PAIN THERAPEUTICS INC
Form 10-Q
May 07, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended March 31, 2008

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)***

2211 Bridgepointe Parkway

Suite 500

San Mateo, CA 94404

(650) 624-8200

(Address, including zip code, of 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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a small reporting company. See definitions of large accelerated filer, accelerated filer and small reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x

Non-accelerated filer ¨ Smaller reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2). Yes ¨ No x

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	**41,861,477** Shares Outstanding at April 16, 2008

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PAIN THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

PAIN THERAPEUTICS, INC.

Condensed Balance Sheets

(Unaudited)

(in thousands)

	March 31, 2008	December 31, 2007[1]
ASSETS		
Current assets		
Cash and cash equivalents	$ 130,807	$ 86,567
Marketable securities	59,245	118,504
Other current assets	311	303
Total current assets	190,363	205,374
Property and equipment, net	1,490	1,607
Other assets	644	644
Total assets	$ 192,497	$ 207,625
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 2,962	$ 3,624
Accrued development expense	973	817
Deferred program fee revenue - current portion	14,348	14,348
Other accrued liabilities	2,423	1,868
Total current liabilities	20,706	20,657
Non-current liabilities		
Deferred program fee revenue - non-current portion	78,915	82,501
Other liabilities	553	553
Total liabilities	100,174	103,711
Commitments and contingencies		
Stockholders equity		
Preferred stock		
Common stock	42	44
Additional paid-in-capital	214,238	221,415
Accumulated other comprehensive income	905	584
Accumulated deficit	(122,862)	(118,129)
Total stockholders equity	92,323	103,914
Total liabilities and stockholders equity	$ 192,497	$ 207,625

(1) Derived from the Company s audited financial statements as of December 31, 2007, 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.

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PAIN THERAPEUTICS, INC.

Condensed Statements of Operations

(Unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,	
	2008	2007
Revenue		
Collaboration revenue	$ 11,052	$ 15,504
Program fee revenue	3,587	6,550
Total revenue	14,639	22,054
Operating expenses		
Research and development	12,484	9,860
General and administrative	1,819	1,838
Total operating expenses	14,303	11,698
Operating income	336	10,356
Interest income	2,234	2,280
Net income	$ 2,570	$ 12,636
Net income per share		
Basic	$ 0.06	$ 0.28
Diluted	$ 0.06	$ 0.28
Weighted-average shares used in computing net income per share		
Basic	43,848	44,341
Diluted	45,388	45,591

See accompanying notes to condensed financial statements.

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PAIN THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(Unaudited)

(in thousands)

	Three Months Ended March 31, 2008	2007
Cash flows provided by operating activities:		
Net income	$ 2,570	$ 12,636
Adjustments to reconcile net income to net cash provided by operating activities:		
Non-cash stock based compensation	1,526	1,218
Depreciation and amortization	117	92
Non-cash net interest income	942	950
Changes in operating assets and liabilities:		
Deferred program fee revenue	(3,586)	(6,550)
Other current assets	(8)	38
Accounts payable	(662)	(145)
Accrued development expense	156	(1,715)
Collaboration revenue receivable		2,382
Income taxes payable		(2,712)
Other accrued liabilities	555	593
Net cash provided by operating activities	1,610	6,787
Cash flows provided by investing activities:		
Purchase of property and equipment		(48)
Purchase of marketable securities		(42,730)
Sales of marketable securities	37,766	79,625
Maturities of marketable securities	20,872	2,500
Net cash provided by investing activities	58,638	39,347
Cash flows used in financing activities:		
Proceeds from issuance of common stock, net	765	143
Purchase of stock pursuant to the stock repurchase plan	(16,773)	(847)
Net cash used in financing activities	(16,008)	(704)
Net increase in cash and cash equivalents	44,240	45,430
Cash and cash equivalents at beginning of period	86,567	16,386
Cash and cash equivalents at end of period	$ 130,807	$ 61,816
Supplemental cash flow information:		
Cash paid for income taxes	$	$ 2,800

See accompanying notes to condensed financial statements.

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PAIN THERAPEUTICS, INC.

Notes to Condensed Financial Statements

(Unaudited)

Note 1. General

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. We have four drug candidates in clinical programs, including Remoxy, Oxytrex, PTI-202 and a novel radio-labeled monoclonal antibody to treat metastatic melanoma. We are also working on a new treatment for patients with hemophilia.

Although we were profitable in 2006, 2007 and the three months ended March 31, 2008 based on payments from King Pharmaceuticals, Inc., or King, and interest income, in the course of our development activities, we have sustained cumulative operating losses. There are no assurances that additional financing will be available on favorable terms, or at all.

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 month periods ended March 31, 2008 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2008.

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

Marketable Securities - Fair Value Measurements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, Fair Value Measurements . SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value and expands disclosure about such fair value measurements. We adopted SFAS 157 on January 1, 2008, as required. The adoption of SFAS 157 did not have an impact on our results of operations or financial position.

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We measure our cash equivalents and marketable securities at fair value on a recurring basis and have significant observable inputs where there are identical or comparable assets in the market to use in establishing our fair value measurements. We use significant observable inputs that include but are not limited to benchmark yields, reported trades, broker/dealer quotes, and issuer spreads. Generally, the types of instruments we invest in are not traded on a market such as the NASDAQ Global Market. We consider these inputs to be Level 2 within the fair value hierarchy defined by SFAS 157. We use the bid price to establish fair value.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115 . Under SFAS 159, an entity may elect to use fair value to measure eligible items. The Company adopted SFAS No. 159 on January 1. 2008, as required. The adoption of SFAS 159 did not have an impact on our results of operations or financial condition.

Net Income per Share

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

The numerators and denominators in the calculation of basic and diluted net income per share were as follows (in thousands):

	Three Months Ended March 31,	
	2008	2007
Numerator		
Net income	$ 2,570	$ 12,636
Denominator		
Weighted average shares used to compute basic net income per share	43,848	44,341
Effect of dilutive securities:		
Dilution from employee stock plans	1,407	1,118
Dilution from warrants	133	132
Potential dilutive common shares	1,540	1,250
Weighted average shares used to compute diluted net income per share	45,388	45,591
Net income per share:		
Basic	$ 0.06	$ 0.28
Diluted	$ 0.06	$ 0.28

Options to purchase 4.2 million and 2.8 million common shares were excluded from the denominator in the calculation of earnings per share for the three months ended March 31, 2008 and 2007, respectively, as the option exercise price was greater than the average market price per share and the effect would be anti-dilutive.

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Revenue Recognition and Deferred Program Fee Revenue

In connection with our strategic alliance with King we recognize program fee revenue, collaboration revenue and milestone 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 Phase I clinical trials 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 September 2014. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations.

Collaboration revenues from reimbursement of development expenses are generally recognized as costs are incurred pursuant to the strategic alliance with King; however, when we have knowledge that King has not completed its review of the collaboration expenses invoiced to them, we defer recognition of such amounts as revenue until their review is complete.

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.

Income Taxes

We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income or loss for each full fiscal year. 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, except for $0.5 million of deferred tax assets recognized on our balance sheet and included in other assets as of March 31, 2008, we fully offset the net deferred tax assets with a valuation allowance. The non-current tax liability of $0.6 million recorded at March 31, 2008 provides a source of future taxable income against which the non-current deferred tax asset of $0.5 million was recognized without offset by a valuation allowance. We may in the future determine that more 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. We classify interest and penalties recognized pursuant to FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes as interest expense.

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Note 3. Comprehensive Income

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

	Three Months Ended March 31,	
	2008	2007
Net income	$ 2,570	$ 12,636
Other comprehensive income	321	475
	$ 2,891	$ 13,111

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

Note 4. Stock-Based Compensation

We recognize expense in the statement of operations for the fair value of all share-based payments to employees and directors, including grants of employee stock options, pursuant to SFAS Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. We use the Black-Scholes option valuation model and use the single-option award approach and straight-line attribution method for stock options granted. Our non-cash equity related expense is as follows (in thousands):

	Three Months Ended March 31,	
	2008	2007
Research and development	$ 980	$ 684
General and administrative	546	534
	$ 1,526	$ 1,218

Note 5. Income Taxes

We have not provided for income taxes for the three months ended March 31, 2008 because we do not expect to have taxable income for the full year 2008. Our income in 2008 includes program fee revenue. For tax purposes, we recognized all of the related program fee revenue in 2006, which is the primary reason for our expectations of no taxable income for 2008. Interest expense and penalties related to unrecognized tax benefits were immaterial for the three months ended March 31, 2007 and 2008.

We are uncertain about the timing and amount of future earnings. We anticipate increasing our unrecognized tax benefits during 2008 related to net operating losses for tax purposes and certain tax credits. While the increase cannot be estimated at this time, such increase in unrecognized tax benefits would be entirely offset by a change in the valuation allowance and therefore would not have a material effect on our financial statements.

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Note 6. Stock Repurchase Program

We have approved a plan to repurchase up to $30.0 million of our common stock. As of March 31, 2008 we had repurchased 2.5 million shares of common stock on the open market at a cost of $20.6 million. The total number of shares to be repurchased and the timing of repurchases will be based on several factors, including the price of the common stock, general market conditions, corporate and regulatory requirements and alternate investment opportunities. We intend to hold repurchased shares in treasury. We issued 123,734 shares of common stock pursuant to the exercise of stock options during the three months ended March 31, 2008. This plan expires in March 2009 and may be discontinued at any time.

We use the par value method of accounting for our stock repurchases. The excess of the cost of the shares acquired over the par value is allocated to additional paid-in capital based on the weighted average sales price per issued share with the remainder charged to accumulated deficit. As a result, we decreased additional paid-in capital by $9.4 million and increased accumulated deficit by $7.3 million in the three month period ended March 31, 2008.

Note 7. Commitments

We lease general office space. Our leases expire in 2010 and 2012. Under the terms of these leases, remaining annual minimum lease payments are as follows as of December 31, 2007 (in thousands):

	2008	2009	2010	2011	2012	Total
Future minimum lease payments	$ 717	$ 743	$ 713	$ 570	$ 339	$ 3,082

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:

- collaboration, milestone and royalty 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;
- 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;

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expected amounts of, or fluctuations in, collaboration revenue and payments;

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 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 expenses and operating results;

future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;

anticipated hiring and development of our internal systems and infrastructure; and

the sufficiency of our current resources to fund our operations over the next twelve months.

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

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 results of clinical trials may not indicate that our drug candidates are safe and effective);

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 that develops novel drugs. We have the following investigational drug candidates in clinical programs:

Remoxy and PTI-202, which are proprietary, abuse-resistant forms of opioid drugs.

Oxytrex, which is a novel, next-generation painkiller that potentially offers less physical dependence than currently marketed opioid painkillers.

A novel radio-labeled monoclonal antibody drug candidate to treat metastatic melanoma, a rare but deadly form of skin cancer.

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Remoxy and Oxytrex are currently in Phase III clinical programs. PTI-202 and our drug candidate to treat metastatic melanoma are in Phase I clinical programs.

We and King are engaged in a strategic alliance to develop and commercialize Remoxy, PTI-202 and other abuse-resistant opioid painkillers. We could receive from King up to $145.0 million in additional milestone payments in the course of clinical development of Remoxy, PTI-202 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 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 $1.0 billion in net sales of such drugs, for which the royalty is set at 15%.

Although we were profitable in 2006, 2007 and the first three months of 2008 based on payments received from King and interest income, we have yet to generate any revenues from product sales. Through March 31, 2008, we have recorded an accumulated deficit of approximately $122.9 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical 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, directors 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 may 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, our collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

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The following table summarizes expenses by category for research and development efforts (in thousands):

	Three Months Ended March 31,	
	2008	2007
Compensation	$ 3,047	$ 2,457
Contractor Fees[1]	6,945	5,487
Supplies[2]	1,336	1,271
Other Common Costs[3]	1,156	645
	$ 12,484	$ 9,860

(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 certain of 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 may 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. We are also developing a novel antibody drug candidate to treat metastatic melanoma. Research and development expenses related to this technology include approximately $0.7 million and $0.4 million in the three months ended March 31, 2008 and 2007, respectively, primarily in contractor fees and compensation. Research and development expenses related to hemophilia and other product candidates include approximately $1.1 million and $0.1 million in the three months ended March 31, 2008 and 2007, respectively, primarily in contractor fees and compensation.

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.

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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 contracts, 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. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Information about patient enrollment can become available after we report our expenses for clinical trials, in which case we would change our estimate of the remaining cost of a trial. 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. We recognize expense in the statement of operations for the fair value of all share-based payments to employees and directors, including grants of employee stock options, pursuant to Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. We use the Black-Scholes option valuation model, and use the single-option award approach and straight-line 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 and deferred program fee revenue. In connection with our strategic alliance with King we recognize program fee revenue, collaboration revenue and milestone 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, PTI-202 is in the early-stages of clinical development 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 September 2014. Collaboration revenues from reimbursement of development expenses, which are invoiced in arrears, are recognized when costs are incurred pursuant to the strategic alliance with King, unless we know that King has not completed their review of our submitted invoices. Although we only invoice King for development expenses incurred by us that we believe qualify for reimbursement under our collaborative agreement, King may not ultimately agree with our determination of what constitutes a qualifying development expense. King is obligated to pay us milestone payments

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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.

Income Taxes. We have not provided for income taxes for the three months ended March 31, 2008 because we do not expect to have taxable income for the full year 2008. We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income or loss for each full fiscal year. 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, except for $0.5 million of deferred tax assets recognized on our balance sheet as of March 31, 2008, we fully offset the net deferred tax assets with a valuation allowance. The non-current tax liability of $0.6 million recorded at March 31, 2008 provides a source of future taxable income against which the non-current deferred tax asset of $0.5 million was recognized without offset by a valuation allowance. We may in the future determine that more 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 months ended March 31, 2008 and 2007

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 this upfront fee decreased to $3.6 million from $6.6 million for the three months ended March 31, 2008 and 2007, respectively. The decrease in program fee revenue is due to the extension in the fourth quarter of 2007 of the development period over which we recognize the program fee revenue. 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 September 2014.

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Revenue - Collaboration revenue

Collaboration revenues decreased to $11.1 million from $15.5 million in the three months ended March 31, 2008 and 2007, respectively. Collaboration revenues resulted from reimbursement of our development expenses incurred pursuant to the King strategic alliance. The decrease was primarily due to the receipt of $5.7 million in 2007 that was subject to completion of King s review at December 31, 2006. King reviewed and paid, and we recognized collaboration revenue for these expenses in 2007. We incurred expenses of approximately $2.2 million through March 31, 2008 for which we expect King to complete their review and reimburse us in the second calendar quarter of 2008.

We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development activities and the timing of completion of King s review of our expenses related to such collaboration.

Research and Development Expenses

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 $12.5 million from $9.9 million in the three months ended March 31, 2008 and 2007, respectively. This increase was primarily due to the timing of development activities for our abuse-resistant drug candidates. Research and development expenses included non-cash stock related compensation costs of $1.0 and $0.7 million in the three months ended March 31, 2008 and 2007, respectively.

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. King is obligated to reimburse development expenses for Remoxy and other abuse resistant drug candidates pursuant to our collaboration with King. We expect to continue development efforts on these and our other 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 Expenses

General and administrative expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses were $1.8 million for the three months ended March 31, 2008 and 2007. General and administrative expenses included non-cash stock related compensation costs of $0.5 million for the three months ended March 31, 2008 and 2007.

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We expect general and administrative expenses to increase over the next several years in connection with precommercialization and commercialization activities for our drug candidates. This 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 Income

Interest income decreased to $2.2 million from $2.3 million for the three months ended March 31, 2008 and 2007, respectively. The $0.1 million decrease in interest income is primarily due to lower prevailing interest rates as well as lower average cash balances in investments in marketable securities. We expect our interest income to decrease during the remainder of 2008 as we use cash to fund our operations and for our stock buyback plan.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private securities offerings. Additionally, in December 2005, we received a $150.0 million program fee under our strategic alliance with King and we earned interest income from investment of our cash resources. We intend to continue to use our cash resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes, including our stock buyback plan. As of March 31, 2008, cash, cash equivalents and marketable securities were $190.1 million.

Net cash provided by operating activities decreased to $1.6 million from $6.8 million for the three months ended March 31, 2008 and 2007, respectively. The decrease in net cash provided by operating activities was primarily due to reduced net income and the timing of payments received from King for reimbursement of expenses under our collaboration agreement with King.

Our investing activities to purchase property and equipment were immaterial for the three months ended March 31, 2008 and 2007. Cash provided by other investing activities of $58.6 million for the three months ended March 31, 2008 consisted of sales and maturities of marketable securities. Cash provided by other investing activities of $39.3 million for the three months ended March 31, 2007 consisted of net purchases, maturities and sales of marketable securities. We expect to continue to invest in our infrastructure to support our operations.

Net cash used in financing activities was $16.0 million and $0.7 million in the three months ended March 31, 2008 and 2007, respectively. We have approved a plan to repurchase up to $30.0 million of our common stock. As of March 31, 2008 we had repurchased 2.5 million shares of common stock on the open market at a cost of $20.6 million. The total number of shares to be repurchased and the timing of repurchases will be based on several factors, including the price of the common stock, general market conditions, corporate and regulatory requirements and alternate investment opportunities. We intend to hold repurchased shares in treasury. This stock buyback program expires in March 2009 and may be discontinued at any time.

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We lease approximately 41,200 square feet of general office space. Our leases expire in 2010 and 2012. Under the terms of these leases, remaining annual minimum lease payments are as follows as of December 31, 2007 (in thousands):

	2008	2009	2010	2011	2012	Total
Future minimum lease payments	$ 717	$ 743	$ 713	$ 570	$ 339	$ 3,082

We have license agreements that require us to make 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 March 31, 2008. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. Under the King collaboration, King is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

We have an accumulated deficit of $122.9 million. 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 seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

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Off-balance Sheet Arrangements

As of March 31, 2008, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

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 March 31, 2008 by approximately $0.2 million. To minimize this risk, we maintain our portfolio of cash, 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 March 31, 2008, our investments consisted of investments in corporate and government notes and obligations or in money market accounts and checking funds with variable, market rates of interest. We measure our cash equivalents and marketable securities at fair value on a recurring basis and have significant observable inputs where there are identical or comparable assets in the market to use in establishing our fair value measurements. We use significant observable inputs that include but are not limited to benchmark yields, reported trades, broker/dealer quotes, and issuer spreads. Generally, the types of instruments we invest in are not traded on a market such as the NASDAQ Global Market. We consider these data to be Level 2 within the fair value hierarchy defined by SFAS 157. We use the bid price to establish fair value.

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 the Securities and Exchange Commission, or SEC, rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

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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.

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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.

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 with substantive evidence that the drug candidate is both 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.

In December 2007, we and King announced positive results of a Phase III trial of Remoxy in patients with chronic pain. The study met the primary end point that was prospectively defined by the FDA during a special protocol assessment, or SPA, process. Under this process, 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, and because of the positive results of our Phase III trial of Remoxy, we expect to use the Remoxy Phase III data as part of a 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 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.

PTI-202 and our drug candidate to treat metastatic melanoma are in Phase I clinical programs. Results from our Phase I clinical programs may not support moving a drug candidate to Phase II or Phase III clinical trials. Oxytrex is in a Phase III clinical program. Our Phase III clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical studies and early

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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. 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 an NDA or obtain FDA approval for any of our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process 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.

Our clinical trials with Remoxy and Oxytrex measure clinical symptoms, such as pain and physical dependence. These symptoms are not biologically measurable. The success of Remoxy, Oxytrex and our other abuse resistant drug candidates in clinical trials depends on reaching statistically significant changes in patients symptoms based on clinician-rated scales. Due in part to a lack of consensus on standardized processes for assessing clinical outcomes, these scores may or may not be reliable, useful or acceptable to regulatory agencies.

We have no history of developing metastatic melanoma or hemophilia drug candidates. We do not know whether any of our planned clinical trials in metastatic melanoma or hemophilia will result in marketable drugs.

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;
- unanticipated patient drop out rates;
- 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 could significantly 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.

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If we fail to obtain the necessary regulatory approvals, or if such approval is limited, 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. 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 commercial 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. With the exception of our SPA with the FDA for our Phase III clinical trial with Remoxy, 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, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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

The U.S. Drug Enforcement Administration, or 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.

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 drug candidates. 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 drug candidates. 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.

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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, manufacturing and commercialization of Remoxy and other abuse-resistant drug candidates. King may develop or acquire drugs or drug candidates that compete for resources with our drug candidates that are subject to this strategic alliance. For instance, King has acquired a drug candidate for the acute pain market. While we believe this drug candidate will not compete with our drug candidates under the collaboration with King, there can be no assurance that this drug candidate will not be developed to become competitive with our drug candidates under the collaboration with King. 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.

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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 drug development requires us to enter into collaborative agreements with third parties, 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 or legal defense of our potential products.

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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;
- perceptions by physicians regarding the cost benefit of the abuse resistant quality of Remoxy;
- 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 opioid drugs, our revenues and our business will suffer.

Our ability to earn royalties from sales of Remoxy and other abuse-resistant drugs will depend on King s abilities to maintain regulatory approval and achieve 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 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.

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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 our drug candidates, 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 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 drugs already approved or drug candidates in development that will or may compete against our approved drug candidates. 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.

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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 drug candidates. 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.

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.

Risks Relating to our Intellectual Property

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing the intellectual property rights of third parties, such litigation will be costly and time consuming and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Intellectual property rights in the areas of controlled-release oxycodone, antibodies, and more generally, in oncology, neurology and radiopharmaceutical technologies are complicated and are continuously evolving. Holders of patent rights in these areas may allege that the commercialization of Remoxy or our other drug candidates infringes such patent rights. While we believe that we would have valid defenses to any claim of infringement, there can be no assurance that these or other third party patents will not limit our ability to commercialize Remoxy or our other drug candidates.

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In addition, because patent applications are published 18 months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management s attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor s patent or other proprietary rights;
- a court order prohibiting us from commercializing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market. Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

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 drug candidates.

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 and Trademark Office to further protect our technologies. 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.

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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.

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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.

We expanded our research and development activities to include development of potential drug candidates for indications other than pain, and we may not be able to successfully develop or commercialize these potential new drug candidates.

We have expanded our research and development activities to include development of potential drug candidates for indications other than pain, such as metastatic melanoma and hemophilia. We initiated a Phase I clinical trial of our drug candidate in metastatic melanoma in 2007. We have no history of developing metastatic melanoma or hemophilia drug candidates or manufacturing radiopharmaceuticals. We do not know whether any of our planned clinical trials in metastatic melanoma or hemophilia will result in marketable products. We do not anticipate that any additional drug candidates will reach the market for at least several years, if at all.

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.

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Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process and commercialization of 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 GMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

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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 and other abuse resistant drug candidates in certain dosage forms 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 and will continue to 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 will require additional validation studies, which are 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.

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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.

Our operations from our inception 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.

Although we were profitable in 2006, 2007 and the three months ended March 31, 2008 based on payments from King and interest income, we have yet to generate any revenues from product sales. We had an accumulated deficit of $122.9 million as of March 31, 2008. 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 studies and clinical trials for our drug candidates;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional personnel.

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

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

We have funded all of our operations and capital expenditures with the proceeds from our public and private stock offerings, payments received under our strategic alliance with King, and interest earned on our investments. 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 elect to raise additional funds within such twelve-month period or need to raise additional funds 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

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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.

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 efforts to seek regulatory approval for Remoxy, and in preclinical studies and clinical trials for our other drug candidates;
- 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 enacted by applicable governmental or other authorities;
- 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.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, SEC regulations and the rules of The NASDAQ Stock Market LLC create uncertainty for public companies. If we were unable to continue to comply with these requirements, we could be delisted from trading on the NASDAQ Global Market, or Nasdaq, and thereafter trading in our common stock, if any, may be conducted through the over-the-counter or other market. 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.

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We have approved a stock repurchase program under which we can purchase up to $30.0 million of our common stock on the open market. As of March 31, 2008, we have $9.4 million available under this repurchase program. We are not obliged to purchase any additional stock pursuant to the stock repurchase program. The existence of such a program may contribute to the volatility of the price of our common stock and could contribute to a sudden decline in value.

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

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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. 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. In addition, our recently initiated share repurchase program may have the effect of further concentrating the holdings of our officers, directors and principal 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 amounts of collaboration revenue recognized from King, 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.

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Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

Issuer Purchases of Equity Securities [(1)]

Period		Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plan	Approximate dollar value that may yet be purchased under the plan, in millions
Month 1	January 1 to January 31, 2008	100,000	$ 8.86	100,000	$ 15.3
Month 2	February 1 to February 29, 2008	472,660	$ 8.91	472,660	$ 11.1
Month 3	March 1, to March 31, 2008	1,417,900	$ 8.23	1,417,900	$ 9.4
Total		1,990,560	$ 8.43	1,990,560	$ 9.4

(1) We have approved a plan to repurchase up to $30.0 million of our common stock. The total number of shares to be purchased and the timing of purchases will be based on several factors, including the price of the common stock, general market conditions, corporate and regulatory requirements and alternate investment opportunities. We intend to hold repurchased shares in treasury. This plan expires in March 2009 and may be discontinued at any time.

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.

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31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from 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.

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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: May 7, 2008

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