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

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2013

or

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

Commission File Number: 000-29959

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

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

7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731
(512) 501-2444
(Address, including zip code, of registrant's principal executive offices and telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

Common Stock, $0.001 par value	**45,332,131** Shares Outstanding as of April 10, 2013

PAIN THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

PAIN THERAPEUTICS, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands)

	March 31, 2013	December 31, 2012[1]
Current assets		
Cash and cash equivalents	$ 51,591	$ 49,355
Marketable securities	2,800	6,899
Other current assets	127	253
Total current assets	54,518	56,507
Other assets	352	352
Total assets	$ 54,870	$ 56,859
Current liabilities		
Accounts payable	$ 366	$ 361
Accrued development expense	382	929
Deferred program fee revenue—current portion	7,832	7,832
Accrued compensation and benefits	1,114	853
Other current liabilities	—	24
Total current liabilities	9,694	9,999
Non-current liabilities		
Deferred program fee revenue—non-current portion	31,329	33,287
Deferred tax liabilities	437	437
Total liabilities	41,460	43,723
Commitments and contingencies		
Stockholders' equity		
Preferred stock	—	—
Common stock	45	45
Additional paid-in-capital	149,423	148,738
Accumulated other comprehensive income	1	4
Accumulated deficit	(136,059)	(135,651)
Total stockholders' equity	13,410	13,136
Total liabilities and stockholders' equity	$ 54,870	$ 56,859

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

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Three months ended March 31,	
	2013	2012
Revenue		
Program fee revenue	$ 1,958	$ 2,724
Collaboration revenue	—	249
Total revenue	1,958	2,973
Operating expenses		
Research and development	1,183	1,609
General and administrative	1,218	1,512
Total operating expenses	2,401	3,121
Operating loss	(443)	(148)
Interest income	35	178
Net income (loss)	$ (408)	$ 30
Net income (loss) per share, basic and diluted	$ (0.01)	$ 0.00
Weighted-average shares used in computing net income (loss) per share:		
Basic	44,932	44,732
Diluted	44,932	44,756

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Three months ended March 31,	
	2013	2012
Net income (loss)	$ (408)	$ 30
Other comprehensive loss		
Net unrealized losses on marketable securities	(3)	(32)
Comprehensive loss	$ (411)	$ (2)

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

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

	Three months ended March 31,	
	2013	2012
Cash flows used in operating activities:		
Net income (loss)	$ (408)	$ 30
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Deferred program fee revenue	(1,958)	(2,724)
Non-cash stock based compensation	679	907
Depreciation and amortization	—	35
Non-cash net interest income	(7)	133
Changes in operating assets and liabilities:		
Other current assets	126	(117)
Accounts payable	5	38
Accrued development expense	(547)	(495)
Accrued compensation and benefits	261	171
Other accrued liabilities	(24)	(48)
Net cash used in operating activities	(1,873)	(2,070)
Cash flows provided by investing activities:		
Purchases of marketable securities	(2,797)	(4,795)
Maturities of marketable securities	6,900	7,500
Net cash provided by investing activities	4,103	2,705
Cash flows provided by financing activities:		
Proceeds from issuance of common stock, net	6	—
Net cash provided by financing activities	6	—
Net increase in cash and cash equivalents	2,236	635
Cash and cash equivalents at beginning of the period	49,355	73,144
Cash and cash equivalents at end of the period	$51,591	$73,779

See accompanying notes to condensed financial statements.

PAIN THERAPEUTICS, INC.

Notes to Condensed Financial Statements
(Unaudited)

Note 1. General

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

In the course of our development activities, we have sustained cumulative operating losses. There are no assurances that additional financing will be available on favorable terms, or at all.

We have prepared the accompanying unaudited condensed financial statements of Pain Therapeutics, Inc. in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In our opinion, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2013. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2012.

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

Note 2. Significant Accounting Policies

Use of Estimates

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

Revenue Recognition and Deferred Program Fee Revenue

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

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

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

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

Cash, Cash Equivalents and Concentration of Credit Risk

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

Marketable Securities and Fair Value Measurements

We invest in interest bearing marketable securities, generally consisting of corporate and government securities. We may elect to sell these investments before they mature. Therefore, we hold these investments as “available for sale” and include these investments in our balance sheets as current assets, even though the contractual maturity of a particular investment may be beyond one year. We report our marketable securities at fair value, which may include unrealized gains and losses. Our unrealized gains and losses on investments are recorded as a separate component

of stockholders' equity as accumulated other comprehensive income or loss. We recognize all realized gains and losses on our marketable securities in interest income in the accompanying statement of operations on a specific identification basis. We report changes in net unrealized gains or losses on marketable securities in our Statements of Comprehensive Income. Our marketable securities are maintained at one financial institution and are governed by our investment policy as approved by our Board of Directors.

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

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

Stock-based Compensation

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

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

Net Loss per Share

Basic net loss per share is computed on the basis of the weighted-average number of common

shares outstanding for the reporting period. Diluted net loss per share is computed on the basis of the weighted-average number of common shares outstanding plus dilutive potential common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of outstanding stock options, 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 March 31,	
	2013	2012
Numerator		
Net income (loss)	$ (408)	$ 30
Denominator		
Weighted-average shares used in computing net income (loss) per share:		
Basic	44,932	44,732
Diluted	44,932	44,756
Net income (loss) per share, basic and diluted	$ (0.01)	$ 0.00

We excluded weighted options outstanding to purchase common stock of 14.4 million for the first quarter of 2013 and 12.1 million for the first quarter of 2012 from the calculation of diluted net loss per share because the effect of including these shares in this calculation would be anti-dilutive.

Income Taxes

We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income or loss for each full fiscal year. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. We are uncertain about the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with a valuation allowance. We may in the future determine that more of our deferred tax assets will likely be realized, in which case we will reduce our valuation allowance in the quarter in which such determination is made. If the valuation allowance is reduced, we may recognize a benefit from income taxes in our statement of operations in that period. We classify interest recognized pursuant to our deferred tax assets as interest expense, when appropriate.

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

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

	Cash, Cash Equivalents and Marketable Securities					
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Accrued Interest	Total Value
March 31, 2013						
Cash and cash equivalents	$ 28,714	$ —	$ —	$ 28,714	$ —	$28,714
Corporate securities	25,676	1	—	25,677	—	25,677
	$ 54,390	$ 1	$ —	$ 54,391	$ —	$54,391
Reported as:						
Cash and cash equivalents	$ 28,714	$ —	$ —	$ 28,714	$ —	$28,714
Marketable securities	25,676	1	—	25,677	—	25,677
	$ 54,390	$ 1	$ —	$ 54,391	$ —	$54,391
Maturities:						
Matures in one year or less	$ 54,390	$ 1	$ —	$ 54,391	$ —	$54,391
Matures one to three years	—	—	—	—	—	—
	$ 54,390	$ 1	$ —	$ 54,391	$ —	$54,391
December 31, 2012						
Cash and cash equivalents	$ 49,352	$ 3	$ —	$ 49,355	$ —	$49,355
Corporate securities	$ 6,898	1	—	6,899	—	6,899
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$56,254
Reported as:						
Cash and cash equivalents	$ 49,352	$ 3	$ —	$ 49,355	$ —	$49,355
Marketable securities	6,898	1	—	6,899	—	6,899
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$56,254
Maturities:						
Matures in one year or less	$ 56,250	$ 4	$ —	$ 56,254	$ —	$56,254
Matures one to three years	—	—	—	—	—	—
	$ 56,250	$ 4	$ —	$ 56,254	$ —	$56,254

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

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

	Level 1	Level 2	Level 3	Total
March 31, 2013				
Cash and money market fund	$28,714	$ —	$ —	$28,714
Corporate securities	—	25,677	—	25,677
	$28,714	$25,677	$ —	$54,391

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

Note 4. Stock-Based Compensation

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

	Three months ended March 31,	
	2013	2012
Research and development	$ 303	$ 465
General and administrative	376	442
	$ 679	$ 907

Note 5. Income Taxes

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

Note 6. Commitments

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

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

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

Note 7. Legal proceedings

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

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

Note 8. Recently Issued Accounting Pronouncements

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

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

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

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

- activities of Pfizer, Inc., or Pfizer, or its subsidiary King Pharmaceuticals, Inc., or King, with respect to obtaining approval of REMOXY® (oxycodone) Extended-Release Capsules CII, by the U.S. Food and Drug Administration, or FDA, including planned discussions between Pfizer and the FDA regarding REMOXY;
- timing of receiving information regarding Pfizer's recent meeting with the FDA regarding REMOXY;
- royalty, milestone or collaboration revenue we may receive from Pfizer and other payments we may receive from our collaboration and license agreements with Pfizer, or the Pfizer Agreements;
- the benefits of Pfizer's acquisition of King with respect to the commercial success of REMOXY, if approved by the FDA;
- the duration of the development period for expected drug candidates;
- timing of reimbursement of us by Pfizer for reimbursable development expenses we incurred under the Pfizer Agreements;
- expansion of our potential product line, including the formulation of additional dosage forms of our drug candidates;
- operating losses and anticipated operating and capital expenditures;
- expected uses of capital resources;
- the potential benefits of our drug candidates;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital and increasing cash needs;
- potential competitors or competitive products;
- market acceptance of our drug candidates and potential drug candidates;
- expenses increasing, interest income decreasing or fluctuations in our operating results;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- expectations regarding the issuance of shares of common stock to employees pursuant to equity compensation awards net of employment taxes;
- anticipated hiring and development of our internal systems and infrastructure;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- assumptions and estimates used for our disclosures regarding stock-based compensation; and
- estimates concerning the realization of deferred tax assets.

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

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

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

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

Overview

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

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

We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data was required to support the approval of REMOXY. Also, the FDA did not request or recommend

additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the King Agreements. In December 2010, King resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted the resubmission of the REMOXY NDA. In June 2011, we and Pfizer announced that King received a Complete Response Letter from the FDA in response to King's resubmission of the REMOXY NDA. The FDA's Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY.

In March 2013, Pfizer met with the FDA to discuss Pfizer's plans to respond to the Complete Response Letter. We expect to receive information regarding the outcome of Pfizer's meeting with the FDA in the second quarter of 2013.

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

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

We will receive a $15.0 million cash milestone payment from Pfizer upon regulatory approval of REMOXY in the United States. We could also receive from Pfizer up to $105.0 million in additional milestone payments in the course of clinical development of the other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, Pfizer is obligated to fund development expenses incurred by us pursuant to the Pfizer Agreements.

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

Although we were profitable in 2006, 2007 and 2008 based on payments received pursuant to the Pfizer Agreements and interest income, we have yet to generate any revenues from product sales. We have recorded an accumulated deficit of $136.1 million at March 31, 2013. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include

non-cash stock-based compensation associated with options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing of preclinical activities, enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

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

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

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

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

	Three months ended March 31,	
	2013	2012
Compensation	$ 792	$ 1,155
Contractor fees and supplies	286	239
Other common costs	105	215
	$ 1,183	$ 1,609

Contractor fees and supplies generally include expenses for preclinical studies and clinical trials and costs for formulation and manufacturing activities. Other common costs includes the allocation of common costs such as facilities.

Our technology has been applied across certain of our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates also relate to, and further the development of, our other drug candidates. For example, we expect that results of non-clinical studies, such as pharmacokinetics, toxicology and other studies, regarding certain components of our drug candidate REMOXY to be applicable to the other potential drug candidates that may arise out of our strategic alliance with Pfizer since all such potential drug candidates are expected to utilize

such components. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing.

Our contractor fees and supplies expenses in the first quarter of 2013 related to programs outside of the strategic alliance with Pfizer were approximately $0.1 million.

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

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

Critical Accounting Policies

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

- *Stock-based compensation*. We recognize expense in the statement of operations for the fair value of all share-based payments to employees and directors, including grants of employee stock options and other share based awards. For stock options, we use the Black-Scholes option valuation model and the single-option award approach and straight-line attribution method. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

  We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. The value of these awards is the product of the number

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

- *Revenue recognition and deferred program fee revenue.* We recognize program fee revenue, milestone revenue and collaboration revenue in connection with the Pfizer Agreements. Program fee revenue is derived from upfront payments under the Pfizer Agreements. These payments are recognized from receipt ratably over our estimate of the development period for the last to be developed of four drug candidates expected to be developed under the Pfizer Agreements. We currently estimate the development period for all four expected drug candidates to end in the quarter ended March, 2018. We periodically review the estimated development period and change it if appropriate based upon our latest expectations. Deferred program fee revenue represents the amount of the upfront payment that has not yet been recognized as program fee revenue. Pfizer is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the development of REMOXY and the other opioid painkillers under the strategic alliance. We recognize milestone payments as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services we provide are priced at fair value based upon the reimbursement of expenses we incur. Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with Pfizer are generally recognized when Pfizer has completed its review of the expenses invoiced to them.
- *Income Taxes.* We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income or loss for each full fiscal year. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings, if any. We are uncertain as to the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with a valuation allowance. We may in the future determine that more of our deferred tax assets will likely be realized, in which case we will reduce our valuation allowance in the quarter in which such determination is made. If the valuation allowance is reduced, we may recognize a benefit from income taxes in our statement of operations in that period. We classify interest recognized in connection with our tax positions as interest expense, when appropriate.

Results of Operations

Three months ended March 31, 2013 and 2012

Revenue – Program fee revenue

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

Revenue—Collaboration revenue

Collaboration revenue from reimbursement of our development expenses incurred under the Pfizer Agreements was $0.2 million for the first quarter of 2012. We did not receive any reimbursements in the first quarter of 2013. We paid development expenses under the Pfizer Agreements of $0.7 million in 2013 and $0.4 million in 2012 for which we expect Pfizer will reimburse us in the future.

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 $1.2 million in the first quarter of 2013 from $1.6 million in the first quarter of 2012, primarily due to lower headcount and facilities expenses. Research and development expenses included non-cash stock related compensation costs of $0.3 million in the first quarter of 2013 and $0.5 million in the first quarter of 2012.

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

General and Administrative Expense

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense decreased to $1.2 million in the first quarter of 2013 from $1.5 million in the first quarter of 2012, primarily due to lower operating expenses. General and administrative expense included non-cash stock related compensation costs of $0.4 million in both the first quarter of 2013 and the first quarter of 2012.

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

Interest Income

Interest income decreased to $35 thousand in the first quarter of 2013 from $0.2 million in the first quarter of 2012, due to lower average cash balances in the first quarter of 2013. We expect our interest income to decrease in the future as we use cash to fund our operations.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under the Pfizer Agreements and interest earned on our investments. We intend to continue to use our capital resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of March 31, 2013, cash, cash equivalents and marketable securities were $54.4 million.

Net cash used in operating activities was $1.9 million for the first quarter of 2013 and $2.1 million for the first quarter of 2012.

Net cash provided by investing activities was $4.1 million for the first quarter of 2013 and $2.7 million for the first quarter of 2012. These investing activities consisted of purchases and maturities of marketable securities.

Net cash provided by financing activities was $6 thousand for the first quarter of 2013. Financing activities consisted primarily of proceeds from stock option exercises.

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

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

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

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of March 31, 2013. Our formulation agreement with Durect Corporation obligates us to make certain milestone

payments upon achieving clinical milestones and regulatory milestones and pay royalties on related drug sales. Pfizer is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

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

We have an accumulated deficit of $136.1 million at March 31, 2013. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates, the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products and other corporate needs. We believe that our current resources should be sufficient to fund our operations for at least the next 12 months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

Off-balance Sheet Arrangements

As of March 31, 2013, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

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

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, we expect the fair value our investment will decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at March 31, 2013 by an immaterial amount. To minimize this risk, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments.

As of March 31, 2013, our investments consisted of investments in corporate obligations,

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

Item 4. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

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

PART II – OTHER INFORMATION

Item 1. *Legal Proceedings*

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

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

Item 1A. *Risk Factors*

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

Clinical and Regulatory Risks

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

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

Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require additional studies, in which case we or our collaborators would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals would:

- delay commercialization of, and product revenues from, our drug candidates; and
- diminish the competitive advantages that we may have otherwise enjoyed, which would have an adverse effect on our operating results and financial condition.

Even if we or our collaborators comply with all FDA regulatory requirements, our drug candidates may never obtain regulatory approval. If we or our collaborators fail to obtain regulatory approval for any of our drug candidates we will have fewer commercial products, if any, and corresponding lower product revenues, if any. Even if our drug candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us or our collaborators to commit to perform lengthy Phase IV post-approval clinical efficacy or safety studies. Our expending additional resources on such trials would have an adverse effect on our operating results and financial condition.

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

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

In order to obtain FDA approval for any of our drug candidates, we or our collaborators must submit to the FDA an NDA that demonstrates with substantive evidence that the drug candidate is both safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Results from Phase I clinical programs may not support moving a drug candidate to Phase II or Phase III clinical trials. Phase III clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and preclinical studies. Even if the results of Phase III clinical trials are positive, we or our collaborators may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before obtaining FDA approval for any of our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process also consumes a significant amount of time. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we, our collaborators or the FDA believe that participating patients are being exposed to unacceptable health risks, such clinical trials will have to be suspended or terminated. Failure can occur at any stage of the clinical trials, and we or our collaborators could encounter problems that cause abandonment or repetition of clinical trials.

Our clinical trials with REMOXY and our potential future clinical trials for other drug candidates for treatment of pain measure clinical symptoms, such as pain and physical dependence that are not biologically measurable. The success in clinical trials of REMOXY and our other drug candidates designed to reduce potential risks of unintended use depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. Due in part to a lack of consensus on standardized processes for assessing clinical outcomes, these scores may or may not be reliable, useful or acceptable to regulatory agencies.

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

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

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

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

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

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. With the exception of our Special Protocol Assessment, or SPA, such as the one we completed with the FDA with respect to the Phase III clinical trial for REMOXY, these discussions are not binding obligations on the part of regulatory authorities.

Regulatory authorities may revise previous guidance or decide to ignore previous guidance at any time during the course of our clinical activities or after the completion of our clinical trials. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we or our collaborators may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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

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

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

The U.S. Drug Enforcement Administration, or DEA, regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients in our current drug candidates, such as oxycodone, are listed by the DEA as Schedule II under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the DEA and quotas for these substances may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the drugs used in clinical trials for our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand.

Conducting clinical trials of our drug candidates or potential commercial sales of a drug candidate may expose us to expensive product liability claims and we may not be able to maintain product liability insurance on reasonable terms or at all.

The risk of product liability is inherent in the testing of pharmaceutical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our drug candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our drug candidates. We currently carry clinical trial insurance but do not carry product liability insurance. If we successfully commercialize one or more of our drug candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. We may not be able to obtain such insurance at a reasonable cost, if at all. Even if our agreements with any current or future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

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

Any regulatory approvals that our drug candidates receive may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including but not limited to adverse events of unanticipated severity or frequency, or the discovery that adverse events previously observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. For example, on July 9, 2012, the FDA approved a risk management program, known as a Risk Evaluation and Mitigation Strategy, or REMS, for extended-release and long-acting opioid analgesics, or ER/LA opioid analgesics. This REMS will require companies affected by the REMS to make available training for health care professionals who prescribe ER/LA opioid analgesics on proper prescribing practices and also to distribute educational materials to prescribers and patients on the safe use of ER/LA opioid analgesics.

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

Risks Relating to our Collaboration Agreements

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

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

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

We rely on Pfizer and its subsidiaries to devote time and resources to the development, manufacturing and commercialization of REMOXY and other drug candidates under the Pfizer Agreements. Pfizer and its subsidiaries and affiliates may commercialize, develop or acquire drugs or drug candidates that may compete directly or compete for resources with our drug candidates under the Pfizer Agreements. For instance, Pfizer is developing ALO-02 (an extended release abuse resistant formulation of oxycodone that would compete with REMOXY) and owns Embeda® (an extended-release oral formulation of morphine sulfate), and Avinza® (a once-daily morphine treatment for moderate to severe pain). There can be no assurance that these other drugs or other drug candidates in the Pfizer corporate family will not become competitive with our drug candidates being developed under the Pfizer Agreements. If time and resources devoted are limited or there is a failure to fund the continued development of REMOXY or other opioid drug candidates as required by the Pfizer Agreements, or there is otherwise a failure to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected. In addition, if Pfizer fails to perform as required under the Pfizer Agreements, their failure may jeopardize our rights under our license with Durect.

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

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

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

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

Our plan for developing, manufacturing and commercializing REMOXY and other drugs designed to reduce potential risks of unintended use currently requires us to successfully maintain the Pfizer Agreements to advance our programs and provide funding to support our expenditures on REMOXY and other drug candidates and to maintain our license from Durect. If we are not able to maintain the Pfizer Agreements or if Pfizer doesn't provide the required funding under the Pfizer Agreements and the funding required to meet our obligations to Durect, we may have to limit the size or scope of, or delay or abandon the development of other drug candidates or undertake and fund development of these drug candidates ourselves and if we are unable to meet

the obligations necessary to maintain our license with Durect for one or more potential products we may lose the rights to utilize Durect's technology for such potential products. If we elect to fund drug development efforts with respect to REMOXY and other drug candidates on our own, we may need to obtain additional capital, which may not be available on acceptable terms, or at all.

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

We may not successfully in-license drug candidates or technologies to expand our product pipeline. The number of such candidates and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates and technologies is intense because such companies generally desire to expand their product pipelines through in-licensing. If we fail to carry out such in-licensing and expand our product pipeline, our potential future revenues may suffer.

Our collaborative agreements may not succeed or may give rise to disputes over intellectual property, disputes concerning the scope of collaboration activities or other issues.

Our strategy to focus on drug development requires us to enter into collaborative agreements with third parties, such as the Pfizer Agreements and our license agreement with Durect. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations or disputes concerning the scope of collaboration activities. Such disputes can delay or prevent the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Other factors relating to collaborative agreements may adversely affect our business, including:

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

Risks Relating to Commercialization

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

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

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs, and, in particular, the effectiveness of REMOXY in reducing potential risks of unintended use;
- perceptions by physicians regarding the cost benefit of REMOXY in reducing potential risks of unintended use;

- published studies demonstrating the cost-effectiveness of our drugs relative to competing products;
- availability of reimbursement for our products from government or healthcare payers;
- our or our collaborators' ability to implement a risk management plan prior to the distribution of any Schedule II drug; and
- effectiveness of marketing and distribution efforts by Pfizer, us and other licensees and distributors.

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

If Pfizer or its subsidiaries are not successful in developing and commercializing REMOXY and in commercializing other opioid drugs under the Pfizer Agreements, our revenues and our business will suffer.

Our ability to earn royalties from sales of REMOXY and milestone payments depends on Pfizer's ability to obtain regulatory approval for and commercialize REMOXY. Additionally, our ability to earn royalties from sales of REMOXY and other drugs subject to the Pfizer Agreements will depend on Pfizer's ability to maintain regulatory approval and achieve market acceptance of such drugs once commercialized. Pfizer or its subsidiaries may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of REMOXY and other drugs developed under the Pfizer Agreements. Pfizer may not proceed with the commercialization of REMOXY and other drugs developed under the Pfizer Agreements with the same degree of urgency as we would because of other priorities they face. If Pfizer is not successful in developing or commercializing REMOXY for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if Pfizer fails to perform as we expect, our potential for revenue from drugs developed the Pfizer Agreements, if any, could be dramatically reduced and our business would suffer.

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

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

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

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

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

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

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

We and our collaborators will compete for market share against fully integrated pharmaceutical companies or other companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved or drug candidates in development that will or may compete against our approved drug candidates. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

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

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

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

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

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

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

Risks Relating to our Intellectual Property

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

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Intellectual property rights in the areas of controlled-release technology, 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 some time after filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

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

If we are unable to protect our intellectual property our competitors could develop and market products with similar features that may reduce demand for our drug candidates.

Our success, competitive position and potential future revenues will depend in part on our ability to protect our intellectual property. If we or our collaborators fail to file, prosecute, obtain or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result.

We and our collaborators have filed patent applications 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

If we are not successful in attracting and retaining qualified personnel, we could experience delays in completing necessary clinical trials, in the regulatory approval process or in formulating, manufacturing, marketing and selling our potential products.

We depend on the services of our key personnel, including Remi Barbier, our Chairman, President and Chief Executive Officer. The loss of key personnel, including members of executive management as well as key bioengineering, product development, and technical personnel, could disrupt our operations and have an adverse effect on our business. We will need to hire additional qualified personnel with expertise in clinical research, preclinical testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel is critical to our success.

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

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

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

delay our clinical trials, and, consequently, FDA approval of our drug candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.
- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.
- For certain of our drug candidates, the use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products before we may use the alternative manufacturer to produce our supplies.
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.
- If any contract manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

We may not be able to successfully develop or commercialize potential drug candidates for indications other than pain.

Our research and development activities include development of potential drug candidates for indications other than pain. We have no history of developing such drug candidates. We do not know whether any of our planned development activities will result in marketable products. We do not anticipate that our drug candidates in these areas will reach the market for at least several years, if at all.

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

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

Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process and commercialization of our drug candidates very difficult.

Media stories regarding the diversion of opioids and other controlled substances are commonplace. Law enforcement agencies or regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may adversely affect the regulatory approval and commercialization of our drug candidates.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In addition, the active ingredients in nearly all opioid drugs are available in generic form. Drug companies that sell generic opioid drugs represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. Our competitors may market less expensive or more effective drugs that would compete with our drug candidates or reach market with competing drugs before we are able to reach market with our drug candidates. These organizations also compete with us to attract qualified personnel and partners for acquisitions, joint ventures or other collaborations.

Business interruptions could limit our ability to operate our business.

Our operations as well as those of our collaborators on which we depend are vulnerable to damage or interruption from computer viruses, human error, natural disasters, electrical and telecommunication failures, international acts of terror and similar events. We have not established a formal disaster recovery plan and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

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

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

Risks Relating to Manufacturing

We rely on third-party commercial drug manufacturers for drug supply.

Approved third-party commercial drug manufacturers may subsequently be stopped from producing, storing, shipping or testing our drug products due to their non-compliance with federal, state or local regulations. Drug manufacturers are subject to ongoing periodic

unannounced inspection by the FDA, the DEA, and corresponding state and foreign government agencies to ensure strict compliance with GMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

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

We and Pfizer rely on Durect as the sole source provider of certain components of REMOXY and other drug candidates designed to reduce potential risks of unintended use, and will rely solely on Durect to produce commercial supplies of these components. Durect's failure for any reason to provide these components or to achieve and maintain satisfactory manufacturing standards could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially harm our business.

Durect may encounter manufacturing difficulties involving production yields, quality control and quality assurance. Durect is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with government regulations and corresponding foreign standards. We cannot control Durect's compliance with these regulations and standards.

If Pfizer receives marketing approval for and commercially launches REMOXY or other candidates under the Pfizer Agreements, Durect may need to materially expand its manufacturing capacity. Durect may not be able to increase its manufacturing capacity for REMOXY and these other drug candidates in a timely or economic manner, or at all. Moreover, significant scale up of manufacturing will require additional validation studies, which are subject to FDA review and approval. If Durect is unable to successfully increase the manufacturing capacity for such

components of REMOXY and these other drugs, at an acceptable cost or otherwise, and Pfizer is unable to establish alternative manufacturing capabilities, commercialization of REMOXY and these other drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our future revenues and cause our business to suffer.

Risks Relating to our Financial Position and Need for Financing

Our operating history may make it difficult for you to evaluate our business to date and to assess its future viability.

Our operations from our inception to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking preclinical studies and clinical trials of our drug candidates and forming collaborations. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture our drug candidates on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future.

Although we were profitable in some years in the past based on payments received pursuant to the Pfizer Agreements and interest income, we have yet to generate any revenues from product sales. We have an accumulated deficit of $136.1 million at March 31, 2013. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

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

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

Risks Relating to an Investment in our Common Stock

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

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

- results of or delays in efforts to seek regulatory approval for REMOXY, and in preclinical studies and clinical trials for our other drug candidates;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- the status of our collaboration agreements;
- announcements of technological innovations or new commercial products by us or others;
- developments in patent or other proprietary rights by us or others;
- comments or opinions by securities analysts or major stockholders;
- adverse media coverage related to opioid pharmaceuticals;
- future sales of our common stock by existing stockholders;
- developments with respect to potential merger and acquisition activity of companies with whom we have strategic alliances or other agreements;
- regulatory developments or changes in regulatory guidance enacted by applicable governmental or other authorities;

- litigation, including with respect to the lawsuit currently filed against us and our officers, or threats of litigation;
- economic and other external factors or other disaster or crises;
- the departure of any of our officers, directors or key employees;
- period-to-period fluctuations in financial results; and
- limited daily trading volume.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, SEC regulations and the rules of The NASDAQ Stock Market LLC, create uncertainty for public companies. If we were unable to continue to comply with these requirements, we could be delisted from trading on the NASDAQ Global Select Market, or Nasdaq, and thereafter trading in our common stock, if any, may be conducted through the over-the-counter or other market. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

None.

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

None.

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

Not applicable.

Item 5. ***Other Information***

None.

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	Amended and Restated Bylaws.
4.1 (1)	Specimen Common Stock Certificate.
4.2 (2)	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+	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.

101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ended June 30, 2005.
(2) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
+ Confidential treatment has been requested or granted for certain portions of this exhibit. The omitted portions 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: April 24, 2013

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EXHIBIT INDEX

Exhibit Number	Description of Document
3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2	Amended and Restated Bylaws.
4.1 (1)	Specimen Common Stock Certificate.
4.2 (2)	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+	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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AMENDED AND RESTATED BYLAWS

OF

PAIN THERAPEUTICS, INC.
a Delaware corporation

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AMENDED AND RESTATED BYLAWS

OF

PAIN THERAPEUTICS, INC.

a Delaware corporation

ARTICLE I

STOCKHOLDERS

1. ANNUAL MEETINGS

An annual meeting of stockholders shall be held for the election of directors at such date, time and place, either within or without the state of Delaware, as may be designated by resolution of the Board of Directors from time to time. Any other proper business may be transacted at the annual meeting.

2. SPECIAL MEETINGS

Special meetings of stockholders for any purpose or purposes may be called at any time by the Board of Directors, Chairman of the Board, President or the Chief Executive Officer of the corporation and such special meetings may not be called by any other person or persons.

3. NOTICE OF MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, date and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Unless otherwise provided by law, the certificate of incorporation or these by-laws, the written notice of any meeting shall be given not less than ten nor more than sixty days before the date of the meeting to each stockholder entitled to vote at such meeting. If mailed, such notice shall be deemed to be given when deposited in the mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the corporation.

4. ADVANCE NOTICE OF STOCKHOLDER NOMINEES AND STOCKHOLDER BUSINESS

The stockholders' nominees for the election of directors and other business proposed by a stockholder to be voted on at an annual or special meeting of stockholders must be received by the company's secretary not less than 120 days prior to the date the Company's proxy statement was released to the stockholders in connection with the previous year's annual meeting of stockholders.

5. ADJOURNMENTS

Any meeting of stockholders, annual or special, may adjourn from time to time to reconvene at the same or some other place, and notice need not be given of any such adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

6. QUORUM

Except as otherwise provided by law, the certificate of incorporation or these by-laws, at each meeting of stockholders the presence in person or by proxy of the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote at the meeting shall be necessary and sufficient to constitute a quorum. In the absence of a quorum, the stockholders so present may, by majority vote, adjourn the meeting from time to time in the manner provided in Section 1.5 of these by-laws until a quorum shall attend. Shares of its own stock belonging to the corporation or to another corporation, if a majority of the shares entitled to vote in the election of directors of such other corporation is held, directly or indirectly, by the corporation, shall neither be entitled to vote nor be counted for quorum purposes; provided, however, that the foregoing shall not limit the right of the corporation to vote stock, including but not limited to its own stock, held by it in a fiduciary capacity.

7. ORGANIZATION

Meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in his absence by the Vice Chairman of the Board, if any, or in his absence by the President, or in his absence by a Vice President, or in the absence of the foregoing persons by a chairman designated by the Board of Directors, or in the absence of such designation by a chairman chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

8. VOTING; PROXIES

Except as otherwise provided by the certificate of incorporation, each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of stock held by him which has voting power upon the matter in question. Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for him by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by filing an instrument in writing revoking the proxy or another duly executed proxy bearing a later date with the Secretary of the corporation. Voting at meetings of stockholders need not be by written ballot and need not be conducted by inspectors of election unless so determined by the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote thereon which are present in person or by proxy at such meeting. At all meetings of stockholders for the election of directors a plurality of the votes cast shall be sufficient to elect. Stockholders shall not be entitled to cumulative voting rights for the election of directors. All other elections and questions shall, unless otherwise provided by law, the certificate of incorporation or these by-laws, be decided by the vote of the holders of shares of stock having a majority of the votes which could be cast by the holders of all shares of stock entitled to vote thereon which are present in person or represented by proxy at the meeting.

9. FIXING DATE FOR DETERMINATION OF STOCKHOLDERS OF RECORD

In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or if applicable, to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors and which record date: (1) in the case of determination of stockholders entitled to vote at any meeting of stockholders or adjournment thereof, shall, unless otherwise required by law, not be more than sixty nor less than ten days before the date of such meeting; (2) if applicable, in the case of determination of stockholders entitled to express consent to corporate action in writing without a meeting, shall not be more than ten days from the date upon which the resolution fixing the record date is adopted by the Board of Directors; and (3) in the case of any other action, shall not be more than sixty days prior to such other action. If no record date is fixed: (1) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; (2) if applicable, the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting when no prior action of the Board of Directors is required by law, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the corporation in accordance with applicable law, or, if prior action by the Board of Directors is required by law, shall be at the close of business on the day on which the Board of Directors adopts the resolution taking such prior action; and (3) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

10. LIST OF STOCKHOLDERS ENTITLED TO VOTE

The Secretary shall prepare and make, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof and may be inspected by any stockholder who is present. Upon the willful neglect or refusal of the directors to produce such a list at any meeting for the election of directors, they shall be ineligible for election to any office at such meeting. The stock ledger shall be the only evidence as to who are the stockholders entitled to examine the stock ledger, the list of stockholders or the books of the corporation, or to vote in person or by proxy at any meeting of stockholders.

11. NO ACTION BY CONSENT OF STOCKHOLDERS

Stockholders may not take action by written consent without a meeting and may act only at a duly called special or annual meeting of the corporation.

ARTICLE II

BOARD OF DIRECTORS

1. NUMBER; QUALIFICATIONS

The Board of Directors shall consist of one or more members, and is currently set at seven members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. Directors need not be stockholders.

2. ELECTION; RESIGNATION; REMOVAL; VACANCIES

The Board of Directors shall be divided into three classes designated as Class I, Class II, and Class III, respectively. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board of Directors. At the first annual meeting of stockholders following the closing of the first sale of the corporation's common stock pursuant to a firmly underwritten registered public offering (the "IPO"), the term of office of the Class I directors shall expire, and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following the date hereof, the term of office of the Class II directors shall expire, and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following the date hereof, the term of office of the Class III directors shall expire, and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting.

Notwithstanding the foregoing provisions of this Article, each director shall serve until his or her successor is duly elected and qualified or until his or her death, resignation, or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director. Any director, or the entire Board of Directors, may be removed from office at any time (i) with cause by the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of the Voting Stock, voting together as a single class; or (ii) without cause by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the Voting Stock. Any director may resign at any time upon written notice to the corporation. Unless otherwise provided in the certificate of incorporation, any newly created directorship or any vacancy occurring in the Board of Directors for any cause may be filled by a majority of the remaining members of the Board of Directors, and each director so elected shall hold office until the expiration of the term of office of the director whom he has replaced or until his successor is elected and qualified.

3. REGULAR MEETINGS

Regular meetings of the Board of Directors may be held at such places within or without the State of Delaware and at such times as the Board of Directors may from time to time determine, and if so determined notices thereof need not be given.

4. SPECIAL MEETINGS

Special meetings of the Board of Directors may be held at any time or place within or without the State of Delaware whenever called by the Board of Directors, Chairman of the Board, President or Chief Executive Officer of the Corporation. Notice of a special meeting of the Board of Directors shall be given by the person or persons calling the meeting at least twenty-four hours before the special meeting.

5. TELEPHONIC MEETINGS PERMITTED

Members of the Board of Directors, or any committee designated by the Board of Directors, may participate in a meeting thereof by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to this by-law shall constitute presence in person at such meeting.

6. QUORUM; VOTE REQUIRED FOR ACTION

At all meetings of the Board of Directors a majority of the whole Board of Directors shall constitute a quorum for the transaction of business. Except in cases in which the certificate of incorporation or these by-laws otherwise provide, the vote of a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board of Directors.

7. ORGANIZATION

Meetings of the Board of Directors shall be presided over by the Chairman of the Board, if any, or in his absence by the Vice Chairman of the Board, if any, or in his absence by the President, or in their absence by a chairman chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

8. INFORMAL ACTION BY DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Board of Directors, or of any committee thereof, may be taken without a meeting if all members of the Board of Directors or such committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of proceedings of the Board of Directors or such committee.

ARTICLE III

COMMITTEES

1. COMMITTEES

The Board of Directors may, by resolution passed by a majority of the whole Board of Directors, designate one or more committees, each committee to consist of one or more of the directors of the corporation. The Board of Directors may designate one or more directors as

alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in place of any such absent or disqualified member. Any such committee, to the extent permitted by law and to the extent provided in the resolution of the Board of Directors, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers which may require it.

2. COMMITTEE RULES

Unless the Board of Directors otherwise provides, each committee designated by the Board of Directors may make, alter and repeal rules for the conduct of its business. In the absence of such rules each committee shall conduct its business in the same manner as the Board of Directors conducts its business pursuant to Article III of these by-laws.

ARTICLE IV

OFFICERS

1. EXECUTIVE OFFICERS; ELECTION; QUALIFICATIONS; TERM OF OFFICE; RESIGNATION; REMOVAL; VACANCIES

The Board of Directors shall elect a President and Secretary, and it may, if it so determines, choose a Chairman of the Board and a Vice Chairman of the Board from among its members. The Board of Directors may also choose one or more Vice Presidents, one or more Assistant Secretaries, a Treasurer and one or more Assistant Treasurers. Each such officer shall hold office until the first meeting of the Board of Directors after the annual meeting of stockholders next succeeding his election, and until his successor is elected and qualified or until his earlier resignation or removal. Any officer may resign at any time upon written notice to the corporation. The Board of Directors may remove any officer with or without cause at any time, but such removal shall be without prejudice to the contractual rights of such officer, if any, with the corporation. Any number of offices may be held by the same person. Any vacancy occurring in any office of the corporation by death, resignation, removal or otherwise may be filled for the unexpired portion of the term by the Board of Directors at any regular or special meeting.

2. POWERS AND DUTIES OF EXECUTIVE OFFICERS

The officers of the corporation shall have such powers and duties in the management of the corporation as may be prescribed by the Board of Directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board of Directors. The Board of Directors may require any officer, agent or employee to give security for the faithful performance of his duties.

ARTICLE V

STOCK

1. CERTIFICATES

Every holder of stock shall be entitled to have a certificate signed by or in the name of the corporation by the Chairman or Vice Chairman of the Board of Directors, if any, or the President or Vice President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary, of the corporation, certifying the number of shares owned by him in the corporation. Any of or all the signatures on the certificate may be a facsimile. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he were such officer, transfer agent, or registrar at the date of issue.

2. LOST, STOLEN OR DESTROYED STOCK CERTIFICATES; ISSUANCE OF NEW CERTIFICATES

The corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or his legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

ARTICLE VI

INDEMNIFICATION

1. THIRD PARTY ACTIONS

The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director or officer of the corporation, or that such director or officer is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture trust or other enterprise (collectively “Agent”), against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement (if such settlement is approved in advance by the Company, which approval shall not be unreasonably withheld) actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

2. ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the

corporation to procure a judgment in its favor by reason of the fact that he is or was an Agent (as defined in Section 6.1) against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

3. SUCCESSFUL DEFENSE

To the extent that an Agent of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Sections 6.1 and 6.2, or in defense of any claim, issue or matter therein, he shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him in connection therewith.

4. DETERMINATION OF CONDUCT

Any indemnification under Sections 6.1 and 6.2 (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that the indemnification of the Agent is proper in the circumstances because he has met the applicable standard of conduct set forth in Sections 6.1 and 6.2. Such determination shall be made (1) by the Board of Directors or an executive committee by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (2) or if such quorum is not obtainable or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (3) by the stockholders.

5. PAYMENT OF EXPENSES IN ADVANCE

Expenses incurred in defending a civil or criminal action, suit or proceeding shall be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of the director, officer, employee or agent to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation as authorized in this Article VI.

6. INDEMNITY NOT EXCLUSIVE

The indemnification and advancement of expenses provided or granted pursuant to the other subsections of this section shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any by-law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office.

7. INSURANCE INDEMNIFICATION

The corporation shall have the power to purchase and maintain insurance on behalf of any person who is or was an Agent of the corporation, or is or was serving at the request of the corporation, as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify him against such liability under the provisions of this Article VI.

8. THE CORPORATION

For purposes of this Article VI, references to "the corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors and officers, so that any person who is or was a director or Agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under and subject to the provisions of this Article VI (including, without limitation the provisions of Section 6.4) with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

9. EMPLOYEE BENEFIT PLANS

For purposes of this Article VI, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Article VI.

10. INDEMNITY FUND

Upon resolution passed by the Board, the corporation may establish a trust or other designated account, grant a security interest or use other means (including, without limitation, a letter of credit), to ensure the payment of certain of its obligations arising under this Article VI and/or agreements which may be entered into between the corporation and its officers and directors from time to time.

11. INDEMNIFICATION OF OTHER PERSONS

The provisions of this Article VI shall not be deemed to preclude the indemnification of any person who is not an Agent (as defined in Section 6.1), but whom the corporation has the power or obligation to indemnify under the provisions of the General Corporation Law of the State of Delaware or otherwise. The corporation may, in its sole discretion, indemnify an employee, trustee or other agent as permitted by the General Corporation Law of the State of Delaware. The corporation shall indemnify an employee, trustee or other agent where required by law.

12. SAVINGS CLAUSE

If this Article or any portion thereof shall be invalidated on any ground by any court of competent jurisdiction, then the corporation shall nevertheless indemnify each Agent against expenses (including attorney's fees), judgments, fines and amounts paid in settlement with respect to any action, suit, proceeding or investigation, whether civil, criminal or administrative,

and whether internal or external, including a grand jury proceeding and an action or suit brought by or in the right of the corporation, to the full extent permitted by any applicable portion of this Article that shall not have been invalidated, or by any other applicable law.

13. CONTINUATION OF INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VI shall, unless otherwise prided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

ARTICLE VII

MISCELLANEOUS

1. FISCAL YEAR

The fiscal year of the corporation shall be determined by resolution of the Board of Directors.

2. SEAL

The corporate seal shall have the name of the corporation inscribed thereon and shall be in such form as may be approved from time to time by the Board of Directors.

3. WAIVER OF NOTICE OF MEETINGS OF STOCKHOLDERS, DIRECTORS AND COMMITTEES

Any written waiver of notice, signed by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of any regular or special meeting of the stockholders, directors, or members of a committee of directors need be specified in any written waiver of notice.

4. INTERESTED DIRECTORS; QUORUM

No contract or transaction between the corporation and one or more of its directors or officers, or between the corporation and any other corporation, partnership, association, or other organization in which one or more of its directors or officers are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board of Directors or committee thereof which authorizes the contract or transaction, or solely because his or their votes are counted for such purpose, if: (1) the material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the committee, and the Board of Directors or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum: or (2) the material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders; or

(3) the contract or transaction is fair as to the corporation as of the time it is authorized, approved or ratified, by the Board of Directors, a committee thereof, or the stockholders. Common or interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee which authorizes the contract or transaction.

5. FORM OF RECORDS

Any records maintained by the corporation in the regular course of its business, including its stock ledger, books of account, and minute books, may be kept on, or be in the form of, punch cards, magnetic tape, photographs, microphotographs, or any other information storage device, provided that the records so kept can be converted into clearly legible form within a reasonable time. The corporation shall so convert any records so kept upon the request of any person entitled to inspect the same.

6. AMENDMENT OF BY-LAWS

These by-laws may be altered or repealed, and new by-laws made, by the Board of Directors, but except as otherwise provided in the Certificate of Incorporation, the stockholders may make additional by-laws and may alter and repeal any by-laws whether adopted by them or otherwise.

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Exhibit 10.1

DEVELOPMENT AND LICENSE AGREEMENT

This DEVELOPMENT AND LICENSE AGREEMENT (the "Agreement") is entered into as of December 19, 2002 (the "Effective Date") by and among DURECT Corporation, a corporation organized and existing under the laws of Delaware and having its principal office at 10240 Bubb Road, Cupertino, California 95014, and Southern BioSystems, Inc., ("SBS") a corporation organized and existing under the laws of Alabama and having its principal office at 756 Tom Martin Drive, Birmingham, Alabama 35211, a wholly-owned subsidiary of DURECT Corporation (DURECT Corporation and SBS together, "DURECT"), and Pain Therapeutics, Inc., a corporation organized and existing under the laws of Delaware and having its principal office at 416 Browning Way, South San Francisco, CA 94080, ("PTI") (DURECT and PTI hereinafter to be collectively referred to as the "Parties" and singularly as a "Party").

RECITALS

WHEREAS, DURECT is engaged in the research, development and manufacture of controlled-release drug delivery products;

WHEREAS, PTI is engaged in the research, development and commercialization of opioid pharmaceutical products;

WHEREAS, DURECT possesses the right to license proprietary rights to a controlled-release technology that uses a high-viscosity base component to provide controlled release of active ingredients known as the SABER ™ Delivery System (as defined herein below);

WHEREAS, the Parties to this Agreement desire to collaborate in the development of specified oral controlled-release opioid products based on the SABER ™ Delivery System; and

WHEREAS DURECT wishes to license certain of such proprietary rights to the SABER ™ Delivery System to PTI so that PTI may develop and commercialize such products.

NOW, THEREFORE, for and in consideration of the foregoing premises and the mutual covenants set forth herein and other valuable consideration, it is agreed by and between the Parties as follows:

ARTICLE I

DEFINITIONS

For the purposes of this Agreement, the following words and phrases, whether used in the singular or plural, shall have the following meanings:

1.1 "Accounting Period" means a calendar quarter commencing on the first day of an Accounting Period, respectively January 1, April 1, July 1 and October 1, each being the first day, and finishing on the last day of an Accounting Period, respectively March 31, June 30, September 30 and December 31, each being the last day.

***** Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

1.2 “Act” means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as such may be amended from time to time.

1.3 “Acquiror” has the meaning set forth in Section 17.1.

1.4 “Active Ingredient” means any pharmaceutically or pharmacologically active agent or compound alone or in combination with other components, other than a Controlled Release Carrier.

1.5 “Affiliate” means any corporation or other business entity, which controls, is controlled by or is under common control with a Party. For purposes of this definition, “control” means, as of or subsequent to the Effective Date, direct or indirect ownership of more than fifty percent (50%) of the voting interest or income interest in a corporation or business entity.

1.6 “Antagonist” means one or more (either alone or together) of any opioid receptor antagonist, including **[* * *]** .

1.7 “Bulk Dosage Form” has the meaning set forth in Section 5.1(a).

1.8 “Business Day” means a day on which banks are open for business in San Francisco, California.

1.9 “Change of Control” has the meaning set forth in Section 4.3.

1.10 “Clinical Program” has the meaning set forth in Section 3.1

1.11 “Clinical Program Milestone” means an event relating to the clinical development of the Licensed Product as defined in Section 3.2.

1.12 “Commercialize” or “Commercialization” means all ongoing processes and activities generally engaged in by a company marketing pharmaceutical products to establish and maintain a presence and sales for an ethical pharmaceutical product in a particular market, including, but not limited to offering for sale, selling, marketing, promoting, distributing and importing such product.

1.13 “Competing Product” has the meaning set forth in Section 8.4(c).

1.14 “Confidential Information” has the meaning set forth in Section 13.1.

1.15 “Controlled Release Carrier” means one or more molecules, particles, and/or other formulants that are physically and/or chemically associated with the Active Ingredient(s) and that are capable of achieving the controlled release of the Active Ingredient(s) to which they are physically and/or chemically associated (i.e., such Active Ingredient(s) is released and pharmacologically available in the system of a recipient), in each case, as a result of the physical and/or chemical disassociation, release, degradation, decomposition or disintegration of such molecules, particles and/or other formulants from such Active Ingredient(s). **[* * *]**

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1.16 “Controlled Release System” means a delivery system for an Active Ingredient(s) that requires and includes a Controlled Release Carrier, including the SABER ™ Delivery System. **[* * *]** .

1.17 “Current Good Manufacturing Practices” or “cGMP’s” means the requirements of the FDA with regard to the manufacture of Opioid Drugs and finished pharmaceuticals as set forth in 21 CFR 210 and 211, as amended from time to time or any equivalent law in the Territory.

1.18 “DURECT Inventions” has the meaning set forth in Section 12.5(a).

1.19 “DURECT Patent Rights” means: (i) all Patents in the Territory related to the SABER ™ Delivery System, including its manufacture, sale, importation or use, including those Patents listed in Exhibit 1.19, which are owned or controlled by or licensed to DURECT or its Affiliates as of the Effective Date or during the Term and (ii) all Patents covering DURECT Inventions, all to the extent DURECT or its Affiliates have the right to grant licenses or sublicenses hereunder.

1.20 “DURECT Research Expenses” means [* * *]

1.21 “DURECT Technology” means: (i) any and all Technical Information related to the SABER ™ Delivery System, including its manufacture, sale, importation or use, which is owned or controlled by or licensed to DURECT or its Affiliates as of the Effective Date or during the Term and (ii) all DURECT Inventions, all to the extent DURECT or its Affiliates have the right to grant licenses or sublicenses hereunder.

1.22 “Effective Date” has the meaning set forth in the preamble.

1.23 “FDA” means the United States Food and Drug Administration.

1.24 “Field” means any and all prophylactic and therapeutic applications for humans.

1.25 “First Commercial Sale” means, with respect to a Licensed Product in any country in the Territory, the first arms’-length sale of the Licensed Product to a Third Party purchaser in such country of commercial quantities of the Licensed Product by PTI or any of its Sublicensees or Affiliates (i) which is after the Product Registration and commercial launch of the Licensed Product in such country and (ii) which transfers title to the Licensed Product to such Third Party purchaser; provided, however, that the First Commercial Sale shall not be deemed to have occurred if the sale is made to a Sublicensee or Affiliate (unless such Sublicensee or Affiliate is purchasing the Licensed Product as an end user).

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1.26 “Formulation Development” has the meaning set forth in Section 2.4.

1.27 “GAAP” means the then-current applicable United States Generally Accepted Accounting Principles consistently applied as recognized or accepted by the United States Securities and Exchange Commission and the Financial Accounting Standards Board. As used herein, “GAAP” shall also include cost accounting principles and procedures that are generally accepted in the United States consistently applied.

1.28 “IND” means any Investigational New Drug Application (as described in 21 C.F.R. § 312) filed with the FDA to initiate the conduct of human clinical trials with a drug pursuant to the Act and the regulations promulgated thereunder, including any amendments or supplements thereto.

1.29 “Indemnified Party” has the meaning set forth in Section 11.3.

1.30 “Indemnifying Party” has the meaning set forth in Section 11.3.

1.31 “Initial Licensed Product” has the meaning set forth in Section 2.1.

1.32 “Invention” means any and all Technical Information conceived or reduced to practice by a Party or jointly by the Parties in the course of performing the activities under this Agreement.

1.33 “Joint Development Team” or “JDT” has the meaning set forth in Section 7.1.

1.34 “Licensed Product” means any human pharmaceutical product intended for the oral route comprising a Controlled Release Carrier of the SABER ™ Delivery System and Opioid Drug, and optionally an Antagonist, which is selected for development under Section 2.1, including any and all pharmaceutical dosage formulations, forms and dosage strengths thereof.

1.35 “Losses” has the meaning set forth in Section 11.1.

1.36 “Major Market Country” means one of the **[* * *]** ; and “Major Market Countries” shall mean collectively all of the foregoing countries.

1.37 “Manufacturing Cost” has the meaning set forth in Exhibit 1.37.

1.38 “NDA” means a New Drug Application (as described in 21 C.F.R. § 314.50 et. seq.) filed with the FDA for marketing approval for a drug pursuant to the Act and the regulations promulgated thereunder, including any amendments or supplements thereto.

1.39 “Net Sales” means the gross amount invoiced for all arms’ length sales of the Licensed Product by PTI and its Sublicensees and Affiliates to Third Parties in the Territory, other than transfers among PTI and its Sublicensees or Affiliates (unless such Sublicensee or Affiliate is purchasing the Licensed Product as an end user), less deductions in their normal and customary accounts as determined in accordance with GAAP for (a) actual trade, quantity and cash discounts, rebates and administrative fees (including, without limitation, U.S. Medicaid and Medicare programs

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and other private or governmental sponsored rebates and administrative fees paid to purchasing groups), credits, allowances, refunds and retroactive price reductions, including chargebacks; (b) any tax or government charge (other than income tax) levied on the sale, transportation or delivery of the Licensed Product and borne by the seller thereof; (c) any charges for freight, postage, shipping, security or special handling, import or export taxes which are borne by the seller, or insurance or charges for returnable containers which are borne by the seller; and (d) reasonable provisions for allowance for uncollectible amounts determined in accordance with GAAP, consistently applied. For clarity, Net Sales shall not include amounts invoiced for Licensed Products transferred in a country as part of clinical trials prior to receipt of Product Registration of the Licensed Product in such country.

1.40 "Opioid Drug" means one or more Active Ingredients (either alone or together) from the group consisting of **oxycodone, hydrocodone, oxymorphone and hydromorphone** (as such foregoing list may be modified from time to time in accordance with the terms of this Agreement) together with any and all pharmaceutically acceptable salt, free base, prodrug or conjugated form of the Active Ingredient.

1.41 "Patents" means any and all patent and patent applications (and equivalents thereof including certificates of invention) throughout the Territory, including any and all divisions, continuations, provisional applications, continuations-in-part, continued prosecution applications, requests for continued examination, additions, renewals, extension, re-examinations, reissues, supplementary protection certificates and all U.S. and foreign counterparts of the foregoing.

1.42 "Party" or "Parties" has the meaning set forth in the Preamble above.

1.43 "Phase I Clinical Trial" means the initial introduction of a Licensed Product as an investigational new drug into humans as required in 21 C.F.R. § 312, designed to determine the metabolism and pharmacologic actions of the Licensed Product in humans, the side effects associated with increasing doses and, if possible, to gain early evidence on effectiveness, and also includes studies of drug metabolism, structure-activity relationships and mechanism of action in humans.

1.44 "Phase II Clinical Trial" means a controlled or uncontrolled clinical study as required in 21 C.F.R. § 312 conducted to evaluate the effectiveness of a Licensed Product for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the Licensed Product.

1.45 "Phase III Clinical Trial" means an expanded controlled or uncontrolled clinical trial as required in 21 C.F.R. § 312 performed after preliminary evidence suggesting effectiveness of a Licensed Product has been obtained, the primary purpose of which is to establish effectiveness and safety of the Licensed Product in patients with the particular indication or indications being studied and to provide an adequate basis for physician labeling.

1.46 "PTI Inventions" has the meaning set forth in Section 12.5(b).

***** Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

1.47 “PTI Patent Rights” means: (i) all Patents, if any, in the Territory relating to an Opioid Drug, **[* * *]** , including its manufacture, sale, importation or use, which are owned or controlled by or licensed to PTI or its Affiliates as of the Effective Date or during the Term and (ii) all Patents covering PTI Inventions, all to the extent that PTI or its Affiliates have the rights necessary to take the required actions hereunder.

1.48 “PTI Technology” means: (i) any and all Technical Information relating to an Opioid Drug, **[* * *]** , including its manufacture, sale, importation or use which is owned, possessed, developed or acquired by or licensed to PTI or its Affiliates as of the Effective Date or during the Term and (ii) all PTI Inventions, all to the extent that PTI or its Affiliates have the rights necessary to take the required actions hereunder.

1.49 “Pre-Clinical Plan” has the meaning set forth in Section 2.1.

1.50 “Pre-Clinical Program” has the meaning set forth in Section 2.1.

1.51 “Pre-Clinical Program Information” means any Technical Information developed or obtained by either Party or their Affiliates, in the course of performing the Pre-Clinical Program.

1.52 “Product Registration” means, with respect to a Licensed Product, a NDA approved by the FDA in the United States or any other government approval required by a government or Regulatory Authority of a country in the Territory necessary to permit the marketing, import, use and sale of a Licensed Product in such country. Product Registration shall include governmental approval of pricing and/or reimbursement in jurisdictions where such approval is required (either legally or commercially) for commercial sale of a Licensed Product.

1.53 “Regulatory Authority” means the FDA in the United States and any government or regulatory authorities in any country in the Territory that is a counterpart to the FDA and holds responsibility for granting Product Registrations and other marketing approvals for the Licensed Product in such country.

1.54 “SABER ™ Delivery System” means a Controlled Release System comprising a Controlled Release Carrier that is a high viscosity liquid carrier material (HVLCM) including sucrose acetate isobutyrate (SAIB), as such Controlled Release System is claimed in the Patents listed on Exhibit 1.19 as updated from time to time.

1.55 “SABER ™ Ingredients” has the meaning set forth in Section 5.1(a).

1.56 “Sublicensee” means any Third Party to whom PTI has granted (i) the right to make and sell a Licensed Product in the Territory, with respect to Licensed Products made and sold by such Third Party or (ii) the right to distribute a Licensed Product made by or for PTI in the Territory, provided that such Third Party is responsible for the marketing and promotion of such Licensed Product in the applicable territory and has the right to record sales of such Licensed Product for its account.

1.57 “Technical Information” means any and all technical information and other technical subject matter (including medical, toxicological, pharmacological and clinical), trade secrets, know-

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how, ideas, concepts, discoveries, disclosure claims, formulas, formulations, processes, methods, procedures, designs, compositions of matter, specifications, drawings, techniques, results, technologies, compounds, research, data, inventions, discoveries, whether or not patentable.

1.58 “Term” means the term of the Agreement as set forth in Section 15.1.

1.59 “Terminated Country” has the meaning set forth in Section 8.5.

1.60 “Territory” means, with respect to each Licensed Product, all countries of the world and their respective territories and possessions, excluding any country with respect to which the license granted to PTI under Article VIII with respect to such Licensed Product has been terminated in accordance with the terms and conditions of this Agreement.

1.61 “Testing Laboratory” has the meaning set forth in Section 5.3(g).

1.62 “Transfer Price” has the meaning set forth on Exhibit 5.1.

1.63 “Third Party” means any person or entity other than DURECT, PTI, or any of their Affiliates.

1.64 “United States” or “U.S.” means the United States of America and its territories and possessions.

Unless specified to the contrary, references to Articles, Sections and/or Exhibits mean the particular Articles, Sections and/or Exhibits to this Agreement. Whenever used in this Agreement:

(i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”;

(ii) the word “day” means a calendar day unless otherwise specified;

(iii) the word “law” (or “laws”) means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a government entity;

(iv) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; and

(v) the words “commercially reasonable efforts” shall mean the standard that a reasonable business person would use for similar products of similar potential at a similar stage of development in the Territory.

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ARTICLE II

DEVELOPMENT OF LICENSED PRODUCTS

2.1 Initiation of Development of Licensed Products.

(a) Subject to the terms and conditions herein including Article IV, PTI shall diligently develop Licensed Products under this Agreement, including making available such of its personnel, and taking such steps as are reasonably necessary, in order to carry out its obligations hereunder. In the event PTI desires to initiate development work on a Licensed Product under this Agreement, it shall send to DURECT a written notice setting forth a description **[* * *]** of the proposed new Licensed Product. Upon DURECT's receipt of such notice, the JDT shall develop a work plan ("Pre-Clinical Plan") which outlines the pre-clinical program required to establish the feasibility of such Licensed Product for use in humans in the Field, including: **[* * *]** ("Pre-Clinical Program"). The Pre-Clinical Plan for each Licensed Product shall further include an estimated development timeline, allocation of responsibility for performing the tasks between DURECT and PTI and budget for DURECT's performance of its activities under the Pre-Clinical Program (the "Pre-Clinical Budget"). Subject to Article VII, the Pre-Clinical Plan shall be agreed upon by the JDT within thirty (30) days after DURECT's receipt of PTI's written notice referenced above, and upon such agreement of the Pre-Clinical Plan, such Licensed Product shall be included for development under this Agreement. All amendments to the Pre-Clinical Plan of any Licensed Product, including increases or decreases to the Pre-Clinical Budget, shall be agreed to by the JDT in writing.

The Parties anticipate that the first Licensed Product that will be developed under this Agreement (the "Initial Licensed Product") shall incorporate **oxycodone** as the Opioid Drug. In addition to the Pre-Clinical Plan for the Initial Licensed Product, the JDT shall diligently cooperate to develop a written plan within thirty (30) days of the Effective Date for **[* * *]** .

2.2 Pre-Clinical Program.

(a) DURECT and PTI shall be responsible for performance of all activities allocated to it under each Pre-Clinical Plan and shall use diligent and commercially reasonable efforts to perform such activities within the applicable timelines and Pre-Clinical Budgets therefor. In the event that either Party first becomes aware that it is unlikely to perform an activity assigned to such Party under the Pre-Clinical Plan within the applicable timeline or the applicable Pre-Clinical Budget therefor, such Party shall promptly notify the other Party's lead member of the JDT and the JDT shall meet to discuss how to redress such situation. Each Party shall conduct all such activities in accordance with the terms and conditions of this Agreement and all applicable law in the Territory.

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(b) Subject to Section 2.3, DURECT agrees to procure or furnish suitable laboratory facilities and equipment for those activities it is assigned to perform in connection with each Pre-Clinical Plan.

(c) At each [* * *] meeting of the JDT, each Party shall provide the JDT with a progress report summarizing the progress of its activities relating to each Pre-Clinical Program during the past calendar [* * *]. Furthermore, each Party shall promptly communicate to the JDT any Pre-Clinical Program Information as follows: DURECT shall communicate and disclose in writing all previously undisclosed Pre-Clinical Program Information developed, conceived of or acquired by DURECT, and PTI shall communicate and disclose in writing all previously undisclosed Pre-Clinical Program Information developed, conceived of or acquired by PTI.

(d) Within thirty (30) days after completion of a Pre-Clinical Program as shall be determined by the JDT, each Party shall provide to the JDT a completed pharmaceutical development report and a technical documentation package of the work it has performed under such Pre-Clinical Program of sufficient detail and completeness to fully document all activities performed by such Party under the Pre-Clinical Program with respect to such Licensed Product.

2.3 Pre-Clinical Program Expenses.

(a) In consideration for DURECT performing each Pre-Clinical Program, PTI shall reimburse to DURECT all DURECT Research Expenses incurred by DURECT in connection with each Pre-Clinical Program; provided that with respect to the Pre-Clinical Program, PTI shall not be obligated to pay for any portion of the DURECT Research Expenses that exceeds the then-current Pre-Clinical Budget, and DURECT shall not be obligated to perform activities which would result in DURECT Research Expenses in excess of the then-current Pre-Clinical Budget therefor without the prior written agreement of the Parties to amend the budget.

(b) DURECT shall invoice PTI for DURECT Research Expenses under each Pre-Clinical Program on a monthly basis in arrears, and PTI shall render payment to DURECT within thirty (30) days of PTI's receipt of such invoice. DURECT shall retain copies of any receipts, bills, invoices, expense account information and any other supporting data for DURECT's Research Expenses, which PTI shall have the right to audit in accordance with Section 9.8(b). PTI shall be responsible for all of its own expenses relating to each Pre-Clinical Program.

(c) Regardless of the DURECT Research Expenses actually incurred by DURECT for the conduct of the Pre-Clinical Program for each Licensed Product, PTI's compensation to DURECT under Section 2.3(a) for DURECT Research Expenses for the Pre-Clinical Program of each Licensed Product under development shall be at least **[* * *]** for each calendar year until the completion of DURECT's activities under such Pre-Clinical Plan. The foregoing required minimum yearly spend shall be pro-rated (on a weekly basis) for partial years.

2.4 Other Development Activities.

Subject to the terms and conditions herein, with respect to each Licensed Product for which the Pre-Clinical Program is successfully completed as determined by the JDT, PTI shall be solely

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responsible for and shall use reasonable commercial efforts to conduct, as it deems appropriate or useful in its discretion in accordance with its obligations hereunder, all non-clinical and other work not included in the Pre-Clinical Program Plan to the extent required for Product Registration for such Licensed Product including **[* * *]** . Notwithstanding anything herein to the contrary, DURECT shall be solely responsible for all initial and subsequent **[* * *]** with respect to each Licensed Product during the Term of the Agreement in accordance with specifications as are determined by the JDT, and PTI shall reimburse to DURECT all DURECT Research Expenses associated with such **[* * *]** activities in accordance with the procedures set forth in Section 2.3(a) and (b) above with respect to DURECT's Pre-Clinical Program activities; provided, however, if DURECT is unable to perform or fails to carry out any such **[* * *]** , then PTI (itself or through Third Parties) shall have the right to perform such **[* * *]** . **[* * *]** . Accordingly, PTI shall provide to DURECT from time to time, under confidence, information in PTI's possession or control reasonably necessary for DURECT to perform such **[* * *]** or any other development activity required to be performed by DURECT hereunder.

ARTICLE III

CLINICAL PROGRAM

3.1 Clinical Program.

With respect to each Licensed Product for which the Pre-Clinical Program is successfully completed as determined by the JDT, PTI shall, at its sole expense, use commercially reasonable efforts to (i) conduct all reasonable activities relating to the clinical development for such Licensed Product and (ii) make all applications, requests for authorizations and submissions to appropriate Regulatory Authorities, for the purposes of obtaining Product Registration in the Major Market Countries in the Territory for such Licensed Product to the extent reasonably necessary for PTI to discharge its obligations pursuant to Section 8.5 (the "Clinical Program") subject to the remaining terms of this Section 3.1. Subject to the terms and conditions of this Agreement, PTI shall at its sole discretion determine the Clinical Program activities to be performed with respect to each Licensed Product and the Product Registrations to be obtained necessary for the Commercialization of each Licensed Product in the Territory.

3.2 Clinical Program Milestones.

(a) After the date of the successful completion of the Pre-Clinical Program for each Licensed Product as shall be determined by the JDT, PTI shall use commercially reasonable efforts to achieve the milestones relating to the Clinical Program for such Licensed Product on or before the specified date of completion set forth on Exhibit 3.2, which is attached hereto and incorporated

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herein by reference (each a “Clinical Program Milestone”); provided, that DURECT shall have supplied all the Bulk Dosage Form or SABER ™ Ingredients, as appropriate, to PTI in accordance with Article V and shall have provided all necessary information and regulatory documents in accordance with Section 3.3(a). Notwithstanding the foregoing, in the event that DURECT does not supply all the Bulk Dosage Form or SABER ™ Ingredients to PTI in accordance with Article V or provide all necessary information and regulatory documents in accordance with Section 3.3(a), then each date specified on Exhibit 3.2 shall be extended for a reasonable period as agreed to in good faith by the Parties to compensate for any delays experienced by PTI as a result of such failures, but in no case will such extension be less than day for day the number of days that DURECT is late in supplying the applicable Bulk Dosage Form or SABER ™ Ingredients or in providing such information, and PTI shall achieve the milestones relating to the Clinical Program on or before such revised dates. Additionally, the Parties shall agree in good faith to extensions of the specified dates of completion for the Clinical Milestones with respect to a Licensed Product (and shall amend Exhibit 3.2 accordingly) in the event that PTI is unable to complete such Clinical Milestones despite using commercially reasonable efforts to do so and to take into account delays which are due to factors (including regulatory issues) which are out of the reasonable control of or not reasonably foreseeable by PTI (e.g., **[* * *]**).

(b) In the event that PTI does not meet a Clinical Program Milestone for a Licensed Product within the applicable timeframe set forth under Section 3.2(a), DURECT may elect to, at its sole discretion, upon **[* * *]** days written notice to PTI, **[* * *]** . Notwithstanding the foregoing, DURECT shall not have such right to **[* * *]** as described in the previous sentence if PTI within **[* * *]** days of receipt of the notice from DURECT (A) completes such Clinical Program Milestone or (B) provides to DURECT a good faith plan for achieving such Clinical Program Milestone within twelve (12) months of the original date therefor (as may be extended in accordance with Section 3.2(a) above) and pays to DURECT the amount of the corresponding milestone payment pursuant to Section 9.2 or 9.3, as applicable, that would have been due and payable upon completion of such Clinical Program Milestone despite the failure to complete such Clinical Program Milestone at such time in which case the particular Clinical Program Milestone shall be extended for twelve (12) months and the amount so paid will be creditable against the amount due to DURECT under Section 9.2 or 9.3 when such Clinical Program Milestone is actually completed; provided that if PTI fails to achieve such Clinical Program Milestone within such extension period, then DURECT will have the right set forth in the first sentence of this Section 3.2(b) above.

3.3 DURECT’s Cooperation.

(a) DURECT shall reasonably cooperate with PTI to obtain the Product Registration for each Licensed Product in the Territory by providing any information or other materials relating to the conduct of the Pre-Clinical Program or the SABER ™ Delivery System in DURECT’s possession or control as PTI shall reasonably request. Without limiting the generality of the foregoing, DURECT shall assist PTI or its designee in the completion of **[* * *]** as required in the Territory, for each Licensed Product.

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(b) DURECT shall, upon request from PTI make reasonably available to PTI members of the research, development and technical staff of DURECT assigned to the Pre-Clinical Program with respect to a Licensed Product in order to assist PTI in the scale-up of operations and in the Commercialization of such Licensed Product in the Territory.

(c) PTI shall pay DURECT for all costs reasonably incurred by DURECT in connection with DURECT's activities, which are undertaken pursuant to this Section 3.3 as calculated in the same manner as DURECT Research Expenses. DURECT shall invoice PTI on a monthly basis in arrears for such costs. PTI shall pay DURECT the amounts payable within [* * *] days after receipt of such invoice by PTI.

ARTICLE IV

MINIMUM DEVELOPMENT REQUIREMENTS

4.1 Minimum Development Requirements.

Subject to the terms and conditions including the terms of this Article IV below, during the Term, PTI shall diligently develop and Commercialize Licensed Products in accordance with the following minimum development diligence requirements set forth in this Section 4.1 ("Development Diligence Requirements"). Commencing in calendar year 2003 and for each period thereafter during the Term, PTI shall have the minimum required number of **[* * *]** Licensed Products which are either under development or being Commercialized under this Agreement on the first day of each such period as set forth in the table below:

MINIMUM REQUIRED NUMBER OF LICENSED PRODUCTS

Period	**[* * *]**	**[* * *]**	**[* * *]**	**[* * *]**
Minimum number of [* * *] Licensed Products under development or being Commercialized	[* * *]	[* * *]	[* * *]	[* * *]

4.2 Consequences.

If the above Development Diligence Requirements are not met by PTI in any period during the Term, then DURECT shall have the right, upon [* * *] days' written notice to PTI, to **[* * *]** , provided that PTI does not cure such failure by giving notice within such

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[* * *] day period to DURECT of adding additional Licensed Product(s) for development hereunder sufficient to meet such Development Diligence Requirements, and further provided, however, notwithstanding the foregoing, PTI shall retain an exclusive license under Section 8.1 with respect to any Licensed Product that PTI has under development and continues to diligently develop and Commercialize under this Agreement. For purposes of this Agreement, each Licensed Product including **[* * *]** shall be deemed a "different" Licensed Product.

4.3 Expiration of Development Diligence Requirements.

The provisions of Sections 4.1 and 4.2 above shall expire at such time as any **[* * *]** Licensed Products each have generated Net Sales of at least **[* * *]** during **[* * *]** . Notwithstanding the foregoing, in the event that this Agreement is assigned to an Acquiror of PTI pursuant to Section 17.1 as a result of a Change of Control of PTI, then the provisions of Sections 4.1 and 4.2 above shall be applicable to such Acquiror; provided, however, that such diligence requirements shall be suspended with respect to such Acquiror for so long as such Acquiror is Commercializing at least **[* * *]** each of which has generated Net Sales of at least **[* * *]** during the **[* * *]** (the "Suspension Condition"). In the event that after being satisfied the Suspension Condition is no longer then currently satisfied, the provisions of Sections 4.1 and 4.2 shall again apply beginning ninety (90) days immediately following the time and for so long as the Suspension Condition is no longer satisfied. "Change of Control" means any transaction or series of related transactions that would occasion: (i) any share exchange, business combination, consolidation or merger or series of transactions resulting in the exchange of the outstanding shares of a Party unless the stockholders of such Party that exist immediately prior to the closing date of such transaction (or series of related transactions) hold, after the closing date, more than fifty percent (50%) of the voting equity of the surviving entity in such transaction computed on a fully diluted basis, or (ii) a sale or other transfer of all or substantially all of the assets of such Party.

4.4 Addition or Deletion of Licensed Products.

Subject to Sections 2.1, 4.1 and 8.5, PTI may add or delete Licensed Products under this Agreement within its reasonable, good faith judgment provided that PTI provides DURECT with ninety (90) days prior written notice of any such addition or deletion.

ARTICLE V

DURECT MANUFACTURE AND SUPPLY

5.1 DURECT Manufacture and Supply During Clinical Phase.

(a) Subject to the terms and conditions set forth herein, DURECT shall manufacture and supply to PTI, and PTI shall purchase from DURECT: (i) **[* * *]** described in the written specifications designated by the JDT therefor in accordance with Section 5.1(b) (collectively, the "SABER ™ Ingredients") for manufacture of Licensed Products used in the conduct of the Clinical Program and (ii) **[* * *]** as designated by the JDT (**[* * *]** , the "Bulk Dosage Form").

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(b) The specifications for the SABER ™ Ingredients, and the Bulk Dosage Form for each Licensed Product, including any applicable packaging, container-closure system component and labeling specifications, shall be agreed upon in writing by the JDT. Any modifications to such specifications shall be agreed upon in writing by the JDT. The specifications for the SABER ™ Ingredients or the Bulk Dosage Form, and any subsequent amendments thereto, shall be maintained in a Chemistry, Manufacturing and Controls Specification Guide for the Licensed Product and incorporated herein by reference. Without limiting the foregoing, the Parties shall use good faith efforts to modify the specifications for a particular SABER ™ Ingredients or Bulk Dosage Form in the event such modification is necessary for approval of the Product Registration or other regulatory issues with respect to the applicable Licensed Product.

(c) The SABER ™ Ingredients and Bulk Dosage Form supplied by DURECT shall be used by PTI solely in accordance with this Agreement.

(d) DURECT shall supply the SABER ™ Ingredients and Bulk Dosage Form in accordance with the Section 5.3(f) to PTI at the "Transfer Price" set forth in Exhibit 5.1.

5.2 Supply of Opioid Drugs and Antagonists.

With respect to the supply of Bulk Dosage Form supplied by DURECT hereunder, DURECT agrees to obtain quantities of appropriate Opioid Drugs and Antagonists from one or more suppliers designated by PTI that it will require to fulfill its supply obligations hereunder. Any Opioid Drugs or Antagonists so obtained shall be used solely as set forth herein to supply PTI with its requirements of Bulk Dosage Form.

5.3 Terms and Conditions Applicable to Clinical Supply.

(a) It is understood that DURECT agrees to supply (i) Bulk Dosage Form for use in the **[* * *]** and (ii) SABER ™ Ingredients for **[* * *]** . Accordingly, at the time of **[* * *]** , PTI will provide DURECT a plan for requirements and good faith timeline for SABER ™ Ingredients and the Bulk Dosage Form for use during the **[* * *]** for such Licensed Product (the "Clinical Supplies Requirement Plan"). The Clinical Supplies Requirement Plan and each revision shall be reasonably sufficient to provide for the requirements of the **[* * *]** and agreed to in writing by the Parties. Within **[* * *]** days of approval of the Clinical Supplies Requirements Plan, PTI and DURECT shall prepare a plan for DURECT's supply of Bulk Dosage Form and SABER ™ Ingredients pursuant to such Clinical Supplies Requirement Plan (the "Clinical Supplies Delivery Plan").

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(b) DURECT shall use commercially reasonable efforts to deliver the specified quantity of the SABER ™ Ingredients and the Bulk Dosage Form in accordance with the delivery schedule set forth in the Clinical Supplies Delivery Plan. DURECT shall exercise commercially reasonable efforts to comply with changes to Clinical Supplies Delivery Plan that PTI may request but shall not be liable for its inability to do so. The Clinical Supplies Delivery Plan may be amended by mutual agreement of the Parties.

(c) DURECT shall deliver the quantity of the SABER ™ Ingredients and the Bulk Dosage Form in accordance with the Clinical Supplies Delivery Plan, along with appropriate documentation including Certificate of Analysis (describing the specifications therefor, results of tests performed and certifying compliance with such specifications and applicable cGMP requirements) and other documentation to be defined by the Parties, to a location designated in writing by PTI, FOB [* * *]. Title to the SABER ™ Ingredients or Bulk Dosage Form, as applicable, shall pass to PTI [* * *] from DURECT's facility.

(d) DURECT shall promptly invoice PTI for all quantities of the SABER ™ Ingredients and the Bulk Dosage Form delivered in accordance herewith, provided that DURECT shall not submit any invoice prior to the shipment thereof. Payment with respect to a shipment shall be due **[* * *]** days after receipt by PTI of such invoice. The terms and conditions of this Agreement shall exclusively govern the purchase and supply of SABER ™ Ingredients and Bulk Dosage Form hereunder and shall override any conflicting, amending and/or additional terms contained in any order, acceptance or invoice.

(e) Should DURECT experience manufacturing difficulties that, or have reason to believe that it is likely to experience difficulties that would, result in a significant delay in delivery of SABER ™ Ingredients or Bulk Dosage Form hereunder, DURECT shall promptly advise PTI of such delay and work together with PTI in good faith to develop a solution to address and minimize such delay. In the event that DURECT does not deliver the SABER ™ Ingredients or Bulk Dosage Form within **[* * *]** days after the delivery date set forth in the Clinical Supplies Delivery Plan, PTI shall have the right to suspend its payment obligations for such SABER ™ Ingredients or Bulk Dosage Form until DURECT has delivered such SABER ™ Ingredients or Bulk Dosage Form.

(f) DURECT warrants that, at the time of delivery of the SABER ™ Ingredients or Bulk Dosage Form, as applicable, to PTI: (i) such SABER ™ Ingredients or Bulk Dosage Form will have been manufactured, stored and shipped in accordance with all applicable laws in the Territory, including applicable cGMP's; (ii) such SABER ™ Ingredients or Bulk Dosage Form will have been manufactured in accordance, and be in conformity, with the specifications for the SABER ™ Ingredients or Bulk Dosage Form agreed to by the JDT under Section 5.1(b); (iii) such SABER ™ Ingredients or Bulk Dosage Form will not be adulterated or misbranded under the Act or any equivalent law in the Territory; (iv) title to such SABER ™ Ingredients or Bulk Dosage Form will pass to PTI as provided herein free and clear of any security interest, lien or other encumbrance; (v) such SABER ™ Ingredients or Bulk Dosage Form will have been manufactured in facilities that are in material compliance with all applicable laws at the time of such manufacture (including applicable inspection requirements of FDA and other applicable Regulatory Authorities in the Territory); and (vi) such SABER ™ Ingredients or Bulk Dosage Form may be introduced into interstate commerce pursuant to the Act.

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(g) In the event that, within **[* * *]** days after receipt thereof by PTI, any SABER ™ Ingredients or Bulk Dosage Form supplied by DURECT do not conform to the warranties set forth under Section 5.3(f), PTI shall give DURECT notice thereof (including a sample of such SABER ™ Ingredients or Bulk Dosage Form). DURECT shall undertake appropriate testing of such sample and shall notify PTI whether it has confirmed such non-conformity within **[* * *]** days after receipt of such notice from PTI. If DURECT notifies PTI that it has not confirmed such non-conformity, the Parties shall submit the disputed batch to an independent testing laboratory mutually acceptable to the Parties (the "Testing Laboratory") for testing. The findings of the Testing Laboratory shall be binding on the Parties, absent manifest error. The expenses of the Testing Laboratory shall be borne by DURECT if the testing confirms the non-conformity and by PTI if the testing does not confirm the non-conformity. If the Testing Laboratory or DURECT confirms that a batch of SABER ™ Ingredients or Bulk Dosage Form, as applicable, does not conform to the warranties set forth under Section 5.3(f), DURECT shall promptly, at the election of PTI, (i) supply PTI with a replacement conforming quantity of the SABER ™ Ingredients or Bulk Dosage Form at DURECT's expense or (ii) reimburse PTI for the costs paid by PTI for such non-conforming SABER ™ Ingredients or Bulk Dosage Form, and shall additionally reimburse PTI for any out of pocket costs relating to the disposal or return to DURECT of such SABER ™ Ingredients or Bulk Dosage Form. The rights and remedies provided in this Section 5.3 and Section 5.4 shall be the exclusive remedy of PTI for non-conforming products. DURECT EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

(h) DURECT shall maintain, or cause to be maintained (i) all records necessary to comply with all applicable law in the Territory relating to the manufacture of the SABER ™ Ingredients and Bulk Dosage Form supplied to PTI hereunder, including the cGMP's; (ii) all manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks and all raw data relating to the manufacture of SABER ™ Ingredients and Bulk Dosage Form; and (iii) such other records as PTI may reasonably require in order to ensure compliance by DURECT with the terms and conditions of this Agreement. All such material shall be retained for such period as may be required by cGMP's or any other applicable law in the Territory, whichever is longest.

(i) DURECT agrees that PTI and its agents shall have the right, upon reasonable prior notice to DURECT, to inspect any location where SABER ™ Ingredients or Bulk Dosage Form are being manufactured, as applicable, including inspection of (i) the materials used in the manufacture of the SABER ™ Ingredients or Bulk Dosage Form; (ii) the holding facilities used in the manufacture of the SABER ™ Ingredients or Bulk Dosage Form; (iii) the equipment used in the manufacture of the SABER ™ Ingredients or Bulk Dosage Form, and (iv) all records relating to such manufacturing in each such manufacturing facility. Following such audit, PTI shall discuss its observations and conclusions with DURECT and corrective actions shall be agreed in writing upon by PTI and DURECT within **[* * *]** days thereafter. DURECT shall implement such corrective action within **[* * *]** days after the Parties reach such agreement, unless otherwise agreed in writing by the Parties.

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(j) DURECT shall notify PTI by telephone within **[* * *]** business days, and in writing within **[* * *]** business days, after learning thereof, of any proposed or unannounced visit or inspection of any facility used in the manufacture of SABER ™ Ingredients or Bulk Dosage Form or any manufacturing Process used in connection with the manufacture of SABER ™ Ingredients or Bulk Dosage Form, by any Regulatory Authority, and shall permit PTI or its agents to be present and participate in such visit or inspection. DURECT shall provide to PTI a copy of any report and other written communications received from such Regulatory Authority in connection with such visit or inspection, and any written communications received from such Regulatory Authority, within **[* * *]** business days after receipt thereof, including any FDA Form 483 or Notice of Observation, and shall consult with PTI concerning the response of DURECT to each such communication. DURECT shall provide PTI with a copy of all draft responses for comment as soon as possible and all final responses for review and approval, which shall not be unreasonably withheld or delayed, within **[* * *]** business days prior to submission thereof.

5.4 Failure to Supply.

(a) If DURECT fails **[* * *]** or more times within any **[* * *]** period to supply the full quantity of SABER ™ Ingredients or Bulk Dosage Form specified in the Clinical Supplies Delivery Plan by the delivery date specified therein and in conformity with the warranty set forth in Section 5.3(f), PTI may, in its sole discretion, **[* * *]** .

(b) Subject to all other terms and conditions of this Agreement, **[* * *]** .

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5.5 Supply Agreement for the Commercial Phase.

(a) Subject to this Section 5.5, PTI agrees that DURECT shall have the right to supply all GMP-qualified SABER ™ Ingredients for the commercial supply of all Licensed Products. Prior to PTI's receipt of the first Product Registration in the Territory for the first Licensed Product, the Parties shall negotiate in good faith and shall agree in writing to a supply agreement relating to the supply by DURECT of the SABER ™ Ingredients to PTI for purposes of the Commercialization of the Licensed Products, provided that such agreement shall include the pricing terms set forth in Section 5.1(d) and shall further provide that DURECT will (i) qualify a second manufacturing site (which can be another facility owned by DURECT) for the SABER ™ Ingredients when the aggregate Net Sales of Licensed Products hereunder exceed **[* * *]** per year and (ii) establish, at PTI's request and expense, an escrow account and deposit therein the DURECT Deposit Materials which provides release thereof to PTI or its designee in the event that DURECT is unable to or fails to supply quantities of SABER ™ Ingredients as required in the supply agreement. Additionally, the supply agreement shall include provisions for DURECT to qualify a Third Party supplier at PTI's discretion and cost for SABER ™ Ingredients and for backup manufacturing rights similar to those set forth in Section 5.4. For purpose of this Section 5.5(a), "DURECT Deposit Materials" means instructions, specifications, and other Technical Information and materials describing the composition and manufacture of each such SABER ™ Ingredients, including a description of the suppliers, raw materials, processes, equipment, and instruments used for such manufacture, all in sufficient detail to reasonably enable PTI to manufacture, without need for further information, the SABER ™ Ingredients in the same manner as such manufacture is performed by or for DURECT.

(b) Without limiting Section 5.5(a) above, DURECT agrees to transfer to PTI or its designee processes and manufacturing know-how (including process information and methodologies, analytical and validation testing methods and criteria, and qualified sources of raw materials) in its possession and control reasonably necessary for PTI or its designees to manufacture commercial quantities of Licensed Product using SABER Ingredients supplied in accordance with Section 5.5(a). PTI shall pay DURECT for all costs reasonably incurred by DURECT in connection with DURECT's activities, which are undertaken pursuant to this Section 5.5(b) as calculated in the same manner as DURECT Research Expenses. DURECT shall invoice PTI on a monthly basis in arrears for such costs. PTI shall pay DURECT the amounts payable within thirty (30) days after receipt of such invoice by PTI.

5.6 PTI Responsibilities.

Other than DURECT's foregoing supply obligations of SABER ™ Ingredients and Bulk Dosage Form, as between the Parties, PTI shall be solely responsible for manufacturing, or having manufactured, the Licensed Products for use in the conduct of the Clinical Program and for Commercialization.

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ARTICLE VI

PTI MANUFACTURE AND REGULATORY INTERACTIONS

6.1 PTI Manufacture and Supply.

Without limiting Section 5.6 above, PTI shall have the right and responsibility (itself or through others) for (i) the finishing of SABER ™ Ingredients supplied by DURECT into finished Licensed Product for conduct of the Clinical Program and Commercialization hereunder and (ii) all final packaging (including trade dress (product packaging, design and the like), trade names and trademarks used therewith) for the Licensed Product.

6.2 Regulatory Authority Interactions.

Subject to Section 6.3 below, the Parties understand and agree that PTI, itself or through its agents, shall have the sole right to correspond with and submit INDs, NDAs, regulatory applications and other filings to the FDA or other Regulatory Authorities to obtain Product Registration approvals to import, export, sell or otherwise commercialize the Licensed Products as PTI deems useful or necessary to fulfill its obligations hereunder. Accordingly, except as otherwise required by law, DURECT shall not correspond directly with the FDA or any other Regulatory Authority relating to the process of obtaining Product Registrations or any obtained Product Registration for the Licensed Products, without PTI's prior permission. Notwithstanding the foregoing, DURECT agrees to provide such reasonable assistance, as requested by PTI and at PTI's expense, in preparing, submitting and maintaining NDAs and other applications for such Product Registrations.

6.3 DURECT Rights.

Notwithstanding Section 6.2, due to DURECT's continuing interest in development and production of products other than the Licensed Products utilizing the SABER ™ System, DURECT shall have the right to review and provide comments to those portions of any regulatory correspondence and filings relating to the SABER ™ System or its function, manufacture or safety, including manufacturing specifications, adverse event reports and the relevant portions of the Chemistry, Manufacturing and Controls section of any NDA or its equivalent filing with a Regulatory Authority prior to submission thereof, provided that DURECT shall be required to provide any comments to PTI within **[* * *]** business days after receipt of any draft filings or correspondence from PTI, and further provided that PTI shall incorporate in any such correspondence or filing DURECT's reasonable comments. In addition, the Chemistry, Manufacturing and Controls section of any regulatory filing, to the extent it relates to the SABER ™ System, may be maintained by DURECT, in one or more of DURECT's master files (e.g., drug master file as described in 21 C.F.R. § 314.420) to the extent permissible under applicable laws and regulations, for which PTI shall have the right of reference for each Licensed Product hereunder.

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ARTICLE VII

THE JOINT DEVELOPMENT TEAM

7.1 The Joint Development Team.

As soon as practicable after the execution of this Agreement, but no later than thirty (30) days after the Effective Date, the Parties shall establish a joint development team (the "Joint Development Team" or "JDT"). The JDT will be composed of **[* * *]** members selected by DURECT, and **[* * *]** members selected by PTI. The initial members of the JDT are set forth on Exhibit 7.1 hereto. Each Party, at its sole discretion, may at any time upon written notice to the other Party replace the members selected by it. Each Party shall appoint at least one member who shall be an individual within the senior management of such Party (i.e., being a vice president level or higher). Those representatives of each such Party shall, individually or collectively, have expertise in pharmaceutical drug development. Each Party shall use commercially reasonable efforts to cause its respective representatives to attend all meetings of the JDT. Each Party shall bear any travel and out-of-pocket expenses incurred by its members in connection with the JDT's meetings.

7.2 Meetings.

The JDT shall meet **[* * *]** or as otherwise mutually agreed upon by the Parties. Meetings of the JDT may be held by the physical presence of its members or by teleconference or videoconference. At each meeting of the JDT, the JDT shall review the progress with respect to the Pre-Clinical Program during the period since the last meeting.

7.3 Responsibilities.

The JDT shall be charged with managing and overseeing the conduct of the Pre-Clinical Program and performing other tasks and duties specified in the Agreement. The responsibilities and authority of the JDT may be adjusted as the Parties shall agree in writing. The JDT shall perform any additional tasks as shall be agreed to by the Parties in writing.

7.4 Decision Making and Authority.

With respect to any matter for which responsibility is assigned to the JDT hereunder, if the JDT cannot reach consensus within **[* * *]** days after the matter is first identified for resolution, such matter will be promptly presented by the members on the JDT to the chief executive officers of each DURECT and PTI. Such executives shall meet to discuss each Party's view and to explain the basis for disagreement. If such executives are unable to resolve such dispute within **[* * *]** days of their meeting, the matter shall be resolved by the PTI executive who has the principal responsibility for PTI's work under this Agreement or who is designated by PTI. Notwithstanding the foregoing, nothing herein, and no decision made under this Section 7.4 shall be deemed to modify or supersede the express terms and conditions of the Agreement.

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7.5 Termination of JDT.

Once all follow-up review of the Pre-Clinical Program for all Licensed Products then under development has been completed, the activities of the JDT shall terminate on a date as shall be agreed upon by the JDT.

ARTICLE VIII

GRANT OF LICENSE

8.1 License.

On the terms and conditions of this Agreement, as between the Parties hereto, PTI shall have the exclusive right to Commercialize each of the Licensed Products in the Territory, with the right to record sales for its own account. Subject to the terms and conditions of this Agreement, DURECT hereby grants to PTI, and PTI accepts, the non-transferable, sole and exclusive right and license under the DURECT Patent Rights and DURECT Technology (with the right to grant and authorize sublicenses as set forth in Section 8.3) to the extent necessary to develop, manufacture, market, import, use or sell each Licensed Products throughout the Territory.

8.2 Term of License.

(a) Subject to Section 8.2(b), the term of the license granted under Section 8.1 with respect to each Licensed Product shall commence as of the Effective Date and, unless sooner terminated as provided hereunder, shall terminate as to each country in the Territory upon the expiration of the later of:

(i) the expiration or invalidation of the last to expire or be invalidated of the DURECT Patent Rights which but for this Agreement would be infringed by the sale of the Licensed Product based on such DURECT Patent Rights in such country, including any extension of such DURECT Patent Rights; and

(ii) **[* * *]** years after the First Commercial Sale in such country of the Licensed Product.

(b) Except as otherwise expressly provided herein, all licenses granted under this Article VIII shall terminate upon the termination or expiration of the Agreement. In the event of expiration (but not any other termination) of this Agreement under Section 15.1, PTI's licenses under this Article VIII under the DURECT Technology (excluding any Patents) shall **[* * *]** .

8.3 Sublicense.

Subject to the terms and conditions of this Agreement, PTI has the nontransferable, sole and exclusive right to grant and authorize sublicenses under its license pursuant to Section 8.1 to any Third Party or Affiliate, provided that DURECT shall have the right to approve all Sublicensees, as defined in Section 1.56 clause (i), but not clause (ii), which approval shall not be unreasonably

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withheld, delayed or conditioned upon the receipt of additional consideration. PTI shall ensure that (i) each Sublicensee shall be subject to and shall comply with terms and conditions with respect to DURECT Patent Rights and DURECT Technology that are no less stringent than those set forth under this Agreement; and (ii) the rights of DURECT under this Agreement shall not be prejudiced, reduced or limited in any way as a result of such sublicense of rights. In the event that the license granted to PTI in Section 8.1 is terminated with respect to any country in the Territory, all sublicenses granted by PTI to Sublicensees approved by DURECT above in such country survive, provided that upon request of DURECT such Sublicensee promptly agrees in writing to be bound by the applicable terms and conditions of this Agreement including Article IX below.

8.4 Exclusivity.

(a) Subject to Section 4.2, during the Term, DURECT shall not, and shall not authorize nor license any Third Party or Affiliate any right under the DURECT Patent Rights or DURECT Technology to develop, manufacture, market, import, use or sell or otherwise commercialize any product **[* * *]** in any countries in the Territory with respect to which the license granted to PTI under Section 8.1 has not been terminated or expired.

(b) Commencing upon **[* * *]** and thereafter during the Term, except for Licensed Products hereunder, PTI shall not, and shall not authorize nor license any Third Party or Affiliate to develop, manufacture, market, import, use or sell or otherwise commercialize any product **[* * *]** in any country in the Territory with respect to which the license granted to PTI under Section 8.1 has not been terminated or expired. **[* * *]** .

(c) In the event of a Change of Control of PTI pursuant to which this Agreement is assigned to PTI's Acquiror pursuant to Section 17.1, the restrictions contained in Section 8.4(b), shall not prevent the Acquiror or its Affiliates from **[* * *]** . In the event of a Change of Control of DURECT pursuant to which this Agreement is assigned to DURECT's Acquiror pursuant to Section 17.1, the restrictions contained in Section 8.4(a), shall not prevent the Acquiror or its Affiliates from **[* * *]** :

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(i) [* * *]

(ii) [* * *]

(d) [* * *].

8.5 Commercial Diligence.

All activities relating to the Commercialization of the Licensed Product in the Territory shall be determined by PTI at its sole discretion and expense; provided, that PTI shall use commercially reasonable efforts to Commercialize the Licensed Product in the Territory. If PTI has not: (i) applied for Product Registration for a particular Licensed Product in any **[* * *]** Major Market Countries other than the U.S. within **[* * *]** years after obtaining Regulatory Approval for such Licensed Product in the U.S.; (ii) applied for Product Registration for a particular Licensed Product

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in any **[* * *]** Major Market Countries other than the U.S. within **[* * *]** years after obtaining Regulatory Approval for such Licensed Product in the U.S.; (iii) applied for Product Registration for a particular Licensed Product in **[* * *]** Major Market Countries other than the U.S. within **[* * *]** years after obtaining Regulatory Approval for such Licensed Product in the U.S.; or (iv) made the First Commercial Sale in any Major Market Country within **[* * *]** months after receipt of Product Registration for such Particular Product in such Major Market Country, then DURECT may, upon **[* * *]** days prior written notice to PTI (unless PTI applies for such Product Registration or makes such First Commercial Sale within such **[* * *]** day period), terminate the rights granted to PTI under Section 8.1 with respect to such Licensed Product in such country (each, a "Terminated Country"). In such event, DURECT shall have the right to Commercialize such Licensed Product in the Terminated Country in accordance with Section 15.5(b). The Parties shall agree in good faith to extensions of any of the foregoing specified dates related to Commercialization of a Licensed Product in a particular country in the event that PTI is unable to meet such specified dates for completion of requirements despite using commercially reasonable efforts to do so and to take into account delays which are due to factors (including regulatory issues) which are out of the reasonable control of PTI. Notwithstanding anything herein to the contrary, in the event that PTI in its commercially reasonable judgment deems it commercially unreasonable or imprudent to launch a Licensed Product in a particular Major Market Country or other country in the Territory, after considering among other things: (A) **[* * *]** , (B) **[* * *]** , (C) **[* * *]** , (D) **[* * *],** and (E) **[* * *]** , PTI shall notify DURECT in writing of such determination and PTI shall not have any obligation to perform any clinical development or file for any Product Registrations with respect to a Licensed Product in such Major Market Country or other country. Notwithstanding the foregoing, in the event that DURECT disagrees with PTI's determination with respect to a Major Market Country, DURECT shall notify PTI within **[* * *]** days of PTI's notice and the Parties shall resolve such disputepursuant Section 16.1(b); with respect to other countries PTI shall have sole discretion when acting in good faith.

8.6 License to DURECT.

PTI hereby grants to DURECT a limited, royalty-free, nonexclusive license, without right to sublicense, under the PTI Patents and PTI Technology to the extent reasonably necessary and solely to perform its obligations in accordance with this Agreement, which grant shall expire on the termination of this Agreement for any reason.

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ARTICLE IX

PAYMENTS

9.1 Upfront Payments.

PTI shall make the following payments specified below to DURECT within **[* * *]** days following achievement of the corresponding event:

Event	Payment
(a) Execution of this Agreement	**$900,000**
(b) Receipt by PTI of a prototype dosage form of Initial Licensed Product with in-vitro properties meeting the specified criteria for the first human bioavailability study as set forth in the Pre-Clinical Plan therefor.	**$100,000**

9.2 Milestone Payments for Initial Licensed Product.

PTI shall make the following payments specified below to DURECT within **[* * *]** days following achievement of the corresponding event only with respect to the Initial Licensed Product.

Event	Payment
(a) [* * *]	
(b) [* * *]	
(c) [* * *]	
(d) [* * *]	

9.3 Milestone Payments for Each Subsequent Licensed Product.

PTI shall make the following payments specified below to DURECT within **[* * *]** days following achievement of the corresponding event only with respect to each Licensed Product on which development is commenced after the Initial Licensed Product.

******* **Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

Event	Payment
(a) [* * *]	
(b) [* * *]	
(c) [* * *]	
(d) [* * *]	

9.4 Other.

For purposes of this Agreement, (i) **[* * *]** ; (ii) **[* * *]** ; and (iii) **[* * *]** . Additionally, each Licensed Product **[* * *]** shall be deemed a separate Licensed Product for purposes of the payments under Section 9.2 and 9.3.

9.5 Royalties.

Subject to the terms and conditions of this Agreement and for the duration of any surviving license granted to PTI during the term specified in Section 8.2(a), PTI will pay DURECT, in each calendar year, a royalty on Net Sales of each Licensed Product in the each country of the Territory according to the schedule as set forth on Exhibit 9.5, which is attached hereto and incorporated herein by reference.

(a) Royalties in accordance with Exhibit 9.5 shall be paid quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of an Accounting Period) within **[* * *]** days after the end of each Accounting Period in which such Net Sales occur, commencing with the calendar quarter in which the First Commercial Sale of the Licensed Product is made by PTI or its Sublicensees or Affiliates.

(b) The obligation to pay royalties to DURECT under Section 9.5(a) above shall be imposed only once with respect to any sale of the Licensed Product, regardless of the number of DURECT Patent Rights covering or the DURECT Technology licensed by DURECT to PTI. There shall be no obligation to pay royalties to DURECT under Section 9.5(a) above on sales or transfer of the Licensed Product between or among PTI, its Affiliates and its Sublicensees (unless such Sublicensee or Affiliate is an end user of the Licensed Product).

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(c) In the event that a Licensed Product is sold in combination with another product, component or service for which no royalty would be due hereunder if sold separately, Net Sales from such combination sales for purposes of calculating the amounts due under this Section 9.5 shall be calculated by multiplying the Net Sales of the combination product by the fraction A/(A + B), where A is the average gross selling price during the Accounting Period of the Licensed Product sold separately and B is the gross selling price during the Accounting Period of the product(s), component(s) and/or service(s) which was combined with the Licensed Products.

9.6 Mode of Payment.

PTI shall make all payments required under this Agreement in United States Dollars to DURECT by wire transfer of immediately available funds to a bank account of DURECT designated by DURECT from time to time in accordance with this Agreement. With respect to sales which are not denominated in United States Dollars, payments shall be calculated based on currency exchange rates for the calendar quarter for which remittance is made for royalties. For each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates (obtained as described below) during the calendar quarter. Each daily exchange rate shall be obtained from The Wall Street Journal, Western United States Edition, or, if not so available, as otherwise agreed to in writing by the Parties.

9.7 Tax Withholding.

If any law or regulation requires the withholding by PTI or its Affiliates or Sublicensees of any taxes due on payments to be remitted to DURECT, such taxes shall be deducted from the amounts paid to DURECT. If the taxes are deducted from the amounts paid to DURECT, then PTI shall use commercially reasonable efforts to furnish DURECT proof of payment of all such taxes and shall reasonably cooperate with DURECT in any efforts by DURECT to obtain a credit for such taxes.

9.8 Accounting and Audit.

(a) PTI agrees to keep clear, accurate and complete records for a period of at least **[* * *]** years (or such longer period as may correspond to PTI's internal records retention policy) for each reporting period in which sales occur showing the manufacturing, sales, use and other disposition of the Licensed Products in sufficient detail to enable the share of Net Sales payable hereunder to be determined, and further agrees to permit its books and records to be examined by an independent accounting firm selected by DURECT and reasonably satisfactory to PTI, from time-to-time to the extent necessary, but not more frequently than **[* * *]** a year. Such accounting firm shall report to DURECT only whether payment reports provided hereunder are accurate, and, if not accurate, the amount of any discrepancy. Such examination by an independent accounting firm under this Section 9.8(a) is to be made at the expense of DURECT, except that if the results of the audit for any year reveal that PTI has underpaid DURECT with respect to any country by an amount exceeding the audit fees in any individual country of the Territory for such year, then the audit fees

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***** Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

shall be paid by PTI. The amount of any such underpayment will be promptly paid to DURECT. All information accessed or learned by DURECT and its accounting firm pursuant to this Section 9.8(a) shall be deemed to be the Confidential Information of PTI pursuant to Article XIII.

(b) DURECT agrees to keep clear, accurate and complete records for a period of at least **[* * *]** years (or such longer period as may correspond to DURECT's internal records retention policy) in sufficient detail to substantiate the determination of the DURECT Research Expenses and Manufacturing Costs for SABER ™ Ingredients and Bulk Dosage Form supplied by or on behalf of DURECT hereunder, and further agrees to permit its books and records to be examined by an independent accounting firm selected by PTI and reasonably satisfactory to DURECT, from time-to-time to the extent necessary, but not more frequently than **[* * *]** a year. Such accounting firm shall report to PTI only whether invoices or other requests for payment hereunder are accurate, and, if not accurate, the amount of any discrepancy. Such examination by an independent accounting firm under this Section 9.8(b) is to be made at the expense of PTI, except that if the results of the audit for any year reveal that DURECT has overcharged PTI by an amount exceeding the audit fees, then the audit fees shall be paid by DURECT. Any such overpayment by PTI will be promptly reimbursed by DURECT. All information accessed or learned by PTI and its accounting firm pursuant to this Section 9.8(b) shall be deemed to be the Confidential Information of DURECT pursuant to Article XIII.

ARTICLE X

REPRESENTATIONS AND WARRANTIES

10.1 Representations and Warranties of DURECT.

DURECT represents and warrants to PTI that:

(a) The execution, delivery and performance of this Agreement by DURECT Corporation and SBS shall not, with or without notice or the passage of time or both, result in any violation of or constitute a default under any material contract, obligation or commitment to which either DURECT Corporation or SBS is a party or by which either is bound, or any statute, rule or governmental regulation applicable to either DURECT Corporation or SBS. This Agreement constitutes a valid and binding obligation of each of DURECT Corporation and SBS, enforceable in accordance with its terms.

(b) DURECT Corporation is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and SBS is a corporation duly organized, validly existing and in good standing under the laws of the State of Alabama, and each of DURECT Corporation and SBS has all requisite legal and corporate power and authority to carry on its business, grant the licenses to be granted by DURECT hereunder and to carry out and perform its obligations hereunder. All corporate action on the part of DURECT Corporation and SBS and their respective officers and directors necessary for the entering into of this Agreement, the grants of licenses pursuant hereto and the performance of the obligations of DURECT Corporation and SBS hereunder has been taken.

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(c) DURECT shall perform all of its obligations set forth under this Agreement in compliance with all applicable laws in the Territory, including, if applicable, the cGMP's.

(d) DURECT is the owner of, or has sufficient rights to, all of the DURECT Patent Rights and the DURECT Technology in the Territory to grant to PTI the licenses granted hereunder. All DURECT Patent Rights are in full force and effect and free of all liens, charges, encumbrances and security interests. To the best knowledge of DURECT, the use of the SABER ™ Delivery System, the DURECT Patent Rights and the DURECT Technology pursuant to the provisions hereof and contemplated herein has not and does not infringe the rights of any Third Party in the Territory. As of the Effective Date of this Agreement, to the best knowledge of DURECT, there are no adverse actions, suits, or claims pending or threatened against DURECT or its Affiliates in any court or by or before any governmental body or agency in the Territory with respect to the SABER ™ Delivery System, the DURECT Patent Rights or the DURECT Technology.

10.2 Disclaimer of Warranties by DURECT.

EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, THE SABER ™ DELIVERY SYSTEM, DURECT TECHNOLOGY AND DURECT PATENT RIGHTS LICENSED BY DURECT TO PTI UNDER THIS AGREEMENT ARE PROVIDED "AS IS," AND DURECT EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10.3 Representations and Warranties of PTI.

PTI represents and warrants to DURECT that:

(a) The execution, delivery and performance of this Agreement by PTI shall not, with or without notice or the passage of time or both, result in any violation of or constitute a default under any material contract, obligation or commitment to which PTI is a party or by which it is bound, or any statute, rule or governmental regulation applicable to PTI. This Agreement constitutes a valid and binding obligation of PTI, enforceable in accordance with its terms.

(b) PTI is a company duly organized under the laws of Delaware, and has all requisite legal and corporate power and authority to carry on its business and the performance of its obligations under this Agreement. All corporate action on the part of PTI and its officers and directors necessary for the entering into of this Agreement and the performance of PTI' obligations hereunder has been taken.

(c) PTI shall perform all of its obligations set forth under this Agreement in compliance with all applicable laws in the Territory.

(d) PTI has obtained and will maintain at all times during the Term and for so long as any license granted pursuant to Section 8.1 survives, all rights and licenses with respect to the Opioid Drug as necessary to develop and commercialize the Licensed Product in the Territory. To the best knowledge of PTI, the use of the Opioid Drug pursuant to the provisions of this Agreement and as contemplated herein has not and does not infringe the rights of any Third Party in the

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Territory. As of the Effective Date of this Agreement, to the best knowledge of PTI, there are no adverse actions, suits, or claims pending or threatened against PTI or its Affiliates in any court or by or before any governmental body or agency in the Territory with respect to the Opioid Drug.

10.4 Disclaimer of Warranties by PTI.

EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, PTI TECHNOLOGY AND PTI PATENT RIGHTS LICENSED BY PTI TO DURECT UNDER THIS AGREEMENT ARE PROVIDED "AS IS," AND PTI EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE XI

INDEMNIFICATION

11.1 Indemnification by PTI.

PTI shall at all times, during and after the Term of this Agreement, indemnify and hold harmless DURECT and its Affiliates and their respective directors, officers, employees, scientific advisors and consultants (each, a "DURECT Indemnitee") against any and all claims, losses, damages and liabilities, including reasonable attorneys' fees and costs ("Losses"), arising out of or resulting from any claim, action, suit or other proceeding brought by a Third Party against a DURECT Indemnitee arising from or resulting out of (i) any breach of any express representation, warranty or covenant by PTI under this Agreement, (ii) the negligence or willful misconduct of PTI or any of its respective directors, officers and employees or (iii) the development, manufacture, market, import, use or sale of the Licensed Product or the Opioid Drug by PTI or its Sublicensees or Affiliates pursuant to this Agreement, including without limitation any and all product liability and intellectual property infringement claims. The foregoing indemnity obligation shall not apply to the extent that any such claim, loss, damage, liability or Third Party claim or suit is covered by DURECT's indemnity obligation under Section 11.2 hereof, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for the Losses.

11.2 Indemnification by DURECT.

DURECT Corporation and SBS shall jointly and severally at all times, during and after the Term of this Agreement, indemnify and hold harmless PTI and its Affiliates and their respective directors, officers, employees, scientific advisors and consultants (each, a "PTI Indemnitee") against any and all Losses arising out of or resulting from any claim, action, suit or other proceeding brought by a Third Party against a PTI Indemnitee arising from or resulting out of (i) any breach of any express representation, warranty or covenant by DURECT Corporation or SBS under this Agreement, (ii) the negligence or willful misconduct of DURECT Corporation or SBS or any of their respective directors, officers and employees; (iii) the infringement of a Third Party's proprietary rights by reason of practice or other exploitation of the SABER ™ Delivery System in accordance with the terms of this Agreement; and (iv) the development, manufacture, market,

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import, use or sale of the SABER ™ Ingredients supplied by or on behalf of DURECT hereunder, including without limitation any and all product liability and intellectual property infringement claims. The foregoing indemnity obligation shall not apply to the extent that such claim, loss, damage, liability or Third Party claim or suit is covered by PTI's indemnity obligation under Section 11.1 hereof, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for the Losses.

11.3 Obligations of the Party Seeking to Be Indemnified.

If a DURECT Indemnitee or PTI Indemnitee (each an "Indemnified Party") receives any written Third Party claims which it believes is the subject of indemnity hereunder by DURECT or PTI, as the case may be (in each case an "Indemnifying Party"), the Indemnified Party shall, as soon as reasonably practicable after forming such belief, give notice thereof to the Indemnifying Party, including full particulars of such claim to the extent known to the Indemnified Party; provided that the failure to give timely notice to the Indemnifying Party as contemplated hereby shall not release the Indemnifying Party from any liability to the Indemnified Party except to the extent that the Indemnifying Party is injured by such delay. The Indemnifying Party shall have the right, by prompt notice to the Indemnified Party, to assume the defense of such claim at the cost of the Indemnifying Party. If the Indemnifying Party does not assume the defense of such claim or, having done so, does not diligently pursue such defense, the Indemnified Party may assume such defense, with counsel of its choice, but at the cost and for the account of the Indemnifying Party. If the Indemnifying Party so assumes such defense, the Indemnified Party may participate therein through counsel of its choice, but the cost of such counsel shall be for the account of the Indemnified Party. The Party not assuming the defense of any such claim shall render all reasonable assistance to the Party assuming such defense, and all out-of-pocket costs of such assistance shall be for the account of the Indemnifying Party. No such claim shall be settled other than by the Party defending the same, and then only with the consent of the other Party, which shall not be unreasonably withheld; provided that the Indemnified Party shall have no obligation to consent to any settlement of any such claim which imposes on the Indemnified Party any liability or obligation which cannot be assumed and performed in full by the Indemnifying Party.

ARTICLE XII

OWNERSHIP OF INTELLECTUAL PROPERTY, PATENT PROSECUTION, ENFORCEMENT AND INFRINGEMENT

12.1 Patent Prosecution and Maintenance.

Subject to DURECT's right to abandon or to elect not to apply for such Patents as set forth in this Section 12.1(a) below, DURECT shall, at its sole expense and discretion, prepare, file, prosecute, defend and maintain all Patents in the Territory with respect to the DURECT Patent Rights and the DURECT Technology, which are owned by DURECT. DURECT will consult with PTI and its patent counsel regarding all such matters relating to such Patents which cover any Licensed Product in the Territory or arise out of the performance of activities under this Agreement and will take into account in good faith PTI's reasonable requests and comments in order to obtain the maximum patent protection reasonably obtainable for the Licensed Product. DURECT will have

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the right, in its sole discretion, in good faith, to abandon any Patent in any country or to elect not to apply for a Patent in any country; provided, however that with respect to any Patent which covers any Licensed Product in the Territory or arise out of the performance of activities under this Agreement (i) DURECT shall give PTI timely notice in advance of any abandonment of such Patent

and (ii) and if PTI timely notifies DURECT that PTI desires such Patent to be maintained, then DURECT shall maintain such Patent subject to PTI's reimbursement to DURECT of all reasonable out-of-pocket costs incurred by DURECT for maintenance of such Patent and PTI may deduct such maintenance costs from royalties due on Net Sales under Article IX in such country or Territory as applicable to such Patent.

12.2 Notification of Infringement.

If either Party learns of an infringement or threatened infringement by a Third Party of any DURECT Patent Rights, DURECT Technology, PTI Patent Rights or PTI Technology relating to the manufacture, use or sale of products incorporating any Opioid Drug in the Field in the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement.

12.3 Patent Enforcement.

As between DURECT and PTI, DURECT shall have the first right, but not the duty, to institute infringement actions against Third Parties based on any DURECT Patent Rights or DURECT Technology in the Territory. If DURECT does not institute an infringement proceeding against an offending Third Party based on DURECT's Patent Rights or DURECT Technology relating to the manufacture, use or sale of any products incorporating any Opioid Drug intended for the oral route comprising a Controlled Release Carrier in the Field in the Territory within **[* * *]** months after receipt of written notice from PTI, PTI shall have the right, but not the duty, to institute such an action, provided, however, that notwithstanding the foregoing, if DURECT notifies PTI during such **[* * *]** month period that it disputes in good faith whether such Third Party is infringing DURECT Patent Rights or DURECT Technology by the manufacture, use, sale or importation of products incorporating any Opioid Drug intended for the oral route comprising a Controlled Release Carrier in the Field in the Territory, then the Parties shall refer such matter to a mutually acceptable independent patent counsel. The patent counsel will be asked to render his or her opinion on the matter within **[* * *]** days after referral. In the event the patent counsel renders an opinion, based on all facts available to him or her, that the Third Party is so infringing the DURECT Technology and DURECT Patents in the Field in the Territory, then PTI may, at its election, initiate an action against such Third Party. If the patent counsel renders an opinion, based on all facts available to him or her, that the Third Party is not so infringing the DURECT Technology and DURECT Patents in the Field in the Territory, then PTI may not initiate an action against such Third Party. The Party against whom the opinion is rendered shall bear all costs of the patent counsel in rendering such opinion. The costs and expenses of any infringement action (including fees of attorneys and other professionals) brought against a Third Party under this Section 12.3 shall be borne by the Party instituting the action, or, if the Parties elect to cooperate in instituting and maintaining such action, such costs and expenses shall be borne by the Parties in such proportions as they may agree in writing. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to institute and

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prosecute such infringement actions. Any award paid by Third Parties as a result of such an infringement action (whether by way of settlement or otherwise), shall be used first to reimburse the Party(ies) initiating and maintaining such action for the costs and expenses (including attorneys' and professional fees) incurred in connection with such action, and the remainder of the recovery shall be (to the extent the same represents damages from manufacture, use, sales or importation of products incorporating any Opioid Drug intended for the oral route comprising a Controlled Release Carrier within the Field) treated as Net Sales (i.e., paid to or retained by PTI, as applicable, less the applicable royalty as calculated in accordance with Section 9.5 to be retained by or paid to DURECT, as applicable) and any remainder (i.e., that remaining portion, if any, that does not represent damages from manufacture, use, sales or importation of products incorporating any Opioid Drug within the Field intended for the oral route comprising a Controlled Release Carrier) shall be paid to DURECT.

12.4 Infringement of Third Party Rights and Licenses from Third Party.

(a) If either Party identifies or receives notice of an infringement or potential infringement of a Third Party's patent(s) as a result of the development or Commercialization of the Licensed Product under this Agreement, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such potential infringement.

(b) Without limiting Article XI, in the event that during the Term any Third Party institutes against DURECT or PTI any action that alleges that the SABER ™ Delivery System, SABER ™ Ingredients supplied by or on behalf of DURECT, the DURECT Patent Rights or the DURECT Technology in accordance with the terms hereof infringes the intellectual property rights held by such Third Party, then, as between DURECT and PTI and its Affiliates and Sublicensees, DURECT, at its sole expense, shall have the right to contest, and assume direction and control of the defense of, such action, including the right to settle such action on terms determined by DURECT; provided that in no event shall DURECT enter into any settlement that adversely affects the interests of PTI, its Affiliates, or Sublicensees without PTI's prior written consent, which shall not be unreasonably withheld and further provided that if such action was brought against PTI, its Affiliates or Sublicensee, PTI (itself or through a designee) shall have the right to participate in such action at PTI's or its designee's expense and in all events DURECT shall keep PTI or its designee fully informed with respect thereto and integrate reasonable requests or suggestions by PTI or its designee into DURECT's strategy therefor. PTI, at DURECT's expense, shall use all reasonable efforts to assist and cooperate with DURECT as reasonably requested by DURECT in such action. Notwithstanding Section 11.2, if, as a result of any such action, a judgment is entered by a court of competent jurisdiction from which no appeal can be taken or from which no appeal is taken within the time permitted for appeal, or a settlement is entered into by DURECT, such that any of the SABER ™ Delivery System, SABER ™ Ingredients, the DURECT Patent Rights, and the DURECT Technology cannot be used in accordance with this Agreement in a country without infringing the intellectual property rights of such Third Party, then PTI shall have the right either to (i) terminate this Agreement effective immediately or (ii) obtain a license from such Third Party or require DURECT to obtain a license from such Third Party in such country and at PTI's sole discretion, to offset the cost of such license against any royalties owed to DURECT in such country hereunder, provided that the cumulative amount offset by PTI pursuant to this Section 12.4(b) shall not exceed **[* * *]** of the royalty rate then payable by PTI in such country hereunder.

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(c) Without limiting Article XI, in the event that during the Term any Third Party institutes against DURECT or PTI any action that alleges that the Opioid Drug, PTI Patent Rights or the PTI Technology in the Territory in accordance with the terms hereof infringes the intellectual property rights held by such Third Party, then, as between DURECT and PTI, PTI, at its sole expense, shall have the sole obligation to contest, and assume direction and control of the defense of, such action, including the right to settle such action on terms determined by PTI; provided that in no event shall PTI enter into any settlement that adversely affects the interests of DURECT or its Affiliates, whether under this Agreement or otherwise, without DURECT's prior written consent, which shall not be unreasonably withheld or delayed and further provided that if such action was brought against DURECT or its Affiliates, DURECT (itself or through a designee) shall have the right to participate in such action at DURECT's or its designee's expense and in all events PTI shall keep DURECT or its designee fully informed with respect thereto and integrate reasonable requests or suggestions by DURECT or its designee into PTI's strategy therefor. DURECT, at PTI's expense, shall use all reasonable efforts to assist and cooperate with PTI as reasonably requested by PTI in such action. Notwithstanding Section 11.1, if, as a result of any such action, a judgment is entered by a court of competent jurisdiction from which no appeal can be taken or from which no appeal is taken within the time permitted for appeal, or a settlement is entered into by PTI, such that PTI cannot develop or commercialize a Licensed Product in a country in the Territory, then DURECT shall have the right to terminate the rights granted to PTI under Section 8.1 with respect to such Licensed Product with respect to such country and such country shall thereafter no longer be included in the Territory.

(d) For clarity, except as expressly indicated in this Section 12.4, any Third Party claim alleging infringement for which a Party intends to seek indemnification pursuant to Article XI above, shall be subject to the terms and conditions set forth in Article XI.

12.5 Ownership and Inventions.

(a) Without regard to inventorship, all Inventions (together with all intellectual property rights therein) that comprise: (i) **[* * *]** , (ii) **[* * *],** or (iv) **[* * *]** (individually and collectively, the "DURECT Inventions") shall be solely owned by DURECT; provided that **[* * *]** . Without limiting the foregoing **[* * *]** , PTI hereby assigns and conveys to DURECT, all of its rights, title and interest in and to any DURECT Inventions (together with all intellectual property rights therein) made by or on behalf of PTI. PTI shall promptly disclose to DURECT in writing any DURECT Inventions conceived of or reduced to practice by PTI scientists and research, development and technical personnel involved in the performance of activities under this Agreement and shall require such persons to deliver such assignments, confirmations of assignments or other written instruments as are necessary to vest in DURECT clear and marketable title to such DURECT Inventions (together with all intellectual property

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rights therein). Upon DURECT's request and at DURECT's cost, PTI agrees to execute and deliver all papers and perform all acts which are reasonably necessary in order for DURECT to secure, maintain and enforce any Patents claiming DURECT Inventions in any country.

(b) Without regard to inventorship, all Inventions (together with all intellectual property rights therein) excluding the DURECT Inventions described in Section 12.5(a) above shall be solely owned by PTI. The Inventions owned by PTI under this Section 12.5(b) shall be referred to herein as "PTI Inventions" and shall be deemed PTI Technology. For clarity and without limiting the foregoing, it is understood and agreed that the PTI Inventions include any and all Inventions comprising: (i) **[* * *]** , (ii) **[* * *]** , (iii) **[* * *]** , and (iv) **[* * *]** . DURECT hereby assigns and conveys to PTI, all of its rights, title and interest in and to any PTI Inventions (together with all intellectual property rights therein) made by or on behalf of DURECT. DURECT shall promptly disclose to PTI in writing any PTI Inventions conceived of or reduced to practice by DURECT scientists and research, development and technical personnel involved in the performance of activities under this Agreement and shall require such persons to deliver such assignments, confirmations of assignments or other written instruments as are necessary to vest in PTI clear and marketable title to such PTI Inventions (together with all intellectual property rights therein). Upon PTI's request and at PTI's cost, DURECT agrees to execute and deliver all papers and perform all acts which are reasonably necessary in order for PTI to secure, maintain and enforce any Patents claiming the PTI Inventions in any country.

12.6 Ownership of Data and Licensed Product Registrations.

Subject to the provisions of Section 12.5 and the rights and licenses expressly granted hereunder, all rights, title, and interest in and to any and all [* * *] that is developed or collected solely or jointly by the Parties under this Agreement shall be jointly owned by PTI and DURECT and shall be considered the Confidential Information of both PTI and DURECT for purposes hereunder. Subject to the provisions of Section 12.5 and the rights and licenses expressly granted hereunder, all rights, title, and interest in and to [* * *] that is developed or collected solely or jointly by the Parties under this Agreement shall be owned solely by PTI and shall be considered the Confidential Information of PTI for purposes hereunder. Notwithstanding the foregoing, each Party shall have the right to use and disclose (subject to standard confidentiality conditions) the [* * *] for its own business purposes without obtaining the consent of the other Party and may publicly disclose the [* * *] in accordance with Article XIII. All rights, title, and interest in and to [* * *] developed or collected solely or jointly by the Parties during the Term of this Agreement shall be owned exclusively by PTI. [* * *]

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12.7 Ownership of Information related to Intellectual Property.

Any and all information and material, including any and all intellectual property rights therein and thereto, assigned to a Party pursuant to the terms of this Agreement shall constitute Confidential Information of such Party. And for purposes of Article XIII, such Party shall be deemed the Disclosing Party with respect to such Confidential Information.

ARTICLE XIII

CONFIDENTIALITY

13.1 Confidentiality.

Subject to Section 13.2, during the Term of this Agreement and for **[* * *]** years thereafter, each Party (for purposes of this Article XIII, the "Recipient") shall maintain in confidence all information and materials of a confidential or proprietary nature disclosed by the other Party (for purposes of this Article XIII, the "Disclosing Party") pursuant to this Agreement, including, information relating to the SABER ™ Delivery System, the Licensed Product, the Opioid Drugs, the DURECT Patent Rights, the DURECT Technology, the PTI Patent Rights and the PTI Technology, whether provided by the Disclosing Party to the Recipient prior to or after the Effective Date ("Confidential Information"), and shall not use such information or materials for any purpose except as permitted by this Agreement, or disclose the same to anyone other than those of its Affiliates, Sublicensees, employees, consultants, agents or subcontractors as are necessary in connection with the Recipient's activities as contemplated in this Agreement, provided that prior to such disclosure, each Recipient shall obtain a written agreement from any of its Affiliates, Sublicensees, employees, consultants, agents and subcontractors, prior to receipt of such information or materials, to hold in confidence and not make use of such information or materials for any purpose other than as permitted by this Agreement.

13.2 Disclosure.

The obligation of confidentiality contained in this Agreement shall not apply to the extent that:

(a) the Recipient is required to disclose Confidential Information of the Disclosing Party by order or regulation of a governmental agency or a court of competent jurisdiction, or under the securities laws of any jurisdiction or the rules of the U.S. Securities and Exchange Commission or any stock exchange upon which its securities are listed, except that the Recipient will not make any such disclosure (other than as required under the securities laws of any jurisdiction or the rules of the U.S. Securities and Exchange Commission or any stock exchange upon which its securities are listed) without first notifying the Disclosing Party and (i) upon the request of the Disclosing Party, preparing and submitting in good faith a request for confidential treatment pursuant to the

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United States securities laws or other equivalent law in the Territory covering such Confidential Information as shall be identified as confidential by the Disclosing Party and (ii) to the extent practicable, allowing the Disclosing Party a reasonable opportunity to seek injunctive relief from (or protective order with respect to) the obligation to make such disclosure;

(b) the Recipient can demonstrate that (i) the disclosed information was at the time of such disclosure to the Recipient already in (or thereafter enters) the public domain other than as a result of actions of the Recipient or its Affiliates, employees, Sublicensees, consultants, agents or subcontractors in violation hereof; (ii) the disclosed information was rightfully known by the Recipient (as shown by its written records) prior to the date of disclosure to the Recipient in connection with the negotiation, execution or performance of this Agreement; (iii) the disclosed information was received by the Recipient on an unrestricted basis from a source unrelated to the Disclosing Party to this Agreement and who is not under a duty of confidentiality to the Disclosing Party; or (iv) the disclosed information was independently developed by the Recipient without use of the Disclosing Party's information as shown by written evidence contemporaneously prepared with such independent development;

(c) disclosure is made to a government regulatory agency as part of such agency's approval process related to Product Registration for a Licensed Product; or

(d) disclosure is reasonably necessary for the Recipient to exercise the rights and licenses expressly granted hereunder, except that the Recipient will not make any such disclosure without first notifying the Disclosing Party; without limiting the foregoing, upon the reasonable request of the Disclosing Party, the Recipient shall make any reasonably requested modifications so as to limit such disclosure.

13.3 Publicity.

(a) Except as otherwise provided in this Agreement (including without limitation Section 13.2) or required by law or regulation, no Party will originate any publication, news release or other public announcement, written or oral, whether in the public press, stockholders' reports or otherwise, relating to the Pre-Clinical Program Information, this Agreement, any sublicense under this Agreement, or the performance under this Agreement, without the prior written approval (including E-mail) of the other Party, which approval shall not be unreasonably withheld or delayed.

(b) Notwithstanding the provisions of Section 13.3(a), the Parties shall agree upon a press release to announce the execution of this Agreement and generally describe the relationship of the Parties hereunder promptly after the Effective Date, together with a corresponding question and answer outline for use in responding to inquiries about the Agreement. Thereafter, each Party may disclose to Third Parties the information contained in such press release and question & answer outline without the need for further approval by the other. Additionally, the Parties agree to issue joint press releases from time to time announcing the occurrence of significant milestones or other events under the Agreement or the Pre-Clinical Program. For clarity, nothing in this Section 13.3 shall be deemed to prevent PTI from originating a press release or other public announcement with respect to entering into an arrangement with a Sublicensee to the extent such press release or other public announcement does not make direct reference to DURECT or this Agreement.

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(c) Each of the Parties hereto agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior written consent of the other Party hereto, except (i) to advisors and investors on a need-to-know basis under conditions which reasonably ensure the confidentiality thereof; (ii) as required by any court or other governmental body; (iii) as otherwise required by law; (iv) in confidence to legal counsel of such parties; (v) in confidence, in connection with the enforcement of this Agreement or rights under this Agreement; (vi) in confidence, in connection with a merger, acquisition of stock or assets, proposed merger or acquisition, or the like; or (vii) as advisable or required in connection with any government or regulatory filings, including without limitation filings with the SEC; provided however, prior to any such required disclosure the non-disclosing Party shall be allowed to review the proposed disclosure, and the disclosing Party agrees to consider in good faith any proposed revisions thereof provided to the disclosing Party within two (2) business days of the non-disclosing Party's receipt of the proposed disclosure, and the Parties shall seek confidential treatment for such disclosure as permitted by applicable law.

(d) Without limiting Section 13.2 above, to avoid loss of patent rights as a result of premature public disclosure of patentable subject matter, each Party agrees to submit to the other Party, at least **[* * *]** days prior to submission for publication or disclosure, materials intended for publication or disclosure relating to Inventions owned by such other Party pursuant to Article XII. The Party receiving such materials for review shall notify the other Party within **[* * *]** days of receipt of such materials whether or not the receiving Party desires to file a patent application on any Invention disclosed in such materials that is owned by such Party pursuant to Article XII, in which case the public disclosure of such materials shall be delayed for a period of **[* * *]** days from such notification to allow such filing. Further, if the Party receiving such materials believes that such material contains Confidential Information of the receiving Party, the other Party agrees to remove such Confidential Information from the proposed publication or disclosure, unless otherwise allowed pursuant to Section 13.2 above.

ARTICLE XIV

INSURANCE

14.1 Insurance.

(a) PTI shall, at its sole cost and expense, procure and maintain comprehensive general liability insurance and clinical trial insurance policies from a qualified insurance company which has a superior rating from a recognized rating service, with minimum limits of **[* * *]** for combined bodily injury and property damage. Additionally, prior to launch of any Licensed Product hereunder, PTI shall, at its sole cost and expense, procure and maintain products liability insurance policies from a qualified insurance company which has a superior rating from a recognized rating service, with coverage terms and limits standard and customary for commercialization of products similar to the Licensed Products in the pharmaceutical industry, but no less than **[* * *]** for combined bodily injury and property damage.

(b) DURECT Corporation and SBS shall, in combination and at their sole cost and expense, procure and maintain comprehensive general liability insurance and products liability insurance policies from a qualified insurance company which has a superior rating from a recognized rating service, with minimum limits of US **[* * *]** for combined bodily injury and property damage.

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(c) Each Party shall have its insurance carrier or carriers furnish to the other Party, at the other Party's request, certificates that all insurance required under this Section 14.1 is in force, such certificates to indicate any deductible and/or self-insured retention and the effective expiration dates of the policies, and such certificates to stipulate that the other Party shall be given **[* * *]** days written notice of all cancellation or non-renewal of the policy.

ARTICLE XV

TERM AND TERMINATION

15.1 Term.

This Agreement shall commence as of the Effective Date and, unless sooner terminated as expressly provided hereunder, shall expire upon the expiration of all licenses pursuant to Section 8.2(a) granted to PTI pursuant to Section 8.1 above ("Term").

15.2 Termination Without Cause.

PTI may terminate this Agreement without cause upon **[* * *]** days' prior written notice to DURECT.

15.3 Termination For Cause.

Subject to Section 15.5 and 17.8, either Party (the "Non-Breaching Party") may terminate this Agreement if (i) the other Party (the "Breaching Party") fails to materially comply with any of its material obligations under this Agreement (including the material breach of any representation or warranty set forth in Article X), (ii) the Non-Breaching Party gives notice to the Breaching Party specifying the nature of the default and requiring the Breaching Party to cure the default, and (iii) the default is not cured by the Breaching Party within **[* * *]** days after the receipt of such notice (or if such default cannot reasonably be cured within such **[* * *]** day period, then one additional **[* * *] [* * *]** day period if the Breaching Party has commenced and diligently continued actions to cure such default during such initial **[* * *]** day period), in which event the Agreement shall terminate upon the expiration of such applicable cure period. Failure to pay any amounts due under this Agreement within **[* * *]** days after written notice that such amounts are overdue shall be deemed a material breach of this Agreement. Notwithstanding the foregoing, if the alleged Breaching Party disputes by written notice to the Non-Breaching Party such material breach in good faith within **[* * *]** days of receipt of the notice described in clause (ii) above, the Non-Breaching Party shall not have the right to terminate unless it has been determined in accordance with Section 16.1 that the Agreement was materially breached and the Breaching Party fails to thereafter cure such material breach within **[* * *]** days. The right to terminate shall be in addition to and not in substitution for any other available remedy at law or in equity.

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15.4 Termination for Insolvency

Subject to Section 15.5, either Party may terminate this Agreement upon written notice if, at any time, (i) the other Party shall file in any court or agency pursuant to any statute or regulation of the United States or of any foreign country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (ii) the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within **[* * *]** days after the filing thereof, or (iii) if the other Party shall make an assignment for the benefit of creditors. The Agreement shall terminate **[* * *]** days after the delivery of such notice by the terminating Party. The right to terminate shall be in addition to and not in substitution for any other available remedy at law or in equity.

15.5 Effects of Termination.

(a) Upon expiration or termination of this Agreement for any reason other than by DURECT pursuant to Section 15.3, and provided that PTI has commenced marketing of the Licensed Product hereunder, PTI and its Affiliates and Sublicensees shall have the right to continue to sell all inventory of the Licensed Product in such country for a period of **[* * *]** months from and after the effective date of such termination. Royalties consistent with the provisions of Section 9.5 shall continue to paid to DURECT with respect to such continuing sales.

(b) With respect to any country for which the rights granted to PTI under Section 8.1 have expired, or have been terminated pursuant to this Agreement with respect to a Licensed Product, nothing in this Agreement (including Section 8.4(a)) shall be deemed to prevent DURECT from developing, making, having made, using or selling in such country a product in the Field incorporating the Opioid Drug incorporated in such Licensed Product to the extent that DURECT would have otherwise had the right to do so. Likewise, upon the expiration or termination of this Agreement; in its entirety, nothing in this Agreement shall be deemed to prevent DURECT from developing, making, having made, using or selling products in the Field incorporating an Opioid Drug to the extent that DURECT would have otherwise had the right to do so. For clarity, nothing in this Section 15.5(b) is intended to grant any rights to DURECT under any intellectual property of PTI nor is intended to relieve DURECT from any of the surviving obligations hereunder including those obligations under Article XIII.

(c) In the event of the termination or expiration of this Agreement (or any country within the Territory) by PTI, PTI shall pay DURECT in accordance with the terms hereof all amounts due and payable under this Agreement through the date of termination and for all costs not refundable to DURECT in respect of which DURECT reasonably made commitments in connection with the performance of its obligations hereunder before the date of delivery of such notice of termination.

(d) Termination or expiration of this Agreement shall not relieve any Party of any obligations or liabilities arising prior to the effective date of termination or expiration.

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15.6 Return of Records and Data.

Within thirty (30) days after the termination or expiration of this Agreement, each Party shall promptly return to the other Party all tangible copies of Confidential Information received from the other Party except that each Party may keep one (1) copy of any Confidential Information received from the other Party solely for monitoring its confidentiality obligations hereunder.

15.7 Surviving Provisions.

The Parties' rights and obligations under Articles I, XI, XIII, XVI and XVII and Sections 2.3(b), 3.3(c), 5.3(f), 5.3(g), 5.3(h), 8.3 (last sentence), 9.6-9.8, 10.2, 10.4, 12.5-12.7 and 15.5-15.7 shall survive any termination or expiration of this Agreement. Additionally, the last sentence of Section 8.2(b) shall survive expiration, but not earlier termination of this Agreement.

ARTICLE XVI

DISPUTE RESOLUTION

16.1 Arbitration.

(a) Except for disputes, controversies or claims relating to intellectual property rights or the scope of the licenses granted hereunder or which are subject to Section 16.1(b), and subject to Section 16.2, any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof, shall be finally settled under the Rules for Commercial Dispute Resolution Procedures of the Arbitration of American Arbitration Association ("AAA") then in force on the date of commencement of the arbitration by three (3) arbitrators appointed in accordance with those Rules; provided however if the Parties mutually agree, such arbitration may be conducted by a single mutually agreeable arbitrator. The award rendered shall be final and binding on the Parties. Judgment upon the award may be entered in any court having jurisdiction. The place of arbitration shall be in San Jose, CA. The law of the State of California shall be applied. The Parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against either Party. The costs of any arbitration, including administrative fees and fees of the arbitrators, shall be shared equally by the Parties, unless otherwise specified by the arbitrators. Each Party shall bear the cost of its own attorneys' and expert fees; provided that the arbitrators may in their discretion award to the prevailing Party the costs and expenses incurred by the prevailing Party in connection with the arbitration proceeding.

(b) In the event DURECT disputes PTI's determination under Section 8.5 as to the commercially reasonableness or prudence of performing clinical development for or launching a particular Licensed Product in a Major Market Country, then DURECT shall have the right to have such dispute resolved in accordance with this Section 16.1(b) and subject to Section 16.2. The Parties shall agree upon and appoint one (1) arbitrator within twenty (20) days after the notice of arbitration is received by PTI and, failing such agreement, either Party may apply under the applicable rules of the AAA for the appointment of an arbitrator, and the selection of an arbitrator

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under such rules of the AAA shall be final and binding on the Parties. Such arbitrator shall have appropriate experience in marketing pharmaceutical products and be independent of both Parties. The arbitration shall take place in Santa Clara County, CA. Within thirty (30) days after such arbitrator is identified and retained in writing, each Party shall submit to such arbitrator and the other Party a written proposal for resolving such dispute. The arbitrator shall select the proposal of one Party within sixty (60) days of the receipt of both proposals, which proposal shall be deemed the judgment and award with respect to such dispute. The arbitrator shall limit discovery as reasonably practicable to complete the arbitration as soon as practicable. The Party whose proposal was not accepted shall bear all costs of such arbitration, including administrative fees and fees of the arbitrator. Each Party shall bear the cost of its own attorneys' and expert fees; provided that the arbitrator may in his/her discretion award to the prevailing Party the costs and expenses incurred by the prevailing Party in connection with the arbitration proceeding.

16.2 Pre-Arbitration Dispute Resolution.

No dispute under this Agreement shall be referred to arbitration under Section 16.1 until the following procedures in this Section 16.2 have been satisfied. The chief executive officers of PTI and DURECT shall meet as soon as practicable, as reasonably requested by either Party to review any dispute with respect to the interpretation of any provision of this Agreement or with respect to the performance of either Party under this Agreement. If the dispute is not resolved by the chief executive officers by mutual agreement within thirty (30) calendar days after a meeting to discuss the dispute, either Party may at any time thereafter provide the other Party written notice specifying the terms of such dispute in reasonable detail and notifying the other Party of its decision to institute arbitration proceedings under Section 16.1.

16.3 Provisional Remedy.

Nothing in this Agreement shall limit the right of either Party to seek to obtain in any court of competent jurisdiction any equitable or interim relief or provisional remedy, including injunctive relief. Seeking or obtaining such equitable or interim relief or provisional remedy in a court shall not be deemed a waiver of this Agreement to arbitrate. For clarity, any such equitable remedies shall be cumulative and not exclusive and are in addition to any other remedies that either Party may have under this Agreement or applicable law.

16.4 Disputes Related to Intellectual Property Rights and the License Grants.

Any and all disputes, controversies or claims relating to intellectual property rights or the scope of the licenses granted hereunder shall be subject to the exclusive venue and jurisdiction of the state courts of competent jurisdiction located in Santa Clara County, in the State of California and Federal courts of competent jurisdiction located in the Northern District of the State of California. The Parties hereby consent to the exclusive venue and jurisdiction of such courts for such disputes, controversies or claims.

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ARTICLE XVII

MISCELLANEOUS

17.1 Assignment.

Except as expressly provided herein, neither this Agreement nor any interest or obligation hereunder may be assigned or delegated by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, except that either Party may assign this Agreement, in whole but not in part, to any successor of such Party ("Acquiror") by merger, acquisition, sale or otherwise of substantially all of its business or assets to which this Agreement relates, provided that no such assignment shall release the assigning Party from any liability hereunder incurred prior to the date of such assignment. Subject to the foregoing, this Agreement shall be binding upon the successors and permitted assigns of the Parties. A Party shall not assign or otherwise transfer any of its patent rights to a Third Party such that such assignment or transfer materially restricts, in whole or in part, the rights of the other Party under this Agreement. Any assignment not in accordance with this Section 17.1 shall be void.

17.2 Entire Agreement.

This Agreement (including the Exhibits thereto and all associated documents specifically referenced herein) and that certain letter executed simultaneous herewith related to the Pre-Clinical Plan constitute the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements, whether written or oral. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by authorized representatives of both Parties.

17.3 Severability.

In the event that any provision of this Agreement is determined to be invalid or unenforceable for any reason, such provision shall be deemed inoperative only to the extent that it violates or conflicts with law or public policy, and such provision shall be deemed modified to the extent necessary to conform to such law or policy. All other provisions of this Agreement shall remain in full force and effect.

17.4 Notices.

Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be sent by facsimile (receipt confirmed), or prepaid, registered or certified mail, return receipt requested, or other reputable international courier service, to the address as follows and shall be effective upon the earlier of receipt, as evidenced by the return receipt or delivery receipt, or three (3) days after such mailing:

If to DURECT:

DURECT Corporation
10240 Bubb Road
Cupertino, California 95014
Attn: General Counsel
Fax: (408) 777-3577

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If to SBS:	Southern BioSystems, Inc. 756 Tom Martin Drive Birmingham, Alabama 35211 Attn: President Fax: (205) 917-2296
If to PTI:	Pain Therapeutics, Inc. 416 Browning Way South San Francisco, CA 94080 Attn: President & CEO Fax: (650) 624-8222
Copies to:	Wilson Sonsini Goodrich & Rosati 650 Page Mill Road Palo Alto, CA 94304-1050 Attn: Michael O'Donnell, Esq. Fax: (650) 493-6811

or at such other address as DURECT Corporation, SBS or PTI shall have furnished to the other in writing.

17.5 Choice of Law.

This Agreement shall be governed by and interpreted in accordance with the laws of the State of California, U.S.A., without giving effect to the principles of conflicts of laws thereof.

17.6 Waiver.

The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. None of the terms, covenants and conditions of this Agreement can be waived except by the written consent of the Party waiving compliance.

17.7 Force Majeure.

No failure or omission by the Parties in the performance of any obligation according to this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the reasonable control of the Party, including strikes, riots, war, terrorism, acts of God, invasion, fire, explosion, floods, delay of carrier, shortage or failure in the supply of materials, energy shortage and acts of government or governmental agencies or instrumentalities. In the event that due to force majeure either Party hereto shall be delayed or hindered in or prevented from the performance of its duties or doing acts required under the terms of this Agreement and such Party provides written notice to the other Party promptly upon the occurrence of the force majeure event, the performance of such act, shall be excused for the period

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of the delay. Notwithstanding the aforementioned, the Party subject to force majeure shall take all reasonable steps to resolve the condition(s) forming the basis of force majeure. In the event that the performance of a Party is excused pursuant to this Section 17.7 for more than ninety (90) days due to a force majeure event, the other Party shall have the right to terminate this Agreement upon written notice unless the other Party waives such force majeure event; provided however with respect to DURECT's supply obligations pursuant to Article V above, the foregoing provisions of this Section 17.7 shall not prejudice or limit PTI's rights under Section 5.4, in the event of DURECT's failure to supply as set forth therein.

17.8 Bankruptcy

All rights and licenses granted hereunder or pursuant hereto are, and shall be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses to rights of "intellectual property," as defined thereunder. Any escrow agreement entered into pursuant to this Agreement shall be considered an "agreement supplementary to" such rights and licenses as provided in Section 365(n). Notwithstanding any provision contained herein to the contrary, if the Party granting such rights is under any proceeding under the United States Bankruptcy Code and the trustee in bankruptcy of such Party, or such Party, as a debtor in possession, rightfully elects to reject this Agreement, the licensed Party shall have the right, pursuant to Sections 365(n)(1) and 365(n)(2) of the United States Bankruptcy Code, to retain any and all of the rights licensed to it hereunder, to the maximum extent permitted by law, subject to any royalty payments due to the licensor Party as specified herein.

17.9 Headings.

The captions used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits, or limitations.

17.10 Counterparts.

This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument. Execution and delivery of this Agreement by exchange of facsimile copies bearing the facsimile signature of a Party hereto shall constitute a valid and binding execution and delivery of this Agreement by such Party. Such facsimile copies shall constitute enforceable original documents.

17.11 Relationship of Parties.

The Parties shall be deemed to be independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, without the prior written consent of the other Party.

17.12 Limitation of Liability.

EXCEPT FOR EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE XI OR FOR BREACH OF ARTICLE XIII, IN NO EVENT SHALL EITHER PARTY

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BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE).

17.13 No Implied Licenses.

Nothing in this Agreement is or shall be construed as granting by implication, estoppel, or otherwise any licenses or rights under patents or other rights of either Party, regardless of whether such patents or other rights are dominant or subordinate to any patent within such Party's Patent Rights or Technology (i.e., with respect to DURECT, the DURECT Patent Rights or DURECT Technology; and with respect to PTI, the PTI Patent Rights or PTI Technology).

17.14 No Third Party Beneficiaries.

There are no third party beneficiaries under this Agreement.

[remainder of the page intentionally blank]

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IN WITNESS WHEREOF, the Parties have duly caused this Agreement to be executed as of the Effective Date.

DURECT CORPORATION

By: /s/ James E. Brown
Name: James E. Brown
Title: President & Chief Executive Officer

SOUTHERN BIOSYSTEMS, INC.

By: /s/ Arthur J. Tipton
Name: Arthur J. Tipton
Title: Vice President

PAIN THERAPEUTICS, INC.

By: /s/ Remi Barbier
Name: Remi Barbier
Title: President & Chief Executive Officer

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Exhibit 3.2
CLINICAL PROGRAM MILESTONES

[* * *]

*** **Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

Exhibit 9.5
SCHEDULE OF ROYALTY PAYMENTS

For Licensed Products which do not include an Antagonist

Annual Net Sales in the Territory in a calendar year (on a Licensed Product-by-Licensed Product basis)	Applicable Royalty Percentage
Up to U.S. $100,000,000	6.0%
>U.S. $100,000,000—$200,000,000	6.5%
>U.S. $200,000,000—$400,000,000	7.5%
>U.S. $400,000,000—$800,000,000	8.5%
>U.S. $800,000,000—$1,200,000,000	10.5%
>U.S. $1,200,000,000	11.5%

For Licensed Products which include an Antagonist

(on a Licensed Product-by-Licensed Product basis) Annual Net Sales in the Territory in a calendar year	Applicable Royalty Percentage
Up to U.S. $300,000,000	5.0%
>U.S. $300,000,000—$700,000,000	6.0%
>U.S. $700,000,000—$900,000,000	7.0%
>U.S. $900,000,000	10.0%

The following is for purposes of example only. If Net Sales of a Licensed Product (which does not include an Antagonist) during a particular calendar year were Two Hundred Fifty Million Dollars (U.S. $250,000,000) the royalty payable to DURECT with respect to such Net Sales would be Sixteen Million Two Hundred Fifty Thousand Dollars (U.S. $16,250,000) calculated as follows: $100,000,000 X 6.0% + $100,000,000 X 6.5% + $50,000,000 X 7.5% = $16,250,000. Likewise, if Net Sales of another Licensed Product (which includes an Antagonist) during the same calendar year were Seven Hundred Fifty Million Dollars (U.S. $750,000,000) an additional royalty of Forty-Two Million Five Hundred Thousand Dollars ($42,500,000) would be payable to DURECT with respect to Net Sales, calculated as follows: $300,000,000 X 5.0% + $400,000,000 X 6.0% + $50,000,000 X 7.0% = $42,500,000.

Exhibit 5.1
TRANSFER PRICE

Transfer Price means **[* * *]**

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Exhibit 1.37
MANUFACTURING COSTS

"Manufacturing Cost" shall mean **[* * *]**

*** **Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

Exhibit 1.19
DURECT PATENT RIGHTS

[* * *]

***** Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

Exhibit 7.1
JDT MEMBERS

DURECT Members

[* * *]

PTI Members

[* * *]

******* **Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.**

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

I, Remi Barbier, certify that:

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

/s/ REMI BARBIER

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

Date: April 24, 2013

Exhibit 31.2

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

I, Peter S. Roddy, certify that:

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

/s/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: April 24, 2013

Exhibit 32.1

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

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

1. The Company's Periodic Report on Form 10-Q for the period ended March 31, 2013, and to which this certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 24, 2013

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

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