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

FORM 10-Q

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

For Quarterly Period Ended September 30, 2005

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

For the transition period from _____ to _____.

Commission File Number 000-29959

Pain Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (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	43,878,482 Shares
Class	**Outstanding at October 18, 2005**

PAIN THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. *Financial Statements*

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

Condensed Balance Sheets
(Unaudited)
(in thousands)

	September 30, 2005	December 31, 2004
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 1,421	$ 1,379
Marketable securities	70,126	98,018
Prepaid expenses	540	259
Total current assets	72,087	99,656
Property and equipment, net	1,612	1,461
Other assets	75	75
Total assets	$ 73,774	$ 101,192
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 564	$ 877
Accrued development expense	6,539	6,358
Accrued compensation and benefits	416	415
Other accrued liabilities	116	146
Total liabilities	7,635	7,796
Stockholders' equity		
Preferred stock	—	—
Common stock	44	44
Additional paid-in-capital	206,168	205,920
Accumulated other comprehensive loss	(512)	(544)
Deficit accumulated during the development stage	(139,561)	(112,024)
Total stockholders' equity	66,139	93,396
Total liabilities and stockholders' equity	$ 73,774	$ 101,192

(1) Derived from the Company's audited financial statements as of December 31, 2004, 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.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

Condensed Statements of Operations
(Unaudited)
(in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		May 4, 1998 (inception) through September 30, 2005
	2005	2004	2005	2004	
Operating expenses:					
Research and development	$ 8,144	$ 8,547	$ 25,783	$ 26,224	$ 119,716
General and administrative	1,105	861	3,282	2,904	30,184
Total operating expenses	9,249	9,408	29,065	29,128	149,900
Operating loss	(9,249)	(9,408)	(29,065)	(29,128)	(149,900)
Other income:					
Interest and other income, net	482	177	1,528	668	10,339
Net loss	(8,767)	(9,231)	(27,537)	(28,460)	(139,561)
Return to series C preferred stockholders for beneficial conversion feature	—	—	—	—	(14,231)
Loss available to common stockholders	$ (8,767)	$ (9,231)	$ (27,537)	$ (28,460)	$ (153,792)
Basic and diluted loss per share	$ (0.20)	$ (0.26)	$ (0.63)	$ (0.80)	
Weighted-average shares used in computing basic and diluted loss per share	43,853	35,594	43,754	35,507	

Included in research and development and general and administrative expenses are stock-based compensation expenses of $68 thousand and $20 thousand for the three-month periods ended September 30, 2005 and 2004, respectively, $159 thousand and $332 thousand for the nine-month periods ended September 30, 2005 and 2004, respectively, and $12,489 for the period from May 4, 1998 (inception) through September 30, 2005.

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,		May 4, 1998 (inception) through September 30, 2005
	2005	2004	
Cash flows used in operating activities:			
Net loss	$ (27,537)	$ (28,460)	$ (139,561)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	273	282	1,695
Non-cash interest income, net	265	(60)	(184)
Non-cash stock based compensation	159	332	12,523
Changes in operating assets and liabilities:			
Prepaid expenses	(281)	906	(540)
Other assets	—	—	(75)
Accounts payable	(313)	(1,400)	564
Accrued development expense	181	4,570	6,539
Accrued compensation and benefits	1	6	416
Other accrued liabilities	(30)	—	116
Net cash used in operating activities	(27,282)	(23,824)	(118,507)
Cash flows used in investing activities:			
Purchase of property and equipment	(424)	(347)	(3,307)
Purchase of marketable securities	(32,462)	(56,700)	(215,358)
Sales and maturities of marketable securities	60,121	70,181	144,904
Net cash provided by (used in) investing activities	27,235	13,134	(73,761)
Cash flows from financing activities:			
Proceeds from issuance of preferred stock, net	—	—	27,539
Proceeds from issuance of common stock, net	89	413	166,150
Net cash provided by financing activities	89	413	193,689
Net increase (decrease) in cash and cash equivalents	42	(10,277)	1,421
Cash and cash equivalents at beginning of period	1,379	12,027	—
Cash and cash equivalents at end of period	$ 1,421	$ 1,750	$ 1,421

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)

Notes to Condensed Financial Statements
(Unaudited)

Note 1. General

Pain Therapeutics, Inc. is a biopharmaceutical company dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers, which are sometimes referred to as narcotic painkillers.

We incorporated in Delaware in May 1998. We own worldwide commercial rights to all of our drug candidates. Our clinical pipeline consists of three proprietary drug candidates. We are developing these three oral drugs to treat patients who suffer from severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or irritable bowel syndrome, or IBS.

In the course of our development activities, we have sustained operating losses. These losses may continue through the next several years. We expect our current cash, cash equivalents and marketable securities 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 U.S. 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 U.S. 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 only of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2005.

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

Note 2. Loss per Share

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

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

Note 3. Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,		May 4, 1998 (inception) through September 30, 2005
	2005	2004	2005	2004	
Net loss	$(8,767)	$(9,231)	$(27,537)	$(28,460)	$ (139,561)
Other comprehensive income (loss)	(40)	145	32	(172)	(512)
Comprehensive loss	$(8,807)	$(9,086)	$(27,505)	$(28,632)	$ (140,073)

Note 4. Stock-Based Compensation

We use the intrinsic-value method of accounting for stock-based awards granted to employees and directors 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 and directors 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.

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (8,767)	$ (9,231)	$(27,537)	$(28,460)
Deduct: Total stock based employee compensation expense determined under the fair value based method for all awards	(2,201)	(1,732)	(5,646)	(4,162)
Add: Total stock based employee compensation expense	—	—	—	7
Adjusted net loss	$(10,968)	$(10,963)	$(33,183)	$(32,615)
Loss per common share basic and diluted as reported	$ (0.20)	$ (0.26)	$ (0.63)	$ (0.80)
Adjusted net loss per common share basic and diluted	$ (0.25)	$ (0.31)	$ (0.76)	$ (0.92)

The weighted average fair value of stock options granted to employees was $4.89 and $6.22 in the three months ended September 30, 2005 and 2004, respectively, and $4.31 and $6.25 in the nine months ended September 30, 2005 and 2004, 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:

	2005	2004
Employee options:		
Volatility	78% to 86%	91% to 95%
Risk-free interest rates	4%	4%
Expected life of option	5 years	5 years
Dividend yield	—	—

For the 2000 Employee Stock Purchase Plan, the weighted average fair value of purchase rights granted were $2.13 per share and $1.66 per share for the nine months ended September 30, 2005 and 2004, respectively, calculated using Black-Scholes with the following assumptions:

	2005	2004
Employee stock purchase plan:		
Volatility	46% to 55%	91% to 94%
Risk-free interest rates	3% to 4%	3%
Expected life of purchase rights	2 years	2 years
Dividend yield	—	—

Note 5. 1998 Stock Plan

In accordance with the provisions of the 1998 Stock Plan, effective January 1, 2005, the number of shares of common stock authorized for issuance under the 1998 Stock Plan was increased from 10,100,000 to 10,600,000 shares.

Note 6. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board, or FASB, issued a revision of FASB Statement No. 123, or SFAS 123R, which requires all share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. We expect to calculate the value of share-based payments under SFAS 123R on a basis substantially consistent with the fair value approach of SFAS 123. We plan to adopt SFAS 123R on January 1, 2006. We expect the adoption of SFAS 123R will have a material impact on our financial statements in 2006, but we cannot reasonably estimate the impact of adoption because the impact will depend on levels of share-based payments granted in the future and certain assumptions that can materially affect the calculation of the value of share-based payments to employees may change in 2005.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this report. Operating results are not necessarily indicative of results that may occur in future periods.

This document contains forward-looking statements, which are based upon current expectations, within the meaning of the Private Securities Reform Act of 1995. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- the timing of initiation of clinical trials and expected announcements of our clinical trial results;
- future operating losses and anticipated operating and capital expenditures;
- expected uses of proceeds from our securities offerings;
- the sufficiency of materials required for the clinical development of our drug candidates;
- the size of the potential market for our products;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital or increasing cash needs;
- potential competitors or competitive products;
- future market acceptance of our drug candidates;
- expenses increasing substantially or fluctuations in our operating results;
- future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- anticipated hiring and development of our internal systems and infrastructure; and
- the sufficiency of our current resources to fund our operations over the next twelve months.

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, clinical trials (including patient enrollment), regulatory approval, production and commercialization 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;
- pursuing in-license and acquisition opportunities;
- hiring and retaining personnel; and
- our financial position 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 dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers. U.S. sales of opioid painkillers exceeded $5.6 billion in 2003. We own worldwide commercial rights to all of our drug candidates.

Our clinical pipeline consists of three proprietary drug candidates. We are developing these three oral drugs to treat patients who suffer from severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or IBS.

Our drug candidates are:

- Oxytrex™, a new oral opioid painkiller, for the treatment of severe chronic pain;
- PTI-901, a drug candidate to treat men and women with IBS; and
- Remoxy™, a long-acting formulation of oxycodone designed to deter abuse.

We expect to announce top-line data from our completed Phase III clinical trials of Oxytrex and PTI-901 in women by the end of 2005.

In March 2005, we announced positive clinical results from the first of two Phase III clinical trials for Oxytrex. In this variable dose study of 719 patients with severe low-back pain, Oxytrex showed minimal physical dependence, better overall safety, less drug use and similar pain relief to oxycodone. Specifically, Oxytrex patients reported 50% less symptoms of physical dependence and withdrawal ($p<0.01$) after cessation of prolonged, high-dose opioid therapy and about 20% less overall opioid-related side-effects during treatment, including less somnolence ($p<0.05$), less uncontrollable itching ($p<0.05$) and less moderate to severe constipation ($p<0.05$).

In September 2005 we announced top line data from our Phase III clinical trial of Remoxy. In this randomized, double-blinded clinical trial of 209 osteoarthritic patients with moderate to severe chronic pain, Remoxy demonstrated a statistically significant reduction in pain ($p<0.05$) when compared to placebo.

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception on May 4, 1998 through September 30, 2005, we have recorded an accumulated deficit of approximately $139.6 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.

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

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

Revenue from product sales 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, collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

Since our inception, we have focused our research and development efforts on the research and development of opioid drugs for the treatment of pain. Research and development expenses related to this project for the period from inception through September 30, 2005 total $119.7 million. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		May 4, 1998 (Inception) Through September 30, 2005
	2005	2004	2005	2004	
Compensation	$ 1,176	$ 1,036	$ 3,368	$ 2,979	$ 24,056
Contractor Fees	5,159	6,871	18,496	20,125	73,512
Supplies	1,228	290	2,337	1,666	14,458
Other Common Costs	581	350	1,582	1,454	7,690
	$ 8,144	$ 8,547	$25,783	$26,224	$ 119,716

(1) Contractor fees generally include expenses for preclinical studies and clinical trials.
(2) Supplies generally include costs for formulation and manufacturing activities.
(3) Other generally includes the allocation of common costs such as facilities.

Our technology has been applied across our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates also relate to, and further the development of, our other drug candidates. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing.

Estimating the dates of completion of clinical development, and the costs to complete development, of our drug candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical products take a significant amount of time to research, develop and commercialize. The clinical trial portion of the development of a new drug alone usually spans several years. We expect to reassess our future research and development plans based on our review of data we receive from our current research and development activities. The cost and pace of our future research and development activities are linked and subject to change.

Our Critical Accounting Policies are described under Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the Securities and Exchange Commission. There have been no changes to our Critical Accounting Policies for the period ended September 30, 2005.

Results of Operations

Three and Nine Months Ended September 30, 2005 and 2004

Research and Development

Research and development expense consists primarily of costs of drug development work associated with our drug candidates, including:

- preclinical testing,

- clinical trials,
- clinical supplies and related formulation and design costs, and
- salaries and other personnel-related expenses.

The decreases in research and development expense to $8.1 million and $25.8 million from $8.5 million and $26.2 million in the three and nine month periods ended September 30, 2005 and 2004, respectively were primarily due to decreased clinical activities, offset in part by increased development activities for Remoxy, Oxytrex and PTI-901.

We expect research and development expenses to increase over the next several years as we continue our development efforts. Our development efforts are designed to result in our drug candidates progressing through various stages of clinical trials. Also, we expect to continue other development efforts on our product candidates. The increase in research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical trials and preclinical studies.

General and Administrative

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense increased to $1.1 million from $0.9 million for the three months ended September 30, 2005 and 2004, respectively and increased to $3.3 million from $2.9 million for the nine months ended September 30, 2005 and 2004, respectively. The increase was primarily due to increases in pre-commercialization and other personnel-related activities. We expect general and administrative expenses to increase over the next several years in connection with pre-commercialization and commercialization activities for our product candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies.

Interest and Other Income

Interest and other income increased to $0.5 million from $0.2 million in the three months ended September 30, 2005 and 2004, respectively, and to $1.5 from $0.7 million for the nine months ended September 30, 2005 and 2004, respectively. These increases were primarily due to increases in average balances of marketable securities as well as to increases in interest rates. Other income is comprised of non-recurring grant income. We expect our interest income to decrease in the foreseeable future.

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 September 30, 2005, cash, cash equivalents and marketable securities were $71.5 million.

Net cash used in operating activities was $27.5 million for the nine months ended September 30, 2005 compared to $23.8 million for the nine months ended September 30, 2004. Cash used in operating activities in both periods related primarily to the funding of operating losses.

Our investing activities to purchase property and equipment were $0.2 million for the nine months ended September 30, 2005. Other investing activities for the nine months ended September 30, 2005 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 less than $0.1 million in the nine months ended September 30, 2005, primarily from the exercise of stock options issued under our stock plans.

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 facility and equipment leases, annual minimum lease payments are as follows (in thousands):

	2005	2006	2007	2008	2009	2010 and Thereafter	Total
Minimum lease payments	$187	$191	$187	$196	$206	$ 160	$ 1,127

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. We believe the amount of each of these milestone payments will be immaterial within the period such milestone is achieved. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements and in some cases modest license maintenance payments. All of these potential future payments are cancelable as of September 30, 2005.

Since our inception we have used cash of $118.5 million in operating activities and have an accumulated deficit of approximately $139.6 million. We expect to incur significant additional losses and expect our cash requirements to increase in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug 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 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 our drug candidates on a commercial scale 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 $139.6 million as of September 30, 2005. 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 studies and clinical trials for our drug candidates;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates, we will not be able to generate such revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would have a material adverse impact on the market price of our common stock.

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

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 equivalents 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 within such twelve-month period or thereafter 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 raise additional capital through strategic alliance and license arrangements, we may have to trade our rights to our technology, intellectual property or drug candidates to others in such arrangements on terms that may not be favorable to us.

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 seek or obtain FDA approval of our drug candidates. We then could be forced to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts or 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 drug candidates, 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 trials or preclinical studies, in which case we would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. In particular, the FDA may require additional toxicology studies for certain excipients used in Remoxy or any of our other drug candidates. 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, which would have an adverse effect on our operating results and financial condition.

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, if any, and corresponding lower product revenues,

if any. Even if we receive regulatory approval of our drug candidates, such approval may involve limitations on the indications and conditions of use or marketing claims we may make for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy Phase IV 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 jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before we can commercialize our drugs. Regulatory approval processes outside the United States 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 drug candidates.

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.

Our Phase III clinical 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. This means that even if one of our Phase III clinical trials demonstrates positive results for our drug candidates, we are likely to have to demonstrate positive results in one or more additional Phase III clinical trials prior to receiving broad label FDA approval for treatment of severe chronic pain. Even if the results of one or more of our Phase III clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies or and clinical trials before we can submit NDAs or obtain FDA approvals for our drug candidates, and positive results of a Phase III clinical trial may not be replicated in subsequent trials.

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 or terminate 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 trials.

In addition, completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- increases in time required to complete monitoring of patients during or after participation in a clinical trial; and
- unexpected need for additional patient-related data.

Any of these delays, if significant, could impact the timing, approval and commercialization of our drug candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing 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.

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 clinical trials or preclinical studies 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 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 Administration, 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 or to 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 under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and 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 drug candidates.

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

Conducting clinical trials of our drug candidates or potential commercial sales of a drug candidate may expose 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. If we successfully commercialize one or more of our drug candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. 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.

If we receive regulatory approval for our drug candidates, we and our collaborators will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our ability to commercialize our potential drugs.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies or clinical trials. In addition, if the FDA approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our drugs and our business could suffer.

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;
- published studies demonstrating the 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, or at all, 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 number of potential collaborators is

limited and because of competition from others for similar alliances with potential 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 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. We currently have not generated pharmacoeconomic data on any of our products. 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. Adequate 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 our product candidates 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. The Ex Parte Reexamination proceedings have been resolved by a Reexamination Certificate or a Notice of Patent to issue a Reexamination Certificate.

We may be involved in additional challenges to our intellectual property. An adverse outcome of any challenges to our intellectual property 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.

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 or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, 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 contract 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.

Our employees and consultants are generally subject to confidentiality or other agreements with their former employers and they may inadvertently or otherwise violate those agreements.

Many of our employees and consultants were previously employed at universities or biotechnology or pharmaceutical companies. While we require our employees and consultants to honor any agreements they may have entered into prior to working with us, we may be subject to claims that we inadvertently or otherwise used or disclosed trade secrets or other confidential information belonging to former employers. Failure to defend such claims could result in loss of valuable rights or personnel, which in turn could harm or prevent commercialization of our drug candidates. Successful defense against such claims can be expensive and might distract us from executing our strategies.

Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process very time consuming, difficult and expensive 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. Our competitors may market less expensive or more effective drugs that would compete with our product candidates or reach market with competing drugs before we are able to reach market with our drug candidates. 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

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.

In addition, even if we enter into long-term supply arrangements with third-party suppliers, we cannot control changes in strategy by third-party suppliers that affect their ability or willingness to continue to supply our drug products on acceptable terms.

If our drug supply for one of our drug candidates was interrupted, our operations could be negatively affected.

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. If we are unsuccessful in our formulation or scale-up activities with Remoxy, our future sales may be less than expected and our operations may suffer.

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.

We may not succeed at in-licensing drug candidates or technologies to expand our product pipeline.

We may not successfully in-license drug candidates or technologies to expand our product pipeline. The number of such candidates or technologies may be limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates or technologies is intense because such companies generally desire to expand their product pipelines through in-licensing.

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 of our common stock 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 or delays in our preclinical studies 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 including the risk of class action lawsuits related to opioid misuse or abuse;
- 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 rules that we must continue to meet in order to be listed for trading on the NASDAQ National Market, or Nasdaq. If we were unable to continue to comply with the rules, we could be delisted from trading on the 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.

Anti-takeover provisions in our charter documents, our Stockholder Rights Plan and Delaware law may prevent or delay removal of incumbent management or a change of control.

Anti-takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws, our Stockholder Rights Plan and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

- a classified board so that only one of the three classes of directors on our board of directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our board of directors to amend our bylaws without stockholder approval; and
- the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

The rights issued pursuant to our Stockholder Rights Plan will become exercisable, subject to certain exceptions, the tenth day after a person or group announces acquisition of 15% or more of our common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203.

These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

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.

Publicly available information regarding stockholders' ownership may not be comprehensive because the SEC does not require certain large stockholders to publicly disclose their stock ownership positions.

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 clinical, financial or operating results may not meet the expectations of securities analysts and investors that 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 prevailing interest rates later rise, the fair value 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 September 30, 2005. 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 September 30, 2005, 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.

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. ***Unregistered Sales of Equity 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***

The following exhibits have been filed with this report:

Exhibit Number	Description of Document
3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2 (2)	Amended and Restated Bylaws.
4.1 (1)	Specimen Common Stock Certificate
4.2 (3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the Company and Mellon Investor Services LLC, including the Certificate of Designation, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005.
(2) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005.
(3) Incorporated by reference from our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2005.

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: November 4, 2005

/s/ Remi Barbier

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

/s/ Peter S. Roddy

Peter S. Roddy
Vice President and Chief Financial Officer

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EXHIBIT INDEX

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3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2 (2)	Amended and Restated Bylaws.
4.1 (1)	Specimen Common Stock Certificate
4.2 (3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the Company and Mellon Investor Services LLC, including the Certificate of Designation, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005.
(2) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005.
(3) Incorporated by reference from our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2005.

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. 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
    d. 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.

/s/ REMI BARBIER

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

Date: November 4, 2005

Exhibit 31.2

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. 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
    d. 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.

/s/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer

Date: November 4, 2005

Exhibit 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)

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, Vice President and Chief Financial Officer of Pain Therapeutics, Inc. (the "Company"), hereby certify that to the best of our knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2005, 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: November 4, 2005

/s/ REMI BARBIER

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

/s/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer