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

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended June 30, 2013

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)

7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731
(512) 501-2444
(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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting Company	☐

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

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

Common Stock, $0.001 par value	45,437,801
	Shares Outstanding as of July 10, 2013

PAIN THERAPEUTICS, INC.

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

PAIN THERAPEUTICS, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands)

	June 30, 2013	December 31, 2012[(1)]
Current assets		
Cash and cash equivalents	$ 51,545	$ 49,355
Marketable securities	1,300	6,899
Other current assets	3	253
Total current assets	52,848	56,507
Other assets	352	352
Total assets	$ 53,200	$ 56,859
Current liabilities		
Accounts payable	$ 435	$ 361
Accrued development expense	572	929
Deferred program fee revenue—current portion	7,832	7,832
Accrued compensation and benefits	379	853
Other current liabilities	—	24
Total current liabilities	9,218	9,999
Non-current liabilities		
Deferred program fee revenue—non-current portion	29,370	33,287
Deferred tax liabilities	437	437
Total liabilities	39,025	43,723
Commitments and contingencies		
Stockholders' equity		
Preferred stock	—	—
Common stock	45	45
Additional paid-in-capital	150,489	148,738
Accumulated other comprehensive income	1	4
Accumulated deficit	(136,360)	(135,651)
Total stockholders' equity	14,175	13,136
Total liabilities and stockholders' equity	$ 53,200	$ 56,859

(1) Derived from the Company's audited financial statements as of December 31, 2012, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Three months ended June 30, 2013	Three months ended June 30, 2012	Six months ended June 30, 2013	Six months ended June 30, 2012
Revenue				
Program fee revenue	$ 1,959	$ 2,724	$ 3,917	$ 5,448
Collaboration revenue	—	—	—	249
Total revenue	1,959	2,724	3,917	5,697
Operating expenses				
Research and development	1,139	1,516	2,322	3,125
General and administrative	1,139	1,461	2,357	2,973
Total operating expenses	2,278	2,977	4,679	6,098
Operating loss	(319)	(253)	(762)	(401)
Interest income	18	123	53	300
Net loss	$ (301)	$ (130)	$ (709)	$ (101)
Net loss per share, basic and diluted	$ (0.01)	$ (0.00)	$ (0.02)	$ (0.00)
Weighted-average shares used in computing net loss per share, basic and diluted	44,999	44,777	44,966	44,754

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

Condensed Statements of Comprehensive Income
(Unaudited)
(in thousands)

	Three months ended June 30, 2013	Three months ended June 30, 2012	Six months ended June 30, 2013	Six months ended June 30, 2012
Net loss	$ (301)	$ (130)	$ (709)	$ (101)
Other comprehensive loss				
Net unrealized gains (losses) on marketable securities	—	(53)	3	(85)
Comprehensive loss	$ (301)	$ (183)	$ (706)	$ (186)

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Six months ended June 30, 2013	Six months ended June 30, 2012
Cash flows used in operating activities:		
Net loss	$ (709)	$ (101)
Adjustments to reconcile net loss to net cash used in operating activities:		
Deferred program fee revenue	(3,917)	(5,448)
Non-cash stock based compensation	1,491	1,776
Depreciation and amortization	—	70
Non-cash net interest income	(8)	270
Changes in operating assets and liabilities:		
Other current assets	250	263
Other non-current assets	—	1
Accounts payable	74	37
Accrued development expense	(357)	(309)
Accrued compensation and benefits	(474)	(538)
Other accrued liabilities	(24)	(41)
Net cash used in operating activities	(3,674)	(4,020)
Cash flows provided by investing activities:		
Purchases of marketable securities	(4,096)	(9,590)
Maturities of marketable securities	9,700	19,300
Net cash provided by investing activities	5,604	9,710
Cash flows provided by financing activities:		
Proceeds from issuance of common stock, net	260	186
Net cash provided by financing activities	260	186
Net increase in cash and cash equivalents	2,190	5,876
Cash and cash equivalents at beginning of the period	49,355	73,144
Cash and cash equivalents at end of the period	$ 51,545	$ 79,020

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

Notes to Condensed Financial Statements
(Unaudited)

Note 1. General

We are a biopharmaceutical company that develops novel drugs. Our lead drug candidate is called REMOXY® (oxycodone) Extended-Release Capsules CII. REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. REMOXY and three other abuse-resistant painkillers are being developed pursuant to the collaboration agreement and license agreement, or the Pfizer Agreements, between us and King Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc., or Pfizer.

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 and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2013. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2012.

We have evaluated subsequent events through the date of filing this Form 10-Q. No material subsequent events have occurred that require recognition or disclosure in these financial statements.

Note 2. Significant Accounting Policies

Use of Estimates

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.

Revenue Recognition and Deferred Program Fee Revenue

We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

We recognize program fee revenue, milestone revenue and collaboration revenue in connection with the Pfizer Agreements. Program fee revenue is derived from program fee payments we received under the Pfizer Agreements. These payments are recognized from receipt ratably over our estimate of the development period through the last to be developed of four drug candidates expected to be developed under the Pfizer Agreements. We currently estimate the development period for all four drug candidates to end by March 31, 2018. We periodically review the estimated development period and change it if appropriate based upon our latest expectations. Deferred program fee revenue represents the amount of the upfront program fee payments that have not yet been recognized as revenue.

Pfizer is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the development of REMOXY and the other opioid painkillers under the strategic alliance. We recognize milestone payments 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 we provide are priced at fair value based upon the reimbursement of expenses we incur.

Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with Pfizer are generally recognized when Pfizer has completed its review of the expenses invoiced to them.

Cash, Cash Equivalents and Concentration of Credit Risk

We consider all highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist of cash maintained at one financial institution and in money market funds. We believe the financial risks associated with these instruments are minimal. We have not experienced material losses from our investments in these securities.

Marketable Securities and Fair Value Measurements

We invest in interest bearing marketable securities, generally consisting of corporate and government securities. We may elect to sell these investments before they mature. Therefore, we hold these investments as “available for sale” and include these investments in our balance sheets as current assets, even though the contractual maturity of a particular investment may be beyond one year. We report our marketable securities at fair value, which may include unrealized gains and losses. Our unrealized gains and losses on investments are recorded as a separate component of stockholders' equity as accumulated other comprehensive income or loss. We recognize all realized gains and losses on our marketable securities in interest income in the accompanying statement of operations on a specific identification basis. We report changes in net unrealized gains or losses on marketable securities in our Statements of Comprehensive Income. Our marketable securities are maintained at one financial institution and are governed by our investment policy as approved by our Board of Directors.

To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. We would recognize an impairment charge when the decline in the estimated fair value of a marketable security below the amortized cost is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including materiality, any adverse changes in the investees' financial condition, how long the fair value has been below the amortized cost and whether it is more likely than not that we would elect to or be required to sell the marketable security before its anticipated recovery.

We measure our cash equivalents and marketable securities at fair value on a recurring basis. We use significant observable inputs where there are identical or comparable assets in the market to use in establishing our fair value measurements, including but not limited to benchmark yields, reported trades, broker/dealer quotes and issuer spreads. We consider these inputs to be Level 2 inputs. Generally, the types of instruments we invest in are not traded on a market such as the NASDAQ Global Market, which we would consider to be Level 1 inputs. We do not have any investments that would require inputs considered to be Level 3. We use the bid price to establish fair value where a bid price is available.

Stock-based Compensation

We recognize expense in the statement of operations for the fair value of all share-based payments, including grants of employee stock options and other share based awards. For stock options, we use the Black-Scholes option valuation model and the single-option award approach and straight-line attribution method. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years. We estimate forfeitures and adjust this estimate periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates.

We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. The value of these awards is the product of the number of shares of our common stock to be issued under the award multiplied by the fair market value of a share of our common stock on the date of grant. These awards include future performance criteria. We estimate an implicit service period for achieving these performance criteria. Performance Awards vest and common stock is issued on achieving performance criteria. We recognize stock-based compensation expense for Performance Awards when we conclude that achieving performance criteria is probable. We periodically review and update as appropriate our estimates of the implicit service periods and the likelihood of achieving the performance criteria.

Net Loss per Share

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

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

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Numerator				
Net loss	$ (301)	$ (130)	$ (709)	$ (101)
Denominator				
Weighted-average shares used in computing net loss per share, basic and diluted	44,999	44,777	44,966	44,754
Net loss per share, basic and diluted	$ (0.01)	$ (0.00)	$ (0.02)	$ (0.00)

We excluded weighted options outstanding to purchase common stock of 14.7 million for the second quarter of 2013 and 10.2 million for the second quarter of 2012, 14.6 million for the first half of 2013 and 11.3 million from the first half of 2012 from the calculation of diluted net loss per share because the effect of including these shares in this calculation would be anti-dilutive.

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 certain deferred tax assets is dependent upon future earnings. We are uncertain about the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with 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 recognized pursuant to our deferred tax assets as interest expense, when appropriate.

Table of Contents

Note 3. Cash, Cash Equivalents and Marketable Securities and Assets Measured at Fair Value

Our cash, cash equivalents and marketable securities are as follows (in thousands):

	Cash, Cash Equivalents and Marketable Securities					
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Accrued Interest	Total Value
June 30, 2013						
Cash and cash equivalents	$ 45,915	$ 1	$ —	$ 45,916	$ —	$ 45,916
Commercial paper	6,929	—	—	6,929	—	6,929
	$ 52,844	$ 1	$ —	$ 52,845	$ —	$ 52,845
Reported as:						
Cash and cash equivalents	$ 51,544	$ 1	$ —	$ 51,545	$ —	$ 51,545
Marketable securities	1,300	$ —	—	1,300	—	1,300
	$ 52,844	$ 1	$ —	$ 52,845	$ —	$ 52,845
Maturities:						
Matures in one year or less	$ 52,844	$ 1	$ —	$ 52,845	$ —	$ 52,845
Matures one to three years	—	—	—	—	—	—
	$ 52,844	$ 1	$ —	$ 52,845	$ —	$ 52,845
December 31, 2012						
Cash and cash equivalents	$ 49,352	$ 3	$ —	$ 49,355	$ —	$ 49,355
Corporate securities	$ 6,898	1	—	6,899	—	6,899
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$ 56,254
Reported as:						
Cash and cash equivalents	$ 49,352	$ 3	$ —	$ 49,355	$ —	$ 49,355
Marketable securities	6,898	1	—	6,899	—	6,899
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$ 56,254
Maturities:						
Matures in one year or less	$ 56,250	$ 4	$ —	$ 56,254	$ —	$ 56,254
Matures one to three years	—	—	—	—	—	—
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$ 56,254

We did not realize any gains or losses on our investments in marketable securities during the first half of 2013 or 2012. To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Our assets measured at fair value on a recurring basis are as follows (in thousands):

	Level 1	Level 2	Level 3	Total
June 30, 2013				
Cash and money market fund	$ 45,916	$ —	$ —	$ 45,916
Commercial paper	—	6,929	—	6,929
	$ 45,916	$ 6,929	$ —	$ 52,845

	Level 1	Level 2	Level 3	Total
December 31, 2012				
Cash and money market fund	$ 1,817	$ —	$ —	$ 1,817
Corporate securities	—	54,437	—	54,437
	$ 1,817	$ 54,437	$ —	$ 56,254

Note 4. Stock-Based Compensation Expense

Our non-cash stock-based compensation expense is as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Research and development	$ 337	$ 375	$ 641	$ 840
General and administrative	475	494	850	936
	$ 812	$ 869	$ 1,491	$ 1,776

Note 5. Income Taxes

We did not provide for income taxes in 2013 because we have projected a net loss for the full year 2013. Interest expense and penalties related to unrecognized tax benefits were immaterial for 2013 and 2012.

Note 6. Commitments

We conduct our product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. We have contractual arrangements with these organizations that are cancelable. Our obligations under these contracts are largely based on services performed.

We currently lease approximately 6,000 square feet of office space pursuant to a non-cancelable operating lease in Austin, TX that expires in 2014. Future minimum lease payments by year are as follows (in thousands):

	2013	**2014**	**Total**
Future minimum lease payments	$ 115	$ 81	$ 196

Note 7. Legal proceedings

KB Partners I, L.P., Individually and On Behalf of All Others Similarly Situated v. Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann and Peter S. Roddy.

On December 2, 2011, a purported class action was filed against us and our executive officers in the U.S. District Court for the Western District of Texas. This complaint alleges, among other things, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status during the purported class period, February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified.

Note 8. ***Recently Issued Accounting Pronouncements***

We reviewed recently issued accounting pronouncements and have adopted or plan to adopt those that are applicable to us. We do not expect the adoption of these pronouncements to have a material impact on our financial position, results of operations or cash flows.

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 about:

- development activities and future plans of Pfizer, Inc., or Pfizer, or its subsidiary King Pharmaceuticals, Inc., or King, with respect to obtaining approval of REMOXY® (oxycodone) Extended-Release Capsules CII, by the U.S. Food and Drug Administration, or FDA;
- timing of any updates regarding the development of REMOXY under our strategic alliance with Pfizer;
- royalty, milestone or collaboration revenue we may receive from Pfizer and other payments we may receive from our collaboration and license agreements with Pfizer, or the Pfizer Agreements;
- the benefits of Pfizer's acquisition of King with respect to the commercial success of REMOXY, if approved by the FDA;
- the duration of the development period for expected drug candidates;
- timing of reimbursement of us by Pfizer for reimbursable development expenses we incurred under the Pfizer Agreements;
- expansion of our potential product line, including the formulation of additional dosage forms of our drug candidates;
- operating losses and anticipated operating and capital expenditures;
- expected uses of capital resources;
- the potential benefits of our drug candidates;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital and increasing cash needs;
- potential competitors or competitive products;
- market acceptance of our drug candidates and potential drug candidates;
- expenses increasing, interest income decreasing or fluctuations in our operating results;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- expectations regarding the issuance of shares of common stock to employees pursuant to equity compensation awards net of employment taxes;

- anticipated hiring and development of our internal systems and infrastructure;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- assumptions and estimates used for our disclosures regarding stock-based compensation; and
- estimates concerning the realization of deferred tax assets.

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

- difficulties or delays in the potential regulatory approval of the REMOXY NDA, including responding to current requests from the FDA and the potential for additional requests by the FDA for additional data which may require an extended period of time to obtain and submit, that could significantly delay or prevent such approval;
- the successful development and commercialization of REMOXY and other drug candidates pursuant to the Pfizer Agreements, and development of other drug candidates pursuant to our other collaboration agreements, and the continuation of such agreements;
- difficulties or delays in development, testing, clinical trials (including patient enrollment), regulatory approval, production and commercialization of our drug candidates;
- unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials) or potential post-approval market acceptance;
- the uncertainty of protection of our intellectual property rights or trade secrets;
- potential infringement of the intellectual property rights of third parties;
- pursuing in-license and acquisition opportunities;
- maintenance or third party funding of our collaboration and license agreements;
- 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.

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.

Overview

We are a biopharmaceutical company that develops novel drugs. Our lead drug candidate is called REMOXY. REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. REMOXY is being developed pursuant to a strategic alliance we have with Pfizer under the Pfizer Agreements.

Pfizer acquired King in early 2011, and references in this section to Pfizer include references to King. We expect REMOXY will be commercialized within Pfizer's primary care unit. We believe Pfizer's acquisition of King may facilitate REMOXY's commercial success, if approved by the FDA.

We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data was required to support the approval of REMOXY. Also, the FDA did not request or recommend additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the King Agreements. In December 2010, King resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted the resubmission of the REMOXY NDA. In June 2011, we and Pfizer announced that King received a Complete Response Letter from the FDA in response to King's resubmission of the REMOXY NDA. The FDA's Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY.

In March 2013, Pfizer met with the FDA to discuss Pfizer's plans to respond to the Complete Response Letter. Pfizer described the meeting with the FDA in their Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 as follows: "We met with the FDA in March 2013 to discuss our plan to address the June 2011 "complete response" letter. We received written guidance from the FDA in May regarding required next steps, including additional clinical studies, to address the letter. Based on this guidance, we are considering our options with respect to Remoxy. If we elect to continue development of Remoxy, we would not expect to submit a response to the "complete response" letter before mid-2015."

On May 9, 2013, Pfizer provided us with a copy of minutes of their FDA meeting, and a letter that we filed with the SEC on Form 8-K on May 10, 2013.

We believe that Pfizer is continuing to develop REMOXY while they consider their options. We expect to provide additional information about Pfizer's future plans for REMOXY in the fall of 2013.

We have received the following program fee and milestone payments under the Pfizer Agreements:

Description	Year Received	Amount Received (mm)
Upfront program fee payment	2005	$ 150
Program fee payment related to an amendment to the strategic alliance	2010	$ 5
Milestone payments related to:		
acceptance by the FDA of the NDA for REMOXY	2008	$ 15
acceptance by the FDA of the IND for abuse-resistant oxymorphone	2011	$ 5
acceptance by the FDA of the IND for abuse-resistant hydrocodone	2008	$ 5
acceptance by the FDA of the IND for abuse-resistant hydromorphone	2006	$ 5

We will receive a $15.0 million cash milestone payment from Pfizer upon regulatory approval of REMOXY in the United States. In addition, subject to certain limitations, Pfizer is obligated to fund development expenses incurred by us pursuant to the Pfizer Agreements.

Pfizer is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, REMOXY pursuant to the Pfizer Agreements. The royalty rate for net sales of REMOXY and other products covered by the strategic alliance in the United States is 20%, except as to the first $1.0 billion in cumulative net sales in the United States, for which the royalty is 15%. The royalty rate for net sales of products covered by the strategic alliance outside the United States is 10%. Pfizer is also obligated to reimburse us for our payment of third-party royalty obligations related to this strategic alliance.

We have yet to generate any revenues from product sales. We have recorded an accumulated deficit of $136.4 million at June 30, 2013. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing of preclinical activities, 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:

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

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

We focus substantially all our research and development efforts on research and development in the areas of neurology. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Compensation	$ 652	$ 1,089	$ 1,444	$ 2,243
Contractor fees and supplies	348	281	633	519
Other common costs	139	146	245	363
	$ 1,139	$ 1,516	$ 2,322	$ 3,125

Contractor fees and supplies generally include expenses for preclinical studies and clinical trials and costs for formulation and manufacturing activities. Other common costs 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 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 strategic alliance with Pfizer 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.

Our contractor fees and supplies expenses in the first half of 2013 related to programs outside of the strategic alliance with Pfizer were approximately $0.3 million.

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.

On December 2, 2011, a purported class action was filed against us and our executive officers in the U.S. District Court for the Western District of Texas. This complaint alleges, among other things, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status during the purported class period, February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified.

Critical Accounting Policies

The preparation of our financial statements in accordance with United States 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 agreements, 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:

- *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 and other share based awards. For stock options, we use the Black-Scholes option valuation model and the single-option award approach and straight-line attribution method. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

  We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. The value of these awards is the product of the number of shares of our common stock to be issued under the award multiplied by the fair market value of a share of our common stock on the date of grant. These awards include future performance conditions. We estimate an implicit service period for achieving these performance conditions. Performance Awards vest and common stock is issued on achieving performance conditions. We recognize stock-based compensation expense for Performance Awards when we conclude that achieving a performance condition is probable. We periodically review and update as appropriate our estimates of the implicit service periods and the likelihood of achieving the performance conditions.

- *Revenue recognition and deferred program fee revenue.* We recognize program fee revenue, milestone revenue and collaboration revenue in connection with the Pfizer Agreements. Program fee revenue is derived from upfront payments under the Pfizer Agreements. These payments are recognized from receipt ratably over our estimate of the development period for the last to be developed of four drug candidates expected to be developed under the Pfizer Agreements. We currently estimate the development period for all four expected drug candidates to end in the quarter ended March, 2018. We periodically review the estimated development period and change it if appropriate based upon our latest expectations. Deferred program fee revenue represents the amount of the upfront payment that has not yet been recognized as program fee revenue. Pfizer is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the development of REMOXY and the other opioid painkillers under the strategic alliance. We recognize milestone payments 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 we provide are priced at fair value based upon the reimbursement of expenses we incur. Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with Pfizer are generally recognized when Pfizer has completed its review of the expenses invoiced to them.

- *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 certain deferred tax assets is dependent upon future earnings, if any. We are uncertain as to the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with 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 recognized in connection with our tax positions as interest expense, when appropriate.

Results of Operations

Three and six months ended June 30, 2013 and 2012

Revenue – Program fee revenue

Program fee revenue recognized from the program fees we received under the Pfizer Agreements were $2.0 million for the second quarter of 2013, $2.7 million for the first quarter of 2012, $3.9 million for the first half of 2013 and $5.4 million for the first half of 2012.

Revenue – Collaboration revenue

Collaboration revenue from reimbursement of our development expenses incurred under the Pfizer Agreements was $0.2 million for the first half of 2012. We did not receive any collaboration revenue in the first half of 2013.

Research and Development Expense

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

- preclinical testing,
- clinical trials,
- clinical supplies and related formulation and design costs, and
- compensation and other personnel-related expenses.

Research and development expense decreased to $1.1 million in the second quarter of 2013 from $1.5 million in the second quarter of 2012 and to $2.3 million in the first half of 2013 from $3.1 million in the first half of 2012, primarily due to lower cash-based bonus and other compensation in 2013 as compared to 2012. Research and development expenses included non-cash stock related compensation expense of $0.3 million in the second quarter of 2013, $0.4 million in the second quarter of 2012, $0.6 million in the first half of 2013 and $0.8 million in the first half of 2012.

We expect research and development expenses to fluctuate over the next several years as we continue our development efforts. We expect our development efforts to result in our drug candidates progressing through various stages of clinical trials. Our 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. We also expect non-cash equity related expenses to increase in the future.

General and Administrative Expense

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense decreased to $1.1 million in the second quarter of 2013 from $1.5 million in the second quarter of 2012 and to $2.4 million in the first half of 2013 from $3.0 million in the first half of 2012, primarily due to lower cash-based bonus compensation in 2013 as compared to 2012. General and administrative expense included non-cash stock related compensation expense of $0.5 million in the second quarter of 2013, $0.5 million in the second quarter of 2012, $0.9 million in the first half of 2013 and $0.9 million in the first half of 2012.

We expect general and administrative expense to increase over the next several years in connection with support of pre-commercialization and commercialization activities for our drug candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies. We also expect non-cash equity related expenses to increase in the future.

Interest Income

Interest income decreased to $0.1 million in the first half of 2013 from $0.3 million in the first half of 2012, due to lower average cash balances in the first half of 2013 compared to the first half of 2012. We expect our interest income to decrease in the future as we use cash to fund our operations.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under the Pfizer Agreements and interest earned on our investments. We intend to continue to use our capital resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of June 30, 2013, cash, cash equivalents and marketable securities were $52.8 million.

Net cash used in operating activities was $3.7 million for the first half of 2013 and $4.0 million for the first half of 2012.

Net cash provided by investing activities was $5.6 million for the first half of 2013 and $9.7 million for the first half of 2012. Investing activities consisted of purchases and maturities of marketable securities.

Net cash provided by financing activities was $0.3 million for the first half of 2013 and $0.2 million in the first half of 2012. Financing activities consisted primarily of proceeds from stock option exercises.

Realization of our other deferred tax assets is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with a valuation allowance.

We currently lease approximately 6,000 square feet of office space pursuant to a non-cancelable operating lease in Austin, TX that expires in 2014. Future minimum lease payments by year are as follows (in thousands):

	2013	2014	Total
Future minimum lease payments	$ 115	$ 81	$ 196

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of June 30, 2013. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones and pay royalties on related drug sales. Pfizer is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

Our employees have Performance Awards that vest upon certain conditions. If these Performance Awards vest, we may issue the employees shares of our common stock net of statutory employment taxes. This net issuance results in fewer shares issued and uses our cash to cover these taxes. The use of cash could be higher or lower, depending on the fair value of our common stock on the date the Performance Awards vest.

We have an accumulated deficit of $136.4 million at June 30, 2013. 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, the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products and other corporate needs. We believe that our current resources should be sufficient to fund our operations for at least the next 12 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.

Off-balance Sheet Arrangements

As of June 30, 2013, 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, we expect the fair value of our investment will decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at June 30, 2013 by an immaterial amount. To minimize this risk, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We are not aware of holdings of derivative financial or commodity instruments.

As of June 30, 2013, our investments consisted of investments in corporate obligations, money market accounts and checking funds with variable market rates of interest. We believe our credit risk is immaterial. 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. We consider these inputs to be Level 2 inputs. Generally, the types of instruments we invest in are not traded on a market such as the NASDAQ Global Market, which we would consider to be Level 1 inputs. We do not have any investments that would require inputs considered to be Level 3. We use the bid price to establish fair value where a bid price is available.

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 our 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.

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

PART II – OTHER INFORMATION

Item 1. *Legal Proceedings*

KB Partners I, L.P., Individually and On Behalf of All Others Similarly Situated v. Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann and Peter S. Roddy.

On December 2, 2011, a purported class action was filed against us and our executive officers in the U.S. District Court for the Western District of Texas. This complaint alleges, among other things, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status during the purported class period, February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified.

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 or our collaborators fail to obtain the necessary regulatory approvals, or if such approvals are limited, we and our collaborators will not be allowed to commercialize our drug candidates, and we will not generate product revenues.

Satisfaction of all regulatory requirements for commercialization of a drug candidate 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. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data is required to support the approval of REMOXY. Also, the FDA did not request or recommend additional clinical efficacy studies prior to approval. In March 2009, King assumed sole responsibility for the regulatory approval of REMOXY. In December 2010, King resubmitted the NDA for REMOXY. In June 2011, we and Pfizer announced that King received a Complete Response Letter from the FDA in response to their resubmission of the REMOXY NDA. The FDA's Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during in vitro testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency. There can be no assurance that the FDA will approve an NDA for REMOXY (even with additional data) or that the FDA will not require additional clinical or non-clinical data to be submitted. If the FDA were to require additional clinical or non-clinical data, providing such data may significantly delay the potential approval of REMOXY and could result in Pfizer ceasing their development of or pursuing regulatory approval of REMOXY.

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 additional studies, in which case we or our collaborators would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. 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 or our collaborators comply with all FDA regulatory requirements, our drug candidates may never obtain regulatory approval. If we or our collaborators 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 our drug candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims 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 or our collaborators to commit to perform lengthy Phase IV post-approval clinical efficacy or safety studies. Our expending additional resources on such trials would have an adverse effect on our operating results and financial condition.

In jurisdictions outside the United States, we or our collaborators must receive marketing authorizations from the appropriate regulatory authorities before commercializing our drugs. Regulatory approval processes outside the United States generally include all of the aforementioned requirements and risks associated with FDA approval.

If we or our collaborators are unable to design, conduct and complete clinical trials successfully, our drug candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our drug candidates, we or our collaborators must submit to the FDA an 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.

Results from Phase I clinical programs may not support moving a drug candidate to Phase II or Phase III clinical trials. Phase III clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and preclinical studies. Even if the results of Phase III clinical trials are positive, we or our collaborators may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before obtaining 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, our collaborators or the FDA believe that participating patients are being exposed to unacceptable health risks, such clinical trials will have to be suspended or terminated. Failure can occur at any stage of the clinical trials, and we or our collaborators could encounter problems that cause abandonment or repetition of clinical trials.

Our clinical trials with REMOXY and our potential future clinical trials for other drug candidates for treatment of pain measure clinical symptoms, such as pain and physical dependence that are not biologically measurable. The success in clinical trials of REMOXY and our other drug candidates designed to reduce potential risks of unintended use 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.

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

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

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. With the exception of our Special Protocol Assessment, or SPA, such as the one we completed with the FDA with respect to the Phase III clinical trial for 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 or our collaborators may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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

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

The DEA limits the availability of the active ingredients in certain of our current drug candidates and, as a result, quotas for these ingredients 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 that can be obtained for clinical trials and commercial distribution is limited by the DEA and quotas for these substances 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 clinical trials for our product candidates, and, in the future, the 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.

If our drug candidates receive regulatory approval, we and our collaborators will 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 and our collaborators' ability to commercialize our potential drugs.

Any regulatory approvals that our drug candidates receive 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. For example, on July 9, 2012, the FDA approved a risk management program, known as a Risk Evaluation and Mitigation Strategy, or REMS, for extended-release and long-acting opioid analgesics, or ER/LA opioid analgesics. This REMS will require companies affected by the REMS to make available training for health care professionals who prescribe ER/LA opioid analgesics on proper prescribing practices and also to distribute educational materials to prescribers and patients on the safe use of ER/LA opioid analgesics.

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

Pfizer's acquisition of King may have an adverse impact on our collaboration.

Pfizer completed its acquisition of King in 2011. Drugs or drug candidates being commercialized or developed by Pfizer, its subsidiaries and affiliates may compete for research, development and commercialization resources with our drug candidates that are subject to the Pfizer Agreements. Further, any post-merger integration of Pfizer's and King's businesses may divert the attention of management and personnel from their focus on seeking approval of REMOXY or otherwise supporting the other drug candidates that are subject to our collaboration. Pfizer is a much larger company than King was prior to Pfizer's acquisition of King. Pfizer may have different strategic interests than King had as an independent company. There can be no assurance that King or Pfizer will devote sufficient resources to the continued development of REMOXY and the other drug candidate that are the subject of our collaboration in a timely manner.

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

We rely on Pfizer and its subsidiaries to devote time and resources to the development, manufacturing and commercialization of REMOXY and other drug candidates under the Pfizer Agreements. Pfizer and its subsidiaries and affiliates may commercialize, develop or acquire drugs or drug candidates that may compete directly or compete for resources with our drug candidates under the Pfizer Agreements. For instance, Pfizer is developing ALO-02 (an extended release abuse resistant formulation of oxycodone that would compete with REMOXY) and owns Embeda® (an extended-release oral formulation of morphine sulfate), and Avinza® (a once-daily morphine treatment for moderate to severe pain). There can be no assurance that these other drugs or other drug candidates in the Pfizer corporate family will not become competitive with our drug candidates being developed under the Pfizer Agreements. Pfizer may also determine, outside of the context of internal resource competition, to cease pursuit of development of REMOXY due to perceived difficulties of achieving regulatory approval, including as a result of potential time and cost concerns and concerns regarding any potential additional requests by the FDA for clinical or non-clinical data to support approval. If time and resources devoted are limited or there is a failure to fund the continued development of REMOXY or other opioid drug candidates as required by the Pfizer Agreements, or there is otherwise a failure 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. In addition, if Pfizer fails to perform as required under the Pfizer Agreements, their failure may jeopardize our rights under our license with Durect.

We rely on Durect as the sole source provider of certain components of drug candidates under the Pfizer Agreements. Durect's failure for any reason to provide these components could result in delays or failures in product testing or delivery, cost overruns or other problems that could materially harm our business.

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

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

If we fail to maintain our collaboration agreements and licenses for REMOXY and other drugs designed to reduce potential risks of unintended use, we may have to reduce or delay our drug candidate development.

Our plan for developing, manufacturing and commercializing REMOXY and other drugs designed to reduce potential risks of unintended use currently requires us to successfully maintain the Pfizer Agreements to advance our programs and provide funding to support our expenditures on REMOXY and other drug candidates and to maintain our license from Durect. If we are not able to maintain the Pfizer Agreements or if Pfizer doesn't provide the required funding under the Pfizer Agreements and the funding required to meet our obligations to Durect, we may have to limit the size or scope of, or delay or abandon the development of other drug candidates or undertake and fund development of these drug candidates ourselves and if we are unable to meet the obligations necessary to maintain our license with Durect for one or more potential products we may lose the rights to utilize Durect's technology for such potential products. If we elect to fund drug development efforts with respect to REMOXY and other 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 and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates and technologies is intense because such companies generally desire to expand their product pipelines through in-licensing. If we fail to carry out such in-licensing and expand our product pipeline, our potential future revenues may suffer.

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 the Pfizer Agreements and our license agreement with Durect. 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 our business, 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 or license agreement; or
- failure by a collaborative partner to provide required funding, to devote sufficient resources to the development of or legal defense of our potential products or to provide data or other information to us as required by our collaborative agreements.

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, and, in particular, the effectiveness of REMOXY in reducing potential risks of unintended use;
- perceptions by physicians regarding the cost benefit of REMOXY in reducing potential risks of unintended use;
- 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 or our collaborators' ability to implement a risk management plan prior to the distribution of any Schedule II drug; and
- effectiveness of marketing and distribution efforts by Pfizer, us and other 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 Pfizer or its subsidiaries are not successful in developing and commercializing REMOXY and in commercializing other opioid drugs under the Pfizer Agreements, our revenues and our business will suffer.

Our ability to earn royalties from sales of REMOXY and milestone revenue depends on Pfizer's ability to obtain regulatory approval for and commercialize REMOXY. Additionally, our ability to earn royalties from sales of REMOXY and other drugs subject to the Pfizer Agreements will depend on Pfizer's ability to maintain regulatory approval and achieve market acceptance of such drugs once commercialized. Pfizer or its subsidiaries may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of REMOXY and other drugs developed under the Pfizer Agreements. Pfizer may not proceed with the commercialization of REMOXY and other drugs developed under the Pfizer Agreements with the same degree of urgency as we would because of other priorities they face. If Pfizer is not successful in developing or commercializing REMOXY for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if Pfizer fails to perform as we expect, our potential for revenue from drugs developed the Pfizer Agreements, 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 the Pfizer Agreements, in order to commercialize our products, if any are approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any of our drugs ourselves, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new drugs and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

If we decide to enter into new co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the number of potential collaborators is limited and because of competition from others for similar alliances with potential collaborators. Even if we are able to identify one or more acceptable new collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

In addition, due to the nature of the market for our drug candidates, it may be necessary for us to license all or substantially all of our drug candidates not covered by the Pfizer Agreements 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 and our collaborators 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.

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

Our ability to earn royalties from sales of REMOXY and other drugs subject to the Pfizer Agreements, and our ability to commercialize drugs we (alone or with other collaborators) may develop outside the Pfizer Agreement, will depend in part on the extent to which reimbursement can be obtained for such drugs 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 clinical use or commercial appeal 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 technology and pharmaceutical ingredients 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.

In addition, because patent applications are published some time after 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 rights, 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 in the United States and select international jurisdictions to further protect our intellectual property. The coverage sought in a patent application can be denied or significantly reduced before or after the patent is issued. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, or if any existing or future patents will provide significant protection or commercial advantage or will be circumvented by others. There can be no assurance that patents will issue from our pending or future patent applications or, if issued, that such patents will be of commercial benefit to us, afford us adequate protection from competing products, or not be challenged or declared invalid. Thus, if these patent applications do not result in issued patents or result is a patent that is challenged by others, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

We may be involved in challenges to our intellectual property. An adverse outcome of a challenge to our intellectual property could result in loss of claims of patents or other intellectual property rights that pertain to certain drugs we currently have under development and could have a material adverse impact on our future revenues.

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

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

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

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

Risks Relating to our Business and Strategy

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 depend on the services of our key personnel, including Remi Barbier, our Chairman, President and Chief Executive Officer. The loss of key personnel, including members of executive management as well as key bioengineering, product development, and technical personnel, could disrupt our operations and have an adverse effect on our business. 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 is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel is critical to our success.

We have employees whose equity ownership in the Company could result in a substantial increase in personal wealth if the fair value of our common stock increases. Over time, this increase in personal wealth may make it more challenging to retain these employees.

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

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

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- For certain of our drug candidates, 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 may not be able to successfully develop or commercialize potential drug candidates for indications other than pain.

Our research and development activities include development of potential drug candidates for indications other than pain. We have no history of developing such drug candidates. We do not know whether any of our planned development activities will result in marketable products. We do not anticipate that our drug candidates in these areas 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.

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.

Unfavorable media coverage of opioid pharmaceuticals could negatively affect our business.

Opioid drug abuse receives a high degree of media coverage. Unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse-resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, or the independent actions of Pfizer regarding the sales, marketing, distribution or storage of our drug products, could adversely affect our reputation. Such negative publicity could have an adverse effect on the potential size of the market for our drug candidates and decrease revenues and royalties, which would adversely affect our business and financial results.

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.

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 and Pfizer cannot formulate and scale-up a wide range of dosage forms of REMOXY and other drug candidates designed to reduce potential risks of unintended use, we and Pfizer might determine that the commercial opportunity for REMOXY and these other drug candidates in certain dosage forms is too limited to warrant further investment in clinical testing and development.

We and Pfizer plan to formulate and scale-up a wide range of dosage forms of REMOXY and other drug candidates designed to reduce potential risks of unintended use. We and Pfizer may not be able to successfully complete our formulation or scale-up activities or we may determine that the commercial opportunity for REMOXY and these other drug candidates in certain dosage forms is too limited to warrant further investment. If we and Pfizer are unsuccessful in our formulation or scale-up activities with REMOXY and these other drug candidates, our future revenue from milestones and royalties under the Pfizer Agreements may be less than expected and our operations may suffer.

We and Pfizer rely solely on Durect to provide us with certain components of REMOXY and other drug candidates designed to reduce potential risks of unintended use and will continue to rely on Durect to produce commercial supplies of these components.

We and Pfizer rely on Durect as the sole source provider of certain components of REMOXY and other drug candidates designed to reduce potential risks of unintended use, and will rely solely on Durect to produce commercial supplies of these components. Durect's failure for any reason to provide these components or 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.

If Pfizer receives marketing approval for and commercially launches REMOXY or other candidates under the Pfizer Agreements, Durect may need to materially expand its manufacturing capacity. Durect may not be able to increase its manufacturing capacity for REMOXY and these other 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 these other drugs, at an acceptable cost or otherwise, and Pfizer is unable to establish alternative manufacturing capabilities, commercialization of REMOXY and these other drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our future revenues and cause our business to suffer.

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 some years in the past based on payments received pursuant to the Pfizer Agreements and interest income, we have yet to generate any revenues from product sales. We have an accumulated deficit of $136.4 million at June 30, 2013. 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 or our collaborators 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 the Pfizer Agreements 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 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 the Pfizer Agreements, 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 efforts to seek regulatory approval for REMOXY, and in preclinical studies and clinical trials for our other drug candidates;

- announcements by Pfizer regarding progress in, or decisions regarding whether to pursue, development of drug candidates subject to our strategic alliance;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- the status of our collaboration agreements;
- 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;
- adverse media coverage related to opioid pharmaceuticals;
- future sales of our common stock by existing stockholders;
- developments with respect to potential merger and acquisition activity of companies with whom we have strategic alliances or other agreements;
- regulatory developments or changes in regulatory guidance enacted by applicable governmental or other authorities;
- litigation, including with respect to the lawsuit currently filed against us and our officers, 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, the Dodd-Frank Act of 2010, 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 Select 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.

We are involved in a class action filed against us and our officers that is expensive and time consuming, and, in the event of an adverse outcome, could harm our business, financial condition or results of operations.

On December 2, 2011, a purported class action was filed against us and our executive officers in the U.S. District Court for the Western District of Texas. This complaint alleges, among other things, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status during the purported class period, February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of any outstanding legal actions. We have incurred expenses in connection with the defense of this lawsuit, and we may have to pay damages or settlement costs in connection with any resolution thereof. Any such expenses, damages or settlement costs may be substantial. In addition, because of the number of shareholders involved, plaintiffs in class action lawsuits may claim enormous monetary damages even if the alleged claim is small on a per-shareholder basis. Any such expenses, damages or settlement costs may be substantial. Although we have insurance coverage against which we may claim recovery against some of these expenses and costs, the amount of coverage may not be adequate to cover the full amount or certain expenses and costs may be outside the scope the policies we maintain. In the event of an adverse outcome or outcomes, our business could be materially harmed from depletion of cash resources, negative impact on our reputation, or restrictions or changes to our governance or other processes that may result from any final disposition of the lawsuit. Moreover, responding to and defending pending litigation significantly diverts management's attention from our operations.

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 business 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.

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

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In particular, Remi Barbier, our founder, Chairman of the Board of Directors, President and Chief Executive Officer, owns or controls a significant amount of the voting power of our outstanding capital stock. This concentration of ownership may delay or prevent a change in control of the Company and may make some transactions, including but not limited to any merger, consolidation, or sale of substantially all of our assets, more difficult or impossible to complete without the support of key 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.

If the fair value of our stock increases and outstanding Performance Awards vest, we expect to use substantial amounts of cash to fund employee tax liabilities.

We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. If these Performance Awards vest, we expect to issue the employees shares of our common stock net of statutory employment taxes. This net issuance results in fewer shares issued and uses our cash to fund these taxes. The use of cash could be substantially higher, depending on the fair value of our common stock on the date the Performance Awards vest. If our use of cash to fund these taxes is substantial, our stock price could decline.

We may in the future seek to fund the cash used for Performance Awards through the sale of our common stock. However, we may not be successful in selling shares of our common stock to fund the cash used for Performance Awards. If the number of shares we sell to fund the cash used for Performance awards is significant, our stock price could decline.

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

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

Our 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 under the Pfizer Agreements, 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 may not be 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.

If securities or industry analysts publish inaccurate or unfavorable research about our business or product candidates, our stock price could decline.

Securities or industry analysts publish research and reports about our business or product candidates. An analyst’s conclusions regarding prospects for product candidates in the biopharmaceutical industry can include judgments based on the limited publicly-available data. If one or more analysts issues unfavorable research about our business or our product candidates, including a downgrade of our common stock, the price of our stock may decline.

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

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

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

None.

Item 3. ***Defaults Upon Senior Securities***

None.

Item 4. ***Mine Safety Disclosures***

Not applicable.

Item 5. ***Other Information***

None.

Table of Contents

Item 6. *Exhibits*

The following exhibits have been filed with this report:

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
4.2(3)	Amended and Restated Preferred Stock Rights Agreement, dated as of June 20, 2013, between Registrant and Computershare Shareowner 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.
10.1 *	Amendment Number 1 to the 2008 Equity Incentive Plan.
10.2 *	Amendment No. 2 to Employment Agreement between Registrant and Remi Barbier.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal 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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended June 30, 2005.
(2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended March 31, 2013.
(3) Incorporated by reference from the Company's current report on Form 8-K filed June 20, 2013.
* Management contract, compensatory plan or arrangement.

[Table of Contents](#)

SIGNATURES

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

Pain Therapeutics, Inc.
(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: August 1, 2013

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
4.2(3)	Amended and Restated Preferred Stock Rights Agreement, dated as of June 20, 2013, between Registrant and Computershare Shareowner 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.
10.1 *	Amendment Number 1 to the 2008 Equity Incentive Plan.
10.2 *	Amendment No. 2 to Employment Agreement between Registrant and Remi Barbier.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal 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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended June 30, 2005.
(2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended March 31, 2013.
(3) Incorporated by reference from the Company's current report on Form 8-K filed June 20, 2013.
* Management contract, compensatory plan or arrangement.

AMENDMENT NUMBER 1 TO THE 2008 EQUITY INCENTIVE PLAN

This Amendment Number 1 to the 2008 Equity Incentive Plan (the "Plan") is effective as of June 14, 2013:

1. The Plan is hereby amended by adding the following definitions to the Plan:

"Cause" means, with respect to the termination by the Company, a Parent or Subsidiary of the Participant's relationship as a Service Provider, that such termination is, in the determination of the Administrator, based on the Participant's: (i) performance of any act or failure to perform any act in bad faith and to the detriment of the Company, a Parent or Subsidiary; (ii) dishonesty, intentional misconduct or material breach of any agreement with the Company, a Parent or Subsidiary; or (iii) commission of a crime involving dishonesty, breach of trust, or physical or emotional harm to any person.

"Continuing Directors" means Directors who either (i) have been Directors continuously for a period of at least twelve (12) months or (ii) have been Directors for less than twelve (12) months and were appointed, elected or nominated for election as Directors by at least a majority of the Directors described in clause (i) who were still in office at the time such appointment, election or nomination was approved by the Board.

"Good Reason" means the occurrence after a Change in Control of any of the following events or conditions, provided the Participant notifies the Company in writing within 30 days following the initial existence of the Good Reason event or condition and the Company shall be then be given 30 days from its receipt of such notice during which it may remedy or cure such event condition ("Remedy Period"). If the Company does not cure or remedy such Good Reason event or condition during the Remedy Period, then the Participant must terminate his or her relationship as a Service Provider within 120 days after the end of the Remedy Period for Good Reason to apply.

(i) a change in the Participant's authority, responsibilities, titles, reporting relationship or duties which represents a material and substantial diminution in the Participant's responsibilities or duties as in effect immediately preceding the consummation of a Change in Control, provided that a mere change in title or reporting relationship where the Participant continues to perform the same functions and report to the same individual (except in the case of the Chief Executive Officer or President formerly reporting to the Board) within the business unit of the Successor Corporation which was formerly the Company shall not constitute Good Reason;

(ii) a material diminution in the annual research budget over which the Participant retains authority in the twelve (12) months preceding the consummation of the Change in Control;

(iii) a material reduction in the Participant's base salary to a level below that in effect at any time within twelve (12) months preceding the consummation of a Change in Control or at any time thereafter;

(iv) requiring the Participant to be based at any place outside a fifty (50)-mile radius from the Participant's job location or residence prior to the Change in Control except for reasonably required travel on business which is not materially greater than such travel requirements within the twelve (12) months prior to the Change in Control; or

(v) any other action or inaction by the successor that constitutes a material breach of the terms of the Participant's employment agreement (if any) then in effect.

2. The Plan is hereby amended by adding the following new subsection to the section of the Plan titled "Change in Control":

Acceleration of Certain Awards upon a Change in Control

In the event of a merger Change in Control, for the portion of each Award that is assumed or substituted for:

(i) each Award which is outstanding under the Plan as of June 14, 2013, and

(ii) each Award which is granted under the Plan after June 14, 2013, except as determined otherwise by the Administrator at the time the Award is granted

the Participant will fully vest in and have the right to exercise all of his or her outstanding Options and Stock Appreciation Rights, including Shares as to which such Awards would not otherwise be vested or exercisable, all restrictions on Restricted Stock will lapse, and, with respect to Restricted Stock Units, Performance Shares and Performance Units, all Performance Goals or other vesting criteria will be deemed achieved at target levels and all other terms and conditions met, immediately upon termination of the Participant's relationship as a Service Provider if the Participant's relationship as a Service Provider is terminated by the Company without Cause or voluntarily by the Participant with Good Reason.

Notwithstanding the foregoing, in the event of a merger or Change in Control that is not endorsed by a majority of the Continuing Directors, and except as determined otherwise by the Administrator at the time the Award is granted, the Participant will fully vest in and have the right to exercise all of his or her outstanding Options and Stock Appreciation Rights, including Shares as to which such Awards would not otherwise be vested or exercisable, all restrictions on Restricted Stock will lapse, and, with respect to Restricted Stock Units, Performance Shares and Performance Units, all Performance Goals or other vesting criteria will be deemed achieved at target levels and all other terms and conditions met, immediately prior to the specified effective date of such Change in Control, provided that the Participant's relationship as a Service Provider has not terminated prior to such date.

3. The Plan is hereby amended by adding the following new subsection to the section of the Plan titled "Amendment and Termination of the Plan":

Section 409A of the Code. To the extent an Award is subject to Section 409A of the Code, the impact of this Amendment Number 1 with respect to such Award will not change the time or manner of payment of such Award.

4. The Plan is hereby amended by adding the following new section to the end thereof:

Section 409A of the Code. Awards are intended to be exempt from or comply with Section 409A of the Code (as amplified by any Internal Revenue Service or U.S. Treasury Department guidance), and shall be construed and interpreted in accordance with such intent. The Company, in the exercise of its sole discretion and without the consent of the Participant, may amend or modify the Plan or any Award Agreement in any manner in order to meet the requirements of Section 409A of the Code as amplified by any Internal Revenue Service or U.S. Treasury Department guidance. The Company makes no representation that Awards will comply with Section 409A of the Code and makes no undertaking to prevent Section 409A of the Code from applying to Awards or to mitigate its effects on any deferrals or payments in respect of any Award.

IN WITNESS OF THE FOREGOING, the undersigned Peter S. Roddy, Vice President and Chief Financial Officer, certifies that the foregoing Amendment Number 1 to the 2008 Equity Incentive Plan was duly adopted by the Board on June 14, 2013:

/s/ PETER S. RODDY

Peter S. Roddy, Vice President and Chief Financial Officer

AMENDMENT NO. 2 TO EMPLOYMENT AGREEMENT

This Amendment No. 2 to Employment Agreement (the “Amendment”) is made by and between Remi Barbier (the “Executive”) and Pain Therapeutics, Inc., a Delaware corporation (the “Company” and together with the Executive hereinafter collectively referred to as the “Parties”), on June 20, 2013.

WITNESSETH:

WHEREAS, the Parties previously entered into an employment agreement, dated as of July 1, 1998 (as subsequently amended pursuant to that certain Amendment to Employment Agreement, dated as of December 17, 2008, the “Employment Agreement”); and

WHEREAS, the Company and Executive wish to amend the Employment Agreement, as set forth below.

NOW, THEREFORE, for good and valuable consideration, Executive and the Company agree that the Employment Agreement is hereby amended as follows:

1. The following language is inserted immediately following Section 3(g) of the Employment Agreement and shall constitute Sections 3(h) and 3(i) of the Employment Agreement:

> “(h) Non-Assumption of Agreement. In the event of the Change in Control (as defined below) in which this Agreement and the obligations of the Company are not assumed by the successor entity either by operation of law or by assignment, Executive’s employment with the Company shall be deemed to be terminated for Other than Cause, and Executive shall be entitled to the benefits sect forth in Section 3(d) above. For purposes of this Agreement, “Change in Control” shall have the meaning set forth in the Company’s 2008 Equity Incentive Plan, as may be amended from time to time, or the same or similar term set forth in any successor plan thereto.
>
> (i) Clawback. Executive’s incentive-based compensation that is earned based on financial performance or financial metrics of the Company shall not be subject to clawback or other recovery from the Executive in the event of a restatement of the Company’s financial statements upon which such compensation is based, except to the extent required by applicable law or regulation (including pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any regulations that have or may be promulgated thereunder) or pursuant to the listing rules or regulations of any securities exchanges or listing services on which the Company’s securities are traded or quoted.”

These provisions are not intended to increase or to decrease any severance or other compensation arrangements currently in place between Executive and the Company.

(Signature page follows)

IN WITNESS WHEREOF, each of the Parties has executed this Amendment, in the case of the Company by its duly authorized officer, as of the day and year set forth above.

Pain Therapeutics, Inc.		**Executive**
By:	/s/ Peter S. Roddy	By: /s/ Remi Barbier
Name:	Peter S. Roddy	Remi Barbier
Title:	Vice President & CFO	

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

I, Remi Barbier, certify that:

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

/s/ REMI BARBIER

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

Date: August 1, 2013

Exhibit 31.2

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

I, Peter S. Roddy, certify that:

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

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

Date: August 1, 2013

Exhibit 32.1

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

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

1. The Company's Periodic Report on Form 10-Q for the period ended June 30, 2013, and to which this certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 1, 2013

/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