms of Remoxy, we 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 dosage forms of Remoxy. We may not be able to successfully complete our formulation or scale-up activities or we may determine that the commercial opportunity for Remoxy in certain dosage forms is too limited to warrant further investment.

Risks Relating to our Collaboration Agreements

If 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.

We depend on independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside 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.

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 will be less than expected.

Our collaborative agreements may not succeed or may give rise to disputes over intellectual property 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 agreements are generally complex and contain provisions that could give rise to legal disputes. Such disputes can delay 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 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 our preclinical and clinical trials;
- 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 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 such market, 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.

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

The stock market in general, and the NASDAQ National Market 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 and development 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 shareholders (shareholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring shareholder 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 shareholders.

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 and the re-measurement of certain deferred stock 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 operating results may not meet the expectations of securities analysts and investors which 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 the NASDAQ National Market. 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 7A. ***Quantitative and Qualitative Disclosures About Market Risks***

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 would not have a material effect on the fair value of our available-for-sale securities at December 31, 2003. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments 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 instrument. As of December 31, 2003, 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.

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

INDEX TO FINANCIAL STATEMENTS

Report of Ernst & Young LLP, Independent Auditors

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited the accompanying balance sheet of Pain Therapeutics, Inc. (a development stage enterprise) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended and for the period from May 4, 1998 (inception) through December 31, 2003. The financial for the period from May 4, 1998 (inception) through December 31, 2001 (not separately presented herein), were audited by other auditors whose report dated March 1, 2002 expressed an unqualified opinion on those statements. The financial statements for the period from May 4, 1998 (inception) through December 31, 2001 (not separately presented herein) include a net loss of $50,937,327. Our opinion on the statements of operation, stockholders' equity (deficit) and cash flows for the period from May 4, 1998 (inception) through December 31, 2003, insofar as it relates to amounts for periods prior to January 1, 2002, is based solely on the report of other auditors. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of Pain Therapeutics, Inc. (a development stage enterprise) as of December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the years then ended and for the period from May 4, 1998 (inception) through December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 16, 2004

Independent Auditors' Report

The Board of Directors and Stockholders
Pain Therapeutics, Inc.:

We have audited the accompanying statements of operations, stockholders' equity (deficit), and cash flows of Pain Therapeutics, Inc. for the year ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects the results of operations and the cash flows of Pain Therapeutics, Inc. for the year ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

San Francisco, California
March 1, 2002

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
BALANCE SHEETS
(in thousands except share and per share data)

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,027	$ 50,091
Marketable securities	65,402	55
Prepaid expenses	1,321	1,101
Total current assets	78,750	51,247
Property and equipment, net	1,688	2,003
Other assets	75	75
Total assets	$ 80,513	$ 53,325
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,441	$ 2,648
Accrued compensation and benefits	369	273
Other accrued liabilities	141	180
Total liabilities	3,951	3,101
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; 35,381,309 and 27,200,508 shares issued and outstanding in 2003 and 2002, respectively	35	27
Additional paid-in-capital	150,732	103,254
Deferred compensation	(7)	(304)
Notes receivable from stockholders	—	(122)
Accumulated other comprehensive income	50	—
Deficit accumulated during the development stage	(74,248)	(52,631)
Total stockholders' equity	76,562	50,224
Total liabilities and stockholders' equity	$ 80,513	$ 53,325

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF OPERATIONS
(in thousands except per share data)

	Years Ended December 31,			May 4, 1998 (Inception) Through December 31, 2003
	2003	2002	2001	
Operating expenses:				
Research and development	$ 18,913	$ 11,396	$ 11,668	$ 58,840
General and administrative	3,338	5,523	5,647	23,034
Total operating expenses	22,251	16,919	17,315	81,874
Operating loss	(22,251)	(16,919)	(17,315)	(81,874)
Other income:				
Interest income	634	994	2,978	7,626
Net loss	(21,617)	(15,925)	(14,337)	(74,248)
Return to series C preferred stockholders for beneficial conversion feature	—	—	—	(14,231)
Loss available to common stockholders	$ (21,617)	$ (15,925)	$ (14,337)	$ (88,479)
Basic and diluted loss per common share	$ (0.73)	$ (0.59)	$ (0.57)	
Weighted-average shares used in computing basic and diluted loss per common share	29,483	27,039	25,332	

Included in research and development and general and administrative expenses are stock-based compensation expenses of $139, $210, and $1,198 for the years ended December 31, 2003, 2002 and 2001, respectively, and $11,929 for the period from May 4, 1998 (inception) through December 31, 2003.

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For the period May 4, 1998 (inception) through December 31, 2003
(in thousands except share data)

	Common and Preferred stock		Additional paid-in capital	Deferred compensation	Notes receivable for stock	Accumulated other comprehensive income	Deficit accumulated during development stage	Stockholders' equity (deficit)
	Shares	Par value						
Balance at May 4, 1998 (inception)	—	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Common stock issued in June 1998 at $0.001 per share	8,500,000	9	—	—	—	—	—	9
Series A convertible preferred stock issued between August 1998 and October 1998 at $1.00 per share	2,659,489	3	2,637	—	—	—	—	2,640
Common stock issued in September 1998 at $0.10 per share for notes receivable	350,000	—	35	—	(35)	—	—	—
Common stock issued in September 1998 at $0.10 for cash	150,000	—	15	—	—	—	—	15
Net loss and comprehensive loss	—	—	—	—	—	—	(389)	(389)
Balance at December 31, 1998	11,659,489	12	2,687	—	(35)	—	(389)	2,275
Common stock issued between April and May 1999 at $0.10 per share for notes receivable	444,000	—	44	—	(44)	—	—	—
Issuance of common stock pursuant to exercise of stock options	1,000	—	—	—	—	—	—	—
Issuance of warrants in connection with lease in August 1999	—	—	34	—	—	—	—	34
Deferred compensation for options issued to employees	—	—	2,284	(2,284)	—	—	—	—
Amortization of employee deferred compensation, net of reversals	—	—	—	188	—	—	—	188
Compensation with respect to non-employee option grants	—	—	1,435	—	—	—	—	1,435
Stockholder notes receivable	—	—	—	—	5	—	—	5
Net loss and comprehensive loss	—	—	—	—	—	—	(4,500)	(4,500)
Balance at December 31, 1999	12,104,489	12	6,484	(2,096)	(74)	—	(4,889)	(563)
Common stock issued pursuant to initial public offering at $12.00 per share, net of issuance costs in July 2000	5,750,000	6	62,933	—	—	—	—	62,939
Common stock issued at $0.20 per share for notes receivable at various times during 2000	245,000	—	49	—	(49)	—	—	—
Issuance of common stock pursuant to exercise of stock options at various times during 2000	184,740	—	42	—	—	—	—	42
Issuance of warrants in connection with series C preferred stock offering in February 1999	—	—	963	—	—	—	—	963
Deferred compensation for options issued to employees	—	—	4,939	(4,939)	—	—	—	—
Amortization of employee deferred compensation, net of reversals	—	—	—	3,618	—	—	—	3,618
Compensation with respect to non-employee option grants	—	—	2,495	—	—	—	—	2,495
Compensation related to stock purchase rights	—	—	2,646	—	—	—	—	2,646
Issuance of common stock related to employee stock purchase plan in November 2000	4,664	—	48	—	—	—	—	48
Stockholder notes receivable	—	—	—	—	50	—	—	50
Conversion of 2,659,489 shares of series A convertible preferred stock to common at $1.00 per share in July 2000	(2,659,489)	(3)	—	—	—	—	—	(3)
	2,659,489	3	—	—	—	—	—	3
Conversion of series B redeemable convertible preferred stock to common at $1.85 per share in July 2000	5,405,405	6	9,698	—	—	—	—	9,704
Conversion of series C redeemable convertible preferred stock to common at $5.00 per share in July 2000	3,044,018	3	14,229	—	—	—	—	14,232
Beneficial conversion feature of series C preferred stock	—	—	14,232	—	—	—	—	14,232
Return to series C preferred shareholders for beneficial conversion feature	—	—	(14,232)	—	—	—	—	(14,232)
Net loss and comprehensive loss	—	—	—	—	—	—	(17,480)	(17,480)
Balance at December 31, 2000	26,738,316	27	104,526	(3,417)	(73)	—	(22,369)	78,694
Issuance of common stock pursuant to exercise of stock options at various times during 2001	78,635	—	50	—	—	—	—	50

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)—(Continued)
For the period May 4, 1998 (inception) through December 31, 2003
(in thousands except share data)

	Common and Preferred stock		Additional paid-in capital	Deferred compensation	Notes receivable for stock	Accumulated other comprehensive income	Deficit accumulated during development stage	Stockholders' equity (deficit)
	Shares	Par value						
Amortization of employee deferred compensation, net of reversals	—	$ —	$ (347)	$ 2,298	$ —	$ —	$ —	$ 1,951
Compensation with respect to non-employee option grants	—	—	(753)	—	—	—	—	(753)
Issuance of common stock related to employee stock purchase plan in May 2001 and November 2001	20,374	—	119	—	—	—	—	119
Stockholder notes receivable	—	—	—	—	(108)	—	—	(108)
Net loss and comprehensive loss	—	—	—	—	—	—	(14,337)	(14,337)
Balance at December 31, 2001	26,837,325	27	103,595	(1,119)	(181)	—	(36,706)	65,616
Issuance of common stock pursuant to exercise of stock options during 2002	351,278	—	140	—	—	—	—	140
Amortization of employee deferred compensation, net of reversals	—	—	(395)	815	—	—	—	420
Compensation with respect to non-employee option grants	—	—	(210)	—	—	—	—	(210)
Repurchase of restricted stock in August 2002	(19,480)	—	(3)	—	—	—	—	(3)
Issuance of common stock related to employee stock purchase plan in May 2002 and November 2002	31,385	—	127	—	—	—	—	127
Stockholder notes receivable	—	—	—	—	59	—	—	59
Net loss and comprehensive loss	—	—	—	—	—	—	(15,925)	(15,925)
Balance at December 31, 2002	27,200,508	27	103,254	(304)	(122)	—	(52,631)	50,224
Issuance of common stock pursuant to exercise of stock options during 2003	272,150	—	227	—	—	—	—	227
Issuance of common stock at $6.50 per share after issuance costs of $3.6 million pursuant to follow-on offering	7,730,500	8	46,650	—	—	—	—	46,658
Issuance of common stock pursuant to exercise of warrants	120,000	—	600	—	—	—	—	600
Amortization of employee deferred compensation, net of reversals	—	—	(406)	297	—	—	—	(109)
Compensation with respect to non-employee option grants	—	—	248	—	—	—	—	248
Issuance of common stock related to employee stock purchase plan in May 2003 and November 2003	58,151	—	159	—	—	—	—	159
Receipt of payment of stockholder notes receivable	—	—	—	—	122	—	—	122
Unrealized gains on investment in marketable securities	—	—	—	—	—	50	—	50
Net loss	—	—	—	—	—	—	(21,617)	(21,617)
Comprehensive loss								(21,567)
Balance at December 31, 2003	35,381,309	$ 35	$ 150,732	$ (7)	$ —	$ 50	$ (74,248)	$ 76,562

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC
(A Development Stage Enterprise)
STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,			May 4, 1998 (Inception) Through December 31, 2003
	2003	2002	2001	
Cash flows from operating activities:				
Net loss	$ (21,617)	$ (15,925)	$ (14,337)	$ (74,248)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	341	349	245	985
Non-cash stock based compensation	139	210	1,198	11,929
Non-cash expense for warrants issued	—	—	—	34
Loss on disposal of property and equipment	—	2	49	54
Changes in operating assets and liabilities:				
Prepaid expenses	(220)	(778)	77	(1,321)
Other assets	—	—	—	(75)
Accounts payable	793	478	(143)	3,441
Accrued compensation and benefits	96	(10)	204	369
Other accrued liabilities	(39)	114	6	141
Net cash used in operating activities	(20,507)	(15,560)	(12,701)	(58,691)
Cash flows from investing activities:				
Purchase of property and equipment	(26)	(7)	(1,342)	(2,727)
Purchase of marketable securities	(68,829)	—	—	(68,829)
Sales and maturities of marketable securities	3,532	62	329	3,477
Net cash provided by (used in) investment activities	(65,323)	55	(1,013)	(68,079)
Cash flows from financing activities:				
Proceeds from issuance of preferred stock, net	—	—	—	27,539
Stock subscription note payments received	122	59	—	236
Proceeds from issuance of common stock, net	47,644	263	61	111,022
Net cash provided by financing activities	47,766	322	61	138,797
Net increase (decrease) in cash and cash equivalents	(38,064)	(15,183)	(13,653)	12,027
Cash and cash equivalents at beginning of period	50,091	65,274	78,927	—
Cash and cash equivalents at end of period	$ 12,027	$ 50,091	$ 65,274	$ 12,027

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

1. Business

We are a biopharmaceutical research company that develops novel drugs. Our drugs target severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or IBS. We have three proprietary drug candidates in clinical development: Oxytrex™, Remoxy™ and PTI-901. Our two most advanced drugs, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom. We currently retain all commercial rights to our drug candidates.

In the course of our development activities, we have sustained operating losses and expect such losses to continue through the next several years. We expect our current cash and cash equivalents will be sufficient to meet our planned working capital and capital expenditure requirements for at least the next twelve months. 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 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.

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.

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 as current assets and carry them at fair value. Unrealized gains and losses are recorded as a separate component of stockholder’s equity as accumulated other comprehensive income. All realized gains and losses on our available-for-sale securities are recognized in results of operations. Our investments are maintained at one financial institution and are governed by our investment policy as approved by the Board of Directors.

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.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
NOTES TO FINANCIAL STATEMENTS—(Continued)

Impairment of Long-Lived Assets

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

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 clinical development of novel painkillers.

Expenses for clinical trials

Research and development expense includes 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 treatment as well as on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the trial completes enrollment. 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 accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the trial.

Stock Based Compensation

We use the intrinsic-value method of accounting for stock based awards granted to employees in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Accordingly, we would recognize compensation expense in our financial statements in connection with stock options granted to employees with exercise prices less than fair value at the time the stock option is granted. We record stock based compensation expense for non-employees at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123, or SFAS 123 and Emerging Issues Task Force No. 96-18, or EITF 96-18. The fair value of options granted to non-employees is estimated using a Black-Scholes option valuation model. The model considers a number of factors, including the market price and volatility of our common stock at the date of measurement. We periodically re-measure the compensation expense for options granted to non-employees as the underlying options vest. The compensation expense related to all grants is being amortized using the graded vesting method, in accordance with SFAS 123, EITF 96-18 and FASB Interpretation No. 28, over the vesting period of each respective stock option, generally four years. The graded vesting method results in expensing approximately 57% of the total award in year one, 26% in year two, 13% in year three and 4% in year four.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
NOTES TO FINANCIAL STATEMENTS—(Continued)

If we had recorded compensation cost of our stock based plans in a manner consistent with the fair value approach of SFAS 123, our loss and adjusted loss per share would have been increased as follows (in thousands, except per share data):

	Years Ended December 31,		
	2003	2002	2001
Loss available to common stockholders as reported	$(21,617)	$(15,925)	$(14,337)
Deduct: Total stock based employee compensation expense determined under the fair valued based method for all awards	(5,153)	(6,452)	(6,207)
Add (deduct): Total stock based employee compensation	(109)	420	1,951
Adjusted loss available to common stockholders	$(26,879)	$(21,957)	$(18,593)
Loss per share basic and diluted as reported	$ (0.73)	$ (0.59)	$ (0.57)
Adjusted loss per share basic and diluted	$ (0.90)	$ (0.81)	$ (0.73)

The weighted average fair value of stock options granted to employees was $5.48 in 2003, $5.09 in 2002, and $6.20 in 2001. The fair value of each option granted to both employees and non-employees was estimated using the Black-Scholes option pricing model with the following assumptions:

	December 31,		
	2003	2002	2001
Employee options:			
Volatility	91% to 100%	89%	95%
Risk-free interest rates	2% to 3%	4%	5%
Expected life of option	5 years	5 years	5 years
Dividend yield	—	—	—
Non-employees:			
Volatility	91% to 100%	89%	95%
Risk-free interest rates	3% to 5%	3% to 4%	5%
Expected life of option	10 years	10 years	10 years
Dividend yield	—	—	—

For the 2000 Employee Stock Purchase Plan, the weighted-average fair value of purchase rights granted was $2.74 per share in 2003, $3.79 in 2002 and $3.29 in 2001 calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Years ended December 31,		
	2003	2002	2001
Volatility	91% to 100%	89%	95%
Risk-free interest rates	1% to 2%	2%	5%
Expected life of options	2 years	2 years	2 years
Dividend yield	—	—	—

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
NOTES TO FINANCIAL STATEMENTS—(Continued)

Loss per Share

Basic loss per share is computed on the basis of the weighted-average number of shares outstanding for the reporting period. The Company has computed its weighted-average shares outstanding for all periods presented excluding those common shares issued and outstanding that remain subject to the Company's repurchase rights. Diluted loss per share is computed on the basis of the weighted-average number of common shares plus dilutive potential common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of convertible preferred stock, common shares issued and outstanding subject to the Company's repurchase rights, outstanding stock options and outstanding warrants. Upon the closing of our initial public offering in July 2000, all of our convertible preferred stock automatically converted into shares of common stock on a one-to-one basis.

In all years presented we have reported a loss and therefore all potential common shares related to potentially dilutive securities have been excluded from the calculation of diluted loss per share because they are anti-dilutive. The following table sets forth the number of potential weighted-average shares of common stock that are in-the-money for the periods indicated but have not been included in the computation of diluted net loss per share because to do so would be anti-dilutive:

	Years Ended December 31,		
	2003	2002	2001
Options to purchase common shares	1,084,553	767,250	2,352,735
Common stock subject to repurchase	—	51,453	1,639,171
Warrants	220,000	220,000	340,000
	1,304,553	1,038,703	4,331,906

Comprehensive Loss

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

	Years Ended December 31,			May 4,1998 (inception) through September 30, 2003
	2003	2002	2001	
Loss available to common Stockholders	($21,617)	($15,925)	($14,337)	($ 88,479)
Other comprehensive income	50	—	—	50
Comprehensive loss	($21,567)	($15,925)	($14,337)	($ 88,429)

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.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
NOTES TO FINANCIAL STATEMENTS—(Continued)

Reclassifications

Certain reclassifications have been made to the prior year financial statements to conform with the presentation in 2003.

Recent Accounting Pronouncements

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," or SFAS 148, which amends SFAS 123. The new standard provides for a voluntary change to the fair value based method of accounting for stock-based employee compensation and outlines alternative methods of transition for implementing a voluntary change. SFAS 148 also requires prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We adopted the disclosure provisions of SFAS No. 148 in our fiscal quarter ending March 31, 2003.

3. Related Party Transactions

The Company had no outstanding loans to related parties as of December 31, 2003. The Company had full recourse loans aggregating $122,000 and $157,000 to a former officer of the Company at December 31, 2002 and 2001, respectively. The notes bear interest at rates ranging from 4.5% to 8.0% and had maturities through January 2004. In November 2002 a former officer of the Company was retained as a consultant, receiving $28,000 for his services in 2002. In October 2001, a former officer of the Company was retained as a consultant, receiving $65,000 for his services in 2001.

4. Research and Collaboration Agreements

Durect Corporation

In December 2002, we entered into an exclusive, worldwide licensing agreement with Durect Corporation. Under this agreement, Durect will formulate certain oral opioids into long-acting formulations. We have exclusive worldwide rights to develop and commercialize these opioid drugs formulated with Durect's proprietary technology. We paid Durect an undisclosed upfront fee and will make milestone payments based upon achievement of certain technical, clinical or regulatory milestones. We will fund certain formulation activities performed by Durect and will pay Durect royalties on sales of products resulting from the agreement.

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

5. Cash and Cash Equivalents and Marketable Securities

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

	Amortized Cost	Unrealized Gains	Unrealized Loss	Estimated Fair Value
December 31, 2003				
Cash and Cash Equivalents:				
Money Market Securities	$ 3,725	$ —	$ —	$ 3,725
Municipal Securities	3,500	—	—	3,500
Corporate Obligations	4,802	—	—	4,802
	12,027	—	—	12,027
Marketable Securities:				
Money Market Securities	7,688	—	—	7,688
U.S. Government and Agency Obligation	22,890	52	—	22,942
Corporate Obligations	34,774	10	(12)	34,772
	$ 77,379	$ 62	$ (12)	$ 77,429
December 31, 2002				
Cash and Cash Equivalents:				
Money Market Securities	$ 50,091	$ —	$ —	$ 50,091
Marketable Securities:				
Money Market Securities	55	—	—	55
	$ 50,146	$ —	$ —	$ 50,146

The gross realized losses and gains on the sale of available-for-sale securities during the years ended December 31, 2003 and 2002 were not material.

The contractual maturities of our marketable securities at December 31, 2003, consisted of the following (in thousands):

Less than one year	$27,849
Greater than one year	37,553
	$65,402

6. Property and Equipment

Property and equipment at December 31, consisted of the following (in thousands):

	2003	2002
Furniture and fixtures	$ 509	$ 492
Computers and software	239	230
Leasehold improvements	1,891	1,891
	2,639	2,613
Accumulated depreciation and amortization	(951)	(610)
Total	$1,688	$2,003

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

7. Redeemable Convertible Preferred Stock

In 1999, we issued 5,405,405 shares of series B redeemable convertible preferred stock at a price of $1.85 per share. In February 2000, we issued 3,044,018 shares of series C redeemable convertible preferred stock at a price of $5.00 per share. Upon the closing of our initial public offering in July 2000, all shares of our then outstanding redeemable convertible preferred stock automatically converted into shares of common stock on a one to one basis.

Return to Series C Preferred Stockholders for Beneficial Conversion Feature

In 2000, we issued 3,044,018 shares of series C redeemable convertible preferred stock for $14.2 million, net of issuance costs. We determined that our series C redeemable convertible preferred stock was issued with a beneficial conversion feature. The value of the beneficial conversion feature was recognized by allocating to additional paid in capital a portion of the preferred stock, limited to the net proceeds received. As our series C redeemable convertible preferred stock was convertible into common stock at the option of the holder, at the issuance date of the preferred stock the entire $14.2 million was allocated to the intrinsic value of that feature and has been treated as a dividend and recognized as a return to the preferred stockholders for purposes of computing basic and diluted loss per share for the period ended December 31, 2000. Upon the closing of our initial public offering in July 2000, all 3,044,018 shares of our series C redeemable convertible preferred stock automatically converted into shares of common stock on a one to one basis.

8. Stockholders' Equity (Deficit)

Initial and Follow-On Public Offering of Common Stock and Conversion of Preferred Stock

In 2000, we completed an initial public offering in which we sold 5,750,000 shares of common stock at $12.00 per share. We received net proceeds from the initial public offering of approximately $62.9 million, after deducting underwriting discounts, commissions and other expenses. Upon the closing of the offering, all 11,108,922 shares of our then outstanding preferred stock automatically converted into common stock on a one to one basis. In 2003, we issued 7,730,500 shares of common stock at $6.50 per share in a follow-on public offering and received approximately $46.7 million, after deducting underwriting discounts and related expenses.

Common Stock

Under the terms of the 1998 Stock Plan, in 1998 through 2002, we granted stock purchase rights and subsequently issued shares of common stock to certain employees and non-employees in exchange for full-recourse promissory notes or cash. As of December 31, 2003 all such previously issued shares were vested and all related promissory notes were paid.

Preferred Stock

The 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.

Warrants

In 1998, we issued a warrant to purchase 150,000 shares of series A convertible preferred stock at an exercise price of $1.00 per share to one of the holders of the series A convertible preferred stock, in consideration

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

of such holder's advance of funds to us prior to the closing of the series A convertible preferred stock financing. The warrant expires on June 5, 2010. Upon the closing of our initial public offering in July 2000, this warrant to purchase 150,000 shares of series A convertible preferred stock was converted to a warrant to purchase the same number of common shares. The shares of common stock underlying this warrant are entitled to certain registration rights.

In 1999, we issued a warrant to purchase 70,000 shares of common stock at an exercise price of $1.00 per share to our prior landlord in connection with the commercial lease of our previous facilities. The warrant will expire on July 19, 2005, or sooner under certain circumstances. The shares of common stock underlying this warrant are not entitled to any registration rights. The fair value of this warrant of $34,000 was estimated using a Black-Scholes model and the following assumptions: estimated volatility of 60%, a risk-free interest rate of 5.27%, no dividend yield, and an expected life equal to the contractual life of 5 years. This fair value was amortized to rent expense over the related lease term.

2000 Employee Stock Purchase Plan

In June 2000, our stockholders approved the Company's 2000 Employee Stock Purchase Plan, or the Purchase Plan. A total of 500,000 shares of common stock have been reserved for issuance under the 2000 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 the Board of Directors. The Purchase Plan permits eligible participants to purchase common stock through payroll deductions of up to 15% of the participant'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. We have issued 114,574 shares of common stock pursuant to the Purchase Plan through December 31, 2003, leaving 385,426 shares reserved for issuance.

1998 Stock Plan

Under the 1998 Stock Plan, 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 and directors. At December 31, 2003 a total of 8,350,000 of common stock were authorized for issuance under the 1998 Stock Plan. The 1998 Stock Plan allows for annual increases, beginning fiscal year 2001, 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 the Board of Directors.

The 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 the Company's 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 the Company's 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 stockholder's meeting, each outside director is automatically

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

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 table summarizes option activity under the 1998 Stock Plan:

	Options outstanding	
	Number of options	Weighted-average exercise price
Options outstanding as of December 31, 2000	2,006,251	$ 3.13
Granted	1,423,000	7.39
Exercised	(78,635)	0.63
Forfeited	(465,900)	2.61
Options outstanding as of December 31, 2001	2,884,716	$ 5.39
Granted	1,692,213	6.38
Exercised	(351,278)	0.40
Forfeited	(232,022)	6.91
Options outstanding as of December 31, 2002	3,993,629	$ 6.15
Granted	1,146,300	6.70
Exercised	(272,150)	0.83
Forfeited	(499,270)	7.00
Options outstanding as of December 31, 2003	4,368,509	$ 6.53

Shares available for grant under the 1998 Stock Plan were 1,904,688 as of December 31, 2003.

The following table summarizes information about stock options outstanding as of December 31, 2003:

	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—$2.00	486,400	5.94	$ 1.01	453,252	$ 0.95
$ 2.00—$3.95	446,947	8.93	3.18	117,734	3.13
$ 6.06—$6.62	351,513	9.88	6.23	6,075	6.22
$ 6.71—$6.71	550,000	7.81	6.71	297,916	6.71
$ 6.90—$6.90	700,000	8.51	6.90	335,416	6.90
$ 7.00—$7.05	238,000	9.53	7.03	71,083	7.03
$ 7.16—$7.16	611,100	7.87	7.16	58,965	7.16
$ 7.30—$8.83	446,549	8.89	8.00	230,037	7.97
$ 8.86—$14.13	463,000	7.49	10.54	286,371	10.88
$ 18.63—$18.63	75,000	6.71	18.63	60,938	18.63
$ 0.10—$18.63	4,368,509	8.22	$ 6.53	1,917,787	$ 6.34

As of December 31, 2003, a total of 1,917,787 shares were fully vested and exercisable with a weighted average exercise price of $6.34 per share.

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

At December 31, 2003, the number of shares available for future grants pursuant to our stock plans consisted of the following:

1998 Stock Plan	1,904,688
Purchase Plan	385,426
Total available for future grants	2,290,114

Stock Based Compensation

We use the intrinsic-value method of accounting for stock based awards granted to employees in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Accordingly, we would recognize compensation expense in our financial statements in connection with stock options granted to employees with exercise prices less than fair value at the time the stock option is granted. We record stock based compensation expense for non-employees at the fair value of the options granted in accordance with SFAS 123 and EITF 96-18. The fair value of options granted to non-employees is estimated using a Black-Scholes option valuation model. The model considers a number of factors, including the market price and volatility of our common stock at the date of measurement. We periodically re-measure the compensation expense for options granted to non-employees as the underlying options vest. The compensation expense related to all grants issued prior to 2003 is being amortized using the graded vesting method, in accordance with SFAS 123, EITF 96-18 and FASB Interpretation No. 28, over the vesting period of each respective stock option, generally four years. The graded vesting method results in expensing approximately 57% of the total award in year one, 26% in year two, 13% in year three and 4% in year four.

Compensation expense is being recognized over the vesting period for employees and the service period for non-employees using the graded vesting method. Amounts amortized in the statement of operations as compensation expense for employees were $(109,000), $420,000, and $1,951,000 for the years ended December 31, 2003, 2002, and 2001, respectively. Amounts amortized in the statement of operations as compensation expense for non-employees were $249,000, ($210,000) and ($753,000) for the years ended December 31, 2003, 2002, and 2001, respectively.

9. Employee 401(k) Benefit Plan

In October 2001, the Company implemented 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 the Company to make additional matching contributions on behalf of all employees. Through December 31, 2003, the Company has not made any matching contributions.

PAIN THERAPEUTICS, INC.
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NOTES TO FINANCIAL STATEMENTS—(Continued)

10. Income Taxes

There is no provision for income taxes because the Company has incurred losses. 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. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,		
	2003	2002	2001
Deferred tax assets:			
Net operating loss carryforwards	$ 25,300	$ 16,000	$ 9,580
Research and development credits	4,800	1,090	1,429
Stock related compensation	4,700	4,680	4,613
Other	800	1,240	105
Total deferred tax assets	35,600	23,010	15,727
Valuation allowance	(35,600)	(23,010)	(15,727)
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. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $12,590, $7,283, and $6,381, during 2003, 2002 and 2001, respectively.

As of December 31, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately $60.3 million, which expire in the years 2018 through 2023 and federal research and developments tax credits of approximately $2.6 million, which expire in the years 2018 through 2023. As of December 31, 2003, the Company had net operating loss carryforwards for state income tax purposes of approximately $60.3 million, which expire in the years 2009 through 2013 and state research and development tax credits of approximately $2.3 million, which do not expire.

Utilization of the Company's net operating loss and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss and credits before utilization.

11. 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 contracts are cancelable on thirty days notice and are largely based on services performed.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

We currently lease office space and equipment pursuant to non-cancelable operating leases that will expire at various dates through 2010. Future minimum lease payments for these leases are as follows for the years ended December 31, (in thousands):

	2004	2005	2006	2007	2008	2009 and Thereafter	Total
Future minimum lease payments	$ 183	$ 187	$ 191	$ 187	$ 196	$ 366	$ 1,310

Rent expense was $171,000, $186,000, and $187,000 for the years ended December 31, 2003, 2002, and 2001 respectively.

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

	Quarters Ended			
	March 31	June 30	September 30	December 31
2003				
Net loss	$ (4,617)	$(4,346)	$ (5,969)	$ (6,685)
Basic and diluted loss per common share	$ (0.17)	$ (0.16)	$ (0.21)	$ (0.19)
2002				
Net loss	$ (4,026)	$(3,714)	$ (3,050)	$ (5,135)
Basic and diluted loss per common share	$ (0.15)	$ (0.14)	$ (0.11)	$ (0.19)

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 the Company's 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.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. *Directors and Officers of the Registrant*

The information regarding our directors, executive officers and the audit committee of the board of directors is incorporated by reference from "Directors and Executive Officers" in our Proxy Statement for our 2004 Annual Meeting of Stockholders.

Code of Ethics

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended requires the Company's 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, 2003.

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*

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 information required by this Item regarding equity compensation plans is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above of this Annual Report on Form 10-K.

Item 13. *Certain Relationships and Related Transactions*

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, Financial Statement Schedules, and Reports on Form 8-K***

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

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

Report of Ernst & Young LLP, Independent Auditors

Report of KPMG LLP, Independent Auditors

Balance Sheets

Statements of Operations

Statement of Stockholders' Equity (Deficit)

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*	Amended and Restated Certificate of Incorporation.
3.2*	Amended and Restated Bylaws.
4.1*	Specimen Common Stock Certificate.
10.1*	Form of Indemnification Agreement between Pain Therapeutics and each of its directors and officers.
10.2*	2000 Stock Plan and form of agreements thereunder.
10.3*	2000 Employee Stock Purchase Plan and form of agreements Thereunder.
10.21**	Lease Agreement dated July 21, 2000 between the Registrant and Goss-Jewett Company of Northern California.
10.4(3)	Employment Agreement, dated August 29, 2000, between Grant L. Schoenhard, Ph.D. and Pain Therapeutics.
10.5(3)	Employment Agreement, dated October 23, 2001, between Nadav Friedmann, M.D., Ph.D. and Pain Therapeutics.
10.6(3)	Consulting Agreement, Settlement Agreement and Mutual Release, dated October 19, 2001, between Barry Sherman, M.D. and Pain Therapeutics.
10.7(3)	Note, dated April 20, 2001, between David L. Johnson and Pain Therapeutics.
10.7a*	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.
10.8(3)	Agreement, dated January 31, 2002, between David L. Johnson and Pain Therapeutics.

Exhibit Number	Description of Document
10.9(3)	Note, dated March 1, 2000, between David L. Johnson and Pain Therapeutics.
23.1	Consent of KPMG LLP, Independent Certified Public Accountants.
23.2	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (see page F-24).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief 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 Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).

* 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.

** Incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000.

(3) Incorporated by reference from exhibits to the Company's report on Form 10-K for the period ending December 31, 2001.

(b) *Reports on Form 8-K*

The Company filed a Report on Form 8-K on October 21, 2003 reporting earnings for the third quarter of 2003.

(c) *Exhibits*

The exhibits listed under Item 14(a)(3) hereof are filed as part of this Form 10-K other than Exhibit 32.1 which shall be deemed furnished.

(d) *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: March 12, 2004

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)	March 10, 2004
/s/ PETER S. RODDY **Peter S. Roddy**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2004
/s/ NADAV FRIEDMANN, PH.D., M.D., **Nadav Friedmann, Ph.D., M.D.**	Chief Operating Officer and Director	March 10, 2004
/s/ ROBERT Z. GUSSIN, PH.D. **Robert Z. Gussin, Ph.D.**	Director	March 10, 2004
/s/ VERNON R. LOUCKS, JR. **Vernon R. Loucks, Jr.**	Director	March 10, 2004
/s/ MICHAEL J. O'DONNELL, ESQ. **Michael J. O'Donnell, Esq.**	Director and Secretary	March 10, 2004
/s/ SANFORD R. ROBERTSON **Sanford R. Robertson**	Director	March 10, 2004
/s/ RICHARD G. STEVENS **Richard G. Stevens**	Director	March 10, 2004

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** Incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000.

(3) Incorporated by reference from exhibits to the Company's report on Form 10-K for the period ending December 31, 2001.

Exhibit 23.1

INDEPENDENT AUDITORS' CONSENT

The Board of Directors
Pain Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statement (Nos. 333-68118 and 333-41660) on Form S-8 of Pain Therapeutics, Inc. of our report dated March 1, 2002, with respect to the statements of operations, stockholders' equity (deficit), and cash flows, for the year ended December 31, 2001, which report appears in the December 31, 2003, annual report on Form 10-K of Pain Therapeutics, Inc.

/s/ KPMG LLP

San Francisco, California
March 10, 2004

Exhibit 23.2

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-68118 and 333-41660) pertaining to the 1998 Stock Plan of Pain Therapeutics, Inc. of our report dated January 16, 2004, with respect to the 2003 financial statements of Pain Therapeutics, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Palo Alto, California
March 10, 2003

Exhibit 31.1

CEO 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)) 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. 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
   c. 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

Date: March 12, 2004

Exhibit 31.2

CFO 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)) 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. 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
   c. 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,
Chief Financial Officer

Date: March 12, 2004

Exhibit 32.1

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

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, 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, 2003, 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: March 12, 2004

/S/ REMI BARBIER

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

/S/ PETER S. RODDY

Peter S. Roddy,
Chief Financial Officer