# \_\_\_\_\_

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) [X]

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

0R

[ ] 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 (State or other jurisdiction of incorporation or organization) 91-1911336 (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 [X] No []

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

The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately \$116,242,333 as of February 28, 2002, based upon the closing price on the Nasdaq National Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose. The number of shares outstanding of the Registrant's common stock on February 28, 2002 was 27,166,603 shares. Portions of the Registrant's Proxy Statement for its 2002 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.

# FORM 10-K

# INDEX

PAGE PART I ITEM 1.
Business 1 ITEM 2.
I IIEM 2. Properties
12 ITEM 3. Legal
Proceedings
Matters 14 ITEM 6. Selected Financial
Data 15 ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations 16 ITEM 7A.
Quantitative and Qualitative Disclosures About Market
Risks
50

i

Our business is subject to numerous risks and uncertainties. See "Risk Factors."

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 products; statements about the size and scope of potential markets for our products; statements relating to the timing, breadth, status or anticipated results of the clinical development of our products; statements relating to the protection of our intellectual property; statements about expected future sources of revenue; statements about potential competitors or products; statements about future market acceptance of our products; 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 future non-cash charges related to option grants; 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 future negative operating cash flows; statements about fluctuations in our operating results; statements about potential additional applications of our technology; 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**

Pain Therapeutics, Inc., is developing a new generation of opioid painkillers with improved clinical benefits. We believe our drugs will offer enhanced pain relief and reduced tolerance/physical dependence or addiction potential compared to existing opioid painkillers. If approved by the Food and Drug Administration, or FDA, we believe our proprietary drugs could replace many existing opioid painkillers commonly used to treat moderate to severe pain. The Company was incorporated in Delaware in May 1998.

#### INDUSTRY BACKGROUND

# CLINICAL PAIN

Clinical pain is any unpleasant sensation that occurs as a result of injury or disease. Pain can have a protective role by warning of imminent or actual tissue damage, which can help prevent additional injury. Pain can also trigger a biological response that helps to preserve or regenerate damaged tissue. In this respect, pain is usually a normal, predictable response to events such as surgery, trauma and illness.

# TYPES OF PAIN AND PAIN RELIEF

Drugs are often used to reduce or eliminate pain, especially when the pain is severe. The type of drug used to relieve pain depends on both the severity and the duration of the pain. Pain can be classified into three categories of severity:

Mild Pain. Almost everyone experiences mild pain, such as headaches or joint pain, at one time or another. People typically treat mild pain with over-the-counter drugs such as aspirin and acetaminophen.

Moderate Pain. Pain resulting from minor surgery or arthritis are examples of moderate pain. Physicians typically prescribe opioid painkillers to treat moderate pain. Opioid painkillers come in three varieties: weak opioids, strong opioids and synthetic opioids. Weak opioids such as hydrocodone or codeine are generally used to treat patients with moderate pain.

Severe Pain. Patients experiencing severe pain often suffer from a serious underlying illness, such as AIDS or cancer. Severe pain can also result from major surgery, nerve damage or undetermined causes. Patients experiencing severe pain often require a strong opioid, such as morphine or oxycodone, to achieve adequate pain relief.

Pain can also be classified in terms of its duration as either acute or chronic. Acute pain, such as pain resulting from knee surgery, is brief and rarely results in long-term consequences. Most acute pain subsides within hours, days or weeks. Chronic pain persists long after an injury has healed, and typically results from a chronic illness or appears spontaneously and persists for undefined reasons. Examples of chronic pain include chronic lower back pain, and pain resulting from bone cancer or advanced arthritis. The effect of chronic pain tends to be more pervasive than that of acute pain. Chronic pain often affects a patient's mood, personality and social relationships. As a result, a patient with chronic pain commonly suffers from both their state of physical pain as well as a general decline in their quality of life.

In general, the more severe or chronic the pain, the more likely an opioid painkiller will be prescribed to treat the pain. The following diagram illustrates the types of pain which physicians typically treat with opioid painkillers:

# PAIN MANAGEMENT MARKET

# [DIAGRAM]

The medical effort to treat pain, known as pain management, addresses a large market. Clinical pain is a worldwide problem with serious health and economic consequences. For example, in the United States:

- medical economists estimate that the effects of pain result in approximately \$100 billion of costs annually, including costs associated with an estimated 515 million lost work days;
- according to the National Institutes of Health, approximately 40 million Americans are unable to find relief from their pain;

# 2

- more than 30 million Americans suffer chronic pain for which they visit a doctor;
- approximately one million cancer patients suffer from severe pain at any given time; and
- an estimated 10% of the more than 200,000 AIDS patients suffer severe pain.

Drugs are the key element in the treatment of pain. The worldwide market for pain drugs totaled over \$13 billion in 1999. In the United States and Western Europe the corresponding market for pain drugs totaled over \$9 billion. The pain management market has grown significantly in recent years and is expected to continue to grow significantly. The U.S. market for prescription pain drugs has grown by approximately 15% per year during the past five years due to a number of factors, including:

- a rapidly aging population;
- patients' demand for effective pain relief;
- increasing recognition of the therapeutic and economic benefits of effective pain management by physicians and healthcare providers and payers; and
- longer survival times for patients with painful chronic conditions, such as cancer and AIDS.

This accelerating growth rate appears to be attributable in part to recent innovations in the treatment of mild pain. For example, COX-2 inhibitors, which are non-opioid prescription pain relievers, were launched in 1999 and achieved first-year sales exceeding \$1.0 billion and sales for 2001 exceeding \$5.0 billion in the United States. COX-2 inhibitors have fewer side effects than aspirin, and sell for more than twenty times the price of aspirin. The success of COX-2 inhibitors demonstrates the potential for rapid market acceptance and premium pricing of pain products that offer reduced side effects.

There have been few scientific innovations in the area of opioid painkillers since morphine was discovered in 1865. Sales of opioid painkillers in the United States consist primarily of older off-patent pain drugs, such as morphine and oxycodone. Notwithstanding the lack of novel drugs, U.S. opioid painkiller sales were approximately \$3.0 billion in 2000.

Approximately 90% of U.S. patients who receive opioids are treated on an outpatient basis. A portion of these patients receives care at one of the 3,400 specialty pain programs. The relatively low number of pain treatment centers allows for focused distribution channels for pain management products. This market structure permits midsize pharmaceutical companies to market and sell pain products cost-effectively.

#### OPIOID DRUGS

The history of opium use dates back more than 3,000 years. Today, the use of opioid drugs to treat patients with moderate to severe pain is widely accepted throughout the world. Opioids are the drugs of preference for many caregivers because they have an extensive clinical history, are easy to use and are available in a variety of doses and formulations. In the United States, Europe and Japan, physicians use a variety of strong, weak and synthetic opioids to manage patients' pain.

#### OPIOID DRUG SEGMENTS

MARKET SEGMENT TYPICAL USE EXAMPLES
REPRESENTATIVE
BRAND 2000 U.S.
BRAND 2000 0.5.
SALES
(IN
MILLIONS)
,
Strong
Opioids
Cancer pain

Morphine and MS Contin, (R) \$2,000 oxycodone Oxycontin, (R) Duragesic(R) and others Weak Opioids..... Outpatient surgery Hydrocodone and Vicodin(R), 500 codeine Vicoprofen(R), and others Synthetic Opioids.... Back pain Tramadol Ultram(R) 500 ----- Total \$3,000 ======

3

Patients experiencing acute pain require fast acting, short-lived opioids and rapid delivery. The most common acute use of opioids is post-surgical pain. Opioid drugs used to treat acute pain include intravenous morphine and hydrocodone, which provide rapid pain relief.

In contrast, patients experiencing chronic severe pain often require long-term, regular use of opioid drugs. Because rapid dose adjustments are not necessary, patients experiencing chronic pain typically use opioid drugs in sustained release formulations. Such formulations include fentanyl patches, sustained release morphine and oxycodone. Although curing chronic pain is possible, it is infrequent. The aim of using opioid drugs for patients with chronic pain is to decrease pain and suffering while improving overall physical and mental functions.

#### SHORTCOMINGS OF CURRENT PAIN MANAGEMENT

Despite widespread clinical use of opioids, pain management remains less than optimal. At all doses, opioid painkillers have significant adverse side effects that limit their usefulness. Adverse side effects include: respiratory depression, nausea, vomiting, dizziness, sedation, mental clouding, constipation, urinary retention and severe itching. In addition, chronic use of opioid painkillers can lead to the need for increasing dosage, and potentially, addiction. Concerns about addiction often influence clinicians to prescribe less than adequate doses of opioids. Many patients dislike the adverse side effects of opioid treatment and voluntarily take less than the prescribed dosage. In all cases, however, patients and clinicians must reach an appropriate balance between pain relief and adverse side effects. In addition, patients often use a process of trial and error with different opioids to identify an opioid that yields the optimal balance between pain relief and adverse side effects. Some patients may even prefer to endure pain rather than to withstand the side effects of opioid therapy. As a result, many patients are seriously under-treated and may be suffering from pain unnecessarily. In particular, infants and children receive disproportionately fewer and lower doses of opioid painkillers than adults.

Historically, there have been few scientific innovations with the opioid painkillers used to treat moderate to severe pain. To date, product innovations have focused on increasing convenience, rather than improving clinical benefits. For example, novel dosing or delivery systems make it more convenient for patients to use opioid drugs, but these more convenient formulations neither enhance pain relief nor reduce adverse side effects.

#### OUR SOLUTION

We are developing a new generation of drugs that address the shortcomings of existing opioid painkillers. We believe our drugs will offer enhanced pain relief and reduced tolerance/physical dependence or addiction potential as compared to many of today's commonly prescribed opioid painkillers.

If approved by the FDA, we believe our drugs could replace many commonly used opioid painkillers. We also believe our drugs could be used in chronic pain cases where physicians have been reluctant to prescribe opioid painkillers due to concerns about adverse side effects or addiction.

Our product candidates use a novel technology developed at Albert Einstein College of Medicine. Our technology combines very low doses of opioid antagonists with standard opioid painkillers. We believe that the addition of a low dose of an opioid antagonist to opioid painkillers has an unexpected and beneficial effect. We believe that this effect includes enhancing potency and attenuating tolerance/physical dependence or addiction potential.

#### STRATEGY

Our goal is to build a leading specialty pharmaceutical company in pain management. We intend to achieve this goal by:

Building a Drug Franchise in Pain Medications. We intend to develop drugs that we believe may have broad use for patients with moderate to severe pain where the use of an opioid painkiller is appropriate. We believe this approach may help alleviate physicians' current tendency to under-prescribe opioid painkillers.

Focusing on Clinical Development and Late Stage Products. We continue to focus on managing clinical trials including our two lead product candidates which are in various stages of Phase II clinical trials. The conduct of human trials is a complex, highly regulated and highly specialized effort. We believe that our clinical development focus will enable us to generate product revenues earlier than if we were discovering and developing new chemical entities.

Retaining Significant Rights. We currently retain worldwide commercialization rights to all of our technology and pain management product candidates in all markets and indications. In general, we intend to independently develop our product 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 drugs earlier in the development process. In market segments that require large or specialized sales forces, such as the market for morphine products, we may seek sales and marketing alliances with third parties. We believe that such alliances will enable us to commercialize our drugs rapidly and cost-effectively.

Using Our Technology to Develop Multiple Drugs for Both Pain and Non-Pain Indications. We are initially focusing our efforts on developing opioid painkillers. However, we believe our technology can be broadly applied to additional segments of the pain market, as well as non-pain indications.

Outsourcing Key Functions. We intend to continue to outsource preclinical studies, clinical trials, formulation and manufacturing. We believe outsourcing will produce significant time savings and allow for more efficient deployment of our resources.

#### PRODUCTS IN DEVELOPMENT

We have four painkillers in various stages of Phase II clinical trials. Each product is a proprietary combination of opioids. The first component is an opioid agonist, such as morphine. The second component is an opioid antagonist, such as naltrexone or naloxone. 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 and addiction. Our technology takes advantage of this effect by combining opioid agonists with low doses of opioid antagonists. Company sponsored research and development expenditures were \$4.0 million, \$12.6 million and \$11.7 million in 1999, 2000 and 2001, respectively.

Our trials are designed to produce clinical information about how our painkillers perform compared to placebo and existing opioid drugs. We plan to test each of our products 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 acute and chronic pain. FDA guidelines recommend that we demonstrate efficacy of our new painkillers in more than one clinical presentation of pain, such as post-operative pain, cancer pain and various types of trauma and arthritis pain. Because clinical models differ in their sensitivity to detect pain, we expect to complete Phase II studies in multiple clinical models of pain. We have designed most 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.

# MORVIVA(TM)

MorViva(TM) is the brand name for our next generation version of morphine. We are developing this drug candidate to treat patients with severe pain in acute or chronic settings. We have both oral and injectible versions of MorViva(TM) on file with the FDA under separate investigational new drug applications, or INDs. Oral MorViva(TM) (previously known as PTI-555) consists of a proprietary combination of morphine plus lowdose naltrexone. Injectible MorViva(TM) (previously known as PTI-501) consists of a proprietary combination of morphine plus low-dose naloxone. If the FDA approves MorViva(TM), we believe it could be an effective substitute for morphine. The principal use of morphine is the treatment of patients suffering from chronic or acute severe pain, such as cancer pain or pain that follows major surgery or trauma.

More than 1,000 patients have been enrolled in various studies of MorViva(TM) completed to date. The purpose of these trials was to obtain pharmacokinetics data and to demonstrate the safety or the efficacy of morphine in combination with different low doses of naltrexone or naloxone in various clinical settings of pain.

In October 2001, we announced results of a Phase II clinical trial with oral MorViva(TM). This trial was a multi-center, randomized, double-blind, placebo and active controlled clinical study comparing oral MorViva(TM) to morphine sulfate and placebo. The trial enrolled 210 male patients with moderate to severe pain following major oral surgery significant enough to warrant opioid analgesia. Immediately after surgery, patients were randomly assigned to receive a single oral dose of MorViva(TM), morphine sulfate or placebo. The primary endpoint of pain relief was achieved with a high degree of statistical significance against both morphine (p<0.01) and placebo (p<0.001). In this trial MorViva(TM) was well tolerated and was not associated with any reported serious adverse events, either during the trial or the subsequent follow-up period. The percentage of patients reporting any drug related adverse events during the 24 hours following dosing was approximately the same in the morphine and MorViva(TM) treatment groups.

In March 2002, we announced the results of a preclinical experiment to test the hypothesis that MorViva(TM) offers minimal opioid tolerance and physical dependence following chronic administration. In this experiment, two groups of healthy mice were given chronic doses of either morphine or MorViva(TM) over ten days. The mice that received morphine quickly became tolerant to drug and no longer responded to a standard assay of analgesia by day three. Mice that received MorViva(TM) did not show drug tolerance; these mice showed a continuous analgesic response during the entire seven day study (p<0.01). Furthermore, when morphine tolerant mice were switched over to MorViva(TM), these mice showed an analgesic response without subsequent redevelopment of tolerance (p<0.01). These results demonstrate the ability of MorViva(TM) to prevent and to reverse opioid tolerance in lab animals after chronic treatment. At the end of the study, mice were given naloxone to reverse the effects of morphine. Mice that had been receiving morphine went into a classic opioid withdrawal behavior, indicating the presence of physical dependence. Mice that had been receiving MorViva(TM) did not do so, indicating the absence of physical dependence (p<0.01).

Based on these encouraging results, and the results of earlier clinical studies, we are designing and conducting new trials to further demonstrate MorViva's(TM) safety and efficacy in different clinical settings of pain.

#### OXYTREX(TM)

In April 2001, we announced the addition of OxyTrex(TM) (previously known as PTI-801) to the Company's pipeline. OxyTrex(TM) is the brand name for our next generation version of immediate release oxycodone. In 2001, sales of various formulations of oxycodone exceeded \$1 billion in the U.S. We are developing this drug candidate to treat patients with moderate to severe pain in a chronic setting. OxyTrex(TM) consists of a proprietary combination of immediate release oral oxycodone plus low-dose naltrexone. If the FDA approves OxyTrex(TM), we believe it could be an effective substitute for immediate release oral oxycodone. The principal use of oxycodone is the treatment of patients suffering from chronic moderate to severe pain, such as chronic lower back pain.

To date, we have limited clinical data using OxyTrex(TM). Approximately 20 patients have received OxyTrex(TM) in two pharmacokinetic and safety studies completed to date. The purpose of these trials was to obtain pharmacokinetics data and to demonstrate the safety of a fixed dose of immediate release oxycodone in combination with different low doses of naltrexone in human volunteers and patients with chronic pain. Low-dose naltrexone is an active ingredient in both oral MorViva(TM) and OxyTrex(TM).

In January 2002, we announced that the Medicines Control Agency and the local Institutional Review Board approved our protocol to conduct a clinical study of OxyTrex(TM) in the U.K. We plan to initiate a

Phase II study in England in the first quarter of 2002 and if the results of this trial are positive then we expect these clinical results to support regulatory filings for approval in both the U.S. and Europe.

In March 2002, we announced the results of a preclinical experiment to test the hypothesis that OxyTrex(TM) offers minimal opioid tolerance and physical dependence following chronic administration. In this experiment, two groups of healthy mice were given chronic doses of either oxycodone or OxyTrex(TM) over seven days. Mice that received oxycodone quickly developed drug tolerance. In contrast, mice that received OxyTrex(TM) showed an absence of opioid tolerance. In addition in this experiment, OxyTrex(TM) was shown to be more potent than oxycodone over the entire duration of the study. At the end of the study, mice were given naloxone to reverse the effects of oxycodone. Mice that had been receiving oxycodone went into a classic opioid withdrawal behavior, indicating the presence of physical dependence. Mice that had been receiving OxyTrex(TM) did not do so, indicating the absence of physical dependence (p<0.01).

Based on these encouraging safety results, we are designing and conducting clinical trials to demonstrate OxyTrex's(TM) safety and efficacy in different clinical settings of pain.

#### PTI-701

PTI-701 is a next generation version of hydrocodone. In 2000, U.S. sales of hydrocodone and similar weak opioids exceeded \$500 million. We are developing this proprietary combination drug to treat patients with acute moderate to severe pain. PTI-701 is a proprietary combination of hydrocodone, acetaminophen and low-dose naltrexone. If the FDA approves PTI-701, we believe it could be an effective substitute for hydrocodone/acetaminophen combination. In the US, all hydrocodone products are sold in combination with acetaminophen.

We are currently developing PTI-701 on a very limited basis. In 2001 we made the clinical development of PTI-701 a lower priority in order to focus our financial resources on MorViva(TM) and OxyTrex(TM). We conducted no significant clinical activities with regard to PTI-701 in 2001. No significant trials are planned in the near future using PTI-701.

#### PTI-601

PTI-601 is a next generation version of tramadol. In 2000, U.S. sales of tramadol exceeded \$500 million. We are developing this proprietary combination drug to treat patients with moderate pain in an acute setting. PTI-601 is a combination of tramadol and low-dose naltrexone. If the FDA approves PTI-601, we believe it could be an effective substitute for tramadol. Tramadol is principally used to treat patients with acute or chronic moderate pain, such as arthritis pain.

We are currently developing PTI-601 on a very limited basis. In 2001 we made the clinical development of PTI-601 a lower priority in order to focus our financial resources on MorViva(TM) and OxyTrex(TM). In February 2001, we announced the completion of a 350 patient Phase II clinical trial using PTI-601. The clinical results of this study have not been publicly disclosed. We conducted no further clinical activities with regard to PTI-601 in 2001. No significant trials are planned in the near future using PTI-601.

#### OTHER PRODUCT CANDIDATES

We believe the use of low-dose opioid antagonists, either alone or in combination with existing opioid drugs, may have commercial applications beyond our current product candidates. We believe that our technology can be broadly applied to additional segments of the pain market, as well as non-pain indications. Until we undertake preclinical studies and clinical trials, we cannot be certain that our technology will have such additional applications.

#### MANUFACTURING

We have no manufacturing facilities. We have entered into agreements with qualified third parties for the formulation and manufacture of our clinical supplies. These supplies and the manufacturing facilities must comply with U.S. Drug Enforcement Agency, or DEA, regulations and current good manufacturing practices, or GMPs, enforced by the FDA. We plan to continue to outsource formulation and manufacturing.

#### TECHNOLOGY OVERVIEW

According to the current understanding of pain mediation, opioid painkillers produce their pain relieving effect by activating an inhibitory pathway in the nervous system. Inhibitory pathways inhibit the transmission of pain signals into the brain. Scientists at Albert Einstein College of Medicine have published results suggesting that opioids also stimulate an excitatory pathway in the nervous system. The excitatory pathway partially 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. In vitro studies on isolated nerve cells have helped researchers detect and analyze the unique properties of the inhibitory and excitatory pathways. At the normal clinical doses, the activation of the excitatory pathway was previously undetected probably due to masking by the inhibitory pathway.

Published results suggest that the selective blockade of the excitatory pathway promotes the pain relieving potency of morphine in mice by blocking the excitatory pain-enhancing effect. In addition, preclinical studies have demonstrated that co-treatment with a very low dose of an opioid antagonist, such as naloxone or naltrexone, preferentially blocks the excitatory pathway over the inhibitory pathway, thereby enhancing morphine's ability to inhibit pain.

We believe that the excitatory pathway plays an important role in modulating the adverse side effects of opioid use. After repeated administration of morphine 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 dependent. Published results also show that tolerance and dependence in mice are due to sustained activation of the excitatory pathway, and that tolerance and dependence can be prevented by co-administration of low-dose naltrexone, a pure opioid antagonist. At very low concentrations, we believe such opioid antagonists preferentially block excitatory pathways. These results provided the rationale for our human clinical trials.

The low-dose effect is the most important component of our technology wherein a very low dose of an opioid antagonist is combined with an opioid painkiller. Optimal dose ratios of low-dose opioid antagonist to opioid painkiller depend on their specific pharmacology and the mode of administration. Published preclinical and clinical dose response studies provide guidance in formulating optimal ratios of low-dose opioid antagonist to opioid painkiller for clinical development.

Upon our formation in May 1998, we licensed our 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 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.

We seek to protect our technology by, among other methods, filing and prosecuting U.S. and foreign patents and patent applications with respect to our technology and products and their uses. The issued patents are scheduled to expire no earlier than September 2012. We plan to prosecute and defend our patent applications, issued patents and proprietary information. The patent portfolio includes five issued U.S. patents, one U.S. Notice of Allowance and three pending U.S. patent applications relating to the low-dose opioid antagonist technology under our license agreement with Albert Einstein College of Medicine, and eleven corresponding pending foreign patent applications or issued patents. 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 infringers. 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; 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.

#### GOVERNMENT REGULATION

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of our products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations, require us to spend substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which our products may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Applicable FDA regulations treat our combination of opioid painkillers, such as morphine, and low-dose opioid antagonists, such as naloxone, 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. Our clinical trials seek to demonstrate that an opioid painkiller/low-dose opioid antagonist combination produces greater beneficial effects than either drug alone.

#### 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:

- preclinical studies;
- submission to the FDA of an IND which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate;

- submission to the FDA of an NDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the drug.

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

Based on preclinical testing, an IND is filed with the FDA to begin human testing of the drug. 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, or GCP, regulations. 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 without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Clinical trials are typically conducted in three sequential phases which may overlap. Phase I tests typically take approximately one year to complete. The tests study a drug's safety profile, and may include the safe dosage range. The 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 pain relief in our Phase  ${\tt I}$ trials. Based on discussions with the FDA, our current opioid development programs were allowed to proceed into Phase II studies. 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 if there are any side effects. 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. We currently have four opioid painkillers in various stages of Phase II clinical trials. 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 any reactions that may result from long-term or expanded use of the drug.

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 product candidates. In particular, FDA guidelines recommend that we demonstrate efficacy of our new painkillers in more than one clinical model of pain, typically including dental pain. Other acceptable clinical models of pain include post-operative pain, cancer pain and various types of trauma and arthritis pain. Since models differ in their pain intensity and their sensitivity to detect pain, we expect to complete several Phase II studies in multiple clinical models of 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 product 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 often significantly extended 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 product 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 product candidates that contains 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 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. Such alternatives include Elan's Ziconotide(TM) and Endo Pharmaceuticals' MorphiDex(R). 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 painkiller products already approved by the FDA or in development and operate larger research and development programs in these fields than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater financial resources than we do, as well as significantly greater experience in:

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

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

#### **EMPLOYEES**

As of December 31, 2001, we had approximately 33 employees. We engage consultants from time to time to perform services on a per diem or hourly basis.

# 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. Lease payments under this lease agreement total \$1.8 million and commenced in October 2000 through the ten year term of the lease. In April 2001 we completed the build-out of tenant improvements and relocated to this facility, and subsequently terminated existing sublease agreements on 6,150 square feet of space also located in South San Francisco, California. We believe that this facility will be 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

None.

#### EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth certain information regarding our executive officers as of December 31, 2001:

Remi Barbier, our founder, has served as our President, Chief Executive Officer and Chairman since our inception in May 1998. Prior to that time, Mr. Barbier helped in the growth or founding of: Exelixis Inc., a functional genomics company, ArQule, a chemistry company, and EnzyMed (now owned by Albany Molecular Research), a chemistry company. Mr. Barbier served as Chief Operating Officer of Exelixis from January 1996 to May 1998. Prior to that, he was Vice President of Corporate Development and Clinical Project Manager of Xoma Corporation, a biotechnology company, from October 1993 to December 1995. Mr. Barbier received his B.A. from Oberlin College and his M.B.A. from the University of Chicago. He is a Director of Mendel Biotechnology, Inc. and Poetic Genetics, Inc.

Nadav Friedmann, M.D., Ph.D., has served as director of Pain Therapeutics, Inc. since September 1998. In October 2001 Dr. Friedmann joined the Company as our Chief Operating Officer. Dr. Friedmann is the owner and President of EMET Research Inc., a consulting firm in the pharmaceutical industry. Dr. Friedmann was President and Chief Executive Officer of Daiichi Pharmaceutical Corporation, a pharmaceutical company, from 1997 to April 2000, and before that was a Consultant to the Board of Directors of Daiichi Pharmaceutical Co., Ltd. in Tokyo from 1995 to 1997. From 1992 to 1995, Dr. Friedmann served as Vice President, Clinical Research at Xoma Corporation. From 1980 to 1991, Dr. Friedmann held various leadership positions with Johnson and Johnson, a healthcare company, including the position of Vice President and Head of Research of J&J Biotechnology Center. Prior to that, Dr. Friedmann was Medical Director of Abbott Laboratories. Dr. Friedmann is a graduate of Albert Einstein College of Medicine, where he received an M.D., and of the University of California, San Diego, where he received a Ph.D. degree in Biochemistry.

Edmon R. Jennings joined Pain Therapeutics, Inc. in February 2000. Prior to that time, Mr. Jennings held senior management positions at Genentech, Inc., including Vice President of Corporate Development from December 1995 to January 2000, Vice President of Sales and Marketing from January 1994 to December 1995 and Vice President of Sales from December 1990 to December 1993. Prior to Genentech, Mr. Jennings held positions with Bristol-Myers Oncology and Bristol Laboratories, both of which were divisions of Bristol-Myers (now Bristol-Myers Squibb), a pharmaceutical company, for approximately twelve years. In May 2001, Mr. Jennings became a member of the Board of Directors for ViroLogic, Inc. Mr. Jennings received his B.A. from the University of Michigan.

David L. Johnson, CPA, joined Pain Therapeutics, Inc. in January 2000. From November 1998 to December 1999, Mr. Johnson was an independent financial consultant, and acted as Chief Financial Officer at Aradigm, a drug delivery technology company. From October 1997 to November 1998, Mr. Johnson held positions as Vice President of Finance and Administration of Elan Pharmaceuticals North America and Vice President of Finance and Chief Financial Officer of Athena Neurosciences, both of which were divisions of Elan Pharmaceuticals, a pharmaceutical company. From September 1996 to October 1997, Mr. Johnson was Director of Finance at Gilead Sciences, a biopharmaceutical company. From January 1995 to September 1996, Mr. Johnson was an independent financial consultant and provided accounting services to Chiron, a biotechnology company. From June 1993 to December 1994, Mr. Johnson was Director of Financial Planning and Operational Analysis at Chiron. Mr. Johnson is a former member of the audit staff of KPMG LLP, our auditors. Mr. Johnson received his B.S. in Accounting from Oklahoma State University.

Grant Schoenhard, Ph.D., joined Pain Therapeutics, Inc. in September 2000 as Vice President of Preclinical Development. In September 2001 Dr. Schoenhard was promoted to Chief Scientific Officer. From February 2000 to September 2000, Dr. Schoenhard was a consultant and provided pharmacodynamic research and development services to various organizations. From September 1998 to February 2000, Dr. Schoenhard was Senior Director of Pharmacokinetics, Drug Metabolism and Pharmacology at Genentech, Inc. From 1974 to July 1998, Dr. Schoenhard held various management positions, including Executive Director of Pharmacokinetics, Drug Metabolism and Radiochemistry at Searle, a pharmaceutical company of Monsanto Corporation. Since December 1998, Dr. Schoenhard has been a member of the Board of Directors of LC Resources, Inc. Dr. Schoenhard is also Adjunct Professor of Pharmacology, School of Medicine, University of Pennsylvania. Dr. Schoenhard received his B.S. from Michigan State University and his M.S. and Ph.D. from Oregon State University.

#### PART II

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock has been quoted on the Nasdaq National Market under the symbol "PTIE" since our initial public offering on July 14, 2000. Prior to this time, there was no public market for our stock. The following table sets forth the high and low closing sales prices per share of our common stock as reported on the Nasdaq National Market for the periods indicated. 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 28, 2002 there were 121 holders of record of our common stock.

SALE PRICE HIGH LOW FISCAL 2001: First
Quarter
\$15.750 \$ 6.750 Second
Quarter
\$10.938 \$ 5.400 Third
Quarter
\$ 8.240 \$ 5.910 Fourth
Quarter
\$ 9.250 \$ 5.300 FISCAL 2000: Third Quarter (from
July 14, 2000)\$26.375
\$14.000 Fourth
Quarter
\$23.125 \$ 8.000

On July 19, 2000, we completed our initial public offering (the "IPO") pursuant to a Registration Statement on Form S-1 (File No. 333-32370). In the IPO, we sold an aggregate of 5,750,000 shares of common stock (including an over-allotment option of 750,000 shares) at \$12.00 per share. The IPO generated aggregate gross proceeds of approximately \$69,000,000 for the Company. The aggregate net proceeds to the Company were approximately \$62,939,000, after deducting underwriting discounts and commissions of approximately \$4,830,000 and expenses of the offering of approximately \$1,231,000. From the time of receipt through December 31, 2001 all of the net proceeds of the initial public offering were invested primarily in short-term, investment grade, interest bearing U.S. government securities or money market funds. As of December 31, 2001 all of our cash and cash equivalents were in money market and checking funds.

14

```
MAY 4, 1998 MAY 4, 1998
(INCEPTION) (INCEPTION) THROUGH
   YEARS ENDED DECEMBER 31,
THROUGH DECEMBER 31, -----
DECEMBER 31, 1998 1999 2000
2001 2001 -----
----- STATEMENT OF
  OPERATIONS DATA: Licensing
  fees.....$
   100,000 $ -- $ -- $ -- $
    100,000 Research and
  development: Non-cash stock
         based
compensation.....
 -- 1,505,312 3,926,473 77,080
 5,508,865 Other research and
       development
expense.....
  200,000 2,461,977 8,669,696
11,590,609 22,922,282 ------
     ----- Total
 research and development....
 200,000 3,967,289 12,596,169
11,667,689 28,431,147 ------
----- -----
----- General and
administrative: Non-cash stock
          based
compensation.....
-- 117,555 4,832,793 1,121,279
 6,071,627 Other general and
      administrative
expense.....
  122,168 574,630 2,875,947
4,525,742 8,098,487 -----
  ----- ------ ------
   ----- Total
        general and
administrative.....
  122,168 692,185 7,708,740
5,647,021 14,170,114 -----
----- -----
  ----- Total
 operating expenses.....
 422,168 4,659,474 20,304,909
17,314,710 42,701,261 -----
----- -----
 ----- Operating
   loss.....
    (422,168) (4,659,474)
  (20,304,909) (17,314,710)
    (42,701,261) Interest
  income.....
   33,961 160,689 2,825,919
2,978,160 5,998,729 ----- -
  ----- -----
  ----- Net loss
  before income taxes.....
  (388,207) (4,498,785)
(17,478,990) (14,336,550)
   (36,702,532) Income tax
expense..... 800 800
800 800 3,200 -----
     ----- Net
loss.....
    (389,007) (4,499,585)
  (17,479,790) (14,337,350)
(36,705,732) Return to series C
  preferred shareholders for
    beneficial conversion
  feature..... -- --
(14,231,595) (14,231,595) -----
```

```
----- Loss
    available to common
shareholders.....
  $(389,007) $(4,499,585)
 $(31,711,385) $(14,337,350)
  $(50,937,327) =======
  ======= ========= Basic
   and diluted loss per
share.....
 $ (0.39) $ (1.35) $ (2.33) $
 Weighted-average shares used in
 computing basic and diluted
       loss per
 share....
 985,961 3,345,397 13,634,513
   25,331,541 =======
  =============
DECEMBER 31, -----
····· 1998 1999 2000 2001 ·····
--- BALANCE
       SHEET DATA: Cash and cash
  equivalents.....
$2,333,512 $9,339,669 $78,926,830 $65,274,291
            Working
capital.....
  2,264,038 9,095,831 77,320,445 63,194,831
            Total
assets.....
  2,382,600 9,441,173 81,147,046 68,135,796
            Total
liabilities.....
108,108 300,587 2,452,378 2,519,471 Series B
redeemable convertible preferred stock..... -
  - 9,703,903 -- -- Series A convertible
preferred stock..... 2,660 2,660 -
 - -- Stockholders' equity (deficit)..... 2,274,492
```

(563,317) 78,694,668 65,616,325

15

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.

The following discussion 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 products; statements about the size and scope of potential markets for our products; statements relating to the timing, breadth, status or anticipated results of the clinical development of our products; statements relating to the protection of our intellectual property; statements about expected future sources of revenue; statements about potential competitors or products; statements about future market acceptance of our products; 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 future non-cash charges related to option grants; 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 future negative operating cash flows; statements about fluctuations in our operating results; statements about potential additional applications of our technology; 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.

#### OVERVIEW

Pain Therapeutics, Inc. is developing a new generation of opioid painkillers with improved clinical benefits. We believe our drugs will offer enhanced pain relief and reduced tolerance/physical dependence or addiction potential compared to existing opioid painkillers. We conduct our research and development programs through a combination of internal and collaborative programs. Our management relies on arrangements with universities, contract research organizations and clinical research sites for a significant portion of our product development efforts.

We currently have four opioid painkillers in various stages of Phase II clinical trials, including our two lead product candidates, MorViva(TM) and OxyTrex(TM), and two other product candidates, PTI-701 and PTI-601:

- MorViva(TM) is the brand name for our product previously known as PTI-501 (injectible version) and PTI-555 (oral version) which we are developing to treat patients with severe pain.
- OxyTrex(TM) is the brand name for our product previously known as PTI-801 which we are developing to treat patients with moderate to severe pain in a chronic setting.
- PTI-701 is the next generation version of hydrocodone, which we are developing to treat patients with acute moderate to severe pain.
- PTI-601 is the next generation version of tramadol, which we are developing to treat patients with moderate pain in an acute setting.

Based on the results of multiple Phase I and Phase II studies completed for MorViva(TM) and two pharmacokinetic and safety studies completed for OxyTrex(TM), we are designing and conducting clinical trials to demonstrate the safety and efficacy of these two drug candidates in different clinical settings of pain. We are currently developing PTI-701 and PTI-601 on a very limited basis in order to focus our financial resources on MorViva(TM) and OxyTrex(TM). No significant trials are planned in the near future using PTI-701 or PTI-601.

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception, we have incurred a cumulative deficit of approximately \$36.7 million through December 31, 2001. These losses have resulted principally from costs incurred in connection with research and development activities, including costs of preclinical and clinical trials as well as clinical supplies associated with our product candidates, salaries and other personnel related costs, including the amortization of deferred compensation associated with options granted to employees and non-employees, and general corporate expenses. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our product candidates, our need for clinical supplies, as well as the re-measurement of certain deferred stock compensation.

We expect to incur significant additional operating losses for the next several years. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical and clinical trials for our product candidates;
- seek regulatory approvals for our product 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.

Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our product candidates. In the event that our development efforts result in regulatory approval and successful commercialization of our product candidates, we will generate revenue from direct sales of our products and/or, if we license our products to future collaborators, from the receipt of license fees and royalties from licensed products.

Sources of revenue for the foreseeable future may also include payments from potential collaborative arrangements, including license fees, funded research payments, milestone payments and royalties based on revenues received from products commercialized under such arrangements.

#### CRITICAL ACCOUNTING POLICIES

We believe that of our significant accounting policies (see Note 2 of Notes to Financial Statements), the policies regarding Research and Development Costs and Non-cash Stock Based Compensation are most important to the portrayal of our financial condition and results of operations.

#### Research and Development Costs

Research and development costs are expensed as incurred and consist of drug development work associated with our product candidates, primarily including costs of preclinical and clinical trials, clinical supplies and related formulation and design costs, research payments to the Albert Einstein College of Medicine and salaries and other personnel related expenses including non-cash stock based compensation. Research and development expenses are expected to increase significantly over the next several years as our development efforts are expanded and our product candidates enter into various stages of clinical trials, and may vary significantly from period to period due to the timing of these activities. There will also continue to be future non-cash charges included in research and development expenses for stock based compensation related to options granted to employees and consultants.

## Non-Cash Stock Based Compensation

Deferred stock compensation for options granted to employees represents the difference between the exercise price of the option and the fair value of our common stock on the date of grant in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Deferred compensation for non-employees is recorded at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123 and is periodically re-measured until the underlying options vest in accordance with Emerging Issues Task Force No. 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 expected volatility of our common stock at the date of measurement or re-measurement. The compensation expense related to all grants is amortized over the vesting period of the related stock options in accordance with Financial Accounting Standards Board Interpretation No. (FIN) 28.

The amount of compensation expense we record could fluctuate significantly from period to period as a result of: (a) the periodic re-measurement of deferred stock compensation for non-employees principally as a result of fluctuations in the market price of our common stock, (b) the amount of additional options granted to non-employees and (c) the method by which deferred stock compensation is amortized as charges to operations.

#### **RESULTS OF OPERATIONS**

YEARS ENDED DECEMBER 31, 2001 AND 2000

# Agreement with Albert Einstein College of Medicine

In May 1998, we entered into an exclusive, worldwide license agreement with Albert Einstein College of Medicine for all patents and pending patent applications relating to low-dose opioid antagonist 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 agreement, in 1998 we paid Albert Einstein College of Medicine a one-time licensing fee, which was recognized as license fee expense in accordance with Financial Accounting Standards No. 2, Accounting for Research and Development Costs, as this technology has no alternative future use. In addition, we have paid Albert Einstein College of Medicine research payments that have been recognized as research and development expense. We are also required to make milestone payments to Albert Einstein College of Medicine upon the achievement of certain regulatory and clinical events. In the aggregate these success based milestones may total up to \$4.8 million including amounts due upon receipt of our first drug approval in the U.S. and in specified foreign countries. We must pay Albert Einstein College of Medicine royalties based on a percentage of net sales of our products. If a product is combined with a drug or other substance for which we are paying an additional royalty, the royalty rate we pay to Albert Einstein College of Medicine will be reduced by one-half of the amount of such additional royalty.

## Research and Development

Research and development expense consists of non-cash stock based compensation (as described below) and other research and development expense. Other research and development expense consists of drug development work associated with our product candidates, primarily including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, research payments to the Albert Einstein College of Medicine and salaries and other personnel related expenses. Other research and development expense was \$11.6 million in the 2001 period compared to \$8.7 million in the 2000 period. The period to period increase of \$2.9 million was primarily due to increases in preclinical and clinical development activities, clinical supplies and related formulation and design costs, salaries and other personnel related costs associated with increases in staff to support these activities. Other research and development expenses are expected to increase significantly over the next several years as our development efforts are expanded and our product candidates enter into various stages of clinical trials, and may vary from period to period due to the timing of these activities.

General and Administrative

General and administrative expense consists of non-cash stock based compensation (as described below) and other general and administrative expense. Other general and administrative expense consists primarily of salaries and other personnel related expenses to support our activities, consulting and professional services expenses, facilities expenses and other general corporate expenses. Other general and administrative expenses were \$4.5 million in the 2001 period compared to \$2.9 million in the 2000 period. The period to period increase of \$1.6 million was primarily due to increases in salaries and other personnel related costs associated with increased staffing, consulting and professional services expenses and other general corporate expenses.

## Non-Cash Stock Based Compensation

Deferred stock compensation for options granted to employees represents the difference between the exercise price of the option and the fair value of our common stock on the date of grant in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Deferred compensation for non-employees is recorded at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123 and is periodically re-measured until the underlying options vest in accordance with Emerging Issues Task Force No. 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 expected volatility of our common stock at the date of measurement or re-measurement. The compensation expense related to all grants is amortized over the vesting period of the related stock options in accordance with FIN 28.

The amount of compensation expense we record could fluctuate significantly from period to period as a result of: (a) the periodic re-measurement of deferred stock compensation for non-employees principally as a result of fluctuations in the market price of our common stock, (b) the amount of additional options granted to non-employees and (c) the method by which deferred stock compensation is amortized as charges to operations.

In connection with the grant of stock options to employees as well as the re-measurement of deferred stock compensation for grants of stock options to non-employees, we recorded a decrease in deferred compensation on the balance sheet of \$2.1 million for the period ended December 31, 2001 compared to an increase of \$6.2 million for the period ended December 31, 2000. These amounts were recorded as a component of stockholders' equity (deficit) and are being amortized as charges to operations. We recognized non-cash stock based compensation expense for options granted as well as restricted stock purchase agreements as components of both research and development expense and general and administrative expense

totaling \$1.2 million and \$8.7 million for the periods ended December 31, 2001 and 2000, respectively. The decrease was principally the result of the lower market price of our common stock at the end of 2001 as compared to 2000, the amortization methodology utilized in accordance with FIN 28 and the inclusion of \$2.6 million of compensation expense related to restricted stock purchase agreements in the 2000 period. There will also continue to be future non-cash charges for the amortization of deferred compensation related to options granted to employees and consultants.

#### Interest Income

Interest income increased to \$3.0 million for the year ended December 31, 2001 from \$2.8 million for the year ended December 31, 2000. This increase resulted from higher average balances of cash and cash equivalents principally as a result of the completion of our initial public offering in July 2000, partially offset by declining interest rates in the 2001 period.

#### Return to Series C Preferred Stockholders for Beneficial Conversion Feature

In February 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 preferred stock was issued with a beneficial conversion feature. The beneficial conversion feature has been recognized by allocating a portion of the preferred stock proceeds equal to the intrinsic value of that feature, limited to the net proceeds received (\$14.2 million), to additional paid-in capital. The intrinsic value is calculated at the date of issue as the difference between the conversion price of the preferred stock and the fair value of our common stock, into which the preferred stock is convertible, multiplied by the number of common shares into which the preferred stock is convertible, limited to the net proceeds received. As our series C 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 discount resulting from the allocation of proceeds to the beneficial conversion feature 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 in the period ended December 31, 2000. Upon completion of our initial public offering in July 2000, all of our convertible preferred and redeemable convertible preferred stock automatically converted into common stock on a one to one basis.

YEARS ENDED DECEMBER 31, 2000 AND 1999

Research and Development

Research and development expense consists of non-cash stock based compensation (as described below) and other research and development expense. Other research and development expenses were \$8.7 million in the 2000 period compared to \$2.5 million in the 1999 period. The increase of \$6.2 million was primarily due to increases in clinical development activities for our product candidates and increases in salaries and other personnel related costs associated with increasing staffing in support of these activities.

# General and Administrative

```
YEARS ENDED DECEMBER 31, ------
2000 1999 ------
General and
administrative: Non-cash stock based
compensation......
$4,832,793 $117,555 Other general
and administrative
expense...... 2,875,947
574,630 ----- Total
general and administrative
expense......
$7,708,740 $692,185 =======
=======
```

General and administrative expense consists of non-cash stock based compensation (as described below) and other general and administrative expense. Other general and administrative expenses were \$2.9 million in the 2000 period compared to \$0.6 million in the 1999 period. The increase of \$2.3 million was primarily attributable to salaries and other personnel related costs associated with increased staffing, consulting and professional services expenses.

#### Non-Cash Stock Based Compensation

In connection with the grant of stock options to employees as well as the re-measurement of deferred stock compensation for grants of stock options to non-employees, we recorded an increase in deferred compensation on the balance sheet of \$6.2 million for the period ended December 31, 2000 and \$6.5 million for the period ended December 31, 1999. These amounts were recorded as a component of stockholders' equity (deficit) and are being amortized as charges to operations. We recognized non-cash stock based compensation expense for options granted as well as restricted stock purchase agreements as components of both research and development expense and general and administrative expense, which totaled \$8.7 million and \$1.6 million for the period ended December 31, 2000 and 1999, respectively. The increase was principally the result of the market price of our common stock at the end of 2000, the amortization methodology utilized in accordance with FIN 28 and the inclusion of compensation expense related to restricted stock purchase agreements in the 2000 period. There will also continue to be future non-cash charges for the amortization of deferred compensation related to options granted to employees and consultants.

#### Interest Income

Interest income increased to \$2.8 million for the year ended December 31, 2000 from \$0.2 million for the year ended December 31, 1999. This increase resulted from higher average balances of cash and cash equivalents following the sale of our series B and series C redeemable convertible preferred stock in the fourth quarter of 1999 and the first quarter of 2000, respectively, and the completion of our initial public offering in July 2000.

#### RELATED PARTY TRANSACTIONS

The Company had outstanding full recourse loans aggregating \$51,246 and \$157,168 to certain officers and employees of the Company at December 31, 2000 and 2001, respectively. The notes bear interest at rates ranging from 5.5% to 8.0% and have maturities through January 2004. An officer of the Company is also a director of a private company that provided preclinical drug development services to the Company totaling \$388,805 in 2001. In October 2001, a former officer of the Company was retained as a consultant. For these services he received \$65,000 in 2001. An officer and director of the Company is also the president of a consulting firm in the pharmaceutical industry that provided \$48,000 in clinical trial design, data review and interpretational services to the Company in 2001.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, we have financed our operations primarily through the private placement of our preferred stock and the public sale of our common stock. We intend to continue to use these proceeds to fund research and development activities, capital expenditures, working capital and other general corporate purposes. As of

December 31, 2001, cash and cash equivalents were \$65.3 million. Currently, our cash and cash equivalents are primarily invested in money market funds.

Net cash used in operating activities was \$12.4 million for the year ended December 31, 2001 compared to \$7.4 million in 2000 and \$2.7 million in 1999. Cash used in operating activities related primarily to the funding of net operating losses partially offset by non-cash charges related to amortization of deferred stock compensation as well as stock issuances pursuant to stock purchase agreements in the 2000 period.

Our investing activities used cash of \$1.3 million in each of the years ended December 31, 2001 and 2000 compared to \$38,545 in 1999. Investing activities consisted of purchases of property and equipment as well as the funding of tenant improvements in conjunction with the build-out of new office space in the 2000 and 2001 periods. We expect to continue making investments in our infrastructure to support our operations.

Our financing activities provided cash of \$0.1 million for the year ended December 31, 2001 compared to \$78.3 million for the year ended December 31, 2000 and \$9.7 million in 1999. The 2000 amount consisted primarily of net cash proceeds of \$15.2 million from the issuance of our series C redeemable convertible preferred stock in February 2000 and net proceeds of \$62.9 million from our initial public offering in July 2000. The 1999 cash flows from financing activities were primarily the result of the issuance of \$9.7 million of our Series B redeemable convertible preferred stock.

We currently lease approximately 10,500 square feet of general office space. Lease payments under this lease agreement total \$1.8 million and commenced in October 2000 through the ten-year term of the lease. In April 2001 we completed the build-out of tenant improvements and relocated to this facility and subsequently terminated existing sublease agreements on 6,150 feet of 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:

2002	\$186,249
2003	184,638
2004	178,878
2005	177,726
2006 and thereafter	844,198

Under the terms of our license agreement with Albert Einstein College of Medicine, we are required to make milestone payments upon the achievement of certain regulatory and clinical events. In the aggregate these success-based milestones may total up to \$4.8 million including amounts due upon receipt of our first drug approval in the U.S. and in specified foreign countries. We also must pay Albert Einstein College of Medicine royalties based on a percentage of net sales of our products. If a product is combined with a drug or other substance for which we are paying an additional royalty, the royalty rate we pay to Albert Einstein College of Medicine will be reduced by one-half of the amount of such additional royalty.

Since our inception we have incurred a cumulative deficit of approximately \$36.7 million, including a net loss of \$14.3 million in 2001, and we expect to incur significant additional operating losses for the next several years. Since inception we have used \$22.7 million of cash in operating activities and \$2.7 million of cash in investing activities. Since inception, \$90.7 million of cash has been provided by financing activities. At December 31, 2001 cash and cash equivalents were \$65.3 million. We expect our cash requirements to increase in the foreseeable future as we continue to undertake preclinical and clinical trials for our product candidates; seek regulatory approvals for our product 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, if any, 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.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No 17, "Intangible Assets." SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. Pain Therapeutics, Inc. will adopt SFAS No. 142 during the first quarter of fiscal 2002. Management does not expect the adoption of SFAS No. 142 to have a material impact on the Company's financial position and results of operations.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"), which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and parts of APB Opinion No. 30 ("Opinion 30"), "Reporting the Results of Operations -- Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Pain Therapeutics, Inc. will adopt SFAS No. 144 during the first quarter of fiscal 2002. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial position and results of operations.

#### RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this Form 10-K. Risks and uncertainties, in addition to those we describe below, that are not presently known to us, or that we currently believe are immaterial may also impair our business operations. If any of the following risks occur, our business, operating results and financial condition could be seriously harmed. In addition, the trading price of our common stock could suddenly decline due to the occurrence of any of these risks.

OUR BRIEF 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 we are still 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. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture 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, including a net loss of approximately \$14.3 million in the year ended December 31, 2001. As a result of ongoing operating losses, we had an accumulated deficit of \$36.7 million as of December 31, 2001. We are not currently profitable. Even if we succeed in developing and commercializing one or more of our drugs, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical and clinical trials for our product candidates;
- seek regulatory approvals for our product 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 also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, 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 PRODUCT CANDIDATES.

Until we receive regulatory approval and commercialize one or more of our products, we will have to fund all of our operations and capital expenditures from cash on hand. We expect that our current cash and cash equivalents on hand will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months. However, if we experience unanticipated cash requirements, we may need to raise additional funds much sooner and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional equity 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 do not succeed in raising additional funds, we may be unable to complete planned clinical trials or obtain FDA approval of our product candidates, and we could be forced to discontinue product development, reduce sales and marketing efforts and forego attractive business opportunities.

IF OUTSIDE RESEARCHERS 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. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If outside collaborators assist our competitors at our expense, our competitive position could be harmed.

IF WE ARE UNABLE TO DESIGN, CONDUCT AND COMPLETE CLINICAL TRIALS SUCCESSFULLY, WE WILL NOT BE ABLE TO SUBMIT A NEW DRUG APPLICATION TO THE FDA.

In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a New Drug Application, or NDA, which demonstrates that the product candidate is safe for humans and effective 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. We have four product candidates in various stages of clinical trials including MorViva(TM) (previously known as PTI-501 (injectible version) and PTI-555 (oral version)), OxyTrex(TM) (previously known as PTI-801), PTI-701 and PTI-601. We have completed multiple Phase I and Phase II studies for MorViva(TM) and two pharmacokinetic and safety studies for OxyTrex(TM), and we are designing and conducting clinical trials to demonstrate the safety and efficacy of these two drug candidates in different clinical settings of pain. No significant trials are planned in the near future for PTI-701 or PTI-601. We will have to commit substantial time and additional resources to conducting further preclinical and clinical studies in several types of pain before we can submit NDAs with respect to any of these product candidates. Our other product candidates are at a much earlier stage of development and will require extensive preclinical and clinical testing before we can make any decision to proceed with their clinical development.

Human 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. We estimate that clinical trials of our leading product candidates will take a minimum of three years or more to complete and may take longer. If we or the FDA believe the participating patients are being exposed to unacceptable health risks, we would have to suspend our clinical trials. Furthermore, 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. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Such failure would cause us to abandon a product candidate and may delay development of other product candidates.

IF WE FAIL TO OBTAIN THE NECESSARY REGULATORY APPROVALS, WE WILL NOT BE ALLOWED TO COMMERCIALIZE OUR DRUGS AND WILL NOT GENERATE PRODUCT REVENUES.

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product 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. The FDA may require us to conduct additional clinical testing or to commit to perform post-marketing studies, in which cases we would have to expend additional unanticipated 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 may:

- delay commercialization of, and product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately deny one or more of our NDAs, and we may never obtain regulatory approval for any of our product candidates. If we fail to achieve regulatory approval of any of our leading product candidates we will have fewer saleable products and corresponding 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.

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 requirements and risks associated with the FDA approval procedures described above.

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; 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 product 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 THIRD-PARTY MANUFACTURERS OF OUR PRODUCT 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 RISE.

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 to test the technical performance of our product 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 delay FDA approval of our product 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. 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, FDA must approve any alternative manufacturer of our product before we may use the alternative manufacturer to produce our clinical supplies. It may be difficult or impossible for us to find a replacement 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.
- 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 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 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.

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. On the other hand, 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 product 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 the efforts of our collaborators 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 product candidates is characterized by intense competition and rapid technological advances. If our products 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;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

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. Such alternatives include Elan's Ziconotide(TM) and Endo Pharmaceuticals' MorphiDex(R). In addition, 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, parties for acquisitions, joint ventures or other collaborations.

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 either we or Albert Einstein College of Medicine fails to file, prosecute or maintain any of our existing patents, our competitors could market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result. We intend to file additional patent applications relating to our technology, products and processes. We may direct Albert Einstein College of Medicine 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 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. Moreover, 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.

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 AND 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.

THE DEA LIMITS THE AVAILABILITY OF THE ACTIVE INGREDIENTS IN OUR CURRENT PRODUCT 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. The active ingredients in our current product candidates, including morphine, hydrocodone and oxycodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, 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.

WE MAY INCUR SUBSTANTIAL LIABILITIES AND MAY BE REQUIRED TO LIMIT TESTING OF OUR PRODUCTS IN RESPONSE TO PRODUCT LIABILITY LAWSUITS.

The risk of product liability is inherent in the testing of medical 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.

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 (HMO's) and managed care organizations (MCO's), 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.

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 market price if trading in our stock is not active or the volume is low. The following factors, in addition to general market volatility and other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new commercial products by us or others;
- results of our preclinical and clinical trials;
- developments in patent or other proprietary rights;
- publicity regarding actual or potential medical results relating to products under developments by us or others;
- comments by securities analysts;
- future sales of our common stock by existing stockholders;
- regulatory developments;

- 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

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 product 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.

FUTURE SALES OF OUR COMMON STOCK MAY IMPACT THE PRICE OF OUR COMMON STOCK.

Additional equity financings or other share issuances by us could adversely affect the market price of our common stock. Additionally, sales by existing shareholders of a large number of shares of our common stock in the public market or the perception that additional sales could occur could cause the price of our common stock to decline and may impair our ability to raise capital in the future.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

The primary objective of our 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 prevailing interest rate later rises, the principal amount of our investment will probably decline. 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. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. We had no holdings of derivative financial or commodity instruments, and as of December 31, 2001 all of our cash and cash equivalents were in money market and checking funds with variable, market rates of interest.

# INDEX TO FINANCIAL STATEMENTS

31

The Board of Directors Pain Therapeutics, Inc.:

We have audited the accompanying balance sheets of Pain Therapeutics, Inc. (a development stage enterprise) as of December 31, 2000 and 2001, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three year period ended December 31, 2001 and for the period from May 4, 1998 (inception) through December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Pain Therapeutics, Inc. (a development stage enterprise) as of December 31, 2000 and 2001 and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2001 and for the period from May 4, 1998 (inception) through 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

# BALANCE SHEETS

DECEMBER	31,	2000 2001 ASSETS Current assets: Cash
and cash	equivalent	s\$ 0 \$ 65,274,291 Interest
	445,3	326 116,688 Prepaid
400,66	57 323,323 -	Total
79,77	72,823 65,71	
net		2,346,494 Other
		Total \$
81,147,	046 \$ 68,13	35,796 ========= ===================
LIAB		STOCKHOLDERS' EQUITY Current pilities: Accounts
payabl		\$ 79 \$ 2,170,211 Accrued
liabil		, ,
		Total
liab	ilities	
		471
		JITY Preferred stock, \$.001 par hares authorized, none issued and
		Common stock, \$.001
		000 shares authorized; 26,738,316
		es issued and outstanding in 2000
	2001, respe	ectively 26,739 26,838 Hitional paid-in-
capita	1	106,182,319 ,209,656 Deferred
compe	nsation	
(5,⊍/	(3,091) $(1,1)$	733,524) Notes receivable from 
		lated during the development
		3, 382) (36, 705, 732)
		Total stockholders'
equity		78,694,668 65,616,325
stoc	ckholders' e	equity \$ 81,147,046 \$
	68,135,796	

See accompanying notes to financial statements.

# STATEMENTS OF OPERATIONS

MAY 4, 1998 (INCEPTION) YEARS ENDED DECEMBER 31, THROUGH
DECEMBER 31, 1999 2000 2001 2001
Operating expenses: Licensing fees\$ \$ \$ 100,000 Research and development: Non-cash stock based compensation 1,505,312 3,926,473 77,080 5,508,865 Other research and development expense 2,461,977 8,669,696 11,590,609 22,922,282
research and development 3,967,289 12,596,169 11,667,689 28,431,147 General and administrative: Non-cash stock based compensation
117,555 4,832,793 1,121,279 6,071,627 Other general and administrative expense 574,630 2,875,947 4,525,742 8,098,487
Total general and administrative
operating expenses 4,659,474 20,304,909 17,314,710 42,701,261 Operating loss
(4,659,474) (20,304,909) (17,314,710) (42,701,261) Other income: Interest
income 160,689 2,825,919 2,978,160 5,998,729 Net loss before income taxes (4,498,785) (17,478,990) (14,336,550) (36,702,532) Income tax expense 800 800 800 3,200 Net
loss
(14,231,595) (14,231,595) Loss available to common
shareholders \$(4,499,585) \$(31,711,385) \$(14,337,350) \$(50,937,327) ====================================
<pre>======= Basic and diluted loss per share \$ (1.35) \$ (2.33) \$ (0.57) ==========</pre>
============== Weighted-average shares used in computing basic and diluted loss per
share 3,345,397 13,634,513 25,331,541

See accompanying notes to financial statements.

# STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD MAY 4, 1998 (INCEPTION) THROUGH DECEMBER 31, 1998 AND THE YEARS ENDED DECEMBER 31, 1999, 2000 AND 2001 SERIES A CONVERTIBLE PREFERRED STOCK COMMON STOCK ADDITIONAL NOTE ----- ------ PATD-TN DEFERRED RECEIVABLE SHARES PAR VALUE SHARES PAR VALUE CAPITAL COMPENSATION FOR STOCK ---------- ------ BALANCE AT MAY 4, 1998 (INCEPTION)..... -- \$ -- \$ -- \$ -- \$ --Common stock issued on June 22, 1998 at \$0.001 per share..... -- -- 8,500,000 8,500 -- -- Series A convertible preferred stock issued between August 14, 1998 and October 28,1998 at \$1.00 per share (net of issuance costs of \$19,490)..... 2,659,489 2,660 -- -- 2,637,339 -- -- Common stock issued on September 23, 1998 at \$0.10 per share for notes receivable..... -- -350,000 350 34,650 -- (35,000) Common stock issued on September 23, 1998 at \$0.10 for cash..... -- -- 150,000 150 14,850 -- -- Net loss..... -- -- -- -- -- -- -- ------ --BALANCE AT DECEMBER 31, 1998..... 2,659,489 2,660 9,000,000 9,000 2,686,839 --(35,000) Common stock issued between April 1 and May 3, 1999 at \$0.10 per share for notes receivable..... 444,000 444 43,956 -- (44,400) Issuance of common stock pursuant to exercise of stock options..... -- -- 1,000 1 99 ---- Issuance of warrants in connection with lease in August -- -- Deferred compensation with respect to option issuances..... --- 6,515,027 (6,515,027) --Amortization of deferred compensation..... -- -- -- 1,534,847 --Compensation expense with respect to non-employee option grants.... -- -- -- 88,019 ---- Payment of notes receivable..... -- -- -- ---- 5000 Net loss..... -- -- -- -- -- -- -- ------ ------- -------BALANCE AT DECEMBER 31, 1999..... 2,659,489 2,660 9,445,000 9,445 9,367,750 (4,980,180) (74,400) Common stock issued pursuant to initial public

```
offering at $12.00 per share, net
         of issuance
costs....
         . . . . . . . . . . . . .
 -- -- 5,750,000 5,750 62,933,167
  -- -- Common stock issued at
   $0.20 per share for notes
 receivable..... -- -- 245,000
 245 48,755 -- (49,000) Issuance
   of common stock pursuant to
exercise of stock options..... -
  - -- 184,740 185 42,614 -- --
    Issuance of warrants in
    connection with series C
        preferred stock
offering.....
    -- -- 963,240 -- --
   Deferred compensation with
       respect to option
issuances..... -
   -- 6,206,177 (6,206,177) --
    Amortization of deferred
compensation.....
   -- -- -- 6,113,266 --
  Compensation related to stock
          purchase
rights..... -- -- -
  -- 2,646,000 -- -- Issuance of
common stock related to employee
 stock purchase plan..... -- --
 4,664 5 47,567 -- -- Payment of
       shareholder notes
receivable.....
    -- -- -- -- 50,483
     Conversion of series A
 convertible preferred stock to
      common at $1.00 per
 share.....
  (2,659,489) (2,660) 2,659,489
  2,660 -- -- -- Conversion of
 series B redeemable convertible
  preferred stock to common at
 $1.85 per share..... -- --
 5,405,405 5,405 9,698,498 -- --
Conversion of series C redeemable
 convertible preferred stock to
      common at $5.00 per
share..... -- -- 3,044,018
3,044 14,228,551 -- -- Beneficial
 conversion feature of series C
preferred stock..... -- -- -
 - -- 14,231,595 -- -- Return to
 series C preferred shareholders
   for beneficial conversion
 feature.....
   -- (14,231,595) -- -- Net
loss..... -
- -- -- -- -- -- -- ------ --
BALANCE AT DECEMBER 31,
  2000..... -- -- 26,738,316
 26,739 106,182,319 (5,073,091)
(72,917) Issuance of common stock
  pursuant to exercise of stock
  options..... -- -- 78,635 79
     49,557 -- -- Deferred
  compensation with respect to
option issuances.....
  -- -- (2,141,208) 2,141,208
   -- Amortization of deferred
compensation.....
   -- -- -- -- 1,198,359 --
 Issuance of common stock related
   to employee stock purchase
   plan..... -- -- 20,374 20
 118,988 -- -- Issuance of notes
 receivable..... -- -- -- --
       -- (107,996) Net
loss..... -
- -- -- -- -- -- -- ------ --
```

```
BALANCE AT DECEMBER 31,
 2001..... -- $ -- 26,837,325
$26,838 $104,209,656 $(1,733,524)
  $(180,913) ======== ======
 DEFICIT ACCUMULATED DURING
STOCKHOLDERS' DEVELOPMENT EQUITY
STAGE (DEFICIT) -----
----- BALANCE AT MAY 4, 1998
(INCEPTION).....
$ -- $ -- Common stock issued on
  June 22, 1998 at $0.001 per
share..... -- 8,500 Series A
  convertible preferred stock
 issued between August 14, 1998
and October 28,1998 at $1.00 per
 share (net of issuance costs of
$19,490)..... -
 - 2,639,999 Common stock issued
 on September 23, 1998 at $0.10
      per share for notes
receivable....
    - Common stock issued on
 September 23, 1998 at $0.10 for
   cash..... -- 15,000 Net
 loss.....
(389,007) (389,007) ------
 ----- BALANCE AT DECEMBER
   31, 1998..... (389,007)
 2,274,492 Common stock issued
 between April 1 and May 3, 1999
  at $0.10 per share for notes
 receivable..... -- --
Issuance of common stock pursuant
      to exercise of stock
options..... -- 100 Issuance of
warrants in connection with lease
in August 1999..... -- 33,810
   Deferred compensation with
      respect to option
 issuances.....
    Amortization of deferred
compensation.....
-- 1,534,847 Compensation expense
  with respect to non-employee
  option grants.... -- 88,019
       Payment of notes
 receivable..... -- 5,000 Net
 loss.....
(4,499,585) (4,499,585) -----
      ----- BALANCE AT
    DECEMBER 31, 1999.....
  (4,888,592) (563,317) Common
stock issued pursuant to initial
  public offering at $12.00 per
     share, net of issuance
costs.....
-- 62,938,917 Common stock issued
  at $0.20 per share for notes
receivable..... -- -- Issuance
  of common stock pursuant to
exercise of stock options.....
- 42,799 Issuance of warrants in
    connection with series C
        preferred stock
offering.....
-- 963,240 Deferred compensation
     with respect to option
 issuances.....--
    Amortization of deferred
compensation.....
-- 6,113,266 Compensation related
       to stock purchase
  rights..... --
  2,646,000 Issuance of common
 stock related to employee stock
  purchase plan..... -- 47,572
  Payment of shareholder notes
receivable.....
```

```
-- 50,483 Conversion of series A
 convertible preferred stock to
     common at $1.00 per
share.....
    -- Conversion of series B
redeemable convertible preferred
  stock to common at $1.85 per
   share..... -- 9,703,903
Conversion of series C redeemable
 convertible preferred stock to
      common at $5.00 per
  share..... -- 14,231,595
Beneficial conversion feature of
      series C preferred
  stock..... -- 14,231,595
  Return to series C preferred
   shareholders for beneficial
          conversion
   feature..... --
       (14,231,595) Net
 loss.....
(17,479,790) (17,479,790) ------
  ----- BALANCE AT
    DECEMBER 31, 2000.....
 (22,368,382) 78,694,668 Issuance
   of common stock pursuant to
exercise of stock options..... -
  - 49,636 Deferred compensation
     with respect to option
 issuances..... -- --
    Amortization of deferred
compensation.....
 -- 1,198,359 Issuance of common
 stock related to employee stock
 purchase plan.... -- 119,008
       Issuance of notes
 receivable..... -- (107,996)
             Net
 loss.....
(14,337,350) (14,337,350) ------
  ----- BALANCE AT
   DECEMBER 31, 2001.....
$(36,705,732) $ 65,616,325
```

See accompanying notes to financial statements.

# STATEMENTS OF CASH FLOWS

MAY 4, 1998 (INCEPTION) YEARS ENDED DECEMBER 31, THROUGH ---------- DECEMBER 31, 1999 2000 2001 2001 ---------- Cash flows from operating activities: Net loss..... \$(4,499,585) \$(17,479,790) \$(14,337,350) \$(36,705,732) Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization..... 4,244 44,933 244,974 294,669 Amortization of deferred compensation..... 1,534,847 6,113,266 1,198,359 8,846,472 Non-cash expense for options and warrants issued..... 121,829 2,646,000 -- 2,767,829 Loss on disposal of property and equipment..... 2,729 49,684 52,413 Changes in operating assets and liabilities: Interest receivable..... (12,224) (429,964) 328,638 (116,688) Prepaid expenses..... (5,891) (359,280) 77,344 (323,323) Other assets..... (75,000) -- (75,000) Accounts payable..... 192,479 2,012,692 (143,068) 2,170,211 Accrued liabilities..... -- 139,099 210,161 349,260 ------ ----- Net cash used in operating activities..... (2,664,301) (7,385,315) (12,371,258)(22,739,889) ----- Cash flows used in investing activities: Purchase of property and equipment..... (38,545) (1,302,130) (1,341,929) (2,693,576) ---------- Cash flows from financing activities: Proceeds from issuance of series B redeemable convertible preferred stock, net..... 9,703,903 -- -- 9,703,903 Proceeds from issuance of series C redeemable convertible preferred stock, net..... --15,194,835 -- 15,194,835 Stock subscription received..... 5,000 50,483 -- 55,483 Proceeds from issuance of series A convertible preferred stock, net.... -- -- --2,639,999 Net proceeds from issuance of common stock.... 100 90,371 60,648 174,619 Proceeds from initial public offering, net..... -- 62,938,917 -- 62,938,917 -----Net cash provided by financing activities..... 9,709,003 78,274,606 60,648 90,707,756 ----- ---------- Net increase (decrease) in cash and cash equivalents..... 7,006,157 69,587,161 (13,652,539)

See accompanying notes to financial statements.

# NOTES TO FINANCIAL STATEMENTS

### 1. BUSINESS

Pain Therapeutics, Inc. is a development stage enterprise and was incorporated on May 4, 1998. Since our inception in May 1998, we have licensed proprietary technology from Albert Einstein College of Medicine and have devoted substantially all of our resources to the development of a new generation of opioid painkillers with improved clinical benefits, which are based on the acquired technology. 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 product candidates that have not yet obtained Food and Drug Administration approval. Successful future operations depend on our ability to obtain approval for and commercialize these products.

We currently have four opioid painkillers in various stages of Phase II clinical trials, including our two lead product candidates MorViva(TM) and OxyTrex(TM). We have completed multiple Phase I and Phase II studies for MorViva(TM) and two pharmacokinetic and safety studies completed for OxyTrex(TM) and we are designing and conducting clinical trials to demonstrate the safety and efficacy of these two drug candidates. We are developing PTI-701 and PTI-601 on a very limited basis at the present time.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

# RESEARCH AND DEVELOPMENT COSTS

Research and development costs and the costs of obtaining licenses used in research and development are charged to expense as incurred. Research and development costs consist of drug development work associated with our product candidates, primarily including costs of preclinical and clinical trials, clinical supplies and related formulation and design costs, research payments to the Albert Einstein College of Medicine and salaries and other personnel related expenses including non-cash stock based compensation.

#### NON-CASH STOCK BASED COMPENSATION

Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock Based Compensation, establishes a fair-value method of accounting for stock options and similar equity instruments. The fair-value method requires compensation cost to be measured at the grant date based on the value of the award, and recognized over the service period. SFAS No. 123 allows companies to account for stock based compensation to employees under either the provisions of SFAS No. 123 or the provisions of Accounting Principles Board (APB) Opinion No. 25 and its related interpretations. We have elected to account for our stock based compensation to employees in accordance with the provisions of APB Opinion No. 25 and provide the pro forma disclosures required under SFAS No. 123.

Deferred stock compensation for options granted to employees represents the difference between the exercise price of the option and the fair value of our common stock on the date of grant in accordance with APB Opinion No. 25 and its related interpretations. Deferred compensation for non-employees is recorded at the fair value of the options granted in accordance with SFAS No. 123 and is periodically re-measured as the underlying options vest in accordance with Emerging Issues Task Force (EITF) Issue No. 96-18 Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services. The compensation expense related to all grants is amortized over the vesting period of the related stock options in accordance with Financial Accounting Standards Board Interpretation No. 28 (FIN

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

28), as that methodology most closely approximates the way in which our options are earned by the option holder.

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 one financial institution and money market funds.

#### 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.

#### INCOME TAXES

Income taxes are accounted for under the asset and 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.

### 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.

# FAIR VALUE OF FINANCIAL INSTRUMENTS

Interest and stock subscriptions receivables are considered to have carrying amounts that approximate fair value because of the short maturity of these financial instruments. Notes receivable are considered to have carrying amounts that approximate fair value as they bear a market rate of interest.

# IMPAIRMENT OF LONG-LIVED ASSETS

We review, as circumstances dictate, the carrying amount of our long-lived assets. The purpose of these reviews is to determine whether the carrying amounts are recoverable. Recoverability is determined by comparing the projected undiscounted net cash flows of the long-lived assets against their respective carrying amounts. The amount of impairment, if any, is measured based on the excess of the carrying value over the fair value. No events or changes in circumstances have occurred with respect to the Company's long-lived assets that would indicate that an impairment analysis should have been performed.

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

### COMPREHENSIVE LOSS

We have no components of other comprehensive loss other than our net loss and, accordingly, our comprehensive loss is equivalent to our net loss for all periods presented.

## BUSINESS SEGMENTS

SFAS 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 discovery and development of new opioid painkillers.

#### 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. All potential dilutive common shares were excluded from the calculation of diluted loss per share because the representative share increments would be anti-dilutive. 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.

The following table sets forth potential weighted-average shares of common stock that are not included in the computation of diluted net loss per share because to do so would be anti-dilutive for the periods indicated:

### RECLASSIFICATIONS

Certain reclassifications have been made to the prior year financial statements to conform with the presentation in 2001.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No 17, "Intangible Assets." SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. Pain Therapeutics, Inc. will adopt SFAS No. 142 during the first quarter

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

of fiscal 2002. Management does not expect the adoption of SFAS No. 142 to have a material impact on the Company's financial position and results of operations.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"), which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and parts of APB Opinion No. 30 ("Opinion 30"), "Reporting the Results of Operations -- Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Pain Therapeutics, Inc. will adopt SFAS No. 144 during the first quarter of fiscal 2002. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial position and results of operations.

#### 3. RELATED PARTY TRANSACTIONS

The Company had outstanding full recourse loans aggregating \$51,246 and \$157,168 to certain officers and employees of the Company at December 31, 2000 and 2001, respectively. The notes bear interest at rates ranging from 5.5% to 8.0% and have maturities through January 2004. An officer of the Company is also a director of a private company that provided preclinical drug development services to the Company totaling \$388,805 in 2001. In October 2001, a former officer of the Company was retained as a consultant. For these services he received \$65,000 in 2001. An officer and director of the Company is also the president of a consulting firm in the pharmaceutical industry that provided \$48,000 in clinical trial design, data review and interpretational services to the Company in 2001.

# 4. AGREEMENT WITH ALBERT EINSTEIN COLLEGE OF MEDICINE

In May 1998, we entered into an exclusive, worldwide license agreement with Albert Einstein College of Medicine for all patents and pending patent applications relating to low-dose opioid antagonist 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 agreement, in 1998 we paid Albert Einstein College of Medicine a one-time licensing fee which was recognized as license fee expense in accordance with Financial Accounting Standards No. 2, Accounting for Research and Development Costs, as this technology has no alternative future use. In addition, we have paid Albert Einstein College of Medicine research payments that have been recognized as research and development expense. We are also required to make milestone payments to Albert Einstein College of Medicine upon the achievement of certain regulatory and clinical events. In the aggregate these success based milestones may total up to \$4,800,000, including amounts due upon receipt of our first drug approval in the U.S. and in specified foreign countries. We must pay Albert Einstein College of Medicine royalties based on a percentage of net sales of our products. If a product is combined with a drug or other substance for which we are paying an additional royalty, the royalty rate we pay to Albert Einstein College of Medicine is generally reduced by one-half of the amount of such additional royalty.

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

### 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31:

2000 2001 Furniture and
fixtures\$
68,398 \$ 492,148 Computers and
software
156,278 224,611 Leasehold
improvements
15,626 1,891,485 240,302
2,608,244 Accumulated
depreciation
(48,976) (261,750) 191,326
2,346,494 Construction in
progress
1,107,897
Total
\$1,299,223 \$2,346,494 ======== ===============

Construction in progress at December 31, 2000 represented costs incurred relative to the construction of tenant improvements at a facility to which the Company relocated in 2001.

# 6. 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. At December 31, 2000 and 2001, there were no shares of redeemable convertible preferred stock issued or outstanding.

# RETURN TO SERIES C PREFERRED STOCKHOLDERS FOR BENEFICIAL CONVERSION FEATURE

In February 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 preferred stock was issued with a beneficial conversion feature. The beneficial conversion feature has been recognized by allocating a portion of the preferred stock proceeds equal to the intrinsic value of that feature, limited to the net proceeds received (\$14.2 million), to additional paid-in capital. The intrinsic value is calculated at the date of issue as the difference between the conversion price of the preferred stock and the fair value of our common stock, into which the preferred stock is convertible, multiplied by the number of common shares into which the preferred stock is convertible, limited to the net proceeds received. As our series C 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 discount resulting from the allocation of proceeds to the beneficial conversion feature 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.

## 7. STOCKHOLDERS' EQUITY (DEFICIT)

INITIAL PUBLIC OFFERING OF COMMON STOCK AND CONVERSION OF PREFERRED STOCK

On July 19, 2000, we completed an initial public offering in which we sold 5,000,000 shares of common stock at \$12.00 per share. On July 27, 2000, we sold an additional 750,000 shares of common stock at \$12.00

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

per share per our underwriter's exercise of the underwriters' over-allotment option at \$12.00 per share. We received net proceeds from these sales of common stock of approximately \$62.9 million, after deducting underwriting discounts and commission of approximately \$4.8 million and expenses of the offering of approximately \$1.2 million. Upon the closing of the offering, all 11,108,912 shares of our then outstanding preferred stock automatically converted into common stock on a one to one basis.

After the offering our authorized capital stock consisted of 120,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

### COMMON STOCK

On June 22, 1998, we issued 8,500,000 shares of common stock at \$0.001 per share. All of these shares were issued subject to a repurchase option. The shares are released from our repurchase option over a four-year vesting period at the rate of 1/48 at the end of each month from the vesting start date until all shares are released. Our repurchase option is exercisable only within 90 days following the termination of the purchaser's employment, during which time we are able to repurchase the unvested shares at the original purchase price of \$0.001 per share. As of December 31, 2000, 2,125,000 of these shares of common stock were not vested and, therefore, were subject to repurchase by us in the event of termination of the purchaser's employment. As of December 31, 2001, all shares of common stock subject to this agreement were fully vested.

Under the terms of the 1998 Stock Plan (see below), we have granted stock purchase rights and subsequently issued shares of common stock to employees and non-employees in exchange for full-recourse promissory notes or cash. Such shares were issued pursuant to a restricted stock purchase agreement and are subject to a repurchase option. The shares are released from our repurchase option over the original option vesting period, which ranges from two to four years. Our repurchase option is exercisable only within 90 days following the termination of the purchaser's employment or provision of services, during which time we are able to repurchase the unvested shares at the original purchase price. In September 1998 we granted stock purchase rights and subsequently issued 500,000 shares of common stock at \$0.10 per share in exchange for \$35,000 in full-recourse promissory notes and \$15,000 in cash. In February 1999 we granted stock purchase rights and subsequently issued 444,000 shares of common stock at \$0.10 per share in exchange for full-recourse promissory notes. In December 1999 we granted stock purchase rights and subsequently issued 245,000 shares of common stock at \$0.20 per share in exchange for \$49,000 in full-recourse promissory notes. As of December 31, 2000 and 2001, 412,709 and 226,456 shares of common stock, respectively, were not vested and, therefore, were subject to repurchase by us in the event of termination of the purchaser's employment or provision of services to us.

#### 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.

In 1998 we issued 2,659,489 shares of series A convertible preferred stock at a price of \$1.00 per share. Upon the closing of our initial public offering in July 2000, all shares of our then outstanding convertible preferred stock automatically converted into shares of common stock on a one to one basis. At December 31, 2000 and 2001, there were no shares of preferred stock issued or outstanding.

#### WARRANTS

In June 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

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

consideration 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 August 1999, we issued a warrant to purchase 70,000 shares of common stock at an exercise price of \$1.00 per share to the Company's landlord in connection with the commercial lease of the Company's 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 \$33,810 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.

In connection with the issuance of our series C preferred stock in February 2000, we issued a warrant to purchase 120,000 shares of common stock at \$5.00 per share. The warrant will expire on February 1, 2005. The shares of common stock underlying this warrant are not entitled to any registration rights. The fair value of this warrant of \$963,240 was estimated using a Black-Scholes model and the following assumptions: estimated volatility of 60%, a risk-free interest rate of 4.59%, no dividend yield, and an expected life equal to the contractual life of 5 years. The fair value was recognized as an increase to additional paid-in capital.

### STOCK BASED BENEFIT PLANS

#### 2000 Employee Stock Purchase Plan

In June 2000, our shareholders approved the Company's 2000 Employee Stock Purchase Plan (the "2000 Purchase Plan"). A total of 500,000 shares of common stock have been reserved for issuance under the 2000 Purchase Plan, plus an annual increase equal to the lesser of (i) 500,000 shares, (ii) 1% of the outstanding shares of common stock on such date, or (iii) an amount determined by the Board of Directors. The 2000 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. As of December 31, 2001, 20,374 shares of common stock had been issued pursuant to the 2000 Purchase Plan (4,664 shares as of December 31, 2000).

### 1998 Stock Plan

In June 2000 our stockholders approved an amendment to our 1998 Stock Plan, which amended and restated the 1998 Stock Plan originally approved by the Board of Directors in September 1998. Under the 1998 Stock Plan, employees, directors and consultants ("Service Providers") may be granted options that allow for the purchase of shares of our common stock. Non-statutory stock options may be granted to all Service Providers (see Common Stock above for description of stock purchase rights granted). Incentive stock options may only be granted to employees. At December 31, 2001 a total of 6,000,000 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

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

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 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 beginning in fiscal year 2001, each outside director is automatically granted an option to purchase 20,000 shares of common stock provided the individual continues to serve as an outside director through the date of such meeting. 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.

There were no options granted during the period from May 4, 1998 (inception) through December 31, 1998.

The following table summarizes option activity under the 1998 Stock Plan:

OPTIONS OUTSTANDING ---------- RANGE OF WEIGHTED-NUMBER OF EXERCISE AVERAGE OPTIONS PRICES EXERCISE PRICE ---------- Options outstanding as of December 31, 1998... -- \$ -- \$ -- ------· -----Granted..... 1,361,200 0.10 - 0.20 0.12 Exercised..... (1,000) 0.10 0.10 Forfeited..... (65,000) 0.10 0.10 ---------- Options outstanding as of December 31, 1999... 1,295,200 \$0.10 - \$0.20 \$0.12 ------ ----- -----Granted..... 934,000 1.00 - 18.63 6.98 Exercised..... (184,740) 0.10 - 9.00 0.22 Forfeited..... (38,209) 0.10 - 9.00 3.45 ---------- ---- Options outstanding as of December 31, 2000... 2,006,251 \$0.10 -\$18.63 \$3.14 -----Granted..... 1,423,000 6.78 - 9.10 7.39 Exercised..... (78,635) 0.10 - 8.00 0.63 Forfeited..... (465,900) 0.10 - 9.00 2.61 ---------- Options outstanding as of December 31, 2001... 2,884,716 \$0.10 -\$18.63 \$5.39 ======= ====== =====

Shares available for grant under the 1998 Stock Plan were 14,800, 1,319,009 and 1,661,909 as of December 31, 1999, 2000 and 2001 respectively.

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

The following table summarizes information about stock options outstanding as of December 31, 2001:

OPTIONS OUTSTANDING OPTIONS EXERCISABLE WEIGHTED OPTIONS EXERCISABLE WEIGHTED WEIGHTED REMAINING AVERAGE NUMBER AVERAGE NUMBER CONTRACTUAL EXERCISE OF VESTED EXERCISE RANGE OF EXERCISE PRICES OF OPTIONS LIFE (YEARS) PRICE OPTIONS PRICE .
\$0.10
508,041 7.45 \$ 0.10 372,932 \$ 0.10
\$0.20 -
\$2.00
669,833 8.07 1.07 312,227 0.95
\$6.78
550,000 9.81 6.78 80,208 6.78 \$7.00
- \$8.00
527,842 9.6 7.39 48,519 7.61 \$8.01 -
\$14.13
554,000 8.99 10.39 127,516 10.97
\$18.63
75,000 8.71 18.63 23,438 18.63
\$0.10 -
\$18.63
2,884,716 8.77 \$ 5.39 964,840 \$ 3.19

As of December 31, 1999, 2000 and 2001 there were 133,213, 409,304 and 964,840 fully vested and exercisable shares with a weighted average exercise price of \$0.11, \$1.47 and \$3.19 per share, respectively.

# Pro Forma Information

Pursuant to SFAS No. 123, Accounting for Stock Based Compensation, we are required to disclose the pro forma effects on net loss and net loss per share as if we had elected to use the fair value approach to account for all of our employee stock based compensation plans. Had compensation cost of our plans been determined in a manner consistent with the fair value approach of SFAS No. 123, our pro forma net loss and pro forma net loss per share would have been increased to the pro forma amounts indicated below:

DECEMBER 31,
1999 2000 2001
Net loss available to common
shareholders as
reported
\$4,499,585 \$31,711,385 \$14,337,350 Adjusted
pro forma net loss
\$4,505,402 \$32,757,896 \$18,593,356 Net loss
per share basic and diluted as
reported
\$ (1.35) \$ (2.33) \$ (0.57) Adjusted pro
forma\$ (1.35)
\$ (2.40) \$ (0.73)

The per share weighted-average exercise price of stock options granted was \$4.90 in 1999, \$9.80 in 2000 and \$7.39 in 2001. For employee stock options, the weighted-average fair value of each option granted was estimated on the date of grant using the minimum value method in 1999 or the Black-Scholes option pricing model for 2000 and 2001 with the following weighted-average assumptions used for grants in 1999, 2000 and 2001, respectively: dividend yield of zero for all years; volatility of 0 percent, 75 percent 95 percent; a risk-free interest rate ranging from 5.5% - 6.2%, 5.5% - 7.1% and 5.07%; and expected life of five years for all years. The weighted-average fair value for non-employee options was determined using a Black-Scholes option valuation model and the following

assumptions for 1999, 2000 and 2001 respectively: estimated volatility of 60%, 75% and 95.4%, a risk free interest rate ranging from 5.5% - 6.3%, 5.1% - 6.3%, and 5.07%, no dividend yield, and an expected life of the option equal to the options contractual life of ten years from the date of grant.

For the 2000 Employee Stock Purchase Plan, the weighted-average fair value of purchase rights granted was \$6.84 per share in 2000 and \$3.29 in 2001 calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions: dividend yield of zero; volatility of 75% in 2000 and 95% in 2001; risk-free interest rate of 5.1% in 2000 and 2001; expected life of 2 years.

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

### Deferred Stock Compensation

We granted stock options under the 1998 Stock Plan to employees for which we recorded deferred compensation of \$2,283,565, \$4,939,000 and \$0.00 for the years ended December 31, 1999, 2000 and 2001, respectively. Deferred compensation for options granted to non-employees was \$4,231,462, \$1,267,177 and \$274,305 for the years ended December 31, 1999, 2000 and 2001, respectively.

For employees, deferred compensation represents the difference between the exercise price of the option and the fair value of our common stock on the date of grant in accordance with APB No. 25 and its related interpretations. For non-employees, deferred compensation is recorded at the fair value of the options granted in accordance with SFAS No. 123 and EITF 96-18.

Compensation expense is being recognized over the vesting period for employees and the service period for non-employees in accordance with FIN No. 28. Amounts amortized to the statement of operations as compensation expense for employees were \$187,621, \$3,618,431 and \$ 1,950,883 for the years ended December 31, 1999, 2000 and 2001, respectively. Amounts amortized to the statement of operations as compensation expense for non-employees were \$1,347,226, \$2,494,835 and (\$752,525) for the years ended December 31, 1999, 2000 and 2001, respectively.

### 8. 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, 2001, the Company has not made any matching contributions.

### 9. INCOME TAXES

Income tax expense for the year ended December 31, 1999, 2000 and 2001 is comprised of the following:

CURRENT DEFERRED TOTAL 1999:
Federal\$ \$
State
800 800
Total\$800 - - \$800 ==== ==== 2000:
Federal
\$ \$
State
Total \$800 - - \$800 ==== ==== 2001:
Federal\$ \$
φ φ State
800 800
Total \$800 - - \$800 ==== ==== ====

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

Tax expense differed from the amounts computed by applying the U.S. federal income tax rate of 34% to pretax income for the years ended December 31, 2000 and 2001 as a result of the following:

2000 2001 ----- Computed "expected" tax expense (benefit)..... \$(5,942,856) \$(4,874,427) Current NOLs for which no benefit was realized..... 5,929,137 4,865,116 Permanent differences..... 13,719 9,311 State taxes..... 800 800 ----- \$ 800 \$ 800 

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2000 and 2001 is as follows:

2000 2001 Deferred tax assets: Stock related
compensation\$
4,135,660 \$ 4,613,020 Net operating loss
carryforward
9,580,499 Accrued liabilities and
depreciation
State
taxes
272 272 Research and development
credit
Gross deferred tax
assets
15,726,524 Valuation
allowance
(9,345,623) (15,726,524)
Net deferred tax assets
\$ \$ ======== ====================

We have recorded a valuation allowance of \$9,345,623 and \$15,726,524 against the deferred tax assets related to temporary differences and credits for federal and state income tax purposes as of December 31, 2000 and 2001, respectively. The net change in the total valuation allowance for the years ended December 31, 2000 and 2001 was an increase of \$7,257,502 and \$6,380,901, respectively. We believe that realization of these deferred tax assets does not meet the "more likely than not" criteria, and therefore we have not recognized the related deferred tax benefits.

As of December 31, 2001, we have operating loss carryforwards of \$24,908,000 expiring through 2021 for federal purposes and California net operating loss carryforwards of \$19,053,000 expiring through 2011. We have federal research credits expiring through 2021 of approximately \$1,075,000. We have California research credits, carrying forward indefinitely, of approximately \$537,000.

Under provisions of the Internal Revenue Code, should substantial changes in our ownership occur, the utilization of net operating loss carryforwards may be limited.

# 10. 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 contracts with these organizations, however these contracts are cancelable on thirty days notice and are largely based on services performed.

We currently lease office space and equipment pursuant to non-cancelable operating leases that will expire at various dates through 2010.

# NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

Future minimum lease payments are as follows for the years ended December 31:

2002	\$186,249
2003	184,638
2004	178,878
2005	177,726
2006 and thereafter	844,198

Rent expense under non-cancelable operating leases was \$36,992, \$150,125 and \$186,786 for the years ended December 31, 1999, 2000, and 2001 respectively.

11. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

QUARTER ENDED --------------- MARCH 31 JUNE 30 SEPTEMBER 30 DECEMBER 31 ----- -------- ---------- 2001 Net loss..... \$(2,193,029) \$(3,084,052) \$(3,370,106) \$(5,690,163) Basic and diluted loss per share..... \$ (0.09) \$ (0.12) \$ (0.13) \$ (0.22) 2000 Net loss..... \$(5,808,137) \$(3,513,291) \$(5,270,677) \$(2,887,685) Basic and diluted loss per share(1)..... \$ (4.09) \$ (0.62) \$ (0.26) \$ (0.12)

- -----

(1) In February 2000 we issued our series C redeemable convertible preferred stock and determined that it was issued with a beneficial conversion feature. The allocation of proceeds to the beneficial conversion feature (\$14.2 million) 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 quarter ended March 31, 2000. (See note 6.)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

### PART III

#### ITEM 10. DIRECTORS AND OFFICERS OF THE REGISTRANT

The information regarding our directors is incorporated by reference from "Election of Directors -- Directors and Nominees" in our Proxy Statement for our 2002 Annual Meeting of Stockholders. The required information concerning executive officers of the Company is contained in the section entitled "Executive Officers of the Registrant" in Part I of this Form 10-K.

# Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") 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. Gert Caspritz, a director and indirect owner of greater than 5% of the common shares of the Company, did not file a Form 4 in January 2001 or in December 2001 to reflect that a change in beneficial ownership occurred. The January 2001 transaction was a distribution of shares from TVM Management Corporation, the General Partner to TVM III Limited Partner. The transaction on December 2001 was for the sale of the Company's Common Stock by TVM Medical Ventures GmbH & Co. KG. A Form 5 was subsequently filed to reflect this activity. We believe that, with the above noted exception, our remaining executive officers and directors complied with all applicable filing requirements during the fiscal year ended December 31, 2001.

### 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 under the heading "Executive Compensation and Other Matters."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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 "Security Ownership of Certain Beneficial Owners and Management."

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."

### PART IV

ITEM 14. 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):

Independent Auditors' Report

- Balance Sheets
- Statements of Operations
- Statements of Stockholders' Equity (Deficit)
- Statements of Cash Flows
- Notes to Financial Statements
- (2) Financial Statement Schedules:

None.

(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 Lease Agreement dated July 21, 2000 between the Registrant 10.21\*\* and Goss-Jewett Company of Northern California 10.4 Employment Agreement, dated August 29, 2000, between Grant L. Schoenhard, Ph.D. and Pain Therapeutics 10.5 Employment Agreement,

dated October 23, 2001, between Nadav Friedmann, M.D., Ph.D. and Pain Therapeutics 10.6 Consulting Agreement, Settlement Agreement and Mutual Release, dated October 19, 2001, between Barry Sherman, M.D. and Pain Therapeutics 10.7 Note, dated April 20, 2001, between David L. Johnson and Pain Therapeutics. 10.8 Agreement, dated January 31, 2002, between David L. Johnson and Pain Therapeutics 10.9 Note, dated March 1, 2000, between David L. Johnson and Pain Therapeutics 23.1 Consent of KPMG LLP, Independent Certified Public Accountants 24.1 Power of Attorney (see page 52)

-----

\* 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.

# (b) Reports on Form 8-K

The Company did not file any reports on Form 8-K during the three months ended December 31, 2001 or during Form 10-K reporting period ending December 31, 2001.

(c) Exhibits

The exhibits listed under Item 14(a)(3) hereof are filed as part of this Form 10-K.

(d) Financial Statement Schedules

None

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, 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 22, 2002

# POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Remi Barbier and David L. Johnson, 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 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 Exchange Act, 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
President, Chief
Executive
March 22, 2002
2002
Officer
and
Chairman
of the Remi
Barbier
Board of
Directors
(Principal Executive
Officer)
/s/ DAVID
L. JOHNSON Chief
Financial
Officer
March 22,
March 22, 2002
(Principal
Financial
and David L. Johnson
Accounting
Officer)
/s/ GERT
CASPRITZ,

PH.D. Director March 22, 2002 - ----------------------------Gert Caspritz, Ph.D. /s/ NADAV FRIEDMANN, M.D., PH.D. Director March 22, 2002 - ----------------------------Nadav Friedmann, M.D., Ph.D. /s/ MICHAEL J. O'DONNELL, ESQ. Director and Secretary March 22, 2002 - ----------------------------Michael J. O'Donnell, Esq. /s/ SANFORD R. ROBERTSON Director March 22, 2002 - ----------------------------Sanford R. Robertson /s/ RICHARD G. STEVENS Director March 22, 2002 - -----------------------Richard G. Stevens

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 Lease Agreement dated July 21, 2000 between the Registrant 10.21<sup>\*\*</sup> and Goss-Jewett Company of Northern California 10.4 Employment Agreement, dated August 29, 2000, between Grant L. Schoenhard, Ph.D. and Pain Therapeutics 10.5 Employment Agreement, dated October 23, 2001, between Nadav Friedmann, M.D., Ph.D. and Pain Therapeutics 10.6 Consulting Agreement, Settlement Agreement and Mutual Release, dated October 19, 2001, between Barry Sherman, M.D. and Pain Therapeutics 10.7 Note, dated April 20, 2001, between David L. Johnson and Pain

Therapeutics. 10.8 Agreement, dated January 31, 2002, between David L. Johnson and Pain Therapeutics 10.9 Note, dated March 1, 2000, between David L. Johnson and Pain Therapeutics 23.1 Consent of KPMG LLP, Independent . Certified Public Accountants 24.1 Power of Attorney (see page 52)

- -----
- \* 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.

August 29, 2000

Grant L. Schoenhard, Ph.D. 151 Fleetwood Drive San Carlos, CA 94070

Dear Grant:

Barry Sherman and I are very pleased to offer you the position of Vice President, Preclinical Development at Pain Therapeutics, Inc. We believe this offer reflects both the letter and the spirit of previous discussions. Terms of your offer of employment are outlined below:

- As Vice President, Preclinical Development, you will initially report to Barry Sherman, MD, PTI's Executive Vice President & Chief Medical Officer.
- 2. Your primary responsibilities will include providing PTI with preclinical and clinical pharmacology support for PTI's entire pipeline of products. This role is crucial to PTI's regulatory and clinical groups to assure the timely, successful completion of PTI's clinical programs.
- 3. Your cash compensation will be \$175,000 per year and will be reviewed annually. In addition, PTI will reimburse you for all reasonable business and travel expenses actually incurred on behalf of PTI.
- 4. You will receive an option to buy 50,000 shares of PTI common stock. All options are priced at the fair market value of PTI's common stock at the date of grant. Your option will vest monthly and equally over 48 months, starting on the start date of your full-time employment by PTI.
- 5. Your mutually agreed upon start date is Monday, September 11, 2000.
- 6. You will be eligible to receive medical, life insurance, disability or other health, insurance and other benefits provided to regular full-time PTI.
- 7. You will be entitled to three (3) weeks paid vacation at times mutually agreeable to you and PTI Vacation time is accrued at the rate of 1.25 days per month. Unused vacation may not be reimbursed or carried forward from year to year.
- 8. You acknowledge and agree that in accordance with California law, your employment at PTI is "at will". You understand that PTI or you may terminate your employment at any time, for any reason or no reason, with or without cause and with and without notice.

PTI also reserves the right to make personnel decisions regarding your employment, including but not limited to, promotions, salary adjustment, scope of responsibilities, transfer and termination consistent with PTI's needs.

In the event PTI terminates your employment without cause after your one year anniversary, PTI will continue to provide you with your regular base salary and health benefits until the earlier of a) three months from date of termination, or b) your date of new employment or other compensated position elsewhere. You will not receive severance or other termination benefits or any other benefits (including vesting of unvested stock) in the event either a) you terminate this employment arrangement for any reason or no reason, or b) PTI terminates this employment arrangement for any reason or no reason in the first 12 months of your full-time employment, or c) PTI terminates this employment arrangement with cause.

- 9. You and PTI further agree that all disputes, claims or causes of action arising out of your employment or its termination shall be submitted to binding arbitration before a neutral arbitrator, except where the law specifically forbids the use of arbitration as a final and binding remedy.
- 10. You warrant and represent that you have no commitments or obligations inconsistent with PTI's offer of employment as of the date of your full-time employment with PTI. You further understand that this is a full-time and exclusive position in the services of PTI.
- 11. You agree to sign a CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT (attached).
- 12. This offer expires Thursday, August 31, 2000 unless signed by you and received by PTI before then.

Grant, I believe these terms reflect our discussions. If acceptable to you, please sign, date and return one original copy. We look forward to working with you!

/s/ REMI BARBIER Remi Barbier President & CEO

I agree to all the terms and condition of employment set forth in this letter,

/s/ GRANT L. SCHOENHARD Grant L. Schoenhard

October 23, 2001

Nadav Friedmann, MD, PhD. 91 Beacon Court Lafayette, CA 94549

Dear Nadav,

On behalf of the Board of Directors, I am delighted to offer you the position of Chief Operating Officer at Pain Therapeutics, Inc. The terms of your employment, outlined below, reflect our previous discussions:

- 1. As Chief Operating Officer and an Executive Officer of the Company, you will report to the President & CEO.
- 2. You agree to serve your term as a member of PTI's Board of Directors and Scientific Advisory Board, but you may need to resign from Board Committees that require outside Board members.
- 3. Your primary responsibilities will be to advise the Company on its clinical and regulatory strategies, and to execute such strategies, consistent with company-wide objectives and policies. Other responsibilities will include:
  - assessing outside products, projects and late-stage technology opportunities;
  - contributing to the preparation and implementation of budgets;
  - establishing and maintaining professional relationships with leaders in the field of pain management;
  - assisting in the Company's public relations and investor relations;
  - assuming other responsibilities as these may arise from time-to-time at the request of the President & CEO.

- 4. Your cash compensation will be \$300,000 per year and will be reviewed annually at such time as PTI generally conducts annual reviews for officers. You will be eligible to receive a discretionary year-end cash and/or equity bonus.
- 5. You will receive an option to buy 550,000 shares of PTI common stock, subject to approval by PTI's Board of Directors. Your option will vest monthly and equally over 48 months. Your option will begin vesting on the first day of your full-time employment at PTI. Your option will be priced at the closing price of PTI's stock, as reported by NASDAQ, on the last market-trading day prior to the date of the grant.
- 6. PTI will reimburse you for all reasonable business and travel expenses actually incurred on behalf of PTI, consistent with the Company's Finance and or Travel policies.
- 7. PTI will reimburse you for reasonable relocation expenses and living expenses actually incurred on behalf of PTI while you live away from your normal residence for a period thru May 23, 2002. Such expenses must be documented, are subject to approval by the President & CEO, and in no event shall this amount exceed \$30,000.
- 8. We agree that your full-time start date will be October 23, 2001.
- 9. You will be eligible to receive medical, life insurance, disability or other health, insurance or other benefits provided to regular full-time PTI employees.
- 10. You will be entitled to accrue three (3) weeks paid vacation per year. Vacation time is accrued at a rate of 1.25 days per month of full-time employment. Accrued but unused vacation days beyond 15 days may not be reimbursed or carried forward from calendar year to year.
- 11. You acknowledge and agree that in accordance with California law, your employment at PTI is "at will". You understand that PTI or you may terminate your employment at any time, for any reason or no reason, with or without cause and with and without notice.
- 12. PTI also reserves the right to make personnel decisions regarding your . employment, including but not limited to, promotions, salary adjustment, scope of responsibilities, transfer and termination consistent with PTI's needs.

- 13. You and PTI further agree that all disputes, claims or causes of action arising out of your employment or its termination shall be submitted to binding arbitration before a neutral arbitrator, except where the law specifically forbids the use of arbitration as a final and binding remedy.
- 14. You warrant and represent that you have no commitments or obligations inconsistent with PTI's offer of employment as of the date of your full-time employment with PTI. You further understand that this is a full-time and exclusive position in the services of PTI.
- 15. You agree to sign a "CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT" (attached).

Nadav, I believe these terms reflect our discussions. If acceptable to you, please sign, date and return one original copy. We look forward to working with you!

/s/ REMI BARBIER

Remi Barbier Chairman of the Board President & CEO

I agree to all the terms and condition of employment set forth in this letter.

/s/ NADAV FRIEDMANN	10/24/01
Nadav Friedmann, MD, PhD.	Date

## CONSULTING AGREEMENT, SETTLEMENT AGREEMENT AND MUTUAL RELEASE

This Consulting Settlement Agreement and Mutual Release ("Agreement") is made by and between Pain Therapeutics, Inc. (the "Company") and Barry Sherman, MD ("Employee").

#### WHEREAS, Employee was employed by the Company; and

WHEREAS, the Company and Employee have mutually agreed to terminate the employment relationship, release each other from any claims arising from or related to the employment relationship, and enter into a consulting relationship for a six month transition period;

NOW THEREFORE, in consideration of the mutual promises made herein, the Company and Employee (collectively referred to as "the Parties") hereby agree as follows:

1. Resignation. Employee has resigned from his position as the Company's Executive Vice President, Chief Medical Officer and member of the Scientific Advisory Board, effective October 19, 2001.

### 2. Consideration.

(a) Upon execution of this Agreement, the Company agrees to pay Employee \$32,251.67, less applicable taxes, in respect of his unpaid salary and accrued and unused paid time off earned through October 19, 2001 plus an advance payment of the fee for the first month of his consultancy described herein. In addition, the Company agrees to pay Employee at the rate of \$21,666.67 per month, less applicable withholding, for the period commencing on October 19, 2001 and ending on April 19, 2002, unless earlier terminated as provided in clause (b) below (the "Payment Period"), in each case in accordance with the Company's payroll practices; provided, however, that the parties acknowledge and agree that the first monthly payment has been delivered to Employee as an advance upon signing this Agreement. During the Payment Period, options to purchase Company common stock held by Employee will no longer continue to vest in accordance with applicable option agreements and Company option plans.

(b) During the Payment Period, Employee shall, upon request by the Company's President & Chief Executive Officer, provide consulting services to the Company regarding preclinical, scientific, patent, technology, clinical development projects and business development issues or other Company issues as may arise from time to time. Such consulting services shall be rendered at mutually agreeable times during normal business hours on days when the Company is open for business. Such consulting services may be rendered by telephone, electronically or in person at the

Company's headquarters' or at such other locations as may be mutually agreed by the parties. Employee acknowledges that attending meetings, developing written plans and reports and participating in joint discussions with third parties are included in the services provided by employee in his continuing role as a consultant to the Company and both parties acknowledge that Employee is not obligated to provide more than 20 hours of such services to the Company on a weekly basis. The Company will reimburse Employee for his reasonable expenses incurred in connection with providing consulting services hereunder, in accordance with the Company's expense reimbursement policies. This consulting relationship will terminate on the earliest to occur of (i) the date on which Employee provides written notice of termination to the Company's President & Chief Executive Officer, or (ii) April 19, 2002.

(c) The exercise of any vested stock options held by Employee shall continue to be subject to the terms and conditions of the Company's applicable Stock Plans and the applicable Stock Option Agreement between Employee and the Company. Employee shall continue to be a service provider to the Company for purposes of the Company's applicable Stock Plans until April 19, 2002, and options under such plans held by Employee shall be exercisable until May 19, 2002.

(d) During the Payment Period, the Company will reimburse COBRA expenses for Employee and his spouse at cost. Employee will not be entitled to accrual of any other employee benefits, including, but not limited to, vacation benefits or bonuses. Subsequent to the Payment Period, the Company will not contest unemployment benefits.

3. Confidential Information. Employee shall continue to maintain the confidentiality of all confidential and proprietary information of the Company in the manner provided in, and shall continue to comply with mutually signed NON-DISCLOSURE AGREEMENT dated March 29, 1999, by and between the Company and Employee. Employee shall return all the Company property and confidential and proprietary information in his possession to the Company on or before the Effective Date of this Agreement.

4. Payment of Salary. Employee acknowledges and represents that the Company has paid all salary, wages, bonuses, accrued vacation and any and all other benefits due to Employee accrued on or prior to October 19, 2001.

5. Release of Claims. Employee agrees that the consideration set forth in Section 2 above represents settlement in full of all outstanding obligations owed to Employee by the Company. Employee and the Company, on behalf of themselves, and their respective heirs, family members, executors, officers, directors, employees, investors, shareholders, administrators, affiliates, divisions, subsidiaries, predecessor and successor corporations, and assigns, hereby fully and forever release each other and their respective heirs, family members, executors, officers, directors, employees, investors, shareholders, administrators, affiliates, divisions, subsidiaries, predecessor and successor corporations, and assigns, from, and agree not to sue concerning, any claim, duty, obligation or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that any of them may possess arising from any omissions, acts or facts that have occurred up until and including the date of this Agreement including, without limitation:

- (i) any and all claims relating to or arising from Employee's employment relationship with the Company and the termination of that relationship;
- (ii) any and all claims relating to, or arising from, Employee's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;
- (iii) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; breach of contract, both express and implied; breach of a covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; and conversion;
- (iv) any and all claims for violation of any federal, state or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974, The Worker Adjustment and Retraining Notification Act, Older Workers Benefit Protection Act; the California Fair Employment and Housing Act, and Labor Code section 201, et seq. and section 970, et seq.;
- (v) any and all claims for violation of the federal, or any state, constitution;
- (vi) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination; and
- (vii) any and all claims for attorneys' fees and costs.

The Company and Employee agree that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to Employee's (i) rights to indemnification and exculpation under the Company's Certificate of Incorporation and Bylaws and pursuant to California or Delaware law; and (ii) rights under any applicable director and officer liability insurance policy of the Company.

6. Acknowledgment of Waiver of Claims under ADEA. Employee acknowledges that he is waiving and releasing any rights he may have under the Age Discrimination in Employment Act of 1967 ("ADEA") and that this waiver and release is knowing and voluntary. Employee and the Company agree that this waiver and release does not apply to any rights or claims that may arise under ADEA after the Effective Date of this Agreement. Employee acknowledges that the consideration given for this waiver and release Agreement is in addition to anything of value to which

Employee was already entitled. Employee further acknowledges that he has been advised by this writing that (a) he should consult with an attorney prior to executing this Agreement; (b) he has at least twenty-one (21) days within which to consider this Agreement; (c) he has at least seven (7) days following the execution of this Agreement by the parties to revoke the Agreement; and (d) this Agreement shall not be effective until the revocation period has expired.

7. No Pending or Future Lawsuits. Employee represents that he has no lawsuits, claims, or actions pending in his name, or on behalf of any other person or entity, against the Company or any other person or entity referred to herein. Employee also represents that he does not intend to bring any claims on his own behalf or on behalf of any other person or entity against the Company or any other person or entity referred to herein relating to the Employee's employment relationship with the Company and the termination of that relationship.

8. Application for Employment. Employee understands and agrees that, as a condition of this Agreement, he shall not be entitled to any employment with the Company, its subsidiaries, or any successor, and he hereby waives any right, or alleged right, of employment or re-employment with the Company. Employee further agrees that he will not apply for employment with the Company, its subsidiaries or related companies, or any successor.

9. Confidentiality. The Parties hereto each agree to use their reasonable best efforts to maintain in confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (hereinafter collectively referred to as "Settlement Information"). Each Party hereto agrees to take commercially reasonable precautions to prevent disclosure of any Settlement Information to third parties. The Parties hereto agree to take commercially reasonable precautions to disclose Settlement Information only to those employees, officers, directors, attorneys, accountants, governmental entities, and family members who have a reasonable need to know of such Settlement Information. Notwithstanding the foregoing, the Company shall be permitted to disclose Settlement Information publicly if, and to the extent, in the reasonable opinion of counsel to the Company, such disclosure is required in accordance with applicable state or federal securities laws, including, without limitation, Regulation FD promulgated by the Securities Exchange Commission.

10. Non-Disparagement. Each party agrees to refrain from any defamation, libel or slander of the other, or tortious interference with the contracts and relationships of the other. All inquiries by potential future employers of Employee will be directed solely to the President & Chief Executive Officer. Upon inquiry, the Company shall only state the following: Employee's last position and dates of employment.

11. No Admission of Liability, The Parties understand and acknowledge that this Agreement constitutes a compromise and settlement of disputed claims. No action taken by the Parties hereto, or either of them, either previously or in connection with this Agreement shall be deemed or construed to be (a) an admission of the truth or falsity of any claims heretofore made or (b) an acknowledgment or admission by either party of any fault or liability whatsoever to the other party or to any third party.

12. Costs. The Parties shall each bear their own costs, expert fees, attorneys' fees and other fees incurred in connection with this Agreement.

13. Arbitration. The Parties agree that any and all disputes arising out of the terms of this Agreement, their interpretation, and any of the matters herein released, shall be subject to binding arbitration in Santa Clara County, California before the American Arbitration Association under its California Employment Dispute Resolution Rules, or by a judge to be mutually agreed upon. The Parties agree that the prevailing party in any arbitration shall be entitled to injunctive relief in any court of competent jurisdiction to enforce the arbitration award. The Parties agree that the prevailing party in any arbitration shall be awarded its reasonable attorney's fees and costs.

14. Civil Code Section 1542. The Parties represent that they are not aware of any claim by either of them other than the claims that are released by this Agreement. Employee and the Company acknowledge that they have been advised by legal counsel and are familiar with the provisions of California Civil Code Section 1542, which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR.

Employee and the Company, being aware of said code section, agree to expressly waive any rights they may have thereunder, as well as under any other statute or common law principles of similar effect.

15. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Employee represents and warrants that he has the capacity to act on his own behalf. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

16. No Representations. Each party represents that it has had the opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of this Agreement. Neither party has relied upon any representations or statements made by the other party hereto which are not specifically set forth in this Agreement.

17. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision.

18. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Employee concerning Employee's separation from the Company, and supersedes and replaces the Employment Agreement.

19. No Oral Modification. This Agreement may only be amended in writing signed by Employee and the Chief Executive Officer of the Company.

 $20.\ \mbox{Governing Law.}$  This Agreement shall be governed by the laws of the State of California.

21. Effective Date. This Agreement is effective seven days after it has been signed by both Parties.

22. Counterparts. This Agreement may be executed in counter-parts, and each counterpart shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned.

23. Voluntary Execution of Agreement. This Agreement is executed voluntarily and without any duress or undue influence on the part or behalf of the Parties hereto, with the full intent of releasing all claims. The Parties acknowledge that:

(a) They have read this Agreement;

(b) They have been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of their own choice or that they have voluntarily declined to seek such counsel;

(c) They understand the terms and consequences of this Agreement and of the releases it contains;

(d) They are fully aware of the legal and binding effect of this Agreement.

24. Non-Solicitation. For three years following the Effective Date, Employee shall not solicit, recruit or hire, or assist any other person or entity to solicit, recruit or hire, any employee of the Company or any of its affiliates or any person who was employed by the Company or any of its affiliates during the 30-day period immediately preceding the date hereof.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: October 31, 2001

PAIN THERAPEUTICS, INC. By: /s/ REMI BARBIER Remi Barbier Chairman of the Board President & Chief Executive Officer BARRY SHERMAN, MD, an individual

/s/ Barry Sherman BARRY SHERMAN, MD

\$80,000.00

April 20, 2001

FOR VALUE RECEIVED, the undersigned, a full-time regular employee of Pain Therapeutics, Inc., promises to pay to Pain Therapeutics, Inc., a Delaware corporation (the "COMPANY"), or order, the principal sum of Eighty Thousand Dollars (\$80,000.00), together with interest on the unpaid principal hereof from the date hereof at the fixed rate of eight percent (8.00%) per annum, compounded annually.

NOTE

Principal and interest shall be due and payable no later than January 31, 2004. Should the undersigned fail to make full payment of principal or interest for a period of ten (10) days or more after the due date thereof, the whole unpaid balance on this Note of principal and interest shall become immediately due at the option of the holder of this Note. Payments of principal and interest shall be made in lawful money of the United States of America.

The undersigned may at any time prepay all or any portion of the principal or interest owing hereunder.

Pain Therapeutics, Inc., the holder of this Note shall have full recourse against the undersigned, and shall not be required to proceed against any collateral securing this Note in the event of default.

In the event the undersigned shall cease to be a full-time regular employee, or paid consultant of the Company for any reason, this Note shall, at the option of the Company, be accelerated, and the whole unpaid balance on this Note of principal and accrued interest shall be immediately due and payable.

Should any action be instituted for the collection of this Note, the reasonable costs and attorneys' fees therein of the holder shall be paid by the undersigned.

PAIN THERAPEUTICS, INC.

By:	/s/ REMI BARBIER	/s/ DAVID L. JOHNSON
	Remi Barbier	David L. Johnson
	Remit Bui biel	BUVIU E. COMISON

Title: President, CEO and Chairman of the Board

January 31, 2002

David Johnson Pain Therapeutics, Inc. 416 Browning Way South San Francisco, CA 94080

Dear Dave:

This letter will confirm that, when you joined PTI in early 2000, we sold to you 190,000 shares (the "Shares") of PTI's common stock ("Common Stock") at a price per share of \$0.20, the then fair market value of one share of Common Stock. Unfortunately, due to the rapid acceleration in the fair market value of the Common Stock in the months preceding our initial public offering, the value of the Shares had increased to \$1.00 per share by the time we executed and delivered your Restricted Stock Purchase Agreement (the "Agreement") on March 1, 2000. We estimate that due to the discrepancy in the fair market value of the Common Stock, you incurred an additional \$152,000 of ordinary income, resulting in an additional \$78,174 in taxes owed by you for the year 2000. We are aware that in reliance on the Agreement, you filed an 83b election form with the Internal Revenue Service stating that you had purchased 190,000 shares of Common Stock on March 1, 2000 at a price per share of \$0.20.

In order to ensure that you enjoy the benefit of the bargain we struck in the Agreement and to make the discrepancy regarding the fair market value of the Common Stock neutral to you, we propose the following:

> We will use commercially reasonable efforts to see that you receive the benefits you would have received had the actual fair market value of the Shares at the time of your purchase been \$0.20, including, but not limited to, reimbursing you for the amount of any additional taxes and other identifiable costs you incur as a result of the discrepancy in the fair market value of the Common Stock and paying you a gross up for any tax on reimbursed amounts, as necessary.

-

We will also reimburse you, on a grossed up basis, for any additional tax you incur in the event your 83b election is disallowed as a result of the discrepancy in the fair market value of the Common Stock.

If the foregoing is acceptable to you, please indicate your acceptance by executing this letter in the space provided below, and returning one signed copy to the undersigned.

Very truly yours,

/s/ REMI BARBIER

Remi Barbier President and Chief Executive Officer

Acknowledged and Agreed To This 31st Day of January 2002

/s/ DAVID JOHNSON

- -----

David Johnson

Cc:

Michael O'Donnell, Wilson Sonsini Goodrich & Rosati Marty Waters, Wilson Sonsini Goodrich & Rosati

# EXHIBIT 1

#### NOTE

\$38,000.00

March 1, 2000

FOR VALUE RECEIVED, the undersigned promises to pay to Pain Therapeutics, Inc., a Delaware corporation (the "COMPANY"), or order, the principal sum of Thirty-Eight Thousand Dollars (\$38,000.00), together with interest on the unpaid principal hereof from the date hereof at the rate of five and one-half percent (5.5%) per annum, compounded annually.

Principal and interest shall be due and payable on January 31, 2004. Should the undersigned fail to make full payment of principal or interest for a period of ten (10) days or more after the due date thereof, the whole unpaid balance on this Note of principal and interest shall become immediately due at the option of the holder of this Note. Payments of principal and interest shall be made in lawful money of the United States of America.

The undersigned may at any time prepay all or any portion of the principal or interest owing hereunder.

This Note is secured in part by a pledge of the Company's Common Stock under the terms of a Security Agreement of even date herewith and is subject to all the provisions thereof.

The holder of this Note shall have full recourse against the undersigned, and shall not be required to proceed against the collateral securing this Note in the event of default.

In the event the undersigned shall cease to be an employee or consultant of the Company for any reason, this Note shall, at the option of the Company, be accelerated, and the whole unpaid balance on this Note of principal and accrued interest shall be immediately due and payable.

Should any action be instituted for the collection of this Note, the reasonable costs and attorneys' fees therein of the holder shall be paid by the undersigned.

DAVID L. JOHNSON (printed name) Consent of KPMG LLP, Independent Certified Public Accountants

The Board of Directors Pain Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-68118) on Form S-8 of Pain Therapeutics, Inc. of our report dated March 1, 2002, with respect to the balance sheets of Pain Therapeutics, Inc. as of December 31, 2000 and 2001, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2001, and for the period from May 4, 1998 (inception) through December 31, 2001, which report appears in the December 31, 2001 annual report on Form 10-K of Pain Therapeutics, Inc.

/s/ KPMG LLP

San Francisco, California March 22, 2002