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

FORM 10-Q

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

For Quarterly Period Ended June 30, 2003

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

For the transition period from _____ to _____.

Commission File Number 000-29959

PAIN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1911336**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

416 Browning Way, South San Francisco, CA 94080
(Address of principal executive offices) (Zip Code)

(650) 624-8200
(Registrant's telephone number, including area code)

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

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

Indicate the number of shares outstanding of each of issuer's classes of common stock, as of the latest practicable date.

Common Stock, $0.001 par value	**27,565,505 Shares**
Class	Outstanding at July 15, 2003

PAIN THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

Condensed Balance Sheets
(Unaudited)
(in thousands)

	June 30, 2003	December 31, 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 42,546	$ 50,091
Interest receivable	38	55
Prepaid expenses	41	1,101
Total current assets	42,625	51,247
Property and equipment, net	1,831	2,003
Other assets	75	75
Total assets	$ 44,531	$ 53,325
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,731	$ 2,648
Accrued compensation and benefits	541	273
Other accrued liabilities	123	180
Total current liabilities	2,395	3,101
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	27	27
Additional paid-in-capital	103,770	103,254
Deferred compensation	(58)	(304)
Notes receivable from stockholders	(10)	(122)
Deficit accumulated during the development stage	(61,593)	(52,631)
Total stockholders' equity	42,136	50,224
Total liabilities and stockholders' equity	$ 44,531	$ 53,325

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
Condensed Statements of Operations
(Unaudited)
(in thousands except per share data)

	Three months ended June 30,		Six months ended June 30,		May 4, 1998 (inception) through June 30, 2003
	2003	2002	2003	2002	
Operating expenses(1):					
Research and development	$ 3,715	$ 2,674	$ 7,503	$ 5,490	$ 47,430
General and administrative	751	1,307	1,720	2,812	21,417
Total operating expenses	4,466	3,981	9,223	8,302	68,847
Operating loss	(4,466)	(3,981)	(9,223)	(8,302)	(68,847)
Other income:					
Interest income	120	266	261	561	7,254
Net loss	(4,346)	(3,715)	(8,962)	(7,741)	(61,593)
Return to series C preferred stockholder for beneficial conversion feature	—	—	—	—	(14,231)
Loss available to common stockholders	$ (4,346)	$ (3,715)	$ (8,962)	$ (7,741)	$ (75,824)
Basic and diluted loss per common share	$ (0.16)	$ (0.14)	$ (0.33)	$ (0.29)	
Weighted-average shares used in computing basic and diluted loss per common share	27,334	27,037	27,250	26,973	

(1) Included in research and development and general and administrative expenses are stock-based compensation expenses (reduction in expenses) of ($16) and $191 for the three months ended June 30, 2003 and 2002, respectively, $87 and $533 for the six months ended June 30, 2003 and 2002, respectively and $11,877 for the period from May 4, 1998 (inception) through June 30, 2003.

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Six months ended June 30,		May 4, 1998 (inception) through June 30, 2003
	2003	2002	
Cash flows from operating activities:			
Net loss	$ (8,962)	$ (7,741)	$ (61,593)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	172	176	870
Non-cash stock based compensation expense and other	87	534	11,911
Changes in operating assets and liabilities:			
Interest receivable	17	34	(38)
Prepaid expenses	1,060	(177)	(41)
Other assets	—	—	(75)
Accounts payable	(917)	(764)	1,731
Accrued compensation and benefits	268	173	541
Other accrued liabilities	31	75	211
Net cash used in operating activities	(8,244)	(7,690)	(46,483)
Cash flows used in investing activities:			
Purchase of property and equipment	—	(5)	(2,701)
Cash flows from financing activities:			
Proceeds from issuance of various preferred stock, net	—	—	27,539
Proceeds from initial public offering, net	—	—	62,939
Stock subscription note payments received	24	20	138
Proceeds from issuance of common stock, net	675	207	1,114
Net cash provided by financing activities	699	227	91,730
Net increase (decrease) in cash and cash equivalents	(7,545)	(7,468)	42,546
Cash and cash equivalents at beginning of period	50,091	65,274	—
Cash and cash equivalents at end of period	$ 42,546	$ 57,806	$ 42,546

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
Notes to Condensed Financial Statements
(Unaudited)

Note 1. General

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.

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, the need to design, conduct and complete clinical trials successfully and the 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 have prepared the accompanying unaudited condensed financial statements of Pain Therapeutics, Inc. (“Pain Therapeutics”) in accordance with generally accepted accounting principles for interim financial information and pursuant to the instruction to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In our opinion, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2003 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2003. Certain prior year balances have been reclassified for comparative purposes.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of expenses incurred during the reporting period. Actual results could differ from those estimates.

Note 2. Loss per Share

Basic loss per share is computed on the basis of the weighted-average number of common shares outstanding for the reporting period. Diluted loss per share is computed on the basis of the weighted-average number of common shares plus potential dilutive common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of outstanding stock options and outstanding warrants.

In all periods presented we have reported a loss and therefore all potential shares of common stock related to potentially dilutive securities have been excluded from the calculation of diluted loss per share because they are anti-dilutive.

Note 3. 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.

Note 4. Stock Based Compensation

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

If we had recorded compensation cost of our stock based plans in a manner consistent with the fair value approach of SFAS No. 123, our loss and adjusted loss per share would have been increased as follows:

Pro forma net loss (in thousands except per share data):

	Three months ended June 30,		Six months ended June 30,	
	2003	2002	2003	2002
Net loss, as reported	$ (4,346)	$ (3,715)	$ (8,962)	$ (7,741)
Add (deduct): Total stock based employee compensation expense (reduction in expense) included in net loss, as reported	(237)	206	(128)	451
Deduct: Total stock based employee compensation expense determined under the fair value approach for all awards	(766)	(1,273)	(1,885)	(2,411)
Adjusted net loss	$ (5,349)	$ (4,782)	$ (10,975)	$ (9,701)
Net loss per common share basic and diluted as reported	$ (0.16)	$ (0.14)	$ (0.33)	$ (0.29)
Adjusted net loss per common share basic and diluted	$ (0.20)	$ (0.18)	$ (0.40)	$ (0.36)

The weighted average fair value of options granted was $5.76 and $5.78 in the three months ended June 30, 2003 and 2002, respectively, and $4.89 and $5.85 in the six months ended June 30, 2003 and 2002, respectively.

For employee stock options, the weighted average fair value of each option granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	2003	2002
Volatility	95% – 100%	89%
Risk-free interest rates	2.5% – 2.9%	3.8%
Expected life of option	5 years	5 years
Dividend yield	—	—

For the 2000 Employee Stock Purchase Plan, the weighted average fair value of purchase rights granted were $1.65 and $3.01 per share for the three- and six-month periods ended June 30, 2003 and 2002, respectively, calculated using the Black-Scholes option pricing model with the following assumptions:

	2003	2002
Volatility	89%	89%
Risk-free interest rates	1.4%	2.0%
Expected life of option	2 years	2 years
Dividend yield	—	—

Note 5. 1998 Stock Plan

In accordance with the provisions of the 1998 Stock Plan, effective January 1, 2003 the number of shares of common stock authorized for issuance under the 1998 Stock Plan was increased from 7,000,000 to 8,350,000 shares.

Note 6. Recent Accounting Pronouncements

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, “Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity” (“FAS 150”). FAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity and it requires that an issuer classify a financial instrument that is within its scope as a liability. We adopted FAS 150 in June 2003 and it had no impact on our financial position and results of operations.

Item 2. ***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.

This document contains forward-looking statements that are based upon current expectations that are within the meaning of the Private Securities Reform Act of 1995. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to: statements about future operating losses and anticipated operating and capital expenditures; statements about the potential benefits of our drug candidates; statements relating to the timing or anticipated results of the clinical development of our drug candidates; statements relating to the size of the potential market for our products; statements relating to the utility and protection of our intellectual property; statements about filing of patents; statements about expected future sources of revenue and capital; statements about potential competitors or products; statements about future market acceptance of our drug candidates; statements about expenses increasing substantially or fluctuating; statements about future expectations regarding trade secrets, technological innovations, licensing agreements, trademarks 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 development of our internal systems and infrastructure; and statements about the liquidity and price fluctuations of our common stock.

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 our drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials), 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, our ability to obtain additional financing if necessary and those risks and uncertainties relating to the fact that our common stock is thinly traded. 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 or 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. We rely on arrangements with universities, our collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

We have several drug candidates in various stages of clinical testing. In June 2003 we announced the results of a 21-day Phase II study of our lead product candidate, Oxytrex™, in patients with severe osteoarthritic pain. The Phase II study met its primary efficacy endpoint, showing a statistically significant reduction in chronic pain using Oxytrex™. In June 2003 we announced initiation of a Phase III clinical trial of Oxytrex™ to demonstrate the safety and efficacy of Oxytrex™ in patients with documented severe chronic low back pain. In May 2003, we announced the results of a 50 patient pilot study using PTI-901, a proprietary new drug we are developing to treat irritable bowel syndrome. We plan to initiate in the fourth quarter of 2003 a Phase III trial with PTI-901 following discussion with regulatory agencies. We will have to commit substantial time and additional resources to conducting further preclinical or clinical studies in several types of pain before we can submit NDAs with respect to any of our product candidates.

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception through June 30, 2003, we have incurred an accumulated deficit of approximately $61.6 million. 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 non-cash stock based 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 and our need for clinical supplies.

We expect to incur significant additional operating losses for the next several years. Our cash requirements for operating activities and capital expenditures will increase substantially in the future as we:

- continue to undertake preclinical and clinical trials for our product candidates, including the Phase III trials of Oxytrex™ and PTI-901;
- 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. If 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.

Results of Operations

Three and Six Months Ended June 30, 2003 and 2002

Research and Development

Research and development expense consists primarily of drug development work associated with our product candidates, including costs of preclinical, clinical trials, clinical supplies and other formulation and design costs and salaries and other personnel related expenses, as well as non-cash stock based compensation. Research and development expense increased to $3.7 million from $2.7 million for the three months ended June 30, 2003 and 2002, respectively, and to $7.5 million from $5.4 million for the six months ended June 30, 2003 and 2002, respectively. The increase in expense was primarily due to expenses incurred in the ongoing clinical development of Oxytrex™, for formulation related expense and for development of our other drug candidates. We have several other opioid painkillers in various stages of clinical testing.

We expect research and development expenses to increase significantly over the next several years as we expand our development efforts and as our product candidates progress through various stages of clinical trials, including the Phase III trials of Oxytrex™ and PTI-901. This increase may fluctuate from quarter to quarter and year to year due to the timing and scope of these activities.

General and Administrative

General and administrative expenses decreased to $0.8 million from $1.3 million for the three months ended June 30, 2003 and 2002, respectively, and to $1.7 million from $2.8 million for the six months ended June 30, 2003 and 2002, respectively. The decreases were primarily due to a decrease in non-cash stock based compensation expenses as well as a reclassification and decrease in 2003 in certain common occupancy expenses. General and administrative expense consists primarily of compensation and other general corporate expenses as well as non-cash stock based compensation. The decrease in non-cash stock based compensation expense was primarily due to the accelerated amortization methodology utilized in accordance with FASB Interpretation No. 28 (“FIN 28”) as well as the recapture of expenses under FIN 28 related to employees who terminated their employment prior to completion of the vesting period for the underlying stock options. Non-cash stock based compensation expense may fluctuate from period to period due in part to fluctuations in the fair market value of our common stock as well as other factors used to calculate such expenses. We expect general and administrative expense to increase in future periods in support of increased research and development or general corporate activities.

Interest Income

Interest income decreased to $0.1 million from $0.3 million for the three months ended June 30, 2003 and 2002, respectively, and to $0.3 million from $0.6 million for the six months ended June 30, 2003 and 2002, respectively. The decrease in interest income is primarily the result of lower average balances of cash and cash equivalents as well as lower returns on the investment of our cash and cash equivalents.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private stock offerings. We intend to continue to use these proceeds to fund research and development activities, working capital requirements, other general corporate purposes and capital expenditures. As of June 30, 2003, cash and cash equivalents were $42.5 million and were invested primarily in money market funds.

Net cash used in operating activities was $8.2 million for the six months ended June 30, 2003. Cash used in operating activities related primarily to the funding of operating losses.

We expect our cash used for capital equipment in 2003 to be approximately $0.1 million. Our requirements for capital equipment may increase in the future.

Our financing activities in the six months ended June 30, 2003 provided cash of $0.7 million, consisting of $0.6 million from the exercise of previously outstanding warrants and $0.1 million in equity from our stock plans.

We lease approximately 10,500 square feet of general 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 $0.2 million in each of the years 2003 through 2010.

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. These agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. These potential future payments are cancelable as of June 30, 2003.

We expect to incur significant additional operating losses for the next several years. We expect our cash requirements to increase in the foreseeable future as we continue to undertake preclinical and clinical trials for our product candidates, including the Phase III trials of Oxytrex™ and PTI-901; 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 candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next twelve months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

Recent Accounting Pronouncements

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("FAS 150"). FAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity and it requires that an issuer classify a financial instrument that is within its scope as a liability. We adopted FAS 150 in June 2003 and it had no impact on our financial position and results of operations.

RISK FACTORS

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

Risks Relating to our Financial Position and Need for Financing

Our 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 are in the development stage. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and undertaking preclinical studies and clinical trials. 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. As a result of ongoing operating losses, we had an accumulated deficit of $61.6 million as of June 30, 2003. Even if we succeed in developing and commercializing one or more of our drugs, we expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical and clinical trials for our product candidates, including the Phase III trials of Oxytrex™ and PTI-901;
- 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 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.

We have funded all of our operations and capital expenditures with the proceeds from public and private stock offerings. We expect that our current cash 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, we may need to raise additional funds sooner and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional equity or convertible debt 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.

Clinical and Regulatory Risks

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 several drug candidates in various stages of clinical testing. In June 2003 we announced the results of a 21-day Phase II study of our lead product candidate, Oxytrex™, in patients with severe osteoarthritic pain. The Phase II study met its primary efficacy endpoint, showing a statistically significant reduction in chronic pain using Oxytrex™. In June 2003 we announced initiation of a Phase III clinical trial of Oxytrex™ to demonstrate the safety and efficacy of Oxytrex™ in patients with documented severe chronic low back pain. In May 2003, we announced the results of a 50 patient pilot study using PTI-901, a proprietary new drug we are developing to treat irritable bowel syndrome. We plan to initiate in the fourth quarter of 2003 a Phase III trial with PTI-901 following discussion with regulatory agencies. 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 our product candidates.

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

Success in early trials may not predict success of future trials.

Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing.

Even if our clinical trials are completed as planned, their results may not support our product claims. 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 could delay development of other product candidates.

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

We discuss with and obtain guidance from regulatory authorities on certain of our clinical trials. Over the course of conducting our clinical trials, circumstances may change, such as standards of safety or efficacy, that could affect regulatory authorities' perception of the adequacy of any of our trial designs. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval.

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

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the 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, in which case we would have to expend additional time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish the competitive advantages that we would 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. The FDA may also require us to commit to perform post-approval studies, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition.

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

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.

Government agencies may establish and promulgate guidelines that directly apply to us and our products that may affect the use of our drugs.

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

Conducting clinical trials of our product candidates exposes us to expensive product liability claims and we may not be able to maintain product liability insurance on reasonable terms or at all.

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

Risks Relating to Commercialization

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

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

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs;
- cost-effectiveness of our drugs relative to competing products;
- availability of reimbursement for our products from government or healthcare payers; 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 we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, our product revenues could be disappointing.

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

If we decide to enter into co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the significant number of recent business combinations among pharmaceutical companies has resulted in a reduced number of potential future collaborators. Even if we are able to identify one or more acceptable collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

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

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

The market for our 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.

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

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products and services and/or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of them could be limited.

Risks Relating to our Intellectual Property

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

Our success, competitive position and potential future revenues will depend in part on our ability to protect our intellectual property. If either we, Albert Einstein College of Medicine or our other collaborators fail to file, prosecute or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result. In January 2003, the U.S. Patent and Trademark Office disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. An adverse outcome of the reexamination process could result in loss of claims of these patents that pertain to certain drugs we currently have under development.

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

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

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

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

Risks Relating to our Business and Strategy

Competition for qualified personnel in the pharmaceutical industry is intense, and if we are not successful in attracting and retaining qualified personnel, we could experience delays in completing necessary clinical trials 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.

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

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

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

Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In addition, companies that sell generic opioid drugs represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and partners for acquisitions, joint ventures or other collaborations.

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

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

Business interruptions could limit our ability to operate our business.

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

Risks Relating to Manufacturing

If third-party manufacturers of our 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 be higher than expected.

We have no manufacturing facilities and have limited experience in drug product development and commercial manufacturing. We lack the resources and expertise to formulate, manufacture or test the technical performance of our 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, 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.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA must approve any alternative manufacturer of our product before we may use the alternative manufacturer to produce our supplies. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

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

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

Risks Relating to our Collaboration Agreements

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

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

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

Our collaborative agreements may not succeed or may give rise to disputes over intellectual property.

Our strategy to focus on drug discovery of novel drugs discovered by third parties requires us to enter into collaborative agreements from time to time. Collaborative agreements are generally complex and contain provisions that could give rise to legal disputes. Such disputes can delay the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Collaborative agreements often take longer to conclude and may be more expensive to conduct than originally expected. Other factors relating to collaborative agreements may adversely affect the success of our potential products, including:

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

Risks Relating to an Investment in our Common Stock

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

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

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

In addition, because our stock is thinly traded, very few shares are available for borrowing arrangements. As a result investors may not be able to engage in hedging strategies for managing their risk. In order to increase borrowing capacity and facilitate such hedging activities in our common stock, we have filed a prospectus relating to 5,000,000 shares of the common stock that Remi Barbier, our chairman, president and chief executive officer may loan from time to time to a broker-dealer to be selected by Mr. Barbier and us. It is contemplated that the broker-dealer will borrow the shares from Mr. Barbier for the purpose of facilitating short sales of our common stock for the broker-dealer's own account and for its customers. We do not believe that the prospectus, if declared effective, will have a material effect on the price of our stock. However, such sales of our common stock could have such an effect.

The NASD and the Securities and Exchange Commission have adopted or proposed and are in the process of adopting certain new rules which, if adopted in their current form, may require us to make changes to the membership of our board of directors and audit and compensation committees. If we were unable to continue to comply with the new rules within the time frame prescribed by the NASD, we could be delisted from trading on such market, and thereafter trading in our common stock, if any, would be conducted through the over-the-counter market or on the Electronic Bulletin Board of the National Association of Securities Dealers, Inc. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

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

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

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

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

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

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our 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.

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

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

Item 3. ***Quantitative and Qualitative Disclosures About Market Risks***

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. 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 June 30, 2003 all of our cash and cash equivalents were in money market accounts and checking funds with variable, market rates of interest.

Item 4. ***Controls and Procedures***

As of June 30, 2003, an evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including the Chief Executive Officer and Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2003. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls subsequent to June 30, 2003.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 2. Changes in Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

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

The Annual Meeting of Stockholders was held on May 30, 2002 at the offices of Wilson Sonsini Goodrich & Rosati, Professional Corporation located at 650 Page Mill Road, Palo Alto, California 94304 at 10:00 a.m. Of the 27,166,603 shares of Pain Therapeutics' common stock entitled to vote at the meeting, 22,992,899 shares, representing 85% of the votes eligible to be cast, were represented at the meeting in person or by proxy, constituting a quorum. The voting results are presented below.

Proposal I – Election of Two Class II Directors

The stockholders elected two directors to serve until our Annual Meeting of Stockholders held in 2006. The votes regarding the election of directors were as follows:

Name	Votes for Director	Votes Withheld
Remi Barbier	19,381,703	6,261,675
Sanford Robertson	25,570,377	67,226

The Company's other directors with terms of office as directors that continue after the Annual Meeting of Stockholders are Richard Stevens, Robert Gussin, Ph.D., Nadav Friedmann, Ph.D., M.D., and Michael J. O'Donnell.

Proposal II – Ratification of Appointment of Ernst and Young LLP as Independent Auditors to the Company for the Fiscal Year Ending December 31, 2003

The stockholders approved the ratification of Ernst and Young LLP as independent auditors to the Company for the fiscal year ending December 31, 2003. There were 25,627,097 votes cast for the proposal, 11,406 against the proposal, 4,875 abstentions and no broker non-votes.

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits.

The following exhibits have been filed with this report:

3.1*	Amended and restated Certificate of Incorporation.
3.2*	Amended and restated Bylaws.
4.1*	Specimen Common Stock Certificate.
10.7*	Second Amended and Restated Investors Rights Agreement dated as of February 1, 2000 between Registrant and the holders of its series B and series C redeemable convertible preferred stock.
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
32.1	Certifications by the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C Section 1350).

* Incorporated by reference from our registration statement on Form S-1, registration number 333-32370, declared effective by the Securities and Exchange Commission on July 13, 2000.

(b) Reports on Form 8-K.

The Company filed a press release report on Form 8-K on April 29, 2003 during the three months ended June 30, 2003.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PAIN THERAPEUTICS, INC.
(Registrant)

Date: July 31, 2003

/s/ REMI BARBIER

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

/s/ PETER S. RODDY

Peter S. Roddy
Chief Financial Officer

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EXHIBIT INDEX

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Exhibit 31.1

CEO CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. Section 1350)

I, Remi Barbier, certify that:

1. I have reviewed this 10-Q of Pain Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2003

/s/ REMI BARBIER

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

Exhibit 31.2

CFO CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. Section 1350)

I, Peter S. Roddy, certify that:

1. I have reviewed this 10-Q of Pain Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2003

/s/ PETER S. RODDY

Chief Financial Officer

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

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

1. The Company's Periodic Report on Form 10-Q for the period ended June 30, 2003, and to which this certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 31, 2003

/s/ REMI BARBIER

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

/s/ PETER S. RODDY

Peter S. Roddy,
Chief Financial Officer