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

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**FORM 10-Q**

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**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For Quarterly Period Ended March 31, 2004

**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)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**91-1911336**  
(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)

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

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

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

**Common Stock, \$0.001 par value**

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35,462,226 Shares

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Class

Outstanding at April 20, 2004

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PAIN THERAPEUTICS, INC.

TABLE OF CONTENTS

	<u>Page No.</u>
PART I.	
	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Financial Statements</u>
	<u>Condensed Balance Sheets – March 31, 2004 and December 31, 2003</u>
	<u>Condensed Statements of Operations – Three-Month Periods Ended March 31, 2004 and 2003 and the Period from May 4, 1998 (Inception) Through March 31, 2004</u>
	<u>Condensed Statements of Cash Flows – Three-Month Periods Ended March 31, 2004 and 2003 and the Period from May 4, 1998 (Inception) Through March 31, 2004</u>
	<u>Notes to Condensed Financial Statements</u>
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	<u>Controls and Procedures</u>
PART II.	
	<u>OTHER INFORMATION</u>
Item 1.	<u>Legal Proceedings</u>
Item 2.	<u>Change in Securities and Use of Proceeds</u>
Item 3.	<u>Defaults Upon Senior Securities</u>
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>
Item 5.	<u>Other Information</u>
Item 6.	<u>Exhibits and Reports on Form 8-K</u>
<u>Signatures</u>	<u>27</u>

**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****PAIN THERAPEUTICS, INC.**  
**(A Development Stage Enterprise)****Condensed Balance Sheets**  
**(Unaudited)**  
**(in thousands)**

	<b>March 31, 2004</b>	<b>December 31, 2003</b>
	<b>(Unaudited)</b>	<b>(1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,181	\$ 12,027
Marketable securities	63,004	65,402
Prepaid expenses	355	1,321
Total current assets	70,540	78,750
Property and equipment, net	1,810	1,688
Other assets	75	75
Total assets	<b>\$ 72,425</b>	<b>\$ 80,513</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,105	\$ 3,441
Accrued compensation and benefits	580	369
Other accrued liabilities	135	141
Total liabilities	5,820	3,951
<b>Stockholders' equity</b>		
Preferred stock	—	—
Common stock	35	35
Additional paid-in-capital	150,824	150,732
Deferred compensation	—	(7)
Accumulated other comprehensive income	157	50
Deficit accumulated during the development stage	(84,411)	(74,248)
Total stockholders' equity	66,605	76,562
Total liabilities and stockholders' equity	<b>\$ 72,425</b>	<b>\$ 80,513</b>

(1) Derived from the Company's audited financial statements as of December 31, 2003, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

See accompanying notes to condensed financial statements.

[Table of Contents](#)

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

	Three Months Ended March 31,		May 4, 1998 (Inception) through March 31, 2004
	2004	2003	
Operating expenses (1):			
Research and development	\$ 9,496	\$ 3,788	\$ 68,336
General and administrative	937	970	23,971
	<u>10,433</u>	<u>4,758</u>	<u>92,307</u>
Total operating expenses	10,433	4,758	92,307
Operating loss	(10,433)	(4,758)	(92,307)
Other income:			
Interest income	270	141	7,896
	<u>(10,163)</u>	<u>(4,617)</u>	<u>(84,411)</u>
Net loss	(10,163)	(4,617)	(84,411)
Return to series C preferred stockholders for beneficial conversion feature	—	—	(14,231)
	<u>\$ (10,163)</u>	<u>\$ (4,617)</u>	<u>\$ (98,642)</u>
Loss available to common stockholders	\$ (10,163)	\$ (4,617)	\$ (98,642)
Basic and diluted loss per common share	\$ (0.29)	\$ (0.17)	
Weighted-average shares used in computing basic and diluted loss per common share	<u>35,426</u>	<u>27,157</u>	

- (1) Included in research and development and general and administrative expenses are stock-based compensation expenses of \$52 and \$103 for the periods ended March 31, 2004 and 2003, respectively, and \$11,981 of the period from May 4, 1998 (Inception) through March 31, 2004.

See accompanying notes to condensed financial statements.

[Table of Contents](#)

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

	Three Months Ended March 31,		May 4, 1998 (Inception) through March 31, 2004
	2004	2003	2004
<b>Cash flows from operating activities:</b>			
Net loss	\$ (10,163)	\$ (4,617)	\$ (84,411)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	86	85	1,071
Non-cash interest income	270	9	198
Non-cash stock-based compensation	52	103	11,981
Non-cash expense for warrants issued	—	—	34
Loss on disposal of property and equipment	—	—	54
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses	966	775	(355)
Other assets	—	—	(75)
Accounts payable	1,664	(920)	5,105
Accrued compensation and benefits	211	116	580
Other accrued liabilities	(6)	22	135
<b>Net cash used in operating activities</b>	<b>(6,920)</b>	<b>(4,427)</b>	<b>(65,683)</b>
<b>Cash flows used in investing activities:</b>			
Purchase of property and equipment	(208)	—	(2,935)
Purchase of marketable securities	(22,467)	—	(91,296)
Sales and maturities of marketable securities	24,702	—	28,251
<b>Net cash provided by (used in) investment activities</b>	<b>2,027</b>	<b>—</b>	<b>(65,980)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of preferred stock, net	—	—	27,539
Stock subscription note payments received	—	—	236
Proceeds from issuance of common stock, net	47	—	111,069
<b>Net cash provided by financing activities</b>	<b>47</b>	<b>—</b>	<b>138,844</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(4,846)</b>	<b>(4,427)</b>	<b>7,181</b>
Cash and cash equivalents at beginning of period	12,027	50,091	—
<b>Cash and cash equivalents at end of period</b>	<b>\$ 7,181</b>	<b>\$ 45,664</b>	<b>\$ 7,181</b>

See accompanying notes to condensed financial statements.

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

**Note 1. General**

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

In the course of our development activities, we have sustained operating losses and expect such losses to continue through the next several years. We expect our current cash and cash equivalents will be sufficient to meet our planned working capital and capital expenditure requirements for at least the next twelve months. There are no assurances that additional financing will be available on favorable terms, or at all.

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

We have prepared the accompanying unaudited condensed financial statements of Pain Therapeutics, Inc. in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions 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, 2004 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2004. Certain prior year balances have been reclassified for comparative purposes.

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

[Table of Contents](#)**Note 2. Loss per Share**

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

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

**Note 3. Comprehensive Loss**

Comprehensive loss is the sum of net loss and other comprehensive income, which is comprised of net unrealized holding gains and losses on available-for-sale securities, as follows (in thousands):

	Three months ended March 31,		May 4, 1998 (Inception) through March 31, 2004
	2004	2003	
Net loss	\$(10,163)	\$(4,617)	\$(98,642)
Other comprehensive income	107	—	157
Comprehensive loss	\$(10,056)	\$(4,617)	\$(98,485)

**Note 4. Stock-Based Compensation**

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

## [Table of Contents](#)

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

	Three months ended March 31,	
	2004	2003
Loss available to common stockholders as reported	\$ (10,163)	\$ (4,617)
Deduct: Total stock-based employee compensation expense determined under the fair valued based method for all awards	(1,270)	(1,382)
Add (deduct): Stock-based employee compensation expense (reduction in expense) included in loss available to common stockholders	8	109
Adjusted loss available to common stockholders	\$ (11,425)	\$ (5,890)
Net loss per common share basic and diluted as reported	\$ (0.29)	\$ (0.17)
Adjusted net loss per common share basic and diluted	\$ (0.32)	\$ (0.22)

The weighted average fair value of stock options granted to employees was \$6.61 and \$1.52 in the three months ended March 31, 2004 and 2003, respectively.

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

	2004	2003
Employee options:		
Volatility	95%	91% to 100%
Risk-free interest rates	4%	2% to 3%
Expected life of option	5 years	5 years
Dividend yield	—	—

### **Note 5. 1998 Stock Plan**

In accordance with the provisions of the 1998 Stock Plan, effective January 1, 2004 the number of shares of common stock authorized for issuance under the 1998 Stock Plan was increased from 8,350,000 to 10,100,000 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 financial statements and accompanying notes included elsewhere in this report. Operating results are not necessarily indicative of results that may occur in future periods.

## [Table of Contents](#)

This document contains forward-looking statements that are based upon current expectations that are within the meaning of the Private Securities Reform Act of 1995. It is our 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 or relating to: future operating losses and anticipated operating and capital expenditures; the timing, substance, sufficiency of materials required for or anticipated results of our clinical development of our drug candidates; the size of the potential market for our products; protection of our intellectual property; expected future sources of revenue and capital; potential competitors or products; future market acceptance of our drug candidates; future expenses increasing substantially or fluctuating; future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions; anticipated hiring; the sufficiency of our current resources to fund our operations over the next twelve months; increasing cash requirements; fluctuations in our operating results; and 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 our drug candidates; unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials); the uncertainty of patent protection for our intellectual property or trade secrets; potential infringement of the intellectual property rights or trade secrets of third parties; and our 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**

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

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception on May 4, 1998 through March 31, 2004, we have incurred an accumulated deficit of approximately \$84.4 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

## [Table of Contents](#)

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

- continue to conduct preclinical and clinical trials for our drug candidates, including the Phase III trials of Oxytrex and PTI-901 and the formulation activities and additional clinical trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- hire additional personnel;
- develop, formulate, manufacture and commercialize our drug candidates and drugs;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology; and
- maintain, defend and expand the scope of our intellectual property.

Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. If our development efforts result in regulatory approval and successful commercialization of our drug candidates, we will generate revenue from direct sales of our drugs and/or, if we license our drugs to future collaborators, from the receipt of license fees and royalties from sales of licensed products. We conduct our research and development programs through a combination of internal and collaborative programs. We rely on arrangements with universities, our collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

### **Recent Developments**

During the first three months of 2004, we:

- initiated a 700-patient Phase III clinical trial of Oxytrex to demonstrate its safety and efficacy in patients with osteoarthritis;
- initiated a Phase I clinical trial program for Remoxy in the United Kingdom; and
- announced the expansion of our intellectual property portfolio.

### **Results of Operations**

#### ***Research and Development***

Research and development expense consists primarily of drug development work associated with our drug candidates, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs and salaries and other personnel-related expenses. Research and development expense increased to \$9.5 million from \$3.8 million in the three months ended March 31, 2004 and 2003, respectively. This increase was primarily due to the increase in Phase III clinical trials activities for Oxytrex and PTI-901 as well as for the Phase I clinical trial and development activities for Remoxy.

## [Table of Contents](#)

We expect research and development expenses to increase significantly over the next several years as we expand our development efforts and as our drug candidates progress through various stages of clinical trials, including the Phase III trials of Oxytrex and PTI-901 as well as the continued development and clinical studies of Remoxy. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and studies.

### ***General and Administrative***

General and administrative expense consists primarily of compensation and other general corporate expenses as well as non-cash stock-based compensation. General and administrative expense decreased to \$0.9 million for the three months ended March 31, 2004 from \$1.0 million for the three months ended March 31, 2003. This decrease was primarily due to lower non-cash equity related expenses in 2004.

### ***Interest Income***

Interest income increased to \$0.3 million from \$0.1 million for the three months ended March 31, 2004 and 2003, respectively. This increase was primarily the result of higher average balances of cash and cash equivalents and marketable securities.

### ***Liquidity and Capital Resources***

Since inception, we have financed our operations primarily through public and private securities offerings. We intend to continue to use the proceeds from these offerings to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of March 31, 2004, cash, cash equivalents and marketable securities were \$70.2 million.

Net cash used in operating activities was \$7.2 million for the three months ended March 31, 2004 compared to \$4.4 million for the three months ended March 31, 2003. Cash used in operating activities in both periods related primarily to the funding of operating losses.

Our investing activities to purchase property, equipment and leasehold improvements used cash of \$0.2 million for the three months ended March 31, 2004. Other investing activities for the three months ended March 31, 2004 consisted primarily of the purchase and sale of marketable securities. We expect to continue to invest in our infrastructure to support our operations.

Our financing activities provided \$47,000 in the three months ended March 31, 2004 from the exercise of stock options from the 1998 Stock Plan.

## [Table of Contents](#)

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

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009 and Thereafter</u>	<u>Total</u>
Minimum lease payments	\$183	\$187	\$191	\$187	\$196	\$ 366	\$1,310

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. These agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. None of these potential future payments are non-cancelable as of March 31, 2004.

Since our inception we have used cash of \$65.9 million in operating activities and incurred a cumulative deficit of approximately \$84.4 million. We expect to incur significant additional operating losses for the next several years and our cash requirements to increase in the future. The amount and timing our future cash requirements will depend on regulatory and market acceptance of our products candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next twelve months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

### **RISK FACTORS**

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

#### ***Risks Relating to our Financial Position and Need for Financing***

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

We were founded in May 1998 and are in the development stage. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and undertaking preclinical studies and clinical trials of our drug candidates. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture commercial-scale product or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

**We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future.**

We have incurred net losses each year since our inception. As a result of ongoing operating losses, we had an accumulated deficit of \$84.4 million as of March 31, 2004. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to conduct preclinical and clinical trials for our drug candidates, including the Phase III trials of Oxytrex and PTI-901 and formulation activities and Phase I trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drugs;
- hire additional personnel;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies or expand the use of our technology; and
- maintain, defend and expand the scope of our intellectual property.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop and commercialize our products, we will not be able to generate such revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock.

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

We have funded all of our operations and capital expenditures with the proceeds from public and private stock offerings. We expect that our current cash, cash equivalent and marketable securities on hand will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months. However, we may need to raise additional funds sooner and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional securities to raise funds, our existing stockholders' ownership percentage would be reduced and new investors may demand rights, preferences or privileges senior to those of existing stockholders.

If we determine that we need to raise additional funds and we are not successful in doing so, we may be unable to complete the clinical development of some or all of our drug candidates or to obtain FDA approval of our drug candidates, and we could be forced to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts and forego attractive business opportunities.

***Clinical and Regulatory Risks***

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

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the drug candidate, and requires the expenditure of substantial resources for research and development and testing. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require us to conduct additional clinical testing, in which case we would have to expend additional time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals will:

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

Even if we comply with all FDA regulatory requirements, we may never obtain regulatory approval for any of our drug candidates. If we fail to obtain regulatory approval for any of our drug candidates we will have fewer saleable products and corresponding lower product revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition.

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

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

In order to obtain FDA approval for any of our drug candidates, we must submit to the FDA a new drug application, or NDA, that demonstrates that the drug candidate is safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Two of our drug candidates, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom.

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

## [Table of Contents](#)

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

Even if our clinical trials are completed as planned, their results may not support our product claims. The clinical trials process may fail to demonstrate that our drug candidates are safe and effective for indicated uses. Such failure would cause us to abandon a drug candidate and could delay development of other drug candidates.

### **If we are unable to satisfy the FDA's request for additional information on Remoxy, we will not be allowed to conduct clinical testing of this product in the United States.**

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

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

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. These discussions are not binding obligations on the part of regulatory authorities. Regulatory authorities may revise previous guidance or decide to ignore previous guidance at any time during the course of our clinical activities or after the completion of our clinical trials. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval.

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

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

**The Drug Enforcement Agency, or DEA, limits the availability of the active ingredients in certain of our current drug candidates and, as a result, our quota may not be sufficient to complete clinical trials, meet commercial demand or may result in clinical delays.**

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

**Government agencies may establish and promulgate usage guidelines that directly apply to our products.**

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

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

The risk of product liability is inherent in the testing of pharmaceutical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We currently carry clinical trial insurance but do not carry product liability insurance. We may not be able to obtain such insurance at a reasonable cost, if at all. If our agreements with any future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

***Risks Relating to Commercialization***

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

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

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs;

## [Table of Contents](#)

- cost-effectiveness of our drugs relative to competing products;
- availability of reimbursement for our products from government or healthcare payers;
- our ability to implement a risk management plan prior to the distribution of any Schedule II drug; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

**If we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, our product revenues could be disappointing.**

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

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

In addition, due to the nature of the market for pain management products, it may be necessary for us to license all or substantially all of our drug candidates to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products independently. If we enter into any collaborative arrangements, our product revenues are likely to be lower than if we marketed and sold our products ourselves.

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

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

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

We will compete for market share against fully integrated pharmaceutical companies or other companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have opioid painkillers already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

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

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

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

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

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

***Risks Relating to our Intellectual Property***

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

Our success, competitive position and potential future revenues will depend in part on our ability to protect our intellectual property. If we, Albert Einstein College of Medicine or our other collaborators fail to file, prosecute or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result. In January 2003, the U.S. Patent and Trademark Office, or PTO, disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. In each of the reexaminations, the PTO issued a first/initial office action and responses to those office actions were filed. In certain of the reexaminations, the PTO issued second/final office actions in which the PTO affirmed the patentability of certain claims related to uses of our drugs under development while maintaining rejections with respect to other claims, and responses to those office actions have been filed. Reexamination certificates have been issued in certain of the proceedings confirming the patentability of the claims. We cannot provide any assurance as to the outcome of the remaining ongoing PTO proceedings. An adverse outcome of the reexamination process could result in loss of claims of these patents that pertain to certain drugs we currently have under development and could have a material adverse impact on our future revenues.

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

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

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

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

*Risks Relating to our Business and Strategy*

**Competition for qualified personnel in the pharmaceutical industry is intense, and if we are not successful in attracting and retaining qualified personnel, we could experience delays in completing necessary clinical trials, in the regulatory approval process or in formulating, manufacturing, marketing and selling our potential products.**

We will need to hire additional qualified personnel with expertise in clinical research, preclinical testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the San Francisco Bay area, is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel will be critical to our success.

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

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

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

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

**Business interruptions could limit our ability to operate our business.**

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

***Risks Relating to Manufacturing***

**If third-party manufacturers of our drug candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may be higher than expected.**

We have no manufacturing facilities and have limited experience in drug product development and commercial manufacturing. We lack the resources and expertise to formulate, manufacture or test the technical performance of our drug candidates. We currently rely on a limited number of experienced personnel and a small number of contract manufacturers and other vendors to formulate, test, supply, store and distribute drug supplies for our clinical trials. Our reliance on a limited number of vendors exposes us to the following risks, any of which could delay our clinical trials, and, consequently, FDA approval of our drug candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality, and may experience shortages of qualified personnel to adequately staff production operations.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our product before we may use the alternative manufacturer to produce our supplies. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

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

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

**If we cannot formulate and scale-up a wide range of dosage forms of Remoxy, we might determine that the commercial opportunity for Remoxy is too limited to warrant further investment in clinical testing and development.**

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

***Risks Relating to our Collaboration Agreements***

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

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

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

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

Our strategy to focus on development of novel drug candidates discovered by third parties requires us to enter into license agreements with such third parties. In addition, we may enter into collaborative agreements to commercialize our products. Such agreements are generally complex and contain provisions that could give rise to legal disputes. Such disputes can delay the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Other factors relating to collaborative agreements may adversely affect the success of our drug candidates, including:

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

***Risks Relating to an Investment in our Common Stock***

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

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

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

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted certain new rules. If we were unable to continue to comply with the new rules, we could be delisted from trading on the NASDAQ National Market, or Nasdaq, and thereafter trading in our common stock, if any, would be conducted through the over-the-counter market or on the Electronic Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

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

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

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

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder 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 stockholders.

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

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, our need for clinical supplies and the re-measurement of certain deferred stock compensation. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of our stock.

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

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

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

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates would not have a material effect on the fair value of our available-for-sale securities at March 31, 2004. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instrument. As of March 31, 2004, our investments consisted of short-term investments in corporate and government notes and obligations or in money market accounts and checking funds with variable, market rates of interest.

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[Table of Contents](#)

**Item 4. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

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

**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.

## [Table of Contents](#)

### **Item 6. Exhibits and Reports on Form 8-K**

#### (a) Exhibits.

The following exhibits have been filed with this report:

- 3.1\* Amended and restated Certificate of Incorporation.
- 3.2\* Amended and restated Bylaws.
- 4.1\* Specimen Common Stock Certificate.
- 10.7\* Second Amended and Restated Investors Rights Agreement dated as of February 1, 2000 between Registrant and the holders of its series B and series C redeemable convertible preferred stock.
- 10.10 Consulting agreement dated March 24, 2004 between Richard G. Stevens and Pain Therapeutics.
- 31.1 Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications by the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C Section 1350).

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

#### (b) Reports on Form 8-K.

The Company filed a press release report on Form 8-K on January 27, 2004.

[Table of Contents](#)

**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.

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(Registrant)

/s/ Remi Barbier

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

/s/ Peter S. Roddy

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Peter S. Roddy  
Chief Financial Officer

Date: April 28, 2004

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[Table of Contents](#)

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description of Document</u>
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31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).

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\* 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.

## CONSULTING AGREEMENT

This Consulting Agreement ("Agreement") is made and entered into as of March 24, 2004 by and between Pain Therapeutics, Inc. (the "Company"), and Richard Stevens ("Consultant"). The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company and Consultant is able and willing to perform such services, on terms set forth more fully below. In consideration of the mutual promises contained herein, the parties agree as follows:

**1. SERVICES AND COMPENSATION**

- (a) Consultant agrees to perform for the Company the services described in Exhibit A ("Services").
- (b) The Company agrees to pay Consultant the compensation set forth in Exhibit A for the performance of the Services.

**2. CONFIDENTIALITY**

(a) "Confidential Information" means any Company proprietary information, technical data, trade secrets or know-how, including, but not limited to, clinical or pre-clinical research or results, product plans, patent applications, products, services, customers, customer lists, markets, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances or other business information disclosed by the Company either directly or indirectly in writing, orally or by drawings or inspection of parts or equipment.

(b) Consultant will not, during or subsequent to the term of this Agreement, use the Company's Confidential Information for any purpose whatsoever other than the performance of the Services on behalf of the Company or disclose the Company's Confidential Information to any third party, and it is understood that said Confidential Information shall remain the sole property of the Company. Consultant further agrees to take all reasonable precautions to prevent any unauthorized disclosure of such Confidential Information including, but not limited to, having each employee of Consultant, if any, with access to any Confidential Information, execute a nondisclosure agreement containing provisions in the Company's favor substantially similar to Sections 2 and 5 of this Agreement. Confidential Information does not include information which (i) is known to Consultant at the time of disclosure to Consultant by the Company as evidenced by written records of Consultant, (ii) has become publicly known and made generally available through no wrongful act of Consultant or (iii) has been rightfully received by Consultant from a third party who is authorized to make such disclosure. Without the Company's prior written approval, Consultant will not directly or indirectly disclose to anyone the existence of this Agreement or the fact that Consultant has this arrangement with the Company.

(c) Consultant agrees that Consultant will not, during the term of this Agreement, improperly use or disclose any proprietary information or trade secrets of any former or current employer or other person or entity with which Consultant has an agreement or duty to keep in confidence information acquired by Consultant in confidence, if any, and that Consultant will not bring onto the premises of the Company any unpublished document or proprietary information belonging to such employer, person or entity unless consented to in writing by such employer, person or entity. Consultant will indemnify the Company and hold it harmless from and against all claims, liabilities, damages and expenses, including reasonable attorneys fees and costs of suit, arising out of or in connection with any violation or claimed violation of a third-party's rights resulting in whole or in part from the Company's use of the work product of Consultant under this Agreement.

(d) Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that Consultant owes the Company and such third parties, during the term of this Agreement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation or to use it except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

(e) Upon the termination of this Agreement, or upon Company's earlier request, Consultant will deliver to the Company all of the Company's property or Confidential Information in tangible form that Consultant may have in Consultant's possession or control.

### **3. NO LICENSE GRANTED**

Nothing in this Agreement is intended to grant any rights to the Third Party under any patent, copyright, trade secret or other intellectual property right nor shall this Agreement grant the Third Party any rights in or to the Company's Confidential Information, except the limited right to review such Confidential Information solely for the purposes of determining whether to enter into the proposed business relationship between the parties.

### **4. REPORTS**

Consultant agrees that it will from time to time during the term of this Agreement or any extension thereof keep the Company advised as to Consultant's progress in performing the Services hereunder and that Consultant will, as requested by the Company, prepare written reports with respect thereto. It is understood that the time required in the preparation of such written reports shall be considered time devoted to the performance of Consultant's Services.

### **5. CONFLICTING OBLIGATIONS**

(a) Consultant certifies that Consultant has no outstanding agreement or obligation that is in conflict with any of the provisions of this Agreement, or that would preclude Consultant from complying with the provisions hereof, and further certifies that Consultant will not enter into any such conflicting Agreement during the term of this Agreement.

(b) In view of Consultant's access to the Company's trade secrets and proprietary know-how/Consultant further agrees that Consultant will not, without Company's prior written consent, design identical or substantially similar designs as those developed under this Agreement for any third party during the term of this Agreement and for a period of twelve (12) months after the termination of this Agreement.

### **6. TERM AND TERMINATION**

(a) This Agreement will commence on the date first written above and will continue until the earlier of (i) May 1, 2007 or (ii) earlier termination as provided below.

(b) The Company may terminate this Agreement immediately and without prior notice if Consultant (i) refuses to or is unable to perform the Services or (ii) is in breach of any material provision of this Agreement; provided, however that the Company first gives Consultant prior written notice of such termination. Any such notice shall be addressed to Consultant at the address shown below or such other address as Consultant may notify the Company of and shall be deemed given upon delivery if personally delivered, or forty-eight (48) hours after deposited in the United States mail, postage prepaid, registered or certified mail, return receipt requested. In the event of an early termination pursuant to clause (ii), Consultant shall have ten (10) business days from notice of termination to cure any breach, to the extent such breach is curable, and to the reasonable satisfaction of the Company.

(c) Upon such termination all rights and duties of the parties toward each other shall cease except that Sections 2 (Confidentiality) and 8 (Independent Contractor) shall survive termination of this Agreement.

## **7. ASSIGNMENT**

Neither this Agreement nor any right hereunder or interest herein may be assigned or transferred by Consultant without the express written consent of the Company.

## **8. INDEPENDENT CONTRACTOR**

Consultant shall perform the Services hereunder as an independent contractor. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the Company at any time. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this contract, and shall incur all expenses associated with performance, except as expressly provided on Exhibit A of this Agreement. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement, and Consultant agrees to and acknowledges the obligation to pay all self-employment and other taxes thereon. Consultant further agrees to indemnify the Company and hold it harmless to the extent of any obligation imposed on Company (i) to pay in withholding taxes or similar items or (ii) resulting from Consultant's being determined not to be an independent contractor.

## **9. BENEFITS**

Consultant acknowledges and agrees, and it is the intent of the parties hereto, that Consultant will receive no benefits from the Company, either as an independent contractor or employee. If Consultant is reclassified by a state or federal agency or court as an employee for tax or other purposes, Consultant will become a non-benefit employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the benefit plans or programs of the Company in effect at the time of such reclassification Consultant would otherwise be eligible for such benefits.

## **10. ARBITRATION AND EQUITABLE RELIEF**

(a) Except as provided in Section 10(d) below, the Company and Consultant agree that any dispute or controversy arising out of, relating to or in connection with the interpretation, validity, construction, performance, breach or termination of this Agreement shall be settled by binding arbitration to be held in the San Francisco Bay Area, CA, in accordance with the Commercial Arbitration Rules, supplemented by the Supplemental Procedures for Large Complex Disputes, of the American Arbitration Association as then in effect (the "Rules"). The arbitrator may grant injunctions or other relief in such dispute or controversy. The decision of the arbitrator shall be final, conclusive and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court of competent jurisdiction.

(b) The arbitrator(s) shall apply California law to the merits of any dispute or claim, without reference to conflicts of law rules. The arbitration proceedings shall be governed by federal arbitration law and by the Rules, without reference to state arbitration law. Consultant hereby consents to the personal jurisdiction of the state and federal courts located in California for any action or proceeding arising from or relating to this Agreement or relating to any arbitration in which the parties are participants.

(c) The Company and Consultant shall each pay one-half of the costs and expenses of such arbitration, and each shall separately pay its counsel fees and expenses.

(d) Consultant agrees that it would be impossible or inadequate to measure and calculate the Company's damages from any breach of the covenants set forth in Sections 2 herein. Accordingly, Consultant agrees that if Consultant breaches Section 2, the Company will have available, in addition to any other right or remedy available, the right to obtain from any court of competent jurisdiction an injunction restraining such breach or threatened breach and specific performance of any such provision. Consultant further agrees that no bond or other security shall be required in obtaining such equitable relief and Consultant hereby consents to the issuances of such injunction and to the ordering of such specific performance.

(e) CONSULTANT HAS READ AND UNDERSTANDS SECTION 10, WHICH DISCUSSES ARBITRATION. CONSULTANT UNDERSTANDS THAT BY SIGNING THIS AGREEMENT, CONSULTANT AGREES TO SUBMIT ANY CLAIMS ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH THIS AGREEMENT, OR THE INTERPRETATION, VALIDITY, CONSTRUCTION, PERFORMANCE, BREACH OR TERMINATION THEREOF, EXCEPT AS PROVIDED IN SECTION 10 (d), TO BINDING ARBITRATION, AND THAT THIS ARBITRATION CLAUSE CONSTITUTES A WAIVER OF CONSULTANT'S RIGHT TO A JURY TRIAL AND RELATES TO THE RESOLUTION OF ALL DISPUTES RELATING TO ALL ASPECTS OF THE RELATIONSHIP BETWEEN THE PARTIES.

## 11. GOVERNING LAW

This Agreement shall be governed by the internal substantive laws, but not the choice of law rules, of the State of California.

## 12. ENTIRE AGREEMENT

This Agreement is the entire agreement of the parties and supersedes any prior agreements between them, whether written or oral, with respect to the subject matter hereof.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

**PAIN THERAPEUTICS, INC.**  
416 Browning Way  
South San Francisco, CA 94080

By: /s/ Remi Barbier

\_\_\_\_\_  
Remi Barbier  
President & CEO

### CONSULTANT:

Richard Stevens  
One Embarcadero, Suite 3700  
San Francisco, CA 94111

/s/ Richard Stevens

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## EXHIBIT A

### SERVICES AND COMPENSATION

#### 1. Contact. Consultant's principal Company contact:

Name: Peter S. Roddy  
Chief Financial Officer  
Pain Therapeutics, Inc.  
416 Browning Way  
South San Francisco, CA 94080

#### 2. Services.

The Services shall include, but shall not be limited to, the following:

Advising the Company on matters related to the conduct of its internal and external financial reporting policies and procedures; and to provide other financial consulting as requested by the Company from time-to-time.

#### 3. Compensation

From the commencement date of this Agreement, March 24, 2004, through final completion of the Services or termination as provided in Section 6, the Company will provide the following compensation to Consultant:

(a) Options to purchase common stock previously granted options to the Consultant will remain in place and continue to vest in accordance with current applicable vesting schedules; and

(b) The Company shall reimburse Consultant for all reasonable travel and other direct expenses incurred by Consultant in performing the Services pursuant to this Agreement, provided Consultant receives written consent from an authorized agent of the Company prior to incurring such expenses;

Consultant shall not be entitled to any other compensation from the Company for the Services.

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Remi Barbier, certify that:

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

Date: April 28, 2004

/s/ Remi Barbier

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

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter S. Roddy, certify that:

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

Date: April 28, 2004

/s/ Peter S. Roddy

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Chief Financial Officer

CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND THE CHIEF FINANCIAL  
OFFICER PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. Section 1350)

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

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

Date: April 28, 2004

/s/ REMI BARBIER

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

/s/ PETER S. RODDY

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Peter S. Roddy,  
Chief Financial Officer