#### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### **Form 10-Q**

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the Quarterly Period Ended June 30, 2010

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

(State or other jurisdiction of incorporation or organization) 91-1911336 (I.R.S. Employer

Identification Number)

2211 Bridgepointe Parkway Suite 500

San Mateo, CA 94404

(650) 624-8200

(Address, including zip code, of registrant's principal executive offices and telephone number, including area code)

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

Indicate by check mark whether the registrant 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 [X]

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 [X]

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

42,695,625 Shares Outstanding as of July 9, 2010

#### PAIN THERAPEUTICS, INC.

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#### PART I. FINANCIAL INFORMATION

#### Item 1. Financial Statements

#### PAIN THERAPEUTICS, INC.

#### Condensed Balance Sheets (Unaudited) (in thousands)

	June 30, 2010	D	ecember 31, 2009 <sup>(1)</sup>
Current assets			
Cash and cash equivalents	\$ 66,773	\$	35,794
Marketable securities	109,469		139,965
Other current assets	 5,018		2,712
Total current assets	181,260		178,471
Non-current assets			
Property and equipment, net	398		517
Other assets	 426		3,017
Total assets	\$ 182,084	\$	182,005
Current liabilities			
Accounts payable	\$ 625	\$	1,317
Accrued development expense	1,108		1,221
Deferred program fee revenue - current portion	10,897		14,348
Accrued compensation and benefits	1,004		1,138
Other accrued liabilities	126		487
Total current liabilities	13,760		18,511
Non-current liabilities			
Deferred program fee revenue - non-current portion	57,208		53,805
Other liabilities	430		1,437
Total liabilities	 71,398		73,753
Commitments and contingencies			
Stockholders' equity			
Preferred stock	-		-
Common stock	43		42
Additional paid-in-capital	229,563		225,432
Accumulated other comprehensive income	473		347
Accumulated deficit	 (119,393)		(117,569)
Total stockholders' equity	 110,686		108,252
Total liabilities and stockholders' equity	\$ 182,084	\$	182,005

(1) Derived from the Company's audited financial statements as of December 31, 2009, 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,				Six Mo Ju	nths Er une 30,	nded	
		2010		2009	2010		_	2009
Revenue								
Program fee revenue	\$	2,524	\$	3,587	:	\$ 5,048		\$ 7,174
Collaboration revenue		132		2,649		857		5,897
Total revenue		2,656		6,236		5,905		13,071
Operating expenses								
Research and development		2,248		5,090		5,376		12,726
General and administrative		1,663		1,414		3,148		3,145
Total operating expenses		3,911		6,504		8,524		15,871
Operating loss		(1,255)		(268)		(2,619)		(2,800)
Interest income		451		233		795	_	620
Loss before benefit from income taxes		(804)		(35)		(1,824)		(2,180)
Benefit from income taxes		-		(1)		-	_	(322)
Net loss	\$	(804)	\$	(34)	1	\$ (1,824)	_	\$ (1,858)
Net loss per share								
Basic and diluted	\$	(0.02)	\$	(0.00)	1	\$ (0.04)	_	\$ (0.04)
Weighted-average shares used in computing net loss per share							_	
Basic and diluted		42,663	_	42,137	_	42,537	=	42,114

See accompanying notes to condensed financial statements.

#### PAIN THERAPEUTICS, INC.

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

	Six Months E	nded June 30,
	2010	2009
Cash flows used in operating activities:		
Net loss	\$ (1,824)	\$ (1,858)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock based compensation	2,767	3,194
Non-cash tax benefit from carry-back	-	(322)
Depreciation and amortization	119	133
Non-cash net interest income	774	528
Deferred program fee revenue	(5,047)	(7,174)
Changes in operating assets and liabilities:		
Other current assets	2,694	165
Other assets	1,583	-
Accounts payable	(692)	(1,241)
Accrued development expense	(113)	(538)
Other accrued liabilities	(361)	(184)
Accrued compensation and benefits	(134)	(82)
Other liabilities		(16)
Net cash used in operating activities	(234)	(7,395)
Cash flows provided by (used in) investing activities:		
Purchases of marketable securities	(31,854)	(24,648)
Proceeds from sales of marketable securities	-	2,464
Maturities of marketable securities	61,702	21,350
Net cash provided by (used in) investing activities	29,848	(834)
Cash flows provided by financing activities:		
Proceeds from issuance of common stock	1,365	271
Net cash provided by financing activities	1,365	271
Net increase (decrease) in cash and cash equivalents	30,979	(7,958)
Cash and cash equivalents at beginning of the period	35,794	153,158
Cash and cash equivalents at end of the period	\$ 66,773	\$ 145,200
Supplemental cash flow information:		
Cash paid for income taxes	<u>\$ -</u>	\$ 334

See accompanying notes to condensed financial statements.

#### PAIN THERAPEUTICS, INC.

#### Notes to Condensed Financial Statements (Unaudited)

#### Note 1. General

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. Our lead drug candidate is called REMOXY<sup>®</sup>. We are developing REMOXY and other abuse-resistant painkillers pursuant to our strategic alliance with King Pharmaceuticals, Inc, or King.

We are also developing novel drug candidates in the area of hematology and oncology. We have in pre-clinical development a drug candidate to treat hemophilia, a genetic disorder in which patients are unable to stop bleeding. We have in clinical development a monoclonal antibody to treat metastatic melanoma, a deadly form of skin cancer.

Although we were profitable in the past based on payments from King and interest income, in the course of our development activities, we have sustained significant cumulative operating losses. As we continue to incur losses, we may need additional financing and 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 second quarter and first half of 2010 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2010.

We have evaluated subsequent events through the date of the filing this Form 10-Q with the Securities and Exchange Commission. 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**

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

We and King have a strategic alliance to develop and commercialize REMOXY and up to three other opioid painkillers designed to reduce potential risks of unintended use. In connection with the strategic alliance, we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from upfront payments from King, including the \$150.0 million King paid us at the beginning of the strategic alliance and the \$5.0 million we expect King will pay us in July 2010 in connection with an amendment to our strategic alliance. These payments are recognized from receipt ratably over our estimate of the development period for the fourth of four drug candidates expected to be developed under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through September 2016. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. In the first quarter of 2010, we determined that the development period should be extended from the third quarter of 2014. This change in estimate did not and will not affect either the cash provided by or used in our operations. Deferred program fee revenue represents the amount of the upfront payments that have not yet been recognized as revenue.

Collaboration revenues from reimbursement of development expenses are generally recognized after expenses have been incurred and when King has completed its review of the expenses invoiced to them.

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

#### 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 two financial institutions 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 sales of our marketable securities in interest income in the accompanying statement of operations on a specific identification basis. Our marketable securities are maintained at two financial institutions 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 the duration of time and the severity to which the fair value has been less than our amortized cost, any adverse changes in the investees' financial condition and our intent to sell or whether it is more likely than not that we would 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 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.

#### **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 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.

#### **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, restricted stock units and warrants.

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 En June 30,			ded	
		2010		2009		2010		2009
Numerators:								
Net loss	\$	(804)	\$	(34)	\$	(1,824)	\$	(1,858)
Denominators:								
Weighted average shares used to compute basic and dilutive net loss per share		42,663		42,137	_	42,537	_	42,114
Net loss per share:								
Basic and diluted	\$	(0.02)	\$	(0.00)	\$	(0.04)	\$	(0.04)

All options to purchase common shares were excluded from the calculation of diluted loss per share for the three and six months ended June 30, 2010 and 2009 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, 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 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.

#### Note 3. Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash, cash equivalents and available-for-sale securities as of June 30, 2010 and December 31, 2009 (in thousands):

		Cash, Cash Equivalents and Marketable Securities Available for Sale							
	A	Amortized Cost	I	Unrealized Gains	-	nrealized Losses	Estimated Fair Value	Accrued Interest	Total Value
June 30, 2010									
Cash, cash equivalents and money market									
securities	\$	66,766	9	5 3	\$	-	\$ 66,769	\$ 4	\$ 66,773
U.S. government obligations		-		-		-	-	-	-
Corporate securities		97,889		492		(22)	98,359	989	99,348
Certificates of deposit		10,002		-		-	10,002	119	10,121
	\$	174,657	S	\$ 495	\$	(22)	\$ 175,130	\$ 1,112	\$ 176,242
Reported as:									
Cash, cash equivalents and money market									
securities	\$	66,766	9	5 3	\$	-	\$ 66,769	\$ 4	\$ 66,773
Short term investments		107,891		492		(22)	108,361	1,108	109,469
	\$	174,657	5	<b>4</b> 95	\$	(22)	\$ 175,130	\$ 1,112	\$ 176,242
Maturities:									
Matures in one year or less	\$	139,548	9	63	\$	(6)	\$ 139,605	698	\$ 140,303
Matures one to three years		35,109		432		(16)	35,525	414	35,939
	\$	174,657	5	<b>4</b> 95	\$	(22)	\$ 175,130	\$ 1,112	\$ 176,242
December 31, 2009									
Cash, cash equivalents and money market									
securities	\$	35,790	9	5 3	\$	-	\$ 35,793	<b>\$</b> 1	\$ 35,794
Certificates of deposit		30,003		-		-	30,003	159	30,162
Corporate securities		108,452		355		(11)	108,796	1,007	109,803
	\$	174,245	9	358	\$	(11)	\$ 174,592	\$ 1,167	\$ 175,759
Reported as:									
Cash, cash equivalents and money market									
securities	\$	35,790	S	5 3	\$	-	\$ 35,793	\$ 1	\$ 35,794
Short term investments		138,455		355		(11)	138,799	1,166	139,965
	\$	174,245	5		\$		\$ 174,592	\$ 1,167	\$ 175,759
Maturities:			_						
Matures in one year or less	\$	114,377	6	5 116	\$	-	\$ 114,493	\$ 385	\$ 114,878
Matures one to three years		59,868		242		(11)	60,099	782	60,881
	\$	174,245	2	358	\$	(11)	\$ 174,592	\$ 1,167	\$ 175,759
			_			、 /			

Our realized gains or losses during the second quarter of 2010 and 2009 were immaterial. To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

The following table presents our assets measured at fair value on a recurring basis at June 30, 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash, cash equivalents and money market				
securities	\$ 66,773	\$ -	\$ -	\$ 66,773
U.S. government obligations	-	-	-	-
Corporate securities	-	99,348	-	99,348
Certificates of deposit	10,121	-	-	10,121
	\$ 76,894	\$ 99,348	\$ -	\$ 176,242

#### Note 4. Comprehensive Loss

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

	Three Months Ended June 30,				Six Months End			led June 30,	
	2010 2009		2010		2009				
Net loss	\$	(804)	\$	(34)	\$	(1,824)	\$	(1,858)	
Other comprehensive income (loss)		(191)		(96)		126		(226)	
	\$	(995)	\$	(130)	\$	(1,698)	\$	(2,084)	

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

#### Note 5. Stock-Based Compensation

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

	Three Months	s Ended June 30,	Six Months En	ded June 30,
	2010	2009	2010	2009
Research and development	\$716	\$901	\$1,559	\$1,991
General and administrative	633	674	1,208	1,203
	\$1,349	\$1,575	\$2,767	\$3,194

#### Note 6. Income Taxes

We did not provide for income taxes in 2010 because we have projected a tax loss for the full year 2010. Interest expense and penalties related to unrecognized tax benefits were immaterial for 2010 and 2009. We have been selected for an audit of our 2008 federal tax return. We are not aware of any material changes in our tax positions as a result of this audit.

#### Note 7. 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, however these contracts are cancelable on thirty days notice and our obligations under these contracts are largely based on services performed.

We currently lease approximately 41,200 square feet of office space pursuant to non-cancelable operating leases that will expire in 2010 and 2012. Future minimum lease payments for our leases are as follows for the years ended December 31, (in thousands):

	2010	2011	2012	Total
Future minimum lease payments	\$713	\$570	\$339	\$1,622

#### Note 8. Recently Issued Accounting Pronouncements

We reviewed recently issued accounting pronouncements and 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 concerning:

- timing of resubmission by King Pharmaceuticals, Inc., or King, of the New Drug Application, or NDA, for REMOXY<sup>®</sup>;
- potential submission of additional non-clinical data with respect to the REMOXY NDA and that no new clinical efficacy trials will be required by the FDA in connection with the REMOXY NDA;
- collaboration, milestone and royalty revenue that may be received from King and other payments we may receive from our strategic alliances;
- the duration of the development period for all four expected drug candidates under our collaboration with King;
- potential sources of clinical and commercial supply of REMOXY and its components;
- expansion of our product line, including the formulation of additional dosage forms of REMOXY;
- expected amounts of, or fluctuations in, collaboration revenue and payments;
- future operating losses;
- the potential benefits of our drug candidates;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital;
- potential competitors or competitive products;

- future market acceptance of our drug candidates;
- expenses and operating results;
- trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- anticipated hiring and development of our internal systems and infrastructure;
- potential non-realization of deferred tax assets; and
- the sufficiency of our current resources to fund our operations over the next twelve months.

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

- difficulties or delays in regulatory approval, production, commercialization, development, testing and clinical trials (including patient enrollment) of our drug candidates;
- the successful development of drug candidates pursuant to our collaboration agreements, including our collaboration agreement with King, and the continuation of such agreements;
- unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that results of clinical trials may not indicate that our drug candidates are safe and effective) or market acceptance of such products, if approved;
- the uncertainty of patent protection for our intellectual property or trade secrets;
- potential infringement of the intellectual property rights or trade secrets of third parties;
- pursuing in-license and acquisition opportunities;
- hiring and retaining personnel; and
- our financial position and our ability to obtain additional financing if necessary.

In addition, such statements are subject to the risks and uncertainties discussed in the "Risk Factors" section and elsewhere in this document.

When used in this Quarterly Report, unless otherwise indicated, "Pain Therapeutics," "the Company," "we," "our" and "us" refers to Pain Therapeutics, Inc.

#### 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 and other abuse-resistant painkillers are being developed pursuant to a strategic alliance we have with King. King is obligated to fund development expenses incurred by us for REMOXY and other abuse-resistant painkillers pursuant to the terms of our strategic alliance. We will receive a \$15.0 million cash milestone payment from King upon regulatory approval of REMOXY in the United States.

In June 2010, we amended our Collaboration Agreement and License Agreement with King. Under this amendment, the royalty rate for products covered by the License Agreement,

including REMOXY, that are sold outside the United States is now 10% on all of King's net sales of such products. The royalty rates for net sales of products in the United States remain unchanged at 20% of U.S. net sales, except as to the first \$1.0 billion in cumulative net sales in the United States, for which the royalty is set at 15%. In addition, King has assumed development efforts for one product candidate under the strategic alliance. We expect King will pay us a non-refundable, one-time, up-front payment of \$5.0 million in July 2010 in connection with the amendment. This payment does not affect the timing or amount of other milestone payments due under in the Collaboration Agreement.

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 is required to support the approval of REMOXY. The FDA has not requested or recommended 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 our strategic alliance with King. King has announced that they continue to expect to resubmit the REMOXY NDA in the fourth quarter of 2010.

We are also developing a pipeline of novel drug candidates in the area of hematology and oncology. We hold all commercial rights to our pipeline of drug candidates in hematology and oncology.

We are developing a novel drug candidate called PTI-188 to treat metastatic melanoma, a deadly form of skin cancer. PTI-188 is a monoclonal antibody linked to a radioisotope, intended to deliver doses of radiation lethal to melanoma tumors without harming normal tissue. In March 2010, we announced data from two open-label, dose-escalating Phase I studies conducted in Israel to assess the safety, pharmacokinetics, dosimetry and anti-tumor activity of PTI-188. The first Phase I study was completed in 2008 and we announced preliminary data from that study in 2009. The second study was completed in early 2010. In both studies, patients were enrolled with confirmed Stage IV or unresectable Stage III melanoma. All patients were treated with a single intravenous dose of PTI-188. Anti-tumor effects were measured at baseline, post-treatment at weeks two and six, and monthly thereafter. Among evaluable patients at the time of our announcement, top-line preliminary results confirm the preliminary safety and biological activity of PTI-188.

We have a gene transfer program, initially developed at Stanford University, aimed at correcting an underlying genetic defect in patients with hemophilia, a genetic disorder in which patients are unable to stop bleeding. During 2009 and 2010, we conducted a variety of pre-clinical studies with this technology.

All of our collaboration, contract and milestone revenues are recognized pursuant to our strategic alliance with King. King has made non-refundable upfront cash payments of \$155.0 million to us, including the \$5.0 million we expect King will pay us in July 2010. King has made milestone payments to us of \$25.0 million related to clinical and regulatory milestones under the strategic alliance. We could also receive from King up to \$125.0 million in additional milestone payments in the course of clinical development of the opioid painkillers under the strategic alliance.

Although we were profitable in the past based on payments received from King and interest income, we have yet to generate any revenues from product sales. Through June 30, 2010, we have recorded an accumulated deficit of approximately \$119.4 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

We expect to continue to use significant cash resources in our operations for the next several years. Our cash requirements for operating activities and capital expenditures may increase substantially in the future as we:

- continue to conduct preclinical 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 the ability to receive regulatory approvals for, and successfully market, our drug candidates. If development efforts result in regulatory approval and successful commercialization of our drug candidates, we will generate revenue from direct sales and, for those of our drugs that are licensed to 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 of our research and development efforts on the research and development of drugs for the treatment of pain, metastatic melanoma and hemophilia. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three Months E	Ended June 30,	Six Months Er	nded June 30,
	2010	2009	2010	2009
Compensation	\$1,384	\$2,324	\$3,097	\$5,500
Contractor fees <sup>(1)</sup>	558	1,752	1,558	4,901
Supplies <sup>(2)</sup>	24	294	49	785
Other common costs <sup>(3)</sup>	282	720	672	1,540
	\$2,248	\$5,090	\$5,376	\$12,726

(1) Contractor fees generally include expenses for preclinical studies and clinical trials.

(2) Supplies generally include costs for formulation and manufacturing activities.

(3) Other common costs generally include the allocation of common costs such as facilities.

Our technology has been applied across certain of our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates may also relate to, and further the development of, our other drug candidates. For example, we expect that results of non-clinical studies, such as pharmacokinetics, toxicology and other studies, regarding certain components of our drug candidates are expected to utilize such components. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing. We are also developing a novel antibody drug candidate to treat metastatic melanoma. Research and development expenses related to the metastatic melanoma technology include approximately \$0.3 million and \$1.7 million in the three and six month ended June 30, 2009, respectively, primarily in contractor fees and compensation. Research and development expenses related to hemophilia and other product candidates include approximately \$0.4 million and \$0.5 million in the three and six month ended June 30, 2010 and \$0.8 million in the three and six month ended June 30, 2010 and \$0.9 million and \$2.6 million in the three and six months ended June 30, 2009, respectively, primarily in contractor fees and compensation.

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

#### **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:

*Expenses for clinical trials.* We incur expenses for clinical trials from the planning phase through patient enrollment to
reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient
enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are
recognized as each patient in the clinical trial completes enrollment. Estimated clinical

trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Information about patient enrollment can become available significantly after we report our expenses for clinical trials, in which case we would change our estimate of the remaining cost of a trial. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

*Stock-based compensation.* We recognize expense in the statement of operations for the fair value of all share-based payments to employees and directors, including grants of employee stock options 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 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, collaboration revenue and milestone revenue in connection with our strategic alliance with King. Program fee revenue is derived from upfront payments from King, including the \$150.0 million King paid us at the beginning of the strategic alliance and the \$5.0 million we expect King will pay us in July 2010 in connection with an amendment to our strategic alliance. These payments are recognized from receipt ratably over our estimate of the development period for the fourth of four drug candidates expected to be developed under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through September 2016. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. In the first quarter of 2010 we determined that our estimate of the development period should be extended from the third quarter of 2014. Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with King are generally recognized when King has completed its review of the expenses invoiced to them. King 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 from King as revenue when we achieve the underlying

developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King.

• *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, 2010 and 2009

#### *Revenue – Program fee revenue*

Program fee revenues decreased to \$2.5 million from \$3.6 million and to \$5.0 million from \$7.2 million in the three and six months ended June 30, 2010 and 2009, respectively because in the first quarter of 2010 we extended our estimate of the development period over which we recognize the program fee revenue. We expect to recognize the rest of the upfront fee ratably over our estimate of the remainder of the development period under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through September 2016.

#### Revenue - Collaboration revenue

Collaboration revenues decreased to \$0.1 million from \$2.6 million and to \$0.9 million from \$5.9 million in the three and six months ended June 30, 2010 and 2009, respectively. These revenues related to reimbursement of our development expenses incurred pursuant to the King strategic alliance. Collaboration revenues were lower in the three- and six-month periods of 2010 as compared to the same periods in 2009 because the reimbursable expenses we incurred pursuant to the strategic alliance with King were lower from period to period.

We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses, as well as the timing of completion of King's review of submitted expenses.

#### 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
- salaries and other personnel-related expenses.

Research and development expense decreased to \$2.2 million from \$5.1 million and to \$5.4 million from \$12.7 million in the three and six months ended June 30, 2010 and 2009, respectively. The decrease was primarily due to decreases in clinical and development activities for REMOXY including the assumption in 2009 by King of primary regulatory responsibility for REMOXY, personnel-related expenses, as well as decreased clinical and preclinical activities in metastatic melanoma, hemophilia and other projects. Research and development expenses for non-cash stock related compensation costs decreased to \$0.7 million from \$0.9 million and to \$1.6 million from \$2.0 million in the three and six months ended June 30, 2010 and 2009, respectively.

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, including current and potential clinical trials for our other abuse-resistant drug candidates, as well as further clinical development of our product candidates in metastatic melanoma and hemophilia. King is obligated to reimburse certain development expenses for our abuse-resistant drug candidates pursuant to our collaboration. 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.

#### General and Administrative Expense

General and administrative expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses increased to \$1.7 million from \$1.4 million in the three months ended June 30, 2010 and 2009, respectively and were \$3.1 million in the six months ended June 30, 2010 and 2009. The change was primarily due to fluctuations in other operating costs. General and administrative expenses for non-cash stock related compensation costs decreased to \$0.6 from \$0.7 in the three months ended June 30, 2010 and 2009, respectively and were \$1.2 million for the six months ended June 30, 2010 and 2009.

We expect general and administrative expenses to increase over the next several years in connection with support of precommercialization and commercialization activities for our drug candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies.

#### Interest and Other Income, Net

Interest and other income, net, increased to \$0.5 from \$0.2 million and to \$0.8 million from \$0.6 million in the three and six months ended June 30, 2010 and 2009, respectively. We expect our interest income to decrease in the future as we use cash to fund our operations.

#### Benefit from Income Taxes

We did not provide for income taxes in 2010 because we have projected a tax loss for the full year 2010. Our benefit from income taxes in 2009 was due to our election to carryback our tax loss for 2009 to prior years.

#### Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under our strategic alliance with King, 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, 2010, cash, cash equivalents and marketable securities were \$176.2 million.

Net cash used in operating activities was \$0.2 million for the six months ended June 30, 2010 compared to net cash used in by operating activities of \$7.4 million for the six months ended June 30, 2009. This change was primarily due to \$3.8 million received from federal tax refunds and decreased research and development activities.

Net cash provided by investing activities was \$29.8 million for the six months ended June 30, 2010 compared to net cash used in investing activities of \$0.9 million for the six months ended June 30, 2009. Investing activities for both periods consisted primarily of the purchase and sale of marketable securities. There were no significant purchases of any property, equipment or leasehold improvements in 2010 and 2009.

Net cash provided by financing activities was \$1.4 million for the six months ended June 30, 2010 and \$0.3 million for the six months ended June 30, 2009. Financing activities in both periods consisted primarily of employee stock option exercises.

In February 2010, we received a federal tax refund of \$2.2 million from taxes paid for 2006. We also filed our tax return for 2009 and elected to carryback part of our federal tax loss for 2009 against all federal taxes paid for 2008 and a portion of federal taxes paid for 2006. In April 2010, we received an additional federal tax refund of \$1.6 million from our election to carryback the 2009 tax loss.

Our election to carryback our 2009 tax loss to 2008 and 2006 eliminated the use of federal tax credits to reduce our federal tax liability for both 2008 and 2006. As a result, our deferred tax liabilities decreased by \$1.0 million and our current assets related to our deferred tax assets decreased by \$1.0 million. We have been selected for an audit of our 2008 federal tax return. We are not aware of any material changes in our tax positions as a result of this audit.

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. There is a high degree of uncertainty regarding the timing of future cash outflows associated with our liabilities related to uncertain tax positions. Our liability at June 30, 2010 related to our uncertain tax positions is immaterial.

We currently lease approximately 41,200 square feet of general office space pursuant to non-cancelable operating leases that will expire in 2010 and 2012. Future minimum lease payments for our leases are as follows for the years ended December 31, (in thousands):

	2010	2011	2012	Total
Future minimum lease payments	\$713	\$570	\$339	\$1,622

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, 2010. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. Pursuant to our strategic alliance with King, King is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation, except for royalty payments related to sales in Australia and New Zealand.

We have an accumulated deficit of \$119.4 million at June 30, 2010. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next 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, 2010, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

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

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at June 30, 2010 by approximately \$0.5 million. 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 have no holdings of derivative financial or commodity instruments.

As of June 30, 2010, our investments consisted of investments in corporate and government notes and obligations, certificates of deposits or in 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. 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 generally consider our inputs to be Level 2 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.

#### **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

None.

#### Item 1A. Risk Factors

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

#### **Clinical and Regulatory Risks**

### If we 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. The FDA has not requested or recommended additional clinical efficacy studies prior to approval. In March 2009, King assumed sole responsibility for the regulatory approval of REMOXY. In July 2009, King met with the FDA to discuss REMOXY. King has announced that they continue to expect to resubmit the REMOXY NDA in the fourth quarter of 2010. While King has announced that it believes that the outcome of July 2009 meeting provided it with a path for resubmission of the REMOXY NDA, and that the FDA is not requiring additional clinical trials to support approval, there can be no assurance that the FDA will approve the NDA for REMOXY (even with the additional data proposed to be provided by King) 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.

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 may be made 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 trials. 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.

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

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

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

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

Even if 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 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 also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our 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, in 2009, the FDA met with the sponsors of opioid drug products in order to discuss Risk Evaluation and Mitigation Strategies, or REMS, for opioid drugs. These discussions may result in changes to or additional government regulations with respect to our opioid drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our drugs and our business could suffer.

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

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

We rely on King to devote time and resources to the development, manufacturing and commercialization of REMOXY and other drug candidates under our strategic alliance. King may commercialize, develop or acquire drugs or drug candidates that may compete directly or compete for resources with our drug candidates that are subject to this strategic alliance. For instance, King is developing Oxycodone NT (an extended release abuse resistant formulation of oxycodone that would compete with REMOXY) and markets and sells 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 King's other drugs or drug candidates will not become competitive with our drug candidates being developed under the collaboration with King. If King limits its time and resources devoted to the strategic alliance or fails to fund the continued development of REMOXY or other opioid drug candidates as required by our agreement with King, or otherwise fails to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected. In addition, if King fails to perform as required under our collaboration agreement, their failure may jeopardize our rights under our license with Durect.

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 our strategic alliance with King 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 our existing strategic alliance with King or if King doesn't provide the required funding under the strategic alliance 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 our strategic alliance with King 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 the success of our drug candidates, including:

the development of parallel products by our collaborators or by a competitor;

- arrangements with collaborative partners that limit or preclude us from developing certain products or technologies;
- premature termination of a collaborative or license agreement; or
- failure by a collaborative partner to provide required funding or to devote sufficient resources to the development of or legal defense of our potential products.

#### **Risks Relating to Commercialization**

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

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

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs, 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 King, 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 King is not successful in developing and commercializing REMOXY and in commercializing other opioid drugs under our strategic alliance with King, our revenues and our business will suffer.

Our ability to earn royalties from sales of REMOXY depends on King's abilities to obtain regulatory approval for and commercialize REMOXY. Additionally, our ability to earn royalties from sales of REMOXY and other drugs subject to our strategic alliance with King will depend on King's abilities to maintain regulatory approval and achieve market acceptance of such drugs once commercialized. King may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of REMOXY and other drugs developed under our strategic alliance. King may not proceed with

the commercialization of REMOXY and other drugs developed under our strategic alliance with the same degree of urgency as we would because of other priorities they face. If King is not successful in developing or commercializing REMOXY for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if King fails to perform as we expect, our potential for revenue from drugs developed in connection with our strategic alliance with King, if any, could be dramatically reduced and our business would suffer.

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

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

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

In addition, due to the nature of the market for our drug candidates, it may be necessary for us to license all or substantially all of our drug candidates not covered by our strategic alliance with King to a single collaborator, thereby eliminating our opportunity to commercialize these other products independently. If we enter into any such new collaborative arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

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

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

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

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

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

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

#### Government agencies may establish and promulgate usage guidelines that could limit the use of our drug candidates.

Government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our drug candidates. These guidelines could address such matters as usage and dose, among other factors. Application of such guidelines could limit the 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, pharmaceutical ingredients, antibodies, gene integration and more generally, in oncology, neurology, radiopharmaceutical technologies and gene therapy 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 18 months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property 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 with the U.S. Patent and Trademark Office to further protect our technologies. If these patent applications do not result in issued patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

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

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

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

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

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

#### Risks Relating to our Business and Strategy

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

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

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

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

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in
  achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical
  issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of
  pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- 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, such as metastatic melanoma and hemophilia. We have no history of developing metastatic melanoma or hemophilia drug candidates or manufacturing

radiopharmaceuticals. We do not know whether any of our planned clinical trials in metastatic melanoma or hemophilia will result in marketable products. We do not anticipate that 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.

#### **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 King 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 King 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 King 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 King 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 King are unsuccessful in our formulation or scale-up activities with REMOXY and these other drug candidates, our future revenue from milestones and royalties under our strategic alliance with King may be less than expected and our operations may suffer.

# We and King 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 King 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 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 King receives marketing approval for and commercially launches REMOXY or other candidates under our strategic alliance with King, 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 King 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 from King and interest income, we have yet to generate any revenues from product sales. We had an accumulated deficit of \$119.4 million as of June 30, 2010. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

We have funded all of our operations and capital expenditures with the proceeds from our public and private stock offerings, payments received under our strategic alliance with King, and interest earned on our investments. We expect that our current cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months. However, we may elect to raise additional funds within such twelve-month period or need to raise additional funds thereafter and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional securities to raise funds, our existing stockholders' ownership percentage would be reduced and new investors may demand rights, preferences or privileges senior to those of existing stockholders. If we raise additional capital through debt financing, if available, such financings may involve covenants that restrict our business activities. If we raise additional capital through strategic alliance and license arrangements such as our strategic alliance with King, we may have to trade our rights to our technology, intellectual property or drug candidates to others in such arrangements on terms that may not be favorable to us.

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

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

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

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

- results of or delays in efforts to seek regulatory approval for REMOXY, and in preclinical studies and clinical trials for our other drug candidates;
- the success of our collaboration agreements;
- publicity regarding actual or potential medical results relating to products under development by us or others;

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, SEC regulations and the rules of The NASDAQ Stock Market LLC, create uncertainty for public companies. If we were unable to continue to comply with these requirements, we could be delisted from trading on the NASDAQ Global Market, or Nasdaq, and thereafter trading in our common stock, if any, may be conducted through the over-the-counter or other market. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

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

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

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

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

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware

corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203.

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

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

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

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

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. This concentration of ownership may delay or prevent a change in control of the Company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

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

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

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and amounts of collaboration revenue recognized from King, the timing and enrollment rates of clinical trials for our drug candidates, our need for clinical supplies and the valuation of stock-based compensation. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our clinical, financial or operating results may not meet the expectations of securities analysts and investors that could result in a decline in the price of our stock.

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

# Item 5. Other Information

None.

# Item 6. Exhibits

The following exhibits have been filed with this report:

Exhibit	
Number	Description of Document
3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2 (2)	Amended and Restated Bylaws.
$(11)^{(1)}$	Specimen Common Stock Cortificate

- 4.1 (1) Specimen Common Stock Certificate.
- 4.2 (3) Preferred Stock Rights Agreement, dated as of April 28, 2005 between Registrant and Mellon Investor Services LLC, including the Certificate of Designation, the form of Rights Certificate and Summary of Rights attached thereto as Exhibits A, B and C, respectively.
- 10.1 2000 Employee Stock Purchase Plan, as amended and restated
- 10.2 † Letter Agreement dated June 24, 2010 with Amendments to the License and Collaboration Agreements between the Registrant and King Pharmaceuticals, Inc.
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended June 30, 2005.
- (2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended March 31, 2005.
- (3) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
- <sup>†</sup> Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this filing and have been filed separately with the Securities and Exchange Commission.

# 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: July 29, 2010

# EXHIBIT INDEX

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#### PAIN THERAPEUTICS, INC.

#### 2000 EMPLOYEE STOCK PURCHASE PLAN (as amended and restated)

<u>Purpose</u>. The purpose of the Plan is to provide employees of the Company and its Designated Subsidiaries with an opportunity to purchase Common Stock through accumulated payroll deductions. This Plan includes two components: a Code Section 423 Plan Component and a Non-423 Plan Component. The Company's intention is to have the Code Section 423 Plan Component qualify as an "employee stock purchase plan" under Section 423 of the Code, (although the Company makes no undertaking or representation to maintain such qualification). The provisions of the Code Section 423 Plan Component, accordingly, will be construed so as to extend and limit participation in a uniform and nondiscriminatory basis consistent with the requirements of Section 423 of the Code. In addition, this Plan authorizes the grant of options under the Non-423 Plan Component that do not qualify under Section 423 of the Code, pursuant to rules, procedures or sub-plans adopted by the Administrator that are designed to achieve tax, securities laws or other objectives for Eligible Employees and/or the Company. Except as otherwise indicated, the Non-423 Plan Component will operate and be administered in the same manner as the Code Section 423 Plan Component.

#### Definitions.

"Administrator" means the Board or any Committee designated by the Board to administer the Plan pursuant to Section 14.

"<u>Applicable Laws</u>" means the requirements relating to the administration of equity-based awards under U.S. state corporate laws, U.S. federal and state securities laws, the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any foreign country or jurisdiction where options are, or will be, granted under the Plan.

"Board" means the Board of Directors of the Company.

"Change in Control" means the occurrence of any of the following events:

Change in Ownership of the Company. A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; or

Change in Effective Control of the Company. If the Company has a class of securities registered pursuant to Section 12 of the Exchange Act, a change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any 12 month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this clause (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

Change in Ownership of a Substantial Portion of the Company's Assets. A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the 12 month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions. For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this Section 2(d), persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

"<u>Code</u>" means the Internal Revenue Code of 1986, as amended. Reference to a specific section of the Code or Treasury Regulation thereunder will include such section or regulation, any valid regulation or other official applicable guidance promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing or superseding such section or regulation.

"<u>Code Section 423 Plan Component</u>" means the component of this Plan that is intended to meet the requirements set forth in Section 423(b) of the Code, as amended. The provisions of the Code Section 423 Plan Component shall be construed, administered and enforced in accordance with Section 423(b).

"Committee" means a committee of the Board appointed in accordance with Section 14 hereof.

"Common Stock" means the common stock of the Company.

"Company" means Pain Therapeutics, Inc., a Delaware corporation, or any successor thereto.

"<u>Compensation</u>" means shall mean all base straight time gross earnings but exclusive of payments for commissions, overtime, shift premium, incentive compensation, incentive payments, bonuses and other compensation.

"<u>Designated Subsidiary</u>" means any Subsidiary that has been designated by the Administrator from time to time in its sole discretion as eligible to participate in the Plan. The Administrator will determine whether employees of any Designated Subsidiary shall participate in the Code Section 423 Plan Component or the Non-423 Plan Component.

#### "Director" means a member of the Board.

"Eligible Employee" means any individual who is a common law employee of the Company or a Designated Subsidiary and is customarily employed for at least twenty (20) hours per week and more than five (5) months in any calendar year by the Employer, other than an employee of a Designated Subsidiary under the Non-423 Plan Component, who, as of the Enrollment Date, resides in a country that has been excluded from participation in the Plan or who, as of the Enrollment Date, is otherwise determined ineligible for participation in the Non-423 Plan Component, at the discretion of the Administrator. For purposes of the Plan, the employment relationship will be treated as continuing intact while the individual is on sick leave or other leave of absence that the Employer approves. Where the period of leave exceeds three (3) months and the individual's right to reemployment is not guaranteed either by statute or by contract, the employment relationship will be deemed to have terminated three (3) months and one (1) day following the commencement of such leave. The Administrator, in its discretion, from time to time may, prior to an Enrollment Date for all options to be granted on such Enrollment Date, determine (on a uniform and nondiscriminatory basis for employees who may participate in the Code Section 423 Plan Component) that the definition of Eligible Employee will or will not include an individual if he or she: (i) customarily works not more than twenty (20) hours per week (or such lesser period of time as may be determined by the Administrator in its discretion). Notwithstanding the foregoing, for options granted under the Non-423 Plan Component, Eligible Employee shall also mean any other employee of a Designated Subsidiary to the extent that local law requires participation in the Plan to be extended to such employee, as determined by the Administrator. "<u>Employer</u>" means the employer of the applicable Eligible Employee(s).

"Enrollment Date" means the first Trading Day of each Offering Period.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, including the rules and regulations promulgated thereunder.

"Exercise Date" means the last Trading Day of each Purchase Period.

"Fair Market Value" means, as of any date and unless the Administrator determines otherwise, the value of Common Stock determined as follows:

If the Common Stock is listed on any established stock exchange or a national market system, including without limitation the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market of The Nasdaq Stock Market, its Fair Market Value will be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the date of determination (or on the last preceding Trading Day) if the date of determination is not a Trading Day), as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

If the Common Stock is regularly quoted by a recognized securities dealer but selling prices are not reported, its Fair Market Value will be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or on the last preceding Trading Day if the date of determination is not a Trading Day), as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

In the absence of an established market for the Common Stock, the Fair Market Value thereof will be determined in good faith by the Administrator.

"New Exercise Date" means a new Exercise Date if the Administrator shortens any Offering Period then in progress.

"<u>Non-423 Plan Component</u>" means a component of this Plan that is not intended to meet the requirements set forth in Section 423(b) of the Code, as amended.

"<u>Offering Periods</u>" means the periods of approximately twenty-four (24) months during which an option granted pursuant to the Plan may be exercised, commencing on the first Trading Day on or after May 1<sup>st</sup> and November 1<sup>st</sup> of each year and terminating on the first Trading Day on or after the May 1<sup>st</sup> and November 1<sup>st</sup> Offering Period commencement date approximately twenty-four (24) months later. The duration and timing of Offering Periods may be changed pursuant to Sections 4 and 20.

"Parent" means a "parent corporation," whether now or hereafter existing, as defined in Section 424(e) of the Code.

"Participant" means an Eligible Employee that participates in the Plan.

"Plan" means this Pain Therapeutics, Inc. 2000 Employee Stock Purchase Plan, as amended and restated, which includes a Code Section 423 Plan Component and a Non-423 Plan Component.

"<u>Purchase Period</u>" means the approximately six (6) month period commencing after one Exercise Date and ending with the next Exercise Date, except that the first Purchase Period of any Offering Period will commence on the Enrollment Date and end with the next Exercise Date.

"<u>Purchase Price</u>" means an amount equal to eighty-five percent (85%) of the Fair Market Value of a share of Common Stock on the Enrollment Date or on the Exercise Date, whichever is lower; provided however, that the Purchase Price may be determined for subsequent Offering Periods by the Administrator subject to compliance with Section 423 of the Code (or any successor rule or provision or any other applicable law, regulation or stock exchange rule) or pursuant to Section 20. "Subsidiary" means a "subsidiary corporation," whether now or hereafter existing, as defined in Section 424(f) of the Code.

"Trading Day" means a day on which the national stock exchange upon which the Common Stock is listed is open for trading.

#### Eligibility.

Offering Periods. Any Eligible Employee on a given Enrollment Date will be eligible to participate in the Plan, subject to the requirements of Section 5.

Limitations. Any provisions of the Plan to the contrary notwithstanding, no Eligible Employee will be granted an option under the Plan (i) to the extent that, immediately after the grant, such Eligible Employee (or any other person whose stock would be attributed to such Eligible Employee pursuant to Section 424(d) of the Code) would own capital stock of the Company or any Parent or Subsidiary of the Company and/or hold outstanding options to purchase such stock possessing five percent (5%) or more of the total combined voting power or value of all classes of the capital stock of the Company or of any Parent or Subsidiary of the Company, or (ii) to the extent that his or her rights to purchase stock under all employee stock purchase plans (as defined in Section 423 of the Code) of the Company or any Parent or Subsidiary of the Company or any Parent or Subsidiary of the Fair Market Value of the stock at the time such option is granted) for each calendar year in which such option is outstanding at any time, as determined in accordance with Section 423 of the Code and the regulations thereunder.

<u>Offering Periods</u>. The Plan will be implemented by consecutive, overlapping Offering Periods with a new Offering Period commencing on the first Trading Day on or after May 1<sup>st</sup> and November 1<sup>st</sup> each year, or on such other date as the Administrator will determine. The Administrator will have the power to change the duration of Offering Periods (including the commencement dates thereof) with respect to future offerings without stockholder approval if such change is announced prior to the scheduled beginning of the first Offering Period to be affected thereafter.

<u>Participation</u>. An Eligible Employee may participate in the Plan by (i) submitting to the Company's stock administration office (or its designee), on or before a date determined by the Administrator prior to an applicable Enrollment Date, a properly completed subscription agreement authorizing payroll deductions in the form provided by the Administrator for such purpose, or (ii) following an electronic or other enrollment procedure determined by the Administrator.

# Payroll Deductions.

At the time a Participant enrolls in the Plan pursuant to Section 5, he or she will elect to have payroll deductions made on each pay day during the Offering Period in an amount not exceeding fifteen percent (15%) of the Compensation, which he or she receives on each pay day during the Offering Period; provided, however, that should a pay day occur on an Exercise Date, a Participant will have the payroll deductions made on such day applied to his or her account under the subsequent Purchase Period or Offering Period, as the case may be. A Participant's subscription agreement will remain in effect for successive Offering Periods unless terminated as provided in Section 10 hereof.

Payroll deductions for a Participant will commence on the first pay day following the Enrollment Date and will end on the last pay day prior to the Exercise Date of such Offering Period to which such authorization is applicable, unless sooner terminated by the Participant as provided in Section 10 hereof.

All payroll deductions made for a Participant will be credited to his or her account under the Plan and will be withheld in whole percentages only. A Participant may not make any additional payments into such account.

A Participant may discontinue his or her participation in the Plan as provided in Section 0, or may increase or decrease the rate of his or her payroll deductions during the Offering Period by (i) properly completing and submitting to the Company's stock administration office (or its designee), on or before a date determined by the Administrator prior to an applicable Exercise Date, a new subscription agreement authorizing the change in payroll deduction rate in the form provided by the Administrator for such purpose, or (ii) following an electronic or other procedure prescribed by the Administrator; provided, however, that a Participant may only make one payroll deduction change during each month of the Offering Period. If a Participant has not followed such procedures to change the rate of payroll deductions, the rate of his or her payroll deductions will continue at the originally elected rate throughout the Offering Period and future Offering Periods (unless terminated as provided in Section 0). The Administrator may, in its sole discretion, limit the nature and/or number of payroll deduction rate changes that may be made by Participants during any Offering Period, and may establish such other conditions or limitations as it deems appropriate for Plan administration. Any change in payroll deduction rate made pursuant to this Section 0 will be effective as of the first full payroll period following five (5) business days after the date on which the change is made by the Participant (unless the Administrator, in its sole discretion, elects to process a given change in payroll deduction rate more quickly).

Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 3(b), a Participant's payroll deductions may be decreased to zero percent (0%) at any time during a Purchase Period. Subject to Section 423(b)(8) of the Code and Section 3(b) hereof, payroll deductions will recommence at the rate originally elected by the Participant effective as of the beginning of the first Purchase Period scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 10.

Notwithstanding any provisions to the contrary in the Plan, the Administrator may allow Eligible Employees to participate in the Plan via cash contributions instead of payroll deductions if (i) payroll deductions are not permitted under applicable local law, and (ii) the Eligible Employee is participating in the Non-423 Plan Component or the Administrator determines that cash contributions are permissible under Section 423 of the Code.

At the time the option is exercised, in whole or in part, or at the time some or all of the Common Stock issued under the Plan is disposed of, the Participant must make adequate provision for the Company's or Employer's federal, state, or any other tax liability payable to any authority including taxes imposed by jurisdictions outside of the United States, national insurance, social security or other tax withholding obligations, if any, which arise upon the exercise of the option or the disposition of the Common Stock. At any time, the Company or the Employer may, but will not be obligated to, withhold from the Participant's compensation the amount necessary for the Company or the Employer to meet applicable withholding obligations, including any withholding required to make available to the Company or the Employer may, but will not be obligated to sale or early disposition of Common Stock or any other method of withholding the Company or the Employer deems appropriate.

Grant of Option. On the Enrollment Date of each Offering Period, each Eligible Employee participating in such Offering Period will be granted an option to purchase on each Exercise Date during such Offering Period (at the applicable Purchase Price) up to a number of shares of Common Stock determined by dividing such Eligible Employee's payroll deductions accumulated prior to such Exercise Date and retained in the Eligible Employee's account as of the Exercise Date by the applicable Purchase Price; provided that in no event will an Eligible Employee be permitted to purchase during each Purchase Period more than 7,500 shares of the Company's Common Stock (subject to any adjustment pursuant to Section 19), and provided further that such purchase will be subject to the limitations set forth in Sections 3(b) and 13. The Eligible Employee may accept the grant of such option with respect to an Offering Period by electing to participate in the Plan in accordance with the requirements of Section 5. The Administrator may, for future Offering Periods, increase or decrease, in its absolute discretion, the maximum number of shares of Common Stock that an Eligible Employee may purchase during each Purchase Period of an Offering Period. Exercise of the option will occur as provided in Section 8, unless the Participant has withdrawn pursuant to Section 10. The option will expire on the last day of the Offering Period.

#### Exercise of Option.

Unless a Participant withdraws from the Plan as provided in Section 0, his or her option for the purchase of shares of Common Stock will be exercised automatically on the Exercise Date, and the maximum

number of full shares subject to the option will be purchased for such Participant at the applicable Purchase Price with the accumulated payroll deductions from his or her account. No fractional shares of Common Stock will be purchased; any payroll deductions accumulated in a Participant's account, which are not sufficient to purchase a full share will be retained in the Participant's account for the subsequent Purchase Period or Offering Period, subject to earlier withdrawal by the Participant as provided in Section 0. Any other funds left over in a Participant's account after the Exercise Date will be returned to the Participant. During a Participant's lifetime, a Participant's option to purchase shares hereunder is exercisable only by him or her.

If the Administrator determines that, on a given Exercise Date, the number of shares of Common Stock with respect to which options are to be exercised may exceed (i) the number of shares of Common Stock that were available for sale under the Plan on the Enrollment Date of the applicable Offering Period, or (ii) the number of shares of Common Stock available for sale under the Plan on such Exercise Date, the Administrator may in its sole discretion (x) provide that the Company will make a pro rata allocation of the shares of Common Stock available for purchase on such Enrollment Date or Exercise Date, as applicable, in as uniform a manner as will be practicable and as it will determine in its sole discretion to be equitable among all Participants exercising options to purchase Common Stock on such Exercise Date, and continue all Offering Periods then in effect or (y) provide that the Company will make a pro rata allocation of the shares available for purchase on such Enrollment Date or Exercise Date, as applicable for purchase on such Enrollment Date or Exercise Date, as applicable for purchase on such Enrollment Date or Exercise Date, as applicable for purchase on such Enrollment Date or Exercise Date, as applicable for purchase on such Enrollment Date or Exercise Date, as applicable in as uniform a manner as will be practicable and as it will determine in its sole discretion to be equitable among all participants exercising options to purchase Common Stock on such Exercise Date, and terminate any or all Offering Periods then in effect pursuant to Section 20. The Company may make a pro rata allocation of the shares available on the Enrollment Date of any applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional shares for issuance under the Plan by the Company's stockholders subsequent to such Enrollment Date.

Delivery. As soon as reasonably practicable after each Exercise Date on which a purchase of shares of Common Stock occurs, the Company will arrange the delivery to each Participant the shares purchased upon exercise of his or her option in a form determined by the Administrator (in its sole discretion) and pursuant to rules established by the Administrator. The Company may permit or require that shares be deposited directly with a broker designated by the Company or to a designated agent of the Company, and the Company may utilize electronic or automated methods of share transfer. The Company may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. No Participant will have any voting, dividend, or other stockholder rights with respect to shares of Common Stock subject to any option granted under the Plan until such shares have been purchased and delivered to the Participant as provided in this Section 9.

#### Withdrawal.

A Participant may withdraw all but not less than all the payroll deductions credited to his or her account and not yet used to exercise his or her option under the Plan at any time by (i) submitting to the Company's stock administration office (or its designee) a written notice of withdrawal in the form determined by the Administrator for such purpose, or (ii) following an electronic or other withdrawal procedure determined by the Administrator. All of the Participant's payroll deductions credited to his or her account will be paid to such Participant promptly after receipt of notice of withdrawal and such Participant's option for the Offering Period will be automatically terminated, and no further payroll deductions for the purchase of shares will be made for such Offering Period. If a Participant withdraws from an Offering Period, payroll deductions will not resume at the beginning of the succeeding Offering Period, unless the Participant re-enrolls in the Plan in accordance with the provisions of Section 5.

A Participant's withdrawal from an Offering Period will not have any effect upon his or her eligibility to participate in any similar plan that may hereafter be adopted by the Company or in succeeding Offering Periods that commence after the termination of the Offering Period from which the Participant withdraws.

<u>Termination of Employment</u>. Upon a Participant's ceasing to be an Eligible Employee, for any reason, he or she will be deemed to have elected to withdraw from the Plan and the payroll deductions credited to such Participant's account during the Offering Period but not yet used to purchase shares of Common Stock under the Plan will be returned to such Participant or, in the case of his or her death, to the person or persons entitled thereto under Section 15, and such Participant's option will be automatically terminated.

Interest. No interest will accrue on the payroll deductions of a participant in the Plan, except as may be required by applicable law, as determined by the Company, for Participants in the Non-423 Plan Component (or the Code Section 423 Plan Component if permitted under Code Section 423).

<u>Stock</u>.

Subject to adjustment upon changes in capitalization of the Company as provided in Section 19 hereof, the maximum number of shares of Common Stock that will be made available for sale under the Plan will be 500,000 shares of Common Stock.

Until the shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), a Participant will only have the rights of an unsecured creditor with respect to such shares, and no right to vote or receive dividends or any other rights as a stockholder will exist with respect to such shares.

Shares of Common Stock to be delivered to a Participant under the Plan will be registered in the name of the Participant or in the name of the Participant and his or her spouse.

Administration. The Plan will be administered by the Board or a Committee appointed by the Board, which Committee will be constituted to comply with Applicable Laws. The Administrator will have full and exclusive discretionary authority to construe, interpret and apply the terms of the Plan, to determine eligibility and to adjudicate all disputed claims filed under the Plan. Every finding, decision and determination made by the Administrator will, to the full extent permitted by law, be final and binding upon all parties. Notwithstanding any provision to the contrary in this Plan, the Administrator may adopt rules or procedures relating to the operation and administration of the Non-423 Plan Component to accommodate the specific requirements of local laws and procedures for jurisdictions outside of the United States. Without limiting the generality of the foregoing, the Administrator is specifically authorized to adopt rules and procedures regarding eligibility to participate, the definition of Compensation, handling of payroll deductions, making of contributions to the Plan (including, without limitation, in forms other than payroll deductions), establishment of bank or trust accounts to hold payroll deductions, payment of interest, conversion of local currency, obligations to pay payroll tax, determination of beneficiary designation requirements, withholding procedures and handling of stock certificates that vary with local requirements. Further, the Administrator is authorized to adopt sub-plans applicable to particular Designated Subsidiaries or locations under the Non-423 Plan Component. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 13(a) hereof, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan.

#### Designation of Beneficiary.

If permitted by the Administrator, a Participant may file a designation of a beneficiary who is to receive any shares of Common Stock and cash, if any, from the Participant's account under the Plan in the event of such Participant's death subsequent to an Exercise Date on which the option is exercised but prior to delivery to such Participant of such shares and cash. In addition, if permitted by the Administrator, a Participant may file a designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to exercise of the option. If a Participant is married and the designated beneficiary is not the spouse, spousal consent will be required for such designation to be effective.

Such designation of beneficiary may be changed by the Participant at any time by notice in a form determined by the Administrator. In the event of the death of a Participant and in the absence of a beneficiary validly designated under the Plan who is living at the time of such Participant's death, the Company will deliver such shares and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of the Company), the Company, in its discretion, may deliver such shares and/or cash to the spouse or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

All beneficiary designations will be in such form and manner as the Administrator may designate from time to time.

<u>Transferability</u>. Neither payroll deductions credited to a Participant's account nor any rights with regard to the exercise of an option or to receive shares of Common Stock under the Plan may be assigned, transferred, pledged or otherwise disposed of in any way (other than by will, the laws of descent and distribution or as provided in Section 15 hereof) by the Participant. Any such attempt at assignment, transfer, pledge or other disposition will be without effect, except that the Company may treat such act as an election to withdraw funds from an Offering Period in accordance with Section 10 hereof.

<u>Use of Funds</u>. The Company may use all payroll deductions received or held by it under the Plan for any corporate purpose, and the Company will not be obligated to segregate such payroll deductions unless otherwise required under local law, as determined by the Administrator (in which case, the affected options will be granted under the Non-423 Plan Component, if necessary). Until shares of Common Stock are issued, Participants will only have the rights of an unsecured creditor with respect to such shares.

<u>Reports</u>. Individual accounts will be maintained for each Participant in the Plan. Statements of account will be given to participating Eligible Employees at least annually, which statements will set forth the amounts of payroll deductions, the Purchase Price, the number of shares of Common Stock purchased and the remaining cash balance, if any.

#### Adjustments, Dissolution, Liquidation, Merger or Change in Control.

<u>Adjustments</u>. In the event that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Common Stock or other securities of the Company, or other change in the corporate structure of the Company affecting the Common Stock occurs, the Administrator, in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan, will, in such manner as it may deem equitable, adjust the number and class of Common Stock that may be delivered under the Plan, the Purchase Price per share and the number of shares of Common Stock covered by each option under the Plan that has not yet been exercised, and the numerical limits of Sections 7 and 13.

Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, any Offering Period then in progress will be shortened by setting a New Exercise Date, and will terminate immediately prior to the consummation of such proposed dissolution or liquidation, unless provided otherwise by the Administrator. The New Exercise Date will be before the date of the Company's proposed dissolution or liquidation. The Administrator will notify each Participant in writing, at least ten (10) business days prior to the New Exercise Date, that the Exercise Date for the Participant's option has been changed to the New Exercise Date and that the Participant's option will be exercised automatically on the New Exercise Date, unless prior to such date the Participant has withdrawn from the Offering Period as provided in Section 10 hereof.

<u>Merger or Change in Control</u>. In the event of a merger or Change in Control, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or a Parent or Subsidiary of the successor corporation. In the event that the successor corporation refuses to assume or substitute for the option, the Offering Period with respect to which such option relates will be shortened by setting a New Exercise Date on which such Offering Period shall end. The New Exercise Date will occur before the date of the Company's proposed merger or Change in Control. The Administrator will notify each Participant in writing prior to the New Exercise Date, that the Exercise Date for the Participant's option has been changed to the New Exercise Date and that the Participant's option will be exercised automatically on the New Exercise Date, unless prior to such date the Participant has withdrawn from the Offering Period as provided in Section 10 hereof.

#### Amendment or Termination.

The Administrator, in its sole discretion, may amend, suspend, or terminate the Plan, or any part thereof, at any time and for any reason. If the Plan is terminated, the Administrator, in its discretion, may elect to terminate all outstanding Offering Periods either immediately or upon completion of the purchase of shares of Common Stock on the next Exercise Date (which may be sooner than originally scheduled, if determined by the Administrator in its discretion), or may elect to permit Offering Periods to expire in accordance with their terms (and subject to any adjustment pursuant to Section 19). If the Offering Periods are terminated prior to expiration, all amounts then credited to Participants' accounts that have not been used to purchase shares of Common Stock will be returned to the Participants (without interest thereon, except as otherwise required under local laws, as further set forth in Section 12 hereof) as soon as administratively practicable.

Without stockholder consent and without limiting Section 20(a), the Administrator will be entitled to change the Offering Periods, limit the frequency and/or number of changes in the amount withheld during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Common Stock for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Administrator determines in its sole discretion advisable that are consistent with the Plan.

In the event the Administrator determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Administrator may, in its discretion and, to the extent necessary or desirable, modify, amend or terminate the Plan to reduce or eliminate such accounting consequence including, but not limited to:

amending the Plan to conform with the safe harbor definition under FASB ASC Topic 718 – Stock Compensation, including with respect to an Offering Period underway at the time;

altering the Purchase Price for any Offering Period including an Offering Period underway at the time of the change in Purchase Price;

shortening any Offering Period by setting a New Exercise Date, including an Offering Period underway at the time of the Administrator

action;

reducing the maximum percentage of Compensation a Participant may elect to set aside as payroll deductions; and

reducing the maximum number of Shares a Participant may purchase during any Offering Period or Purchase Period.

Such modifications or amendments will not require stockholder approval or the consent of any Plan Participants.

Notices. All notices or other communications by a Participant to the Company under or in connection with the Plan will be deemed to have been duly given when received in the form and manner specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

<u>Conditions Upon Issuance of Shares</u>. Shares of Common Stock will not be issued with respect to an option unless the exercise of such option and the issuance and delivery of such shares pursuant thereto will comply with all applicable provisions of law, domestic or foreign, including, without limitation, the Securities Act of 1933, as amended, the Exchange Act, the rules and regulations promulgated thereunder, and the requirements of any stock exchange upon which the shares may then be listed, and will be further subject to the approval of counsel for the Company with respect to such compliance.

As a condition to the exercise of an option, the Company may require the person exercising such option to represent and warrant at the time of any such exercise that the shares are being purchased only for investment and without any present intention to sell or distribute such shares if, in the opinion of counsel for the Company, such a representation is required by any of the aforementioned applicable provisions of law.

<u>Code Section 409A.</u> The Code Section 423 Plan Component is exempt from the application of Code Section 409A. The Non-423 Plan Component is intended to be exempt from Code Section 409A under the short-term deferral exception and any ambiguities in the Plan shall be construed and interpreted in accordance with such intent. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Administrator determines that an option granted under the Plan may be subject to Code Section 409A or that any provision in the Plan would cause an option under the Plan to be subject to Code Section 409A, the Administrator may amend the terms of the Plan and/or of an outstanding option granted under the Plan, or take such other action

the Administrator determines is necessary or appropriate, in each case, without the Participant's consent, to exempt any outstanding option or future option that may be granted under the Plan from or to allow any such options to comply with Code Section 409A, but only to the extent any such amendments or action by the Administrator would not violate Code Section 409A. Notwithstanding the foregoing, the Company shall have no liability to a Participant or any other party if the option to purchase Common Stock under the Plan that is intended to be exempt from or compliant with Code Section 409A is not so exempt or compliant or for any action taken by the Administrator with respect thereto. The Company makes no representation that the option to purchase Common Stock under the Plan is compliant with Code Section 409A.

<u>Stockholder Approval</u>. The Plan will be subject to approval by the stockholders of the Company within twelve (12) months after the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under Applicable Laws.

<u>Automatic Transfer to Low Price Offering Period</u>. To the extent permitted by Applicable Laws, if the Fair Market Value of the Common Stock on any Exercise Date in an Offering Period is lower than the Fair Market Value of the Common Stock on the Enrollment Date of such Offering Period, then all participants in such Offering Period will be automatically withdrawn from such Offering Period immediately after the exercise of their option on such Exercise Date and automatically re-enrolled in the immediately following Offering Period as of the first day thereof.

# [\*\*\*] CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT MARKED BY BRACKETS HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES AND EXCHANGE ACT OF 1934 AS AMENDED.

June 25, 2010

Mr. Remi Barbier Chairman, President & CEO Pain Therapeutics, Inc. 2211 Bridgepointe Parkway Suite 500 San Mateo, CA 94404

#### **<u>Re: Amendments to License and Collaboration Agreements</u>**

Dear Remi:

This letter agreement reflects our recent communications and understandings. We have agreed to the following matters, which are intended to supersede any terms that may be inconsistent in the License and Collaboration Agreements:

- 1. <u>UP FRONT PAYMENT</u>: In consideration for the agreements made in this letter agreement, King will make a non-refundable cash payment to PTI of \$5,000,000 no later than July 31, 2010. It is agreed that this payment is not a Collaboration Cost and is not subject to offset against any obligations or other amounts which may be owed by King to PTI.
- 2. <u>ROYALTIES</u>: King will pay PTI a flat royalty of 10% on all Net Sales made in ROW. ROW Net Sales will be excluded from the calculation of the step-up in royalty after cumulative Net Sales of \$1 billion under Section 6.1.1 of the License Agreement. For clarity, this paragraph shall not affect any amounts payable by King to PTI as a result of King sublicensing to a Third Party under Section 6.1.4 (<u>Sublicensing Revenue</u>) of the License Agreement. For further clarity, this paragraph shall not affect any calculation of any amounts payable by King to PTI as set forth in Section 6.1.3 (<u>Amounts Payable Under the DLA</u>) of the License Agreement.
- 3. [\_\*\*\*\_]: King and PTI hereby approve the Development Plan and Budget for the Development of [\_\*\*\*\_]by PTI up to the submission of an IND as set forth in <u>Appendix A</u>. [\*\*\*]

- 4. [\_\*\*\*\_]: PTI hereby grants to King the right to exercise in the same manner that King assumed the Development of Remoxy under the Election Agreement, all of PTI's rights and obligations under the Collaboration Agreement to Develop [\_\*\*\* ]and King hereby accepts such grant and agrees to Develop [\_\*\*\* ]in accordance with the Collaboration Agreement and in a manner consistent with PTI's obligations under the DLA. The cost of Development by King shall be a Collaboration Cost.
- 5. <u>\$100,000,000 AMOUNT</u>: PTI and King expressly reserve their rights in relation to the \$100,000,000 amount specified in Section 3.3.2(c) of the Collaboration Agreement and any payment by King of Collaboration Costs as a result of this letter agreement in excess of that amount shall not affect any of King's rights under Section 3.3.2(c) and shall not be deemed to be a waiver of any such rights or an estoppel or laches to bar any assertion of rights or defenses by King under Section 3.3.2(c).
- **6.** <u>E-ROOM</u>: King shall establish and maintain a confidential electronic room into which King and PTI shall upload all final data/technical reports, regulatory filings and other related information for Remoxy and all other Products under the Collaboration and License Agreements. PTI shall have unlimited electronic access to such e-Room, including the right to make copies of all such material.
- 7. <u>GIVING EFFECT</u>: In order to give effect to the contents of this letter agreement, save as expressly reserved in this letter agreement, King and PTI may each propose to suspend, amend and/or revise certain provisions of the Collaboration and License Agreements. King and PTI shall discuss in good faith and attempt to agree on the terms of such suspension, amendment and/or revisions. Should the Parties not agree in good faith, such disagreement(s) shall not be construed or interpreted to relieve a Party of its existing duties or obligations under the Collaboration Agreement or the License Agreement, as amended by this letter agreement.
- 8. **DEFINED TERMS:** Defined terms used in this letter agreement have the same meaning as they do in the Collaboration Agreement and/or in the License Agreement, as applicable.
- 9. <u>NO OTHER CHANGES</u>: Save as may be affected by the provisions of this letter, all other terms of the Collaboration and License Agreements shall remain in full force and effect and shall not be altered by the terms of this letter agreement
- **10.** <u>NO BREACHES</u>: [ \*\*\* ] PTI expressly reserves its rights in relation to the actions and failure to take actions by King prior to the date hereof which may constitute a breach of the Collaboration and/or License Agreements and this letter agreement shall not be deemed to be a waiver of any rights of PTI or an estoppel or laches to bar any assertion of rights or defenses by PTI under the Collaboration and License Agreements.

11. <u>MINIMUM ANNUAL SPEND</u>: King agrees to reimburse PTI for its 2010 minimum annual spend (i.e., \$750,000) under the DLA, irrespective of the status of approved budgets under the Collaboration Agreement.

Please sign below to acknowledge your acceptance and agreement to this letter agreement.

Sincerely,

/s/ Brian A. Markison Brian A. Markison President and Chief Executive Officer

Accepted and Agreed:

PAIN THERAPEUTICS, INC.

/s/ Remi Barbier

Remi Barbier President & Chief Executive Officer

# JOC [ \*\*\* ] Plan & Budget

# Goal: PTI to [ \*\*\* ]

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

I, Remi Barbier, certify that:

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

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

Date: July 29, 2010

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

I, Peter S. Roddy, certify that:

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

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

Date: July 29, 2010

#### 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, 2010, 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: July 29, 2010

/s/ REMI BARBIER

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

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