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

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR QUARTERLY PERIOD ENDED MARCH 31, 2001

[ ] 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 [X] 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	26,776,566 SHARES
Class	Outstanding at April 30, 2001

PAIN THERAPEUTICS, INC.

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED BALANCE SHEETS
(UNAUDITED)

	DECEMBER 31, 2000	MARCH 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,926,830	$ 75,952,528
Interest receivable	445,326	354,537
Prepaid expenses	400,667	277,947
Total current assets	79,772,823	76,585,012
Property and equipment, net	1,299,223	2,170,751
Other assets	75,000	75,000
Total assets	$ 81,147,046	$ 78,830,763
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,313,279	$ 2,404,669
Accrued liabilities	139,099	195,149
Total liabilities	2,452,378	2,599,818
Stockholders' equity:		
Preferred stock	--	--
Common stock	26,739	26,741
Additional paid-in-capital	106,182,319	104,533,189
Deferred compensation	(5,073,091)	(3,694,657)
Notes receivable	(72,917)	(72,917)
Deficit accumulated during the development stage	(22,368,382)	(24,561,411)
Total stockholders' equity	78,694,668	76,230,945
Total liabilities and stockholders' equity	$ 81,147,046	$ 78,830,763

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,		MAY 4, 1998 (INCEPTION) THROUGH MARCH 31,
	2000	2001	2001
Operating expenses:			
Licensing fees	$ --	$ --	$ 100,000
Research and development	3,266,221	2,074,430	18,837,888
General and administrative	2,786,766	1,214,417	9,737,510
Total operating expenses	6,052,987	3,288,847	28,675,398
Operating loss	(6,052,987)	(3,288,847)	(28,675,398)
Other income:			
Interest income	245,050	1,096,018	4,116,587
Net loss before income taxes	(5,807,937)	(2,192,829)	(24,558,811)
Income tax expense	200	200	2,600
Net loss	(5,808,137)	(2,193,029)	(24,561,411)
Return to series C preferred shareholders for beneficial conversion feature	(14,231,595)	--	(14,231,595)
Loss available to common shareholders	$(20,039,732)	$(2,193,029)	$(38,793,006)
Basic and diluted loss per share	$ (4.09)	$ (0.09)	
Weighted-average shares used in computing basic and diluted loss per share	4,895,722	24,404,660	

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,		MAY 4, 1998 (INCEPTION) THROUGH MARCH 31,
	2000	2001	2001
Cash flows from operating activities:			
Net loss	$(5,808,137)	$(2,193,029)	$(24,561,411)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,454	12,249	61,944
Amortization of deferred compensation	1,200,810	(270,894)	7,377,219
Non-cash expense for options and warrants issued	2,646,000	--	2,767,829
Loss on disposal of property and equipment	--	49,684	52,413
Changes in operating assets and liabilities:			
Interest receivable	(16,733)	90,789	(354,537)
Prepaid expenses	(30,263)	122,720	(277,947)
Other assets	--	--	(75,000)
Accounts payable	187,076	91,390	2,404,669
Accrued liabilities	--	56,050	195,149
Net cash used in operating activities	(1,814,793)	(2,041,041)	(12,409,672)
Cash flows used in investing activities:			
Purchase of property and equipment	(83,212)	(933,461)	(2,285,108)
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	--	15,194,835
Stock subscription note payments received	--	--	55,483
Deferred financing costs	(460,179)	--	--
Proceeds from issuance of series A convertible preferred stock, net	--	--	2,639,999
Proceeds from issuance of common stock	3,042	200	114,171
Proceeds from initial public offering, net	--	--	62,938,917
Net cash provided by financing activities	14,737,698	200	90,647,308
Net increase (decrease) in cash and cash equivalents	12,839,693	(2,974,302)	75,952,528
Cash and cash equivalents at beginning of period	9,339,669	78,926,830	--
Cash and cash equivalents at end of period	$22,179,362	$75,952,528	$ 75,952,528

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. (a development stage enterprise) is a clinical-stage specialty pharmaceutical company, which 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.

Our development activities involve inherent risks. These risks include, among others, dependence on key personnel and determination of patentability of our products and processes. In addition, we have product candidates, which have not yet obtained U.S. Food and Drug Administration approval. Successful future operations depend on our ability to obtain approval for and commercialize these products.

We have prepared the unaudited financial statements included herein pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to such rules and regulations. In management's opinion, the accompanying financial statements have been prepared on a basis consistent with the audited financial statements and contain adjustments, all of which are of a normal and recurring nature, necessary to present fairly our financial position and results of operations. Interim financial results are not necessarily indicative of results anticipated for the full year. These unaudited financial statements should be read in conjunction with our audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission. Investors are encouraged to review the Annual Report on Form 10-K for a broader discussion of the Company's business and the opportunities and risks inherent in the Company's business.

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 based on the weighted-average number of shares outstanding for the reporting period, less the weighted-average shares outstanding which are subject to the Company's right of repurchase. 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 convertible preferred stock, common shares issued and outstanding subject to the Company's repurchase rights, outstanding stock options and outstanding warrants. For the three month periods ending March 31, 2000 and 2001, all potential dilutive common shares were excluded from the calculation of diluted loss per share because the representative share increments would be anti-dilutive. Upon the closing of our initial public offering in July 2000, all of our convertible preferred stock automatically converted into shares of common stock on a one to one basis.

NOTE 3. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities ("SFAS 133"),

PAIN THERAPEUTICS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONDENSED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. On January 1, 2001, we implemented SFAS 133. We currently have no derivative instruments or hedging activities to report and the implementation of SFAS 133 had no material effect on our results of operations or financial position.

NOTE 4. 1998 STOCK PLAN

In accordance with the provisions of the 1998 Stock Plan, effective January 1, 2001, the number of shares of common stock authorized for issuance under the 1998 Stock Plan was increased from 4,700,000 to 6,000,000 shares.

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 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, 2000 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. 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 increases in our research and development expenses, statements about the timing and progress of our clinical trials, statements about future non-cash charges related to option grants to our employees, statements about the sufficiency of our current resources to fund our operations for the next twelve months, statements about anticipated hiring, statements about development of our internal systems and infrastructure, and statements about the effect of changes in interest rates on our business and financial results. 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 necessarily indicative of future results of clinical trials), the uncertainty of patent protection for the Company's intellectual property or trade secrets and the Company's ability to obtain additional financing if necessary. In addition such statements are subject to the risks and uncertainties discussed elsewhere in this document and the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission.

OVERVIEW

Pain Therapeutics, Inc. is developing a new generation of opioid painkillers with improved clinical benefits. We use our technology to reformulate existing opioid painkillers into new drugs which we believe offer enhanced pain relief, fewer adverse side effects and reduced tolerance and addiction compared to existing opioid painkillers. We currently have multiple opioid painkillers in various stages of Phase II clinical trials

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 $24.6 million through March 31, 2001. These losses have resulted principally from costs incurred in connection with research and development activities, including costs of clinical trials and 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.

We expect to incur 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 pre-clinical 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 and 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, 2001 AND 2000

Research and Development

Research and development expense consists of drug development work associated with our product candidates, primarily including costs of clinical trials and clinical supplies, research payments to the Albert Einstein College of Medicine and other personnel related expenses. Research and development expenses were $2.1 million for the three months ended March 31, 2001 compared to $3.3 million for the three months ended March 31, 2000. The net decrease was primarily attributable to a decrease in charges resulting from stock issuance pursuant to restricted stock purchase agreements as well as amortization of deferred compensation (as described below), partially offset by an overall increase in clinical development costs for our product candidates as well as increases in salaries and other personnel related costs associated with increased staffing in support of these activities. We expect research and development expenses to increase significantly over the next several years as we increase our development efforts and our product candidates enter into further clinical trials. There will be future non-cash charges for the amortization of deferred compensation related to options granted to employees and consultants.

General and Administrative

General and administrative expense consists primarily of salaries and other personnel related expenses to support our activities, consulting and professional services expenses, travel, facilities expenses and other general corporate expenses. General and administrative expenses were $1.2 million for the three months ended March 31, 2001 compared to $2.8 million for the three months ended March 31, 2000. The net decrease was primarily attributable to a decrease in charges resulting from stock issuance pursuant to restricted stock purchase agreements as well as amortization of deferred compensation (as described below), partially offset by increases in salaries and other personnel related costs associated with increased staffing, consulting and professional services, facilities expenses and other general corporate expenses. There will be future non-cash charges for the amortization of deferred compensation related to options granted to employees and consultants.

Deferred Non-Cash Compensation

Deferred stock compensation for options granted to employees represents the difference between the exercise price of the option and the fair value of our common stock on the date of grant in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Deferred compensation for non-employees is recorded at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123 and is periodically re-measured until the underlying options vest in accordance with Emerging Issues Task Force No. 96-18. Deferred compensation is amortized over the vesting period of the options granted.

In connection with the grant of stock options to employees as well as the re-measurement of deferred stock compensation for grants of stock options to non-employees, we recorded a decrease in deferred stock compensation of $1.6 million for the period ended March 31, 2001 compared to an increase of $4.7 million for the period ended March 31, 2000. These amounts were recorded as a component of stockholders' equity (deficit) and are being amortized as charges to operations. We recognized non-cash stock compensation

amortization expense (credit) for options granted of ($0.5) million and $0.9 million in research and development expense for the period ended March 31, 2001 and 2000, respectively and $0.2 million and $0.3 million in general and administrative expense for the period ended March 31, 2001 and 2000, respectively.

Interest Income

Interest income increased to $1.1 million for the three months ended March 31, 2001 from $0.2 million for the period ended March 31, 2000. The increase resulted from higher average balances of cash and cash equivalents following the sale in February 2000 of our series C redeemable convertible preferred stock, with net cash proceeds of $15.2 million, and the completion in July 2000 of our initial public offering, with net proceeds of $62.9 million.

Return to Series C Preferred Stockholders for Beneficial Conversion Feature

In February 2000 we issued 3,044,018 shares of series C redeemable convertible preferred stock for $14.2 million, net of issuance costs. We determined that our series C preferred stock was issued with a beneficial conversion feature. The beneficial conversion feature has been recognized by allocating a portion of the preferred stock proceeds equal to the intrinsic value of that feature, limited to the net proceeds received ($14.2 million), to additional paid-in capital. The intrinsic value is calculated at the date of issue as the difference between the conversion price of the preferred stock and the fair value of our common stock, into which the preferred stock is convertible, multiplied by the number of common shares into which the preferred stock is convertible, limited to the net proceeds received. As our series C preferred stock was convertible into common stock at the option of the holder, at the issuance date of the preferred stock the entire $14.2 million discount resulting from the allocation of proceeds to the beneficial conversion feature has been treated as a dividend and recognized as a return to the preferred stockholders for purposes of computing basic and diluted loss per share in the three month period ended March 31, 2000. Upon completion of our initial public offering in July 2000, all of our convertible preferred and redeemable convertible preferred stock automatically converted into common stock on a one to one basis.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2001, cash and cash equivalents were $76.0 million. Currently, our cash and cash equivalents are primarily invested in money market funds.

Net cash used in operating activities was $2.0 million for the three months ended March 31, 2001 compared to $1.8 million for the three months ended March 31, 2000. Cash used in operating activities includes the funding of net operating losses as adjusted for non-cash items.

Our investing activities used cash of $0.9 million for the three months ended March 31, 2001 compared to $0.1 million for the three months ended March 31, 2000. Investing activities consisted of purchases of property and equipment as well as the funding of tenant improvements in conjunction with the build-out of new office space in the 2001 quarter. In April 2001 we completed the build-out of, and relocated to, this facility. We expect to continue making investments in our infrastructure to support our operations.

Our financing activities provided cash of $14.7 million for the three months ended March 31, 2000, which included net cash proceeds of $15.2 million from the February 2000 issuance of our series C redeemable convertible preferred stock.

We expect our cash requirements to increase as we continue our development efforts, implement additional internal systems and infrastructure, hire additional personnel and expand our facilities. Additionally, as our clinical development efforts grow we anticipate a significant cash requirement for working capital growth, capital expenditures and investment in infrastructure. 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. However, we may require additional financing within this timeframe and such additional funding, if needed, may not be available on terms acceptable to us or at all. Further, any additional equity financing may be dilutive to current shareholders.

RISK FACTORS

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, 2000 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 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.

Since our inception, we have incurred significant net losses. As a result of ongoing operating losses, we had an accumulated deficit of $24.6 million as of March 31, 2001. We are not currently profitable. Even if we succeed in developing and commercializing one or more of our drugs, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our drugs;
- implement additional internal systems and develop new infrastructure;
- acquire and 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 the net proceeds of our initial public offering and cash on hand. We expect that the net proceeds of approximately $62.9 million from the public offering and cash 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 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 pre-clinical studies, as well as human tests, which are referred to as clinical trials. Our four leading product candidates are still in the early stages of clinical trials and we will have to commit substantial time and additional resources to conducting further pre-clinical and clinical studies in several types of pain before we can submit NDAs with respect to any of these product candidates. Initial clinical trials for our PTI-555, PTI-501, PTI-601 and PTI-701 product candidates are ongoing or were completed only recently. We intend to continue to conduct Phase II trials for these and other product candidates. We will not be able to proceed to Phase III clinical trials for any product candidate until we determine appropriate dosages, submit such data to the FDA and obtain FDA approval to begin Phase III studies. We recently filed an IND for our PTI-801 product candidate and plan to initiate clinical trials in 2001. Our other product candidates are at a much earlier stage of development and will require extensive pre-clinical testing before we can make any decision to proceed to clinical trials.

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 several years to complete. If we or the FDA believe the participating patients are being exposed to unacceptable health risks, we would have to suspend our clinical trials. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies.

Even if our clinical trials are completed as planned, their results may not support our product claims. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Such failure would cause us to abandon a product candidate and may delay development of other product candidates.

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

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research and development and testing. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses. The FDA may require us to conduct additional clinical testing or to commit to perform post-marketing studies, in which cases we would have to

expend additional unanticipated time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and product revenues from, our product candidates;

- impose costly procedures on us; and

- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately deny one or more of our NDAs, and we may never obtain regulatory approval for any of our product candidates. If we fail to achieve regulatory approval of any of our leading product candidates we will have fewer saleable products and corresponding product revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products.

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

IF PHYSICIANS AND PATIENTS DO NOT ACCEPT AND USE OUR DRUGS, WE WILL NOT ACHIEVE SUFFICIENT PRODUCT REVENUES AND OUR BUSINESS WILL SUFFER.

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

- perceptions by members of the health care 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 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 OUTSIDE RESEARCHERS FAIL TO DEVOTE SUFFICIENT TIME AND RESOURCES TO OUR DRUG DEVELOPMENT PROGRAMS, OR IF THEIR PERFORMANCE IS SUBSTANDARD, OUR REGULATORY SUBMISSIONS AND OUR PRODUCT INTRODUCTIONS MAY BE DELAYED.

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

IF 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 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 or state regulations. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

IF WE ARE UNABLE TO DEVELOP OUR OWN SALES, MARKETING AND DISTRIBUTION CAPABILITIES, OR IF WE ARE NOT SUCCESSFUL IN CONTRACTING WITH THIRD PARTIES FOR THESE SERVICES ON FAVORABLE TERMS, OUR PRODUCT REVENUES COULD BE DISAPPOINTING.

We currently have no sales, marketing or distribution capabilities. In order to commercialize our products, if any are approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any of our drugs ourselves, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new drugs and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense. On the other hand, if we decide to enter into co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the significant number of recent business combinations among pharmaceutical companies has resulted in a reduced number of potential future collaborators. Even if we are able to identify one or more acceptable collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all. In addition, due to the nature of the market for pain management products, it may be necessary for us to license all or substantially all of our product candidates to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products independently. If we enter into any collaborative arrangements, our product revenues are likely to be lower than if we marketed and sold our products ourselves. In addition, any revenues we receive would depend upon the efforts of our collaborators which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, further business combinations or other factors outside of our control. Depending upon the terms of our collaboration, the remedies we have against an under-performing collaborator may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, or at all.

IF WE CANNOT COMPETE SUCCESSFULLY FOR MARKET SHARE AGAINST OTHER DRUG COMPANIES, WE MAY NOT ACHIEVE SUFFICIENT PRODUCT REVENUES AND OUR BUSINESS WILL SUFFER.

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

We will compete for market share against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have opioid 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 and selling drugs.

DEVELOPMENTS BY COMPETITORS MAY RENDER OUR PRODUCTS OR TECHNOLOGIES OBSOLETE OR NON-COMPETITIVE.

Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. Such alternatives include Elan's SNX-111, as well as combination products from Endo Pharmaceuticals. 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 OR MEET COMMERCIAL DEMAND.

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

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

The risk of product liability is inherent in the testing of medical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We currently carry clinical trial insurance but do not carry product liability insurance. We may not be able to obtain 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, are challenging the prices charged for medical products and services. 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in interest rates in the United States. To minimize this risk, we 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 which invest in such securities. From the time of receipt through March 31, 2001, all of the net proceeds of the initial public offering were invested primarily in short-term, investment grade, interest bearing, U.S. Government securities or money market funds. As of March 31, 2001 all of our cash and cash equivalents were in money market and checking funds.

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.

None.

(b) Reports on Form 8-K.

The Company did not file any reports on Form 8-K during the three months ended March 31, 2001.

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: May 11, 2001

/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