

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2002-05-14** | Period of Report: **2002-03-31**
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FILER

PAIN THERAPEUTICS INC

CIK: **1069530** | IRS No.: **911911336** | State of Incorporation: **DE** | Fiscal Year End: **1231**
Type: **10-Q** | Act: **34** | File No.: **000-29959** | Film No.: **02645585**
SIC: **2834** Pharmaceutical preparations

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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 MARCH 31, 2002

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)

<Table>

<S>	<C>
DELAWARE	91-1911336
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

</Table>

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

<Table>

<Caption>	
COMMON STOCK, \$0.001 PAR VALUE	27,176,103 SHARES
-----	-----
<S>	<C>
Class	Outstanding at April 30, 2002

</Table>

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)

<Table>
<Caption>

	MARCH 31, 2002	DECEMBER 31, 2001
	-----	-----
<S>	<C>	<C>
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 61,358,569	\$ 65,274,291
Interest receivable.....	96,315	116,688
Prepaid expenses.....	238,076	323,323
	-----	-----
Total current assets.....	61,692,960	65,714,302
Property and equipment, net.....	2,263,731	2,346,494
Other assets.....	75,000	75,000
	-----	-----
Total assets.....	\$ 64,031,691	\$ 68,135,796
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable.....	\$ 1,446,498	\$ 2,170,211
Accrued liabilities.....	546,763	349,260
	-----	-----
Total liabilities.....	1,993,261	2,519,471
	-----	-----
STOCKHOLDERS' EQUITY		
Preferred stock.....	--	--
Common stock.....	27,167	26,838
Additional paid-in-capital.....	104,223,078	104,209,656
Deferred compensation.....	(1,308,526)	(1,733,524)
Notes receivable from stockholders.....	(171,479)	(180,913)
Deficit accumulated during the development stage.....	(40,731,810)	(36,705,732)
	-----	-----
Total stockholders' equity.....	62,038,430	65,616,325
	-----	-----
Total liabilities and stockholders' equity.....	\$ 64,031,691	\$ 68,135,796
	=====	=====

</Table>

See accompanying notes to condensed financial statements.

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PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

<Table>
<Caption>

	THREE MONTHS ENDED MARCH 31,		MAY 4, 1998 (INCEPTION) THROUGH MARCH 31, 2002
	2002	2001	
	-----	-----	-----
<S>	<C>	<C>	<C>
Operating expenses:			
Licensing fees.....	\$ --	\$ --	\$ 100,000
Research and development:			
Non-cash stock based compensation.....	99,828	(446,984)	5,608,693
Other research and development expense.....	2,715,591	2,521,414	25,637,873
	-----	-----	-----
Total research and development expense.....	2,815,419	2,074,430	31,246,566
	-----	-----	-----
General and administrative:			
Non-cash stock based compensation.....	242,921	176,090	6,314,548
Other general and administrative expense.....	1,262,661	1,038,327	9,361,148
	-----	-----	-----
Total general and administrative expense.....	1,505,582	1,214,417	15,675,696
	-----	-----	-----
Total operating expenses.....	4,321,001	3,288,847	47,022,262
	-----	-----	-----
Operating loss.....	(4,321,001)	(3,288,847)	(47,022,262)
Other income:			
Interest income.....	295,123	1,096,018	6,293,852
	-----	-----	-----
Net loss before income taxes.....	(4,025,878)	(2,192,829)	(40,728,410)
Income tax expense.....	200	200	3,400
	-----	-----	-----
Net loss.....	(4,026,078)	(2,193,029)	(40,731,810)
Return to series C preferred shareholders for beneficial conversion feature.....	--	--	(14,231,595)
	-----	-----	-----
Net loss available to common shareholders.....	\$ (4,026,078)	\$ (2,193,029)	\$ (54,963,405)

Basic and diluted net loss per share.....	\$ (0.15)	\$ (0.09)
Weighted-average shares used in computing basic and diluted net loss per share.....	26,909,186	24,404,660

</Table>

See accompanying notes to condensed financial statements.

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PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

<Table>
<Caption>

	THREE MONTHS ENDED MARCH 31,		MAY 4, 1998 (INCEPTION) THROUGH MARCH 31, 2002
	2002	2001	
<S>	<C>	<C>	<C>
Cash flows from operating activities:			
Net loss.....	\$ (4,026,078)	\$ (2,193,029)	\$ (40,731,810)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	87,670	12,249	382,339
Amortization of deferred compensation.....	342,749	(270,894)	9,189,221
Non-cash expense for options and warrants issued.....	--	--	2,767,829
Loss on disposal of property and equipment.....	--	49,684	52,413
Changes in operating assets and liabilities:			
Interest receivable.....	20,373	90,789	(96,315)
Prepaid expenses.....	85,247	122,720	(238,076)
Other assets.....	--	--	(75,000)
Accounts payable.....	(723,713)	91,390	1,446,498
Accrued liabilities.....	197,503	56,050	546,763
Net cash used in operating activities.....	(4,016,249)	(2,041,041)	(26,756,138)
Cash flows used in investing activities:			
Purchase of property and equipment.....	(4,907)	(933,461)	(2,698,483)
Cash flows from financing activities:			
Proceeds from issuance of series B redeemable convertible preferred stock, net.....	--	--	9,703,903
Proceeds from issuance of series C redeemable convertible preferred stock, net.....	--	--	15,194,835
Repayment of notes receivable by stockholders.....	9,434	--	64,917
Proceeds from issuance of series A convertible preferred stock, net.....	--	--	2,639,999
Proceeds from issuance of common stock.....	96,000	200	270,619
Proceeds from initial public offering, net.....	--	--	62,938,917
Net cash provided by financing activities.....	105,434	200	90,813,190
Net increase (decrease) in cash and cash equivalents.....	(3,915,722)	(2,974,302)	61,358,569
Cash and cash equivalents at beginning of period.....	65,274,291	78,926,830	--

Cash and cash equivalents at end of period.....	\$61,358,569	\$75,952,528	\$ 61,358,569
	=====	=====	=====

</Table>

See accompanying notes to condensed financial statements.

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PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONDENSED FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1. GENERAL

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 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.

We have prepared the accompanying unaudited condensed financial statements 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 months ended March 31, 2002 are not necessarily indicative of the results that may be expected for the year ended December 31, 2002. Certain prior year balances have been reclassified for comparative purposes.

These unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and notes to those financial statements for the year ended December 31, 2001 included in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission.

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. NET LOSS PER SHARE

Basic net 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 net 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 common shares issued and outstanding subject to the Company's repurchase rights, outstanding stock options and outstanding warrants. All potential dilutive common shares

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were excluded from the calculation of diluted net loss per share because the representative share increments would be anti-dilutive.

NOTE 3. 1998 STOCK PLAN

In accordance with the provisions of the 1998 Stock Plan, effective January 1, 2002 the number of shares of common stock authorized for issuance under the 1998 Stock Plan was increased from 6,000,000 to 7,000,000 shares.

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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 unaudited condensed financial statements and accompanying notes included in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2001 as filed with the Securities and Exchange Commission. 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 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 competitive 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; 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.

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- 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 \$40.7 million through March 31, 2002. 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.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2002 AND 2001

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 development, 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 \$2.7 million for the three months ended March 31, 2002 compared to \$2.5 million for the three months ended March 31, 2001. The period to period increase of \$0.2 million was primarily due to

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additional staff and increases in salaries and other personnel related costs. 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 \$1.3 million for the three month period ended March 31, 2002 compared to \$1.0 million for the three month period ended March 31, 2001. The period to period increase of \$0.3 million was primarily due to additional staff and increases in salaries and other personnel related costs and amortization on leasehold improvements. General and administrative expense may increase in the future in support of increased research and development or general corporate activities.

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 ("SFAS 123") and is periodically re-measured until the underlying options vest in accordance with 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 expected volatility of our common stock at the date of measurement or re-measurement. 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.

We recognized non-cash stock based compensation expense for options granted as a component of both research and development expense and general and administrative expense totaling \$0.3 million for the three months ended March 31, 2002 compared to a credit of (\$0.3) million for the three months ended March 31, 2001. The change was primarily the result of fluctuations in the market price of our common stock period to period. There will also continue to be future non-cash charges for the amortization of deferred compensation related to options granted to employees and non-employees.

Interest Income

Interest income decreased to \$0.3 million for the period ended March 31, 2002 from \$1.1 million for the period ended March 31, 2001. The decrease of \$0.8 million resulted from declining interest rates and lower average balances of cash and cash equivalents in the 2002 period.

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 March 31, 2002, cash and cash equivalents were \$61.4 million. Currently, our cash and cash equivalents are primarily invested in money market funds.

Net cash used in operating activities was \$4.0 million for the period ended March 31, 2002 compared to \$2.0 million in 2001. Cash used in operating activities related primarily to the funding of net operating losses

partially offset by non-cash charges related to the amortization of deferred stock compensation and changes in operating asset and liability accounts during the quarter.

Our investing activities used \$0.9 million for the three months ended March 31, 2001 and 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. We had minimal investing expenditures in the current quarter. We expect to continue making investments in our infrastructure to support our operations.

Our financing activities provided cash of \$0.1 million for the period ended March 31, 2002 and we had minimal financing activities in the period ended March 31, 2001.

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.

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 \$40.7 million, including a net loss of \$4.0 million in the period ended March 31, 2002, and we expect to incur significant additional operating losses for the next several years. Since inception we have used \$26.8 million of cash in operating activities, used \$2.7 million of cash in investing activities and \$90.8 million of cash has been provided by financing activities, resulting in cash and cash equivalents of \$61.4 million at March 31, 2002. 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.

FACTORS THAT MAY AFFECT OUR FUTURE RESULTS

You should carefully consider the following risk factors and all other information contained in this Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2001 as filed with the Securities and Exchange Commission. 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. As a result of ongoing operating losses, we had an accumulated deficit of \$40.7 million as of March 31, 2002. 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

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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

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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 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.
- 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

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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.

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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

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;

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- 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 March 31, 2002 all of our cash and cash equivalents were in money market and checking funds with variable, market rates of interest.

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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

None.

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:

<Table>	
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3.1*	Amended and restated Certificate of Incorporation.
3.2*	Amended and restated Bylaws.
4.1*	Specimen Common Stock Certificate.
</Table>	

* 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 did not file any reports on Form 8-K during the three months ended March 31, 2002.

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)

/s/ REMI BARBIER

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

/s/ DAVID L. JOHNSON

David L. Johnson
Chief Financial Officer

Date: May 14, 2002