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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2006

or

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

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 Number)***

Remi Barbier
President and Chief Executive Officer
416 Browning Way
South San Francisco, CA 94080
(650) 624-8200
(Address, including zip code, or registrant's principal executive offices and 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2). 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	44,210,642 Shares Outstanding at October 15, 2006

PAIN THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

PAIN THERAPEUTICS, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands)

	September 30, 2006	December 31, 2005[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,558	$ 95,651
Marketable securities	182,360	117,001
Collaboration revenue receivable	2,596	889
Prepaid expenses	345	623
Total current assets	216,859	214,164
Property and equipment, net	1,352	1,556
Other assets	75	75
Total assets	$ 218,286	$ 215,795
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 438	$ 998
Accrued development expense	5,774	4,461
Deferred program fee revenue - current portion	26,200	26,200
Accrued compensation and benefits	409	501
Income taxes payable	3,579	—
Other accrued liabilities	112	187
Total current liabilities	36,512	32,347
Non-current liabilities		
Deferred program fee revenue - noncurrent portion	100,438	120,088
Total liabilities	136,950	152,435
Commitments and contingencies		
Stockholders' equity		
Preferred stock	—	—
Common stock	44	44
Additional paid-in-capital	212,378	206,489
Accumulated other comprehensive loss	(291)	(479)
Accumulated deficit	(130,795)	(142,694)
Total stockholders' equity	81,336	63,360
Total liabilities and stockholders' equity	$ 218,286	$ 215,795

(1) Derived from the Company's audited financial statements as of December 31, 2005, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenue				
Program fee revenue	$ 6,550	$ —	$ 19,651	$ —
Collaboration revenue	6,960	—	22,931	—
Milestone revenue	5,000	—	5,000	—
Total revenue	18,510	—	47,582	—
Operating expenses:				
Research and development[1]	10,471	8,144	33,513	25,783
General and administrative	1,686	1,105	5,706	3,282
Total operating expenses	12,157	9,249	39,219	29,065
Operating income (loss)	6,353	(9,249)	8,363	(29,065)
Interest and other income	2,559	482	7,115	1,528
Income (loss) before provision (credit) for income taxes	8,912	(8,767)	15,478	(27,537)
Provision (credit) for income taxes	(744)	—	3,579	—
Net income (loss)	$ 9,656	$ (8,767)	$ 11,899	$ (27,537)
Earnings per share				
Basic	$ 0.22	$ (0.20)	$ 0.27	$ (0.63)
Diluted	$ 0.21	$ (0.20)	$ 0.26	$ (0.63)
Weighted-average shares used to compute earnings per share				
Basic	44,184	43,853	44,106	43,754
Diluted	45,221	43,853	45,323	43,754

(1) Included in research and development and general and administrative expenses are non-cash stock-based compensation expenses of $1,013 thousand and $657 thousand, respectively, totaling $1,670 thousand for the three months ended September 30, 2006 and $2,763 thousand in research and development and $2,027 thousand in general and administrative, totaling $4,790 thousand for the nine months ended September 30, 2006. The non-cash stock-based compensation expense included was $68 thousand and $159 thousand for the three and nine months ended September 30, 2005, respectively.

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Nine Months Ended September 30,	
	2006	2005
Cash flows used in operating activities:		
Net income (loss)	$ 11,899	$ (27,537)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	260	273
Non-cash change in interest income, net	(1,700)	265
Non-cash stock-based compensation	4,790	159
Loss on disposal of property and equipment	38	—
Changes in operating assets and liabilities:		
Collaboration revenue receivable	(1,707)	—
Prepaid expenses	278	(281)
Accounts payable	(560)	(313)
Accrued development expense	1,313	181
Deferred program fee revenue	(19,650)	—
Accrued compensation and benefits	(92)	1
Income taxes payable	3,579	—
Other accrued liabilities	(75)	(30)
Net cash used in operating activities	(1,627)	(27,282)
Cash flows used in investing activities:		
Purchases of property and equipment	(94)	(424)
Purchases of marketable securities	(111,902)	(32,462)
Sales of marketable securities	20,996	60,121
Maturities of marketable securities	27,435	—
Net cash provided by (used in) investing activities	(63,565)	27,235
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	1,099	89
Net cash provided by financing activities	1,099	89
Net increase (decrease) in cash and cash equivalents	(64,093)	42
Cash and cash equivalents at beginning of period	95,651	1,379
Cash and cash equivalents at end of period	$ 31,558	$ 1,421

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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 have not been profitable for a full fiscal year and we have yet to generate any revenues from product sales.

Our development activities involve inherent risks. These risks include, among others, dependence on our collaboration partners, key personnel and determination of patentability and protection of our products and processes. In addition, we have drug candidates that have not yet obtained approval from the U. S. Food and Drug Administration, or FDA. 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 and nine month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2006.

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 revenue earned and expenses incurred during the reporting period. Actual results could differ from those estimates.

Note 2. Significant Accounting Policies

Revenue Recognition and Deferred Program Fee Revenue

We and King Pharmaceuticals, Inc., or King, are engaged in a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. In connection with the strategic

alliance, we recognize program fee revenue and collaboration revenue. Program fee revenue is derived from the upfront payment from King received in December 2005 and is recognized ratably over our estimate of the development period of four drug candidates expected to be developed under the strategic alliance with King. Of those drug candidates, Remoxy is in Phase III clinical trials, one drug candidate is in a Phase I clinical trial and two potential drug candidates are at the pre-clinical stage. We currently estimate the development period for all four expected drug candidates to extend through July 2011. Collaboration revenues from reimbursement of development expenses are generally recognized as costs that relate to the strategic alliance with King are incurred.

Milestone Revenue

King is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the clinical development of Remoxy and the other abuse-resistant opioid painkillers under the strategic alliance. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King.

Collaboration Revenue Receivable from King

We record a receivable for yet-to-be reimbursed development expenses incurred in connection with the collaboration with King. We classify the receivable as a current asset, unless the reimbursement is not expected to be received within a year of the balance sheet date.

Earnings (Loss) per Share

Basic earnings (loss) per share is computed on the basis of the weighted-average number of common shares outstanding for the reporting period. Diluted earnings 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 warrants.

The following table summarizes the components of the numerator and denominator in the calculation of diluted income (loss) per share for the three and nine months ended September 30, 2006 and 2005 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Numerator:				
Net income (loss)	$ 9,656	$ (8,767)	$11,899	$(27,537)
Denominator:				
Weighted average shares outstanding used to compute basic income per share	44,184	43,853	44,106	43,754
Effect of dilutive stock options and warrants	1,037	—	1,217	—
Weighted average shares outstanding and effect of dilutive securities used to compute diluted income per share	45,221	43,853	45,323	43,754

We excluded the effect of anti-dilutive stock options to purchase 3,417,176 and 2,478,247 shares of common stock for the three and nine months ended September 30, 2006 from the related denominator in the calculation of earnings per share primarily because the exercise prices for these options were greater than the average market price of $8.33 and $8.90 per common share for the three and nine months ended September 30, 2006, respectively.

We reported a loss for the three and nine months ended September 30, 2005. Therefore, all potential shares of common stock-related to potentially dilutive securities have been excluded from the calculation of diluted loss per share for these periods because they are anti-dilutive.

Note 3. Comprehensive Income (Loss)

Comprehensive income (loss) is the sum of net income (loss) and other comprehensive income (loss), as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net income (loss)	$ 9,656	$(8,767)	$11,899	$(27,537)
Other comprehensive income (loss)	839	(40)	188	32
Comprehensive income (loss)	$10,495	$(8,807)	$12,087	$(27,505)

Other comprehensive income (loss) consists of net unrealized holding gains and losses on available-for-sale securities.

Note 4. Stock-Based Compensation

Adoption of SFAS 123R

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. This statement requires companies to recognize expense in the income statement for the fair value all share-based payments to employees and directors, including grants of employee stock options. SFAS 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations, or APB 25, and amends FASB Statement No. 95, *Statement of Cash Flows*.

We adopted SFAS 123R on January 1, 2006 using the modified-prospective transition method. Under this transition method, we record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation expense recognized in the three and nine months ended September 30, 2006 includes compensation cost for all outstanding stock-based awards.

Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and directors in accordance with APB 25 and its interpretations. Accordingly, we did not recognize compensation cost in our financial statements prior to January 1, 2006 for these awards because stock options granted to employees and directors had exercise prices equal to or greater than the fair value of the underlying security at the time the stock option was granted.

In adopting SFAS 123R, companies must choose among alternative valuation models and amortization assumptions. After assessing alternative valuation models and amortization assumptions, we continue to use the Black-Scholes option valuation model, or Black-Scholes, and use the single-option award approach and straight-line attribution method for stock options granted since January 1, 2006. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

Prior to adoption of SFAS 123R, we calculated the value of options granted to employees and directors for disclosure in the footnotes to our financial statements pursuant to Statement of Financial Accounting Standards No. 123, or SFAS 123, using Black-Scholes, the multiple-option award approach and the accelerated attribution method. This approach uses a graded vesting method over the vesting period of each respective stock option, generally four years. The accelerated attribution method results in recognizing as compensation cost more than 50% of the fair value of an option in year one, with the remainder recognized in decreasing amounts from year two to year four. Under the modified-prospective transition method of SFAS 123R, we will continue to calculate compensation cost for options granted prior to January 1, 2006 using the multiple-option award approach and accelerated attribution method.

We estimate forfeitures when recognizing expense under SFAS 123R and adjust this estimate periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption.

As a result of adopting SFAS 123R, our research and development expenses included non-cash stock-based compensation expenses of $1.0 million and $2.8 million and our general and administrative expenses included non-cash stock-based compensation expenses of $0.7 million and $2.0 million for the three and nine months ended September 30, 2006, respectively. These operating expenses decreased our pre- and post-tax net income by $1.7 million and $4.8 million, and our earnings per share by $0.04 and $0.11 per share, basic and diluted, for the three and nine months ended September 30, 2006, respectively.

Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of September 30, 2006 of $9.8 million through the quarter ending September 30, 2010.

We did not retroactively apply SFAS 123R to periods prior to January 1, 2006. If we had recorded compensation expense for our stock-based plans in a manner consistent with the fair value approach of SFAS 123, our net loss and net loss per share for the three and nine months ended September 30, 2005 would have been as follows (in thousands, except per share data):

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss, as reported	$ (8,767)	$ (27,537)
Deduct: Total stock based employee compensation expense determined under the fair value based method for all awards	(2,201)	(5,646)
Adjusted net loss	$ (10,968)	$ (33,183)
Net loss per common share basic and diluted, as reported	$ (0.20)	$ (0.63)
Adjusted net loss per common share basic and diluted	$ (0.25)	$ (0.76)

1998 Stock Plan

Under the 1998 Stock Plan, our employees, directors and consultants may be granted options that allow for the purchase of shares of our common stock. Incentive stock options may only be granted to employees. Through September 30, 2006 a total of 12,600,000 shares of common stock were authorized for issuance under the 1998 Stock Plan. The 1998 Stock Plan allows for annual increases in the number of common shares authorized for issuance equal to the lesser of (i) 2,000,000 shares, (ii) 5% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by our Board of Directors.

Our Board of Directors or a designated Committee of the Board is responsible for administration of the 1998 Stock Plan and determines the terms and conditions of each option granted, consistent with the terms of the plan. Incentive stock options may be granted under the 1998 Stock Plan at a price not less than 100% of the fair market value of the stock on the date of grant (not less than 110% of the fair market value on the date of grant in the case of holders of more than 10% of our voting

stock). Options granted under the 1998 Stock Plan generally expire ten years from the date of grant (five years for incentive stock options granted to holders of more than 10% of our voting stock). Forfeited options become available for reissuance under the 1998 Stock Plan.

The 1998 Stock Plan also provides for the automatic grant of options to purchase shares of common stock to outside directors. On the date of each annual stockholders' meeting, each outside director is automatically granted an option to purchase 25,000 shares of common stock. The term of the option is ten years, the exercise price is 100% of the fair market value of the stock on the date of grant, and the option becomes exercisable as to 25% of the shares on the anniversary of its date of grant provided the optionee continues to serve as a director on such dates.

The following summarizes stock option activity for the nine months ended September 30, 2006 and 2005:

	Nine months ended September 30,			
	2006		2005	
	Number of options	Weighted-average exercise price	Number of options	Weighted-average exercise price
Options outstanding, beginning of period	6,993,492	$ 6.74	5,334,734	$ 6.94
Granted	1,226,000	$ 8.28	1,635,900	$ 5.52
Exercised	(227,947)	$ 4.10	(98,136)	$ 0.61
Forfeited	(23,460)	$ 6.21	(73,406)	$ 7.90
Options outstanding, end of period	7,968,085	$ 7.05	6,799,092	$ 7.96

Shares reserved for issuance and available for grant under the 1998 Stock Plan were 1,994,772 as of September 30, 2006.

The following summarizes information about stock options outstanding at September 30, 2006:

	Options outstanding			Options exercisable	
Range of exercise prices	Number of options	Weighted average remaining contractual life (years)	Weighted average exercise price	Number of vested options	Weighted average exercise price
$ 0.10 - $5.25	1,531,065	7.65	$ 4.42	771,154	$ 3.68
5.34 - 6.82	1,360,713	6.82	6.38	935,103	6.51
6.85 - 7.16	1,654,000	6.41	7.01	1,397,845	7.00
7.17 - 7.78	1,460,883	7.82	7.63	722,908	7.65
8.00 - 8.49	1,384,424	9.02	8.31	268,172	8.24
8.51 - 18.63	577,000	4.77	11.27	571,333	11.30
$ 0.10 - $18.63	7,968,085	7.31	$ 7.05	4,666,515	$ 7.05

We have 7,740,337 options expected to vest at September 30, 2006, with a weighted average exercise price of $7.05 per share.

Determining the Fair Value of Options

We use Black-Scholes to estimate the fair value of options granted. Black-Scholes considers a number of factors, including the market price and volatility of our common stock. We used the following forward-looking range of assumptions to value each stock option granted to employees during the nine months ended September 30, 2006 and 2005:

	2006	2005
Factors:		
Volatility	69% to 74%	78% to 86%
Risk-free interest rates	5%	4%
Expected life of option	5 years	5 years
Forfeiture rate	5%	—
Dividend yield	—	—

Our volatility assumption is based on reviews of the historical volatility of our common stock. Our risk-free interest rate assumption is based on yields of US treasury notes in effect at the date of grant. Our expected life of options granted assumption is based on actual historical option exercises. Our forfeiture rate assumption is based on historical cancellations of options. Our dividend yield assumption is based on the fact that we have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees was $4.90 and $4.89 per share in the three months ended September 30, 2006 and 2005, respectively and $5.17 and $4.31 per share in the nine months ended September 30, 2006 and 2005, respectively.

We estimate the fair value of stock options granted to non-employees and for our Employee Stock Purchase Plan using forward-looking assumptions similar to those used for stock options granted to employees and appropriate for the terms underlying the stock options granted to non-employees and the offerings under the Employee Stock Purchase Plan. We re-measure the compensation expense for options granted to non-employees over the related vesting period. The expense related to stock options granted to non-employees was approximately $0.2 million for the nine months ended September 30, 2006 and 2005. The expense related to the Employee Stock Purchase Plan was immaterial during the period ended September 30, 2006 and 2005.

Note 5. Income Taxes

In 2005, King made an upfront cash payment of $150 million to us in connection with our strategic alliance. We expect to have taxable income for 2006 primarily due to the recognition in 2006 of $146.3 million of the upfront cash payment for income tax purposes. We expect to fully offset that taxable income for 2006 with deductions related to a combination of our net operating losses and tax credits from prior years. However, under current tax laws, the use of such deductions will result in an alternative minimum tax. We estimate the alternative minimum tax for the calendar year 2006 to be approximately $3.7 million. We recognized $3.6 million of tax expense related to this alternative minimum tax for the nine months ended September 30, 2006.

Realization of the $3.7 million deferred tax asset that results from the recognition of tax expense from alternative minimum taxes is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. We have concluded that it was more likely than not that such deferred tax asset would not be realized. Accordingly, we fully offset the deferred tax asset with a valuation allowance.

In addition, we have not recorded any deferred tax assets related to the compensation costs that result from the adoption of SFAS 123R because the utilization of such assets or liabilities is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. We have concluded that it was more likely than not that such deferred tax assets would not be realized. Accordingly, we fully offset the deferred tax asset with a valuation allowance as of September 30, 2006.

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

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

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

- increases in collaboration revenue to be received from King Pharmaceuticals, Inc., or King, and other payments we may receive from our strategic alliances;
- the duration of the development period for all four expected drug candidates under our collaboration with King;
- the anticipated number of patients to be enrolled in clinical trials;
- potential sources of clinical and commercial supply of Remoxy and its components;
- expansion of our product line, including the formulation of additional dosage forms of Remoxy;
- increases in our collaboration fee revenue;
- future operating losses and anticipated operating and capital expenditures;
- uses of proceeds from our securities offerings;
- the potential benefits of our drug candidates;
- 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;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- assumptions and estimates used for our disclosures regarding stock-based compensation in connection with Statement No. 123 (revised 2004), Share-based Payment, or SFAS 123R; and
- estimates concerning the provision for taxes and realization of deferred tax assets for calendar year 2006.

Such forward-looking statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to:

- the successful development of drug candidates pursuant to our collaboration agreements, including our collaboration agreement with King, and the continuation of such agreements;
- 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, which are sometimes referred to as narcotic painkillers. According to IMS Health, sales for opioid painkillers in the United States exceeded $6.0 billion in 2004. We incorporated in Delaware in May 1998.

We are currently developing proprietary drug candidates to treat patients who suffer from severe chronic pain, such as pain associated with advanced osteoarthritis and low-back pain.

We have two novel drug candidates that are currently in Phase III clinical programs:

- Remoxy™, an abuse-resistant version of long-acting oxycodone, and
- Oxytrex™, a new oral opioid painkiller for the treatment of severe chronic pain.

We and King are engaged in a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150 million to us at the closing of this strategic alliance in December 2005.

In February 2006, we and King announced the completion of a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, in connection with the clinical development of Remoxy. We are conducting a pivotal Phase III clinical trial with Remoxy in approximately 400 patients with severe chronic pain, pursuant to the SPA.

In July 2006, we and King announced pursuant to our strategic alliance the initiation of a Phase I clinical trial program of second abuse resistant drug candidate, called PTI-202. In connection with the acceptance by the FDA of the investigational new drug application, or IND, for PTI-202, King made a milestone payment to us of $5 million. In connection with this milestone, we made a milestone payment of an undisclosed amount to Durect Corporation, pursuant to our agreement with Durect. King is obligated to reimburse us for costs, including milestones, we incur under our agreement with Durect, pursuant to our collaboration with King.

We could also receive from King up to an additional $145 million in additional milestone payments in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us related to Remoxy and other abuse-resistant opioid painkillers pursuant to the collaboration agreement. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1 billion in net sales of such drugs, for which the royalty is set at 15%.

We have not been profitable for a full fiscal year and we have yet to generate any revenues from product sales. Through September 30, 2006, we recorded an accumulated deficit of approximately $130.8 million. These cumulative 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 studies 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 continue to use significant cash resources in our operations 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 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.

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 plan to generate revenue from direct sales of our drugs other than the drug candidates developed pursuant to our collaboration with King, for which we will receive royalties, and, if we license our drugs to future collaborators, from the receipt of license fees and royalties from sales of such other 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.

We focus all of our research and development efforts on the research and development of opioid drugs for the treatment of pain. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Compensation	$ 2,391	$ 1,176	$ 7,074	$ 3,368
Contractor Fees[1]	6,939	5,159	21,791	18,496
Supplies[2]	484	1,228	3,035	2,337
Other Common Costs[3]	657	581	1,613	1,582
	$ 10,471	$ 8,144	$33,513	$25,783

(1) Contractor Fees generally include expenses for preclinical studies and clinical trials.
(2) Supplies generally include costs for formulation and manufacturing activities.
(3) Other Common Costs 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. For example, we expect that results of non-clinical studies, such as pharmacokinetics,

toxicology and other studies, regarding certain components of our drug candidate Remoxy to be applicable to the other potential drug candidates that may arise out of our collaboration with King since all such potential drug candidates are expected to utilize such components. 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.

Adoption of SFAS 123R

We adopted SFAS 123R on January 1, 2006 using the modified-prospective transition method. Under this transition method, we record compensation cost for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation cost recognized in the three and nine months ended September 30, 2006 includes compensation cost for all stock-based awards.

As a result of adopting SFAS 123R, our research and development expenses included non-cash stock-based compensation expenses of $1.0 million and $2.8 million and general and administrative expenses included non-cash stock-based compensation expenses of $0.7 million and $2.0 million for the three and nine months ended September 30, 2006, respectively. These operating expenses decreased our pre- and post-tax net income by $1.7 million and $4.8 million, and our earnings per share by $0.04 and $0.11 per share, basic and diluted, for the three and nine months ended September 30, 2006, respectively.

Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of September 30, 2006 of $9.8 million through the quarter ending September 30, 2010.

We did not retroactively apply SFAS 123R to periods prior to January 1, 2006. If we had recorded compensation expense for our stock-based plans in a manner consistent with the fair value based method of SFAS 123, our net loss for the three and nine months ended September 30, 2005 would have been increased to include approximately $2.2 million and $5.6 million, respectively, of stock-based compensation expense and net loss per share basic and diluted would have increased from $0.20 to $0.25 per common share and from $0.63 to $0.76 per common share for the three and nine months ended September 30, 2005, respectively.

Critical Accounting Policies

The preparation of our financial statements in accordance with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and interest income in our financial statements and accompanying notes. We evaluate our estimates on an ongoing basis, including those estimates related to contractual arrangements, research collaborations and investments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our financial statements require significant estimates and judgments:

- *Expenses for clinical trials.* Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes enrollment. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.
- *Stock-based compensation.* In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. This statement requires companies to recognize expense in the income statement for the fair value all share-based payments to employees and directors, including grants of employee stock options. SFAS 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and its interpretations, and amends FASB Statement No. 95, *Statement of Cash Flows*.

  We adopted SFAS 123R on January 1, 2006 using the modified-prospective transition method. Under this transition method, we record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. Accordingly, stock-based compensation expense recognized in the three and nine months ended September 30, 2006 includes compensation cost for all outstanding stock-based awards. We did not restate results for prior periods. Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and directors in accordance with APB 25 and its interpretations. Accordingly, we did not recognize compensation cost in our financial statements prior to January 1, 2006 for these awards because stock options granted to employees and directors had exercise prices equal to the fair value at the time the stock option was granted.

  In adopting SFAS 123R, companies must choose among alternative valuation models and amortization assumptions. After assessing alternative valuation models and amortization assumptions, as of January 1, 2006, we continue to use the Black-Scholes option valuation

model, or Black-Scholes, and use the single-option award approach and straight-line attribution method for stock options granted since January 1, 2006. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

Prior to adoption of SFAS 123R, we calculated the value of options granted to employees and directors for disclosure in the footnotes to our financial statements pursuant to Statement of Financial Accounting Standards No. 123, or SFAS 123, using Black-Scholes, the multiple-option award approach and the accelerated attribution method. This approach uses a graded vesting method over the vesting period of each respective stock option, generally four years. The graded vesting method results in recognizing as compensation cost more than 50% of the fair value of an option in year one, with the remainder recognized in decreasing amounts from year two to year four. Under the modified-prospective transition method of SFAS 123R, we will continue to calculate compensation cost for options granted prior to January 1, 2006 using the multiple-option award approach and accelerated attribution method.

We estimate forfeitures when recognizing expense under SFAS 123R and adjust this estimate periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption.

- *Revenue recognition*. In connection with our strategic alliance with King, we recognize program fee revenue and collaboration revenue. Program fee revenue is derived from the upfront payment from King and is recognized ratably over our estimate of the development period under the strategic alliance with King. If we revise our estimate of this development period, there would be a corresponding impact on the amount of program fee revenue recognized in the period in which we revised our estimate and thereafter. Collaboration revenues from reimbursement of development expenses are recognized as costs are incurred that relate to the strategic alliance with King. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone.
- *Income Taxes*. We make estimates and judgments in determining income tax expense. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of deferred tax assets is dependent upon future earnings, if any. We are uncertain of the timing and amount of any future earnings. Accordingly, we fully offset the total deferred tax assets by a valuation allowance. We may in the future determine that some, or all, of our deferred tax assets will likely be realized, in which case we will reduce our valuation allowance in the quarter in which such determination is made. If the valuation allowance is reduced, we may recognize a benefit from income taxes in our statement of operations in that period.

Results of Operations

Three and Nine Months Ended September 30, 2006 and 2005

Revenue – Program fee revenue

King paid us a $150.0 million upfront fee in connection with the closing of our strategic alliance with King in December 2005. Revenues recognized from amortization of this upfront fee were $6.6 and $19.7 million in the three and nine months ended September 30, 2006. We expect to recognize the remainder of the program fee ratably over our estimate of the development period under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through July 2011. We did not have any corresponding program fee revenue in the first three quarters of 2005.

Revenue - Collaboration revenue

Collaboration revenues were $7.0 million and $22.9 million in the three and nine months ended September 30, 2006, related to reimbursement of our development expenses incurred pursuant to the King strategic alliance. We did not have any corresponding collaboration revenue in the comparable periods of 2005.

We expect collaboration revenues to increase significantly in 2006 and beyond in connection with future increases in our research and development activities for Remoxy and other abuse-resistant drug candidates and reimbursement of these expenses pursuant to the collaboration agreement with King. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses.

Revenue - Milestone Payment

Milestone revenue was $5.0 million for the three and nine months ended September 30, 2006. King made a $5.0 million milestone payment to us following acceptance by the FDA of the IND for for PTI-202.

Research and Development

Research and development expenses consist 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.

Research and development expenses increased to $10.5 million from $8.1 million in the three months ended September 30, 2006 and 2005, respectively, and to $33.5 million from $25.8 million in the nine months ended September 30, 2006 and 2005. The increases were primarily due to increases in clinical and development activities for Remoxy and PTI-202 and non-cash stock-related compensation costs associated with the adoption of SFAS 123R.

We expect research and development expenses to increase over the next several years as we expand our development efforts. We expect our development efforts to result in our drug candidates progressing through various stages of clinical trials, including our Phase III clinical trial of Remoxy and current and potential clinical trials for our other abuse resistant drug candidates, as well as further clinical development of Oxytrex. King is obligated to reimburse development expenses for Remoxy and other abuse resistant drug candidates pursuant to our collaboration with King. Also, we expect to continue other development efforts on our drug 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 expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses increased to $1.7 million from $1.1 million in the three months ended September 30, 2006 and 2005, respectively, and to $5.7 million from $3.3 million in the nine months ended September 30, 2006 and 2005, respectively. The increases were primarily due to increases in non-cash stock-related compensation costs associated with the adoption of SFAS 123R. We expect general and administrative expenses to increase over the next several years in connection with precommercialization and commercialization activities for our drug 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 studies.

Interest and other income

Interest income increased to $2.6 million from $0.5 million in the three months ended September 30, 2006 and 2005, respectively, and to $7.1 million from $1.5 million for the nine months ended September 30, 2006 and 2005, respectively, primarily due to increases in average balances of marketable securities and, to a lesser extent, increases in prevailing interest rates on investments in marketable securities. We expect our interest income to decrease during the remainder of 2006 as we use cash to fund our operations.

Provision for Income Taxes

In 2005, King made an upfront cash payment of $150 million to us in connection with our strategic alliance. We expect to have taxable income for 2006 primarily due to the recognition in 2006 of $146.3 million of the upfront cash payment. We expect to fully offset that taxable income for 2006 for tax purposes with deductions related to a combination of our net operating losses and tax credits

from prior years. However, under current tax laws, the use of such deductions will result in alternative minimum taxes. We currently estimate the alternative minimum taxes for the calendar year 2006 to be approximately $3.7 million. We recognized $3.6 million of tax expense related to this alternative minimum tax for the nine months ended September 30, 2006.

Realization of the $3.7 million deferred tax asset that results from the recognition of tax expense from alternative minimum taxes is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. We have concluded that it was more likely than not that such deferred tax assets would not be realized. Accordingly, we fully offset the deferred tax asset with a valuation allowance.

In addition, we have not recorded any deferred tax assets related to the compensation costs that result from the adoption of SFAS 123R because the utilization of such assets or liabilities is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. We have concluded that it was more likely than not that such deferred tax assets would not be realized. Accordingly, all of our deferred tax assets have been fully offset by a valuation allowance at September 30, 2006.

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 and cash payments under our collaboration with King to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of September 30, 2006, cash, cash equivalents and marketable securities were $213.9 million.

Net cash used in operating activities was $1.6 million for the nine months ended September 30, 2006. Cash used in operating activities related primarily to the cash for operations.

Our investing activities to purchase property and equipment were immaterial for the nine months ended September 30, 2006. Other investing activities for the nine months ended September 30, 2006 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 $1.1 million during the nine months ended September 30, 2006, primarily from the exercise of stock options issued under our 1998 Stock Plan.

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 as of December 31, 2005 (in thousands):

	2006	2007	2008	2009	2010	Total
Future minimum lease payments	$ 191	$ 187	$ 196	$ 206	$ 160	$ 940

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of September 30, 2006. Our formulation agreement with Durect obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. King is obligated to reimburse us for costs, including milestones, we incur under our agreement with Durect, pursuant to our collaboration with King.

We have an accumulated deficit of approximately $130.8 million as of September 30, 2006. While our cash requirements to fund our operations were lower in the nine months of 2006 than the nine months of 2005 due to the obligation of King under the strategic alliance to reimburse us for certain expenses, we expect our cash requirements to be significant 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, however, seek additional future funding through public or private financing within this timeframe, if such funding is available on terms acceptable to us.

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

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 reduces the fair value of our available-for-sale securities at September 30, 2006 by approximately $0.9 million. 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 instruments. As of September 30, 2006, 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 and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

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 1A. *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 in our common stock.

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. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking preclinical studies and clinical trials of our drug candidates and forming collaborations. 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 full year since our inception. As a result of these operating losses, we had an accumulated deficit of $130.8 million as of September 30, 2006. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. 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;
- 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 our public and private stock offerings. We expect that our current cash, cash equivalents and marketable securities 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 debt financing, if available, such financings may involve covenants that restrict our business activities. If we raise additional capital through strategic alliance and license arrangements such as our strategic alliance with King, 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 an additional strategic partner earlier than currently intended, reduce sales and marketing efforts or forego attractive business opportunities.

Clinical and Regulatory Risks

If we are unable to design, conduct and complete clinical trials successfully, we will not be able to 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 preclinical studies 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 preclinical studies. 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 our Phase III clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before we can submit a NDA or obtain FDA approval for any of our drug candidates.

In February 2006, we completed an SPA with the FDA for a pivotal Phase III clinical trial with Remoxy in approximately 400 patients with severe chronic pain. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an efficacy claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness. Under our SPA, if the outcome of our Phase III clinical trial is successful, we expect to use the data from the Phase III clinical trial as part of the basis of approval with respect to efficacy. While we received the SPA for this Phase III clinical trial assessing Remoxy, there can be no assurance that this clinical trial will have a successful outcome or that we will ultimately receive approval for this drug candidate. Furthermore, there can be no assurance that other events will not occur that would allow the FDA to disregard our SPA.

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 consumes a significant amount of time. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical 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 clinical trials, and we could encounter problems that cause us to abandon or 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.

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 studies. 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 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 would:

- 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 clinical trials, 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.

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 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 clinical 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 drug quotas 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 could limit the use of 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. Even if our agreements with any current or 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. 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 but not limited to adverse events of unanticipated severity or frequency, or the discovery that adverse events previously observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, 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 our Collaboration Agreements

If King or other 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.

Pursuant to our strategic alliance with King, we will jointly manage and prepare Phase III clinical trials and NDA submissions in the United States for Remoxy and other abuse resistant drug candidates with King. We rely on King to devote time and resources to the development and commercialization of Remoxy and other abuse resistant drug candidates. If King limits its time and resources devoted to the strategic alliance, or otherwise fails to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected.

We depend on independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. These investigators and collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such activities ourselves. If these investigators or 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 or prevented.

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, if any are commercialized, will be less than expected.

If we fail to maintain our strategic alliance for Remoxy and other abuse resistant drugs, we may have to reduce or delay our drug candidate development.

Our plan for developing, manufacturing and commercializing Remoxy and other abuse resistant drugs currently requires us to successfully maintain our strategic alliance with King to advance our programs and provide funding to support our expenditures on Remoxy and other drug candidates. If we are not able to maintain our existing strategic alliance with King, we may have to limit the size or scope of, or delay or abandon the development of Remoxy and other abuse resistant drug candidates or undertake and fund development of these drug candidates ourselves. If we elect to fund drug development efforts with respect to Remoxy and other abuse resistant drug candidates on our own, we may need to obtain additional capital, which may not be available on acceptable terms, or at all.

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 is 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, disputes concerning the scope of collaboration activities 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 as our strategic alliance with King. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations or disputes concerning the scope of collaboration activities. Such disputes can delay or prevent 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 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.

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our 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 King is not successful in commercializing Remoxy and other abuse resistant drugs, our revenues and our business will suffer.

Our ability to commercialize Remoxy and other abuse resistant drugs and generate royalties from product sales of such drugs will depend on King's abilities in assisting us in developing such drugs and in maintaining regulatory approval and achieving market acceptance of such drugs once commercialized. King may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of Remoxy and other abuse resistant drugs developed under our strategic alliance. King may not proceed with the commercialization of Remoxy and other abuse resistant drugs developed under our strategic alliance with the same degree of urgency as we would because of other priorities they face. If King is not successful in commercializing Remoxy for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if King fails to perform as we expect, our potential for revenue from drugs developed in connection with our strategic alliance with King, if any, could be dramatically reduced and our business would suffer.

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. Except with regard to products developed under our strategic alliance with King, 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 new 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 new 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 not covered by our strategic alliance with King to a single collaborator, thereby eliminating our opportunity to commercialize these other pain management products independently. If we enter into any such new 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, 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 drug 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 or our collaborators fail to file, prosecute, obtain 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.

We and our collaborators have filed patent applications with the U.S. Patent Office to further protect our technologies. Certain patents are issued and a number of patent applications are pending. If issued, we believe these applications would protect our technologies through at least 2020. If these patent applications do not result in issued patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

We may be involved in challenges to our intellectual property. An adverse outcome of a challenge to our intellectual property could result in loss of claims of patents or other intellectual property rights 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 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 patents, 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 is 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 products 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 and commercialization for our drug candidates very difficult.

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 and commercialization of 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 drug 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 and other abuse resistant drug candidates, we and King 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 and other abuse resistant drug candidates. We may not be able to successfully complete our formulation or scale-up

activities or we may determine that the commercial opportunity for Remoxy and other abuse resistant drug candidates in certain dosage forms is too limited to warrant further investment. If we are unsuccessful in our formulation or scale-up activities with Remoxy and other abuse resistant drug candidates, our future revenue from milestones and royalties under our strategic alliance with King may be less than expected and our operations may suffer.

We rely solely on Durect to provide us with certain components of Remoxy and other abuse resistant drug candidates, to produce Remoxy and other abuse resistant drug candidates for clinical supplies and will rely on Durect to produce commercial supplies of these components.

We rely on Durect as our sole source provider of certain components of Remoxy and other abuse resistant drug candidates, and will rely solely on Durect to produce commercial supplies of these components. Durect's failure to achieve and maintain satisfactory manufacturing standards could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially harm our business. Durect may encounter manufacturing difficulties involving production yields, quality control and quality assurance. Durect is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with government regulations and corresponding foreign standards. We cannot control Durect's compliance with these regulations and standards.

To date, Durect has not produced commercial-scale supply of these components. If we and King receive marketing approval for and commercially launch Remoxy or other abuse resistant candidates, we anticipate that Durect will need to materially expand its manufacturing capacity. Durect may not be able to increase its manufacturing capacity for Remoxy and other abuse resistant drug candidates in a timely or economic manner, or at all. Moreover, significant scale up of manufacturing may require additional validation studies, which is subject to FDA review and approval. If Durect is unable to successfully increase the manufacturing capacity for such components of Remoxy and other abuse resistant drugs, at an acceptable cost or otherwise, and we are unable to establish alternative manufacturing capabilities, the commercial launch or continued commercialization after a commercial launch of Remoxy and other abuse resistant drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our revenues and cause our business to suffer.

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 or delays in our preclinical studies and clinical trials;
- the success of our collaboration agreements;

- 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 Global 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.

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 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 valuation of stock-based 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 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 (1)	Amended and Restated Bylaws.
4.1 (2)	Specimen Common Stock Certificate.
4.2 (3)	Preferred Stock Rights Agreement, dated as of April 28, 2005 between Registrant and Mellon Investor Services LLC, including the Certificate of Designation, the form of Rights Certificate and Summary of Rights attached thereto as Exhibits A, B and C, respectively.
4.3 (4)	Amendment to Preferred Stock Rights Agreement, dated as of September 27, 2006, between Registrant and Mellon Investor Services LLC.
10.1 (4)	Agreement, dated as of September 27, 2006, by and among the Registrant, Eastbourne Capital Management, L.L.C. and certain of its affiliates.
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.

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(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending June 30, 2005.
(2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending March 31, 2005.
(3) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
(4) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on September 27, 2006.

SIGNATURES

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

Pain Therapeutics, Inc.
(Registrant)

/s/ REMI BARBIER
Remi Barbier,
Chairman of the Board of Directors,
President and Chief Executive Officer

/s/ PETER S. RODDY
Peter S. Roddy,
Vice President and Chief Financial Officer

Date: November 3, 2006

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EXHIBIT INDEX

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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 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 3, 2006

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 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 3, 2006

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 Periodic Report on Form 10-Q for the period ended September 30, 2006, 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 3, 2006

/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